CareDx, Inc.
Form S-1/A
July 15, 2014
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As filed with the Securities and Exchange Commission on July 15, 2014

Registration No. 333-196494

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Amendment No. 3

to

FORM S-1

REGISTRATION STATEMENT

UNDER

THE SECURITIES ACT OF 1933

CareDx, Inc.

(Exact name of Registrant as specified in its charter)

Delaware	8071	94-3316839
(State or other jurisdiction of incorporation or organization)	(Primary Standard Industrial Classification Code Number)	(I.R.S. Employer Identification Number)

3260 Bayshore Boulevard

Brisbane, California 94005

(415) 287-2300

(Address, including zip code, and telephone number, including area code, of Registrant s principal executive offices)

Peter Maag, Ph.D.

President and Chief Executive Officer

CareDx, Inc.

3260 Bayshore Boulevard

Brisbane, California 94005

(415) 287-2300

(Name, address, including zip code, and telephone number, including area code, of agent for service)

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Approximate date of commencement of proposed sale to the public: As soon as practicable after this registration statement becomes effective.

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, check the following box: ¨

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ¨

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ¨

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ¨

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

Large accelerated filer	¨	Accelerated filer	¨
Non-accelerated filer	x (Do not check if a smaller reporting company)	Smaller reporting company	¨

CALCULATION OF REGISTRATION FEE

Title of each Class of Securities to be Registered	Proposed Maximum Aggregate Offering Price[1][2]	Amount of Registration Fee[3]
Common stock, $0.001 par value per share	$61,093,750	$7,869

(1) Estimated solely for the purpose of computing the amount of the registration fee pursuant to Rule 457(o) under the Securities Act of 1933, as amended.

(2) Includes the aggregate offering price of additional shares that the underwriters have the option to purchase to cover over-allotments, if any.

(3) The Registrant previously paid $7,406 with prior filings of this registration statement.

The Registrant hereby amends this Registration Statement on such date or dates as may be necessary to delay its effective date until the Registrant shall file a further amendment which specifically states that this Registration Statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933 or until the Registration Statement shall become effective on such date as the Commission, acting pursuant to said Section 8(a), may determine.

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The information in this prospectus is not complete and may be changed. We may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This prospectus is not an offer to sell these securities, and we are not soliciting offers to buy these securities in any state where the offer or sale is not permitted.

PROSPECTUS (Subject to Completion)

Issued July 15, 2014

3,125,000 Shares

CAREDX, INC.
Common Stock

$ per share

CareDx, Inc. is offering 3,125,000 shares of its common stock.

This is our initial public offering and no public market currently exists for our shares.

We anticipate that the initial public offering price will be between $15.00 and $17.00 per share.

Proposed NASDAQ trading symbol: CDNA

Investing in our common stock involves risks. See Risk Factors beginning on page 16.

We are an emerging growth company under the federal securities laws and will be subject to reduced public company reporting requirements.

	PRICE $	*A SHARE*

	Per Share	Total
Public offering price	$	$
Underwriting discount	$	$
Proceeds, before expenses, to CareDx, Inc.[1]	$	$

[1] See Underwriting for additional information regarding underwriter compensation

We have granted the underwriters the right to purchase up to an additional 468,750 shares of common stock to cover over-allotments.

Certain of our existing stockholders and their affiliated entities have indicated an interest in purchasing up to an aggregate of approximately 250,000 shares of common stock in this offering at the initial public offering price. However, because indications of interest are not binding agreements or commitments to purchase, the underwriters could determine to sell more, less or no shares to such stockholders and such stockholders could determine to purchase more, less or no shares in this offering.

Neither the Securities and Exchange Commission nor any state securities commission has approved of anyone s investment in these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

The underwriters expect to deliver the shares of common stock to purchasers on , 2014.

Piper Jaffray **Leerink Partners**

Raymond James **Mizuho Securities**

, 2014

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You should rely only on the information contained in this prospectus or any related free writing prospectus we may authorize to be delivered to you. We have not, and the underwriters have not, authorized anyone to provide you with information different from, or in addition to, that contained in this prospectus and any related free writing prospectus. We and the underwriters take no responsibility for, and can provide no assurances as to the reliability of, any information that others may give you. This prospectus is not an offer to sell, nor is it seeking an offer to buy, these securities in any jurisdiction.

Through and including , 2014 (the 25th day after the date of this prospectus), all dealers effecting transactions in these securities, whether or not participating in this offering, may be required to deliver a prospectus. This is in addition to a dealer s obligation to deliver a prospectus

when acting as an underwriter and with respect to an unsold allotment or subscription.

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You should rely only on the information contained in this prospectus. We have not, and the underwriters have not, authorized any other person to provide you with different information. This prospectus is not an offer to sell, nor is it seeking an offer to buy, these securities in any state where the offer or sale is not permitted. The information in this prospectus is complete and accurate as of the date on the front cover, but the information may have changed since that date.

For investors outside of the United States: we have not and the underwriters have not done anything that would permit this offering or possession or distribution of this prospectus in any jurisdiction where action for that purpose is required, other than the United States. Persons outside of the United States who come into possession of this prospectus must inform themselves about, and observe any restrictions relating to, the offering of the ordinary shares and the distribution of this prospectus outside of the United States.

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PROSPECTUS SUMMARY

This summary highlights information contained elsewhere in this prospectus. This summary provides an overview of selected information and does not contain all the information you should consider. Therefore, you should read the following summary together with the more detailed information appearing in this prospectus, including Risk Factors, Selected Financial Data, Management s Discussion and Analysis of Financial Condition and Results of Operations, Business and our financial statements and related notes before deciding whether to purchase shares of our common stock. Our year end is December 31, and our quarters end on March 31, June 30, September 30 and December 31. Our fiscal years ended December 31, 2012 and 2013 are referred to herein as 2012 and 2013, respectively. Unless otherwise stated, all reference to us, our, CareDx, we, the Company and similar designations refer to CareDx, Inc.

CareDx, Inc.

We are a commercial stage company that develops, markets and delivers a diagnostic surveillance solution for heart transplant recipients to help clinicians make personalized treatment decisions throughout a patient s lifetime. Our commercialized testing solution, the AlloMap heart transplant molecular test, or AlloMap, is a blood-based test used to monitor heart transplant recipients for acute cellular rejection. 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 to avoid the use of unnecessary, invasive surveillance biopsies and to determine the appropriate dosage levels of immunosuppressants. We believe there is a significant unmet need for non-invasive post-transplant surveillance solutions and we are applying our expertise in transplantation towards the development of additional solutions for organ transplant recipients, including recipients of heart and kidney transplants.

Transplant recipients are among the highest cost patients in the healthcare system as they require significant healthcare services immediately before, during and after transplantation. Transplant recipients face lifelong risks of illness and death from organ rejection and/or organ failure, and these risks vary significantly among transplant recipients. In order to reduce the risk of organ rejection, drug therapy is used to suppress the recipient s immune system response to the transplanted organ. This immunosuppression therapy can have serious side-effects including infections, cancers, kidney failure and new onset diabetes. Current solutions for the surveillance of organ transplant recipients provide only limited and infrequent information on the presence or absence of rejection. As a result, clinicians tend to administer relatively high levels of immunosuppression therapy to control rejection risk, which may be more than required for an individual recipient. 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. Long-term survival rates for heart and kidney transplant recipients did not improve significantly between 1997 and 2007, and mortality rates for heart transplant and kidney recipients within the first ten years post-transplant remain at approximately 44% and 32%, respectively.

We believe that better post-transplant surveillance solutions that provide objective, personalized and actionable data can help clinicians control rejection risk while reducing the risk of side-effects of immunosuppression for organ transplant recipients. Effective transplant surveillance solutions must be both sensitive enough to detect the early signs of rejection and be non-invasive to allow for frequent testing and timely delivery of information to clinicians. We believe that such solutions can meaningfully improve the care of the approximately 285,000 organ transplant recipients living in the United States and the approximately 285,000 organ transplant recipients living in Europe. Based on published annual transplant data, including the *OPTN & Scientific Registry of Transplant Recipients Data Report 2011*,

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survival rates for transplant recipients, published and estimated testing protocols, reimbursement rates for AlloMap and our estimate of reimbursement rates for our solutions under development, we estimate the total potential market for post-transplant surveillance of heart and kidney transplant recipients to be over $1 billion annually in the United States and over $500 million annually in Europe, with the total potential market for AlloMap alone to be over $130 million annually in the United States and Europe.

AlloMap is the only non-invasive method recommended in the International Society for Heart and Lung Transplantation, or ISHLT, patient care guidelines for surveillance of heart transplant rejection in non-infants. 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 heart transplant recipients with stable organ function and 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. Additionally, we have obtained a CE mark, which indicates a product s compliance with European Union, or EU, legislation and enables the sale of such product within the EU market. Since launch in January 2005, we have performed more than 55,000 commercial AlloMap tests, including more than 10,000 tests in 2013, in our Brisbane, California laboratory. In 2013, AlloMap was used in 105 of the approximately 126 heart transplant centers in the United States. We believe that there is a meaningful opportunity for AlloMap outside of the United States, and through recent partnerships we are expanding our AlloMap offering to Europe and Canada.

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. and WellPoint. In the aggregate, these payers represent approximately 177 million covered lives. In addition, these payers, when taken together with payers from whom we do not have a formal coverage decision but who have been paying a majority of claims for AlloMap, represent approximately 220 million covered lives. We believe our success in achieving reimbursement confirms the value proposition of AlloMap to our key constituents. As of March 31, 2014, we had been reimbursed for approximately 78% of AlloMap results delivered in the twelve months ended September 30, 2013.

We have successfully completed a number of landmark clinical trials in the transplant field demonstrating the clinical utility of AlloMap for surveillance of heart transplant recipients. We initially established the analytical and clinical validity of AlloMap on the basis of our *Cardiac Transplanted Organ Rejection Gene expression Observational* (Crespo-Leiro M et al., Am. J. Transplantation, 2012), or CARGO, study. A subsequent trial, *Invasive Monitoring Attenuation through Gene Expression* (Pham MX et al., N. Eng. J. Med., 2010), or IMAGE, demonstrated that clinical outcomes in recipients managed with AlloMap surveillance were equivalent to outcomes in recipients managed with biopsies.

By developing and commercializing AlloMap, we have gained deep insights into working with transplant centers, transplant clinicians, post-transplant care teams, transplant recipients and payers in the field of managing transplant recipients. Additionally, by conducting numerous clinical trials in transplantation, we have honed our ability to design and execute large trials that have helped to establish the clinical utility of our products. We have also created a proprietary database and blood sample repository over the course of 10 years from over 25 transplant centers containing proprietary, longitudinal samples with clinical outcomes and other data from heart transplant recipients (more than 2,000 recipients with more than 16,000 study visits yielding more than 37,000 samples) and other organ transplant recipients (more than 100 kidney transplant recipients with more than 300 study visits yielding more than 1,000 samples). We believe this proprietary database and sample repository provide us with a significant competitive advantage in the development and validation of solutions for post-transplantation surveillance of organs.

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We believe our success in developing and commercializing AlloMap, combined with our database and sample repository, will accelerate our efforts to develop additional testing solutions in the heart

transplant market and new testing solutions in other organ transplant markets. For instance, we believe we can apply next generation sequencing platforms to detect genetic differences between cell-free DNA, or cfDNA, in the blood stream emanating from the donor heart and cfDNA emanating from the transplant recipient. We are currently developing a research use only cfDNA-based solution for heart transplant recipients. If successful, we intend to offer the cfDNA solution for research use only pursuant to research protocol agreements with participating clinicians. We expect this solution to help determine rejection-specific activity manifested as cell damage in a transplanted heart.

We expect our scientific rationale and clinical understanding of cfDNA to monitor rejection in heart to further our efforts to provide surveillance solutions for additional organs with an initial focus on using a similar cfDNA technology for monitoring kidney transplant recipients.

Recent Developments

On June 10, 2014, we acquired ImmuMetrix, Inc., a privately held development-stage company working on cfDNA-based solutions in transplantation and other fields. Through this acquisition, we added to our existing know-how, expertise and intellectual property in applying cfDNA technology to the surveillance of transplant recipients. The intellectual property rights of ImmuMetrix include an exclusive license from Stanford University to a patent relating to the diagnosis of rejection in organ transplant recipients using cfDNA. In connection with this acquisition, we entered into a consulting agreement with ImmuMetrix founder and Stanford University professor Dr. Stephen Quake. See Management s Discussion and Analysis of Financial Condition and Results of Operations Recent Developments.

On April 17, 2014, we issued a subordinated convertible promissory note to Illumina, Inc. in connection with a $5.0 million investment by Illumina in our company. The convertible note provides for interest at an annual rate of 8.0% and matures one year following its issuance. The convertible note will automatically convert into shares of our common stock upon the effectiveness of the offering described in this prospectus at a conversion price per share equal to the lesser of the price at which shares of common stock are sold in this offering and $21.78 per share.

Our Strategy

We are dedicated to providing novel, clinically actionable and timely information to improve the lifelong care of recipients with organ transplants. Key elements of our strategy include:

Develop and Commercialize Post-Transplant Surveillance Solutions to Improve Recipient Outcomes. We are applying our expertise in the surveillance of heart transplant recipients to develop additional solutions for heart and new solutions for other organs by leveraging our development team, experience in transplant surveillance, research in cfDNA and significant clinically-annotated sample libraries.

Increase Utilization of AlloMap. We are pursuing broad-based adoption of AlloMap through encouraging its regular and clinically appropriate use in transplant recipients to improve monitoring and outcomes. We continue to support transplant centers in establishing and adhering to testing protocols, including the use of AlloMap, because we believe that establishing these standards for surveillance are critical in personalizing a recipient s treatment. We expect to build upon our marketing and medical education programs and leverage our transplant-focused sales and marketing team that interacts directly with clinicians, nurses, laboratory and pathology personnel.

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Expand the Clinical Utility and Actionability of our Current and Future Solutions. We intend to continue to invest in clinical trials to expand the clinical utility, actionability and rate of adoption of our current and future solutions. Many of the investigators in our sponsored trials are well recognized key opinion leaders in the field and contribute to the education of their peers by way of publications, presentations of their clinical knowledge and experience with developing AlloMap.

Build Upon our Reimbursement Success. We intend to build on our success in securing coverage and reimbursement for AlloMap through continued development of testing solutions that become part of routine clinic practice, basing our solutions on rigorous science, including clinical trials and peer-reviewed publications, and educating payers regarding the clinical value of our current solution and its potential to reduce the overall cost of care.

Strategically Offer AlloMap Internationally. We believe there is a meaningful market opportunity internationally for AlloMap and have recently signed distribution agreements with Diaxonhit SA to offer AlloMap in Europe and with LifeLabs Medical Laboratory Services to offer AlloMap in Canada. We intend to continue to investigate partnerships for our offerings in other international regions.

Care of Organ Transplant Recipients

The care of organ transplant recipients is an intense effort and requires life-long surveillance and management by highly specialized clinicians and other healthcare providers. Waiting lists for organ transplants in the United States and internationally continue to grow while the number of available donor organs has remained stable. This situation underscores the need for improvements in post-transplant surveillance and care to help ensure that the limited supply of donor organs provides prolonged benefits to transplant recipients. There were approximately 2,500 heart transplants and 16,900 kidney transplants performed in the United States in 2013 and approximately 25,000 heart transplant recipients and 180,000 kidney transplant recipients living in the United States. There were approximately 2,000 heart transplants and 19,000 kidney transplants in the EU in 2012, and we believe there are similar numbers of heart and kidney transplant recipients living in the EU as in the United States.

Risks of Organ Rejection and the Side-Effects of Immunosuppression

Post-transplant recipient care focuses on the life-long management of immunosuppressive drug regimens to prevent or treat rejection. Immunosuppressive drugs are administered most intensively beginning at the time of transplantation, reduced to maintenance levels in the first year post-transplant and continued throughout the recipient s life.

Immunosuppressive therapy, or drug treatments that are used to decrease the body s immune response to the transplanted organ, has serious short-term and long-term adverse side effects. In addition to reducing the ability of the body to defend itself from cancer and infections, immunosuppressive therapy increases susceptibility of an individual to kidney failure, new onset diabetes, imbalances of blood lipid levels, hypertension and osteoporosis. As reported in *Cancer Incidence and Risk Factors after Organ Transplantation* (Vajdic C M et al., Int. J. Cancer, 2009), a combined analysis of five population-based studies demonstrated a three-fold increased risk of cancer in organ transplant recipients compared with the general population matched for age, sex and calendar period. The article further states that this widespread increase in cancer risk after transplantation strongly implicates immunosuppression as a primary cause of the increased cancer risk.

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Heart Transplants

Immunosuppressive therapy may cause serious adverse side effects in heart transplant recipients. According to the *ISHLT s 30th Adult Heart Transplantation Report 2012* (Lund LH et al., J. Heart and Lung Transplantation, 2013), there is a clear need for better methods to enable physicians to individualize treatment and minimize the intensity of immunosuppression while still avoiding rejection, as a significant amount of deaths are due to infection or cancer. For example, by the fourth year following transplantation, cancer becomes a major cause of death in heart transplant recipients, representing approximately 20% of all deaths. In addition, infections are also a major cause of death in heart transplant recipients, representing approximately 11% of all deaths by the fourth year following transplant and, over time, like cancer, cause more deaths in heart transplant recipients than deaths due to rejection, which is approximately 5% in three to five years post-transplant and which declines to 1% after 10 years post-transplant.

Kidney Transplants

Although short-term survival rates for kidney transplant recipients are generally good, the long-term survival rates and health of kidney transplant recipients remains considerably inferior to that of the general population. The leading causes of death among these recipients include cardiovascular disease, chronic renal failure, cancer and infection. As reported in *Diabetes Mellitus after Kidney Transplantation in the United States* (Kasiske B L et. al., Am. J. Transplantation, 2003), kidney transplant recipients are highly prone to hypertension and lipid metabolism disorders, and 24% of kidney transplant recipients develop diabetes within three years post-transplant. The National Kidney Foundation reports that immunosuppressive drugs commonly used in the treatment of post-transplant kidney recipients cause or exacerbate cardiovascular disorders, renal failure, cancer, infection, diabetes and other metabolic disorders.

Limitations of Existing Approaches for Surveillance of Transplant Recipients

Surveillance of Heart Transplant Recipients

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 to obtain four pieces of tissue from the wall of the heart. This sample is then sent to a laboratory for examination by a pathologist who uses a microscope to look for evidence of cellular rejection. Limitations of biopsies in the surveillance of heart transplant recipients include:

- Pathologist evaluations are subjective and dependent upon qualitative visual assessment;
- Biopsies may not be effective at detecting early stages of rejection;
- Negative biopsy results do not necessarily prove a lack of rejection activity;
- Serious complications such as arrhythmias or injury to the heart occur in 2% of biopsies;
- Biopsies present radiation related risks associated with the x-ray imaging used in biopsies; and

Biopsies require recipients to be admitted to a hospital or other transplant center.

Due to these and other limitations, biopsies are not frequently used by clinicians to tailor the use of immunosuppressants. The typical schedule of biopsy surveillance may involve 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

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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.

Surveillance of Kidney Transplant Recipients

Kidney transplant recipients are typically monitored using clinical laboratory tests that measure kidney function but are not necessarily indicative of rejection. The main clinical test indicator of transplanted kidney dysfunction is an increase in serum creatinine levels above a baseline value. Although widely used, literature suggests that changes in serum creatinine levels may be nonspecific and only detected late, after significant renal function loss has occurred.

The use of renal biopsies for surveillance of kidney transplants is limited due to the risks associated with such biopsies. As reported in the *Timing of Complications in Percutaneous Renal Biopsy* (Whittier W L et. al., J. Am Soc. Nephrol, 2004), overt complications, most related to bleeding, occur in up to 13% of the cases, with half of those complications considered major. Following a renal biopsy, a recipient must often remain under medical supervision and on bed rest for four to six hours due to the risk of bleeding. Accordingly, renal biopsy is generally used only when kidney rejection is suspected.

Immunosuppression of Heart and Kidney Transplant Recipients

The risk of rejection in heart and kidney transplant recipients is managed primarily through the use of immunosuppression. Surveillance biopsies are infrequent, especially in kidney and even in heart 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 make 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;
- Easy to administer;

Differentiate rejection from quiescence;

Detect rejection earlier; and

Timing and frequency of results that allow informed and effective treatment decisions.

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Our Solution

We develop and provide a diagnostic surveillance testing solution for organ transplant recipients. Our commercial testing solution, 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 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 values, or RNA levels, of 20 genes and yields a single integer score which determines the probability 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 supported by numerous clinical trials sponsored by us, the results of which have been published in leading peer-reviewed medical journals. AlloMap is the first and only non-invasive method recommended in the ISHLT patient care guidelines for surveillance of heart transplant recipients for rejection in non-infants. AlloMap has obtained 510(k) clearance from the FDA.

We have performed commercial AlloMap tests for more than 13,000 recipients, and we have performed more than 55,000 commercial AlloMap tests in total.

AlloMap is designed to provide the following benefits:

Better Patient Care. AlloMap is designed to be performed using a sample of the patient s peripheral blood rather than invasive biopsies that are uncomfortable, sometimes painful, time-consuming and present risk of complications. We believe that AlloMap is attractive to patients who may not be fully compliant with their prescribed testing protocol.

Better Long-Term Care. By providing patients and their care providers with timely, accurate and quantitative information about a patient s risk of rejection activity, AlloMap is intended to help improve the quality and effectiveness of patient care in the post-transplant period to help tailor the level of invasive testing and immunosuppression therapy to a particular patient s needs.

Novel, Clinically Actionable Information. The AlloMap score may be used instead of a surveillance heart biopsy to rule out acute cellular rejection in heart transplant recipients and may provide information about the patient s risk for future graft dysfunction or death which has the potential to further guide personalized immunosuppressant treatment. In addition, because AlloMap is non-invasive, patients can be monitored through more frequent testing than would be practical using more invasive methods.

Quantitative Results. AlloMap uses a molecular approach that provides clinicians with a reproducible, quantitative assessment and an associated numerical score which allow comparisons for the same patient over time to identify increases or decreases in the likelihood that the patient is experiencing rejection.

Rapid Turnaround. Rapid, high quality results are essential to enable timely implementation of treatment options. For approximately 95% of patients, we return results to the clinician within three business days after the blood draw.

Reduce Healthcare Costs and Resource Usage. Long-term care of transplant recipients is costly. Providing timely, accurate and non-invasive surveillance data for transplant recipients would help

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clinicians make more informed decisions on use of biopsies and optimal immunosuppression therapy which has the potential to reduce overall healthcare costs by avoiding unnecessary biopsies and their associated risks, reducing the use and adverse effects of immunosuppression therapy and potentially reducing the rate of organ rejection.

Our Development Pipeline

Our development pipeline is focused on further expanding the clinical utility of AlloMap through additional research and analysis of our database and samples acquired from previously completed trials, developing new solutions for the surveillance of organ transplants by applying donor derived cfDNA as a biomarker, and potential in-licensing or acquisition of new products and technologies that further enhance our portfolio of solutions to improve the long-term care of organ transplant recipients.

We are pursuing novel strategies to detect donor specific cfDNA using next generation sequencing. Next generation sequencing has been used to detect donor specific DNA in published studies. We have developed methodologies that we believe will potentially enable us to achieve the turnaround time and cost-efficiency required for practical commercial use in clinical surveillance. We believe our existing repository of specimens suitable for product development in heart will provide us with a competitive advantage in developing and establishing our cfDNA test in heart and extending our approach to kidney and other organs.

Cell-free DNA for Heart Transplants

We are seeking to develop a cfDNA-based test for heart transplant recipients in addition to our established AlloMap test. We believe a cfDNA solution for heart transplant recipients would help to identify recipients with a higher probability of rejection.

We have established our proprietary strategy for quantification of donor specific cfDNA and we have completed initial proof of concept studies. We have defined a strategy to efficiently utilize our repository of 37,000 blood samples to enable further development and validation of our cfDNA solution. We have defined an experimental plan to be conducted in the third quarter of 2014 with the objective of developing a research use only, or RUO, version of our cfDNA solution as early as the end of 2014. We do not currently intend to commercialize our cfDNA test for heart and our RUO test will not generate incremental revenue for us. We believe that a RUO cfDNA-based solution for heart transplant recipients, if developed by us, would provide validation of cfDNA as a meaningful biomarker for post-transplant surveillance, provide us with further insight and expertise in the development of cfDNA-based solutions for the surveillance of organ transplants and enhance our relationships within the heart transplant community through ongoing dialogue.

We also intend to publish an abstract on the results of the clinical performance of our cfDNA test for heart based on our sample and data repository, and publication of abstracts from our initial clinical experience with our research use only test. Timing of these events will depend on the success of our development efforts.

Cell-free DNA for Kidney Transplants

We intend to apply the expertise we gain in developing our heart transplant cfDNA test to develop cfDNA solutions for other organ transplants, beginning with kidney transplants. We have a proprietary library of longitudinal blood samples from kidney transplant recipients obtained from the University of California at San Francisco and are seeking to acquire rights to access well-curated samples from other university

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hospitals and other sample repository consortiums in the United States with which we maintain relationships. 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 cfDNA test for heart transplants and the time required to acquire sufficient samples. We are aiming to initiate a prospective clinical outcomes study in kidney transplant recipients applying a cfDNA-based test as early as the second half of 2015.

Risks Associated with our Business

Our ability to implement our business strategy is subject to numerous risks, as more fully described in the section entitled Risk Factors immediately following this prospectus summary. These risks include, among others:

- We have a history of losses, and we expect to incur net losses for the next several years;
- Our financial results are largely dependent on sales of one test, AlloMap, and we will need to generate sufficient revenues from this and other future solutions to grow our business;
- We receive a substantial portion of our revenues from Medicare, and the loss of, or a significant reduction in, reimbursement from Medicare would adversely affect our financial performance;
- The development and commercialization of additional diagnostic solutions is 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 using cfDNA or other technologies;
- 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;
- In order to operate our laboratory, we have to comply with the Clinical Laboratory Improvement Amendments of 1988, or CLIA, and state laws governing clinical laboratories;
- Our competitive position depends on maintaining intellectual property protection;
- 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; and
- Our operating results may fluctuate, which could cause our stock price to decrease.

Our Corporate Information

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., in June 2002, we changed our name to Expression Diagnostics, Inc., in July 2007, we changed our name to XDx, Inc., and in March 2014, we changed our name to CareDx, Inc.

The trademarks CareDx, XDx, AlloMap, and the CareDx and XDx design logos are the property of CareDx, Inc. Other trademarks mentioned in this prospectus are the property of their respective owners.

Office Location

Our principal executive office is located at 3260 Bayshore Boulevard, Brisbane, CA 94005, and our telephone number is (415) 287-2300. Our website address is *www.caredxinc.com*. The information on, or that may be accessed through, our website is not incorporated by reference into this prospectus and should not be relied upon in making an investment decision.

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Implications of Being an Emerging Growth Company

We are an emerging growth company, as defined in the Jumpstart Our Business Startups Act, or the JOBS Act, and therefore we may take advantage of certain exemptions from various public company reporting requirements, including not being required to have our internal controls over financial reporting audited by our independent registered public accounting firm pursuant to Section 404 of the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act, 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 any golden parachute payments. We may take advantage of these exemptions until we are no longer an emerging growth company. In addition, the JOBS Act provides that an emerging growth company can delay adopting new or revised accounting standards until such time as those standards apply to private companies. We have irrevocably elected not to avail ourselves of this exemption, and, therefore, we will be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies. We will remain an emerging growth company until the earlier of (1) the last day of the fiscal year (a) following the fifth anniversary of this 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 June 30th, and (2) the date on which we have issued more than $1.0 billion in non-convertible debt securities during the prior three-year period.

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THE OFFERING

Common stock offered by us	3,125,000 Shares.
Common stock to be outstanding after this offering	10,504,302 shares (10,973,052 shares if the underwriters exercise their over-allotment option in full).
Over-allotment option	We have granted to the underwriters the option, exercisable for 30 days from the date of this prospectus, to purchase up to 468,750 additional shares of common stock
Use of proceeds	We estimate that the net proceeds from this offering will be approximately $43.5 million, or approximately $50.5 million if the underwriters exercise their over-allotment option in full, at an assumed initial public offering price of $16.00 per share, the midpoint of the range on the cover of this prospectus, after deducting the underwriting discounts and commissions and estimated offering expenses payable by us. We currently intend to use the net proceeds from this offering as follows: approximately $20.2 million for research and development, including the development of our product pipeline; approximately $13.3 million for sales and marketing activities, including expansion of our sales force to support the ongoing commercialization of our products; and the remainder for general and administrative expenses (including personnel related costs and the costs of operating as a public company), and for working capital and other general corporate purposes. See Use of Proceeds for additional information.
Directed Share Program	At our request, the underwriters have reserved up to 156,250 shares of common stock, or approximately 5% of the shares being offered by this prospectus, for sale, at the initial public offering price, to our board members, officers and other parties associated with us. Shares of common stock purchased by our board members, officers, stockholders and other persons subject to a lock-up agreement with the underwriters will be subject to the 180-day lockup restriction described in the Underwriting section of this prospectus. The number of shares of common stock available

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	for sale to the general public will be reduced to the extent these parties purchase such reserved shares. Any reserved shares of common stock that are not so purchased will be offered by the underwriters to the general public on the same basis as the other shares offered by this prospectus.
Risk factors	You should read Risk Factors, beginning on page 16, and the other information included in this prospectus for a discussion of factors you should consider carefully before deciding to invest in our common stock.
Proposed trading symbol	CDNA

Certain of our existing stockholders and their affiliated entities have indicated an interest in purchasing up to an aggregate of approximately 250,000 shares of our common stock in this offering at the initial public offering price. Assuming an initial public offering price of $16.00 per share, which is the midpoint of the price range set forth on the cover page of this prospectus, these stockholders would purchase an aggregate of $4,000,000 in shares or 250,000 of the 3,125,000 shares offered in this offering, based on these indications of interest. However, because indications of interest are not binding agreements or commitments to purchase, these stockholders may determine to purchase fewer shares than they have indicated an interest in purchasing or not to purchase any shares in this offering. It is also possible that these stockholders could indicate an interest in purchasing more shares of our common stock. In addition, the underwriters could determine to sell fewer shares to any of these stockholders than the stockholders have indicated an interest in purchasing or not to sell any shares to these stockholders.

The number of shares of our common stock that will be outstanding immediately after this offering is based on 6,172,417 shares outstanding as of March 31, 2014, 888,135 shares issued upon completion of our acquisition of ImmuMetrix, Inc. in June 2014 and 318,750 shares issuable upon conversion of a subordinated convertible promissory note issued by us in April 2014, as described below. The number of outstanding shares excludes:

- 450,382 shares of common stock issuable upon the exercise of options outstanding under our 2008 Equity Incentive Plan as of March 31, 2014, at a weighted average exercise price of $3.90 per share;
- 97,349 shares of common stock issuable upon the exercise of options outstanding under our 1998 Stock Plan as of March 31, 2014, at a weighted average exercise price of $3.14 per share;
- 623,803 shares of common stock issuable upon the exercise of warrants outstanding as of March 31, 2014, on an as-converted basis and at a weighted average exercise price of $22.58 per share;
- 838,695 shares of common stock reserved for future issuance under our 2014 Equity Incentive Plan (which consist of (1) 803,418 shares of common stock initially reserved for issuance under the 2014 Equity Incentive Plan; and (2) 35,277 shares of common stock reserved for issuance under our 2008 Equity Incentive Plan as of immediately prior to the completion of this offering, which shares will be added to the shares reserved under the 2014 Equity Incentive Plan upon its effectiveness), which will become effective upon the execution and delivery of the underwriting agreement for this offering; and up to 865,252 additional shares as of immediately prior to the completion of this offering that may be added to the

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2014 Equity Incentive Plan upon the expiration, termination, forfeiture or other reacquisition of any shares of common stock issuable upon the exercise of stock awards outstanding under the 2008 Equity Incentive Plan and any automatic increases in the number of shares of common stock reserved for future issuance under the 2014 Equity Incentive Plan;

89,269 shares of common stock to be reserved for issuance under our 2014 Employee Stock Purchase Plan, to be effective in connection with this offering, as well as any automatic increases in the number of shares of common stock reserved for future issuance under this plan;

227,845 shares of common stock issuable to the former stockholders of ImmuMetrix upon achievement of a performance milestone, see Management s Discussion and Analysis of Financial Condition and Results of Operations Recent Developments ; and

23,229 shares of our preferred stock issuable upon the exercise of options that were assumed in connection with our acquisition of ImmuMetrix, Inc. in June 2014, and the conversion of such options into options for common stock immediately prior to the closing of this offering.

Except where we state otherwise, the information we present in this prospectus reflects:

a one-for- 6.85 reverse split of our common stock and preferred stock effected on July 14, 2014;

the conversion upon completion of this offering of a subordinated convertible promissory note issued to Illumina, Inc. in April 2014 in the aggregate principal amount of $5.0 million plus accrued interest into 318,750 shares of common stock (assuming conversion of the note on July 15, 2014 at a common stock price per share equal to $16.00, which is the mid-point of the price range on the cover of this prospectus). For a description of the subordinated convertible promissory note, see Management s Discussion and Analysis of Financial Condition and Results of Operations Liquidity and Funding Requirements;

the issuance of 888,135 shares of our preferred stock on completion of our acquisition of ImmuMetrix, Inc. in June 2014, all of which will be converted into common stock immediately prior to the closing of this offering;

the conversion of all of the outstanding shares of our preferred stock into 6,048,220 shares of common stock upon completion of this offering;

the conversion of all outstanding preferred stock warrants to common stock warrants;

amendments to our certificate of incorporation and bylaws to be effective upon completion of this offering;

no exercise of outstanding options or warrants after March 31, 2014, and

no exercise by the underwriters of their over-allotment option.

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SUMMARY FINANCIAL DATA

The following table summarizes our financial data. The summary statements of operations data presented below for the years ended December 31, 2012 and 2013 and the summary balance sheet as of December 31, 2013 have been derived from audited financial statements that are included elsewhere in this prospectus. We have derived the summary statements of operations data for the three months ended March 31, 2013 and 2014 and the summary balance sheet data as of March 31, 2014 from our unaudited interim condensed financial statements included elsewhere in this prospectus. The following summary financial data should be read together with our audited and unaudited financial statements and the related notes, as well as the section entitled Management s Discussion and Analysis of Financial Condition and Results of Operations included elsewhere in this prospectus. Our unaudited interim condensed financial statements were prepared on the same basis as our audited financial statements and include, in our opinion, all adjustments, consisting of normal recurring adjustments that we consider necessary for a fair presentation of the financial information set forth in those financial statements. Our historical results are not necessarily indicative of our results in any future period, and results of interim periods are not necessarily indicative of results for the entire year.

(dollars in thousands, except share and per share data)	Year Ended December 31, 2012	2013	Three Months Ended March 31, 2013	2014
			(unaudited)	
Statements of Operations Data:				
Revenue:				
Testing revenue	$ 19,730	$ 21,672	$ 4,809	$ 5,834
Collaboration and license revenue	721	426	172	90
Total revenue	20,451	22,098	4,981	5,924
Operating expenses:				
Cost of testing	7,930	9,078	2,124	2,162
Research and development	4,752	3,176	1,002	720
Sales and marketing	5,417	5,892	1,569	1,474
General and administrative	4,694	4,809	1,064	1,795
Total operating expenses	22,793	22,955	5,759	6,151
Loss from operations	(2,342)	(857)	(778)	(227)
Interest expense, net	(2,703)	(2,149)	(565)	(548)
Other expense, net	(14)	(536)	(5)	(529)
Net loss	$ (5,059)	$ (3,542)	$ (1,348)	$ (1,304)
Net loss per common share, basic and diluted[1]	$ (5.01)	$ (3.50)	$ (1.33)	$ (1.29)
Shares used to compute net loss per common share, basic and diluted[1]	1,009,236	1,010,795	1,010,684	1,011,980
Pro forma net loss per common share, basic and diluted (unaudited)[1][2]		$ (0.41)		$ (0.11)
Shares used to compute pro forma net loss per common share, basic and diluted (unaudited)[1][2]		7,371,515		7,372,700

(1) Basic and diluted net loss per common share is calculated by dividing net loss for the period by the weighted average number of common shares outstanding during the period. See Notes 2 and 3 to our audited financial statements and Note 2 to our unaudited interim condensed financial statements included elsewhere in this prospectus.

(2) We have presented pro forma net loss per common share information for the year ended December 31, 2013 and three months ended March 31, 2014 to (i) reflect the issuance of 888,135 shares of our preferred stock on completion of our acquisition of ImmuMetrix, Inc. in June 2014, (ii) the issuance of 312,500 shares of our preferred stock upon conversion of a subordinated convertible promissory note issued in April 2014 in the aggregate principal amount of $5.0 million at an assumed conversion price per share of $16.00, (iii) reflect the conversion of all of our outstanding shares of convertible preferred stock into an aggregate of 6,048,220 shares of common stock and (iv) the reclassification to equity of our convertible preferred stock warrant

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liability in connection with the conversion of our outstanding convertible preferred stock warrants into common stock warrants. The numerator has been adjusted to remove the loss resulting from remeasurement of the warrant liability as these amounts will be reclassified to equity upon the closing of this offering.

	As of March 31, 2014		
	Actual	Pro Forma[1]	Pro Forma As Adjusted[2][3]
		(in thousands) (unaudited)	
Balance Sheet Data:			
Cash and cash equivalents	$ 4,837	$ 4,437	$ 53,008
Working capital	(1,098)	(2,398)	46,191
Total assets	11,095	31,422	80,011
Total debt	15,076	15,076	15,076
Convertible preferred stock	135,202		
Total stockholders (deficit) equity	(151,924)	1,868	50,468

(1) Gives effect to (i) the issuance of 888,135 shares of our preferred stock on completion of our acquisition of ImmuMetrix, Inc. in June 2014, and (ii) the conversion of all outstanding shares of preferred stock into 6,048,220 shares of common stock immediately prior to the closing of this offering and the reclassification to equity of our convertible preferred stock warrant liability in connection with the conversion of our outstanding convertible preferred stock warrants into common stock warrants.

(2) Reflects, in addition to the pro forma adjustments set forth above, the issuance and conversion of a subordinated convertible promissory note issued in April 2014 in the aggregate principal amount of $5.0 million plus accrued interest into 318,750 shares of common stock (assuming conversion of the note on July 15, 2014 at a common stock price per share of $16.00, which is the lower of $21.78 and the mid-point of the price range on the cover of this prospectus), and the sale by us of shares of common stock in this offering at an assumed initial public offering price of $16.00 per share, the midpoint of the price range set forth on the cover page of this prospectus, after deducting discounts and commissions and estimated offering expenses payable by us.

(3) Each $1.00 increase or decrease in the assumed initial public offering price of $16.00 would increase or decrease, respectively, the amount of cash and cash equivalents, working capital total assets and total stockholders equity by $2.9 million, assuming the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting the underwriting discounts and commissions and estimated offering expenses payable by us.

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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 prospectus, including our financial statements and related notes, before investing in our common stock. If any of the following risks occur, our business, financial condition, results of operations and prospects could be materially harmed. In that event, the market price of our common stock could decline, and you could lose part or all of your investment.

Risks Related to Our Business

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 years ended December 31, 2012 and 2013 and the three months ended March 31, 2014, we had a net loss of $5.1 million, $3.5 million and $1.3 million, respectively. From our inception through March 31, 2014, we had an accumulated deficit of $161 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 future diagnostic solutions, including our cell-free DNA, or cfDNA, solutions currently in development;
- 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;
- future clinical trials;
- expansion of the size and geographic reach of our sales force and our marketing capabilities to commercialize potential future solutions;
- employment of additional clinical, quality control, scientific, customer service, laboratory, billing and reimbursement and management personnel; and
- employment of operational, financial, accounting and information systems personnel, consistent with expanding our operations and our status as a newly public company following this offering.

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. 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.

Our financial results are largely dependent on sales of one test, AlloMap, and we will need to generate sufficient revenues from this and other future solutions to grow our business.

Our ability to generate revenue is currently dependent on sales of the AlloMap heart transplant molecular test, or AlloMap, and we expect that sales of AlloMap will account for a substantial portion of our revenue for at least the next several years. Although we are working to develop a cfDNA heart

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transplant solution, even if we are successful in developing this new test, we expect that it would be marketed as part of AlloMap and that it would not generate additional standalone revenue for us. In addition, while we are in the process of developing a cfDNA solution for kidney transplant recipients, even if we are successful in developing this test, we do not expect this test to be commercially available for at least the next several years. If we are unable to increase sales of AlloMap or successfully develop and commercialize other solutions or enhancements, our revenues and our ability to achieve profitability would be impaired, and the market price of our common stock could decline.

We receive a substantial portion of our revenues from Medicare, and the loss of, or a significant reduction in, reimbursement from Medicare would adversely affect our financial performance.

Payments from Medicare for AlloMap represented approximately 50% of testing revenue for the three months ended March 31, 2014, approximately 52% of testing revenue for the year ended December 31, 2012 and approximately 53% of testing revenue for the year ended December 31, 2013. We anticipate that Medicare will continue to be the payer for a significant portion of our claims for the foreseeable future. However, we may not be able to maintain or increase our tests reimbursed by Medicare for a variety of reasons, including changes in reimbursement practices, general policy shifts, or reductions in reimbursement amounts. We cannot predict whether Medicare reimbursements will continue at the same payment amount or with the same breadth of coverage in the future, if at all.

The development and commercialization of additional diagnostic solutions is 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.

A key element of our strategy is to discover, develop, validate and commercialize a portfolio of new diagnostic solutions in addition to AlloMap. While we have engaged in discovery and development activity for our planned cfDNA solution for heart transplant recipients, we will be required to devote considerable additional efforts and resources to the further research and development of this test before it can be made available. Our planned new diagnostic solutions for organs other than the heart, such as our planned cfDNA solution for kidney transplant recipients, are at much earlier stages of development. cfDNA solutions are a novel technology, and to date have not been used commercially in the field of transplantation surveillance. We cannot assure you that we will be able to successfully complete development of or commercialize any of our planned future solutions, or that they will prove to be capable of reliably being used for organ surveillance in the heart or in other types of organs. Before we can successfully develop and commercialize any of our currently planned or other new diagnostic solutions, we will need to:

- conduct substantial research and development;
- 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; 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 fail for many reasons, including:

failure of the test at the research or development stage;

difficulty in accessing testing samples, especially testing samples with known clinical results;

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lack of clinical validation data to support the effectiveness of the test;

delays resulting from the failure of third-party suppliers or contractors to meet their obligations in a timely and cost-effective manner;

failure to obtain or maintain necessary clearances or approvals to market the test; or

lack of commercial acceptance by patients, clinicians, or third-party payers.

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

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

From time to time, we expect to estimate and publicly announce the anticipated timing of the accomplishment of various clinical and other product development goals, which we sometimes refer to as milestones. In addition, we have included a discussion of a number of anticipated milestones elsewhere in this prospectus. The actual timing of these milestones 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 milestones and if we do not meet these milestones 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. Please see the section entitled Business Our Development Pipeline for more information regarding our milestones.

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, and our solutions in development, outdated. We must continually innovate and expand our test offerings to address unmet needs in monitoring transplant related conditions. AlloMap 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 and future diagnostic solutions, if any, compared to new methodologies and technologies, then sales of our solutions could decline, which would harm our business and financial results.

If clinicians and hospital administrators 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 and administrators about AlloMap and, subject to their development, our future solutions, and demonstrate the clinical benefits of these solutions. We believe that clinicians and transplant centers may not use our

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solutions unless they determine, based on published peer-reviewed journal articles and the experience of other clinicians, that our solutions provide accurate, reliable and cost-effective information that is useful in monitoring their post-transplant recipients.

We estimate that there are approximately 126 centers managing heart transplant recipients in the United States. In 2013, AlloMap was used in 105 of these centers, 54 of which have included AlloMap in their treatment protocols to encourage consistent use of AlloMap throughout their recipient population. 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. If clinicians and hospital administrators do not adopt and continue to use AlloMap or our future solutions, 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 loss and other operating results will be affected by numerous factors, including:

- our ability to successfully market and sell AlloMap;
- our ability to commercialize new diagnostic solutions;
- the amount of our research and development expenditures;
- the timing of cash collections from third-party payers;
- the extent to which our current test and future solutions, if any, are eligible for coverage and reimbursement from third-party payers;
- 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;
- announcements by our competitors of new or competitive products;
- regulatory developments affecting our test or competing products;

total operating expenses; and

changes in expectation as to our future financial performance, including financial estimates, publications or research reports by securities analysts;

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

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If the utility of our current solution and solutions in development is not supported by studies published in peer-reviewed medical publications, 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 current and future solutions or the technology underlying AlloMap or future solutions are very important to the commercial success of our current and any future 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 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 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 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.

Transplant centers may not adopt AlloMap or future 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 our test 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.

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If we are unable to successfully compete with larger and more established players in the clinical surveillance of 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 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. 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 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 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.

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 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. While we have a substantial collection of samples from previous clinical trials, we expect that 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. Additionally, the process of negotiating access to new and archive 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 recipient data and blood samples with source

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institutions, or if other laboratories or our competitors secure access to these samples before us, our ability to research, develop and commercialize future solutions will be limited or delayed.

If we cannot enter into and maintain new clinical collaborations, our efforts to commercialize AlloMap and our development of 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 which 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 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 test, our business may suffer.

As our test volume 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.

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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 recent testing revenue growth rates may not be indicative of future growth, and we may not continue to grow at our recent pace, or at all.

From 2012 to 2013, our testing revenue grew from $19.7 million to $21.7 million, which represents a compounded annual growth rate of approximately 9.8%. In the future, our revenue may not grow as rapidly as it has over the past several years. We believe that our future revenue growth 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.

If our sole laboratory facility becomes inoperable, we will be unable to perform AlloMap and future solutions, if any, and our business will be harmed.

We perform all of our diagnostic services in our laboratory located in Brisbane, California. We do not have redundant laboratory facilities. Brisbane 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. The facility 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 would be required to be certified under the Clinical Laboratory Improvement Amendments of 1988, or CLIA, a federal law that regulates

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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.

Our commercial partner in Europe will rely on a third party laboratory to perform AlloMap. We do not have access to redundant facilities in Europe and our exclusive arrangement 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. The Company s business will suffer if these service providers do not support AlloMap or the other solutions that we may develop. For example, these laboratories may deem the effort to process the samples for our solutions to require 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 our proposed cfDNA test for heart and kidney or to develop other solutions for clinical surveillance in transplantation;

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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 or enhancements to that test;

acquire or license products or technologies; 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 cfDNA test for heart transplant recipients and additional solutions for the surveillance of transplantation of other organs;

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 U.S. Food and Drug Administration, or 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. 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, AlloMap 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 our company. If adequate funds are not available, we may have to scale back our operations or limit our research and development activities, which may cause us to grow at a slower pace, or not at all, and our business could be adversely affected.

The loss of key members of our senior management team or our inability to attract and retain highly skilled scientists, clinicians and laboratory and field personnel could adversely affect our business.

Our success depends largely on the skills, experience and performance of key members of our executive management team. The efforts of each of these persons will be critical to us as we continue to develop our technologies and testing processes and as we attempt to transition to a company with more than one commercialized test. If we were to lose one or more of these key employees, we may experience difficulties in competing effectively, developing our technologies and implementing our business strategies.

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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.

Our acquisition of ImmuMetrix, Inc. may not result in material benefits to our business and our development efforts and may dilute your ownership in us.

On June 10, 2014, we acquired ImmuMetrix, Inc., a privately held development-stage company working on cfDNA-based solutions in transplantation and other fields. Through this acquisition, we expect to add to our existing know-how, expertise and intellectual property in applying cfDNA technology to the surveillance of transplant recipients. The intellectual property rights of ImmuMetrix include an exclusive license from Stanford University to a patent relating to the diagnosis of rejection in organ transplant recipients using cfDNA. In connection with this acquisition, we entered into a consulting agreement with ImmuMetrix founder and Stanford University professor Dr. Stephen Quake.

The intellectual property we acquired in this acquisition may not have a material impact on our existing research and development efforts, the exclusive license from Stanford University held by ImmuMetrix is subject to termination if we do not meet certain performance and commercialization conditions, we may not be granted access to various blood and other samples that ImmuMetrix has previously relied upon in their research and development efforts, and the consulting agreement we entered into with Dr. Quake does not contain specific performance requirements and may be terminated at any time by Dr. Quake. In addition, if we complete 2,500 commercial tests involving the measurement of cfDNA in organ transplant recipients, including cfDNA tests conducted in parallel with commercial tests, whether or not such tests utilize ImmuMetrix technology, we will be required to issue an additional 227,845 shares of our common stock to the former stockholders of ImmuMetrix, which would result in dilution to you. While our agreement to acquire ImmuMetrix provided for payment of existing liabilities on or prior to the completion of the acquisition and we have certain rights to indemnification for undisclosed liabilities, such indemnification may not be sufficient or available to cover all future claims and undisclosed liabilities of ImmuMetrix, which would harm our business and results of operations.

We may acquire other businesses or assets or form joint ventures that could harm our operating results, dilute your ownership of us, 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. 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. If we make any acquisitions, we may not be able to integrate these acquisitions successfully into our existing business, and we could assume unknown or contingent liabilities. Any future acquisitions by us also could result in significant write-offs or the incurrence of debt and contingent liabilities, any of which

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could harm our operating results. Integration of an acquired company, product or technology also may require management resources that otherwise would be available for ongoing development of our existing business. We may not identify or complete these transactions in a timely manner, on a cost-effective basis, or at all, and we may not realize the anticipated benefits of any acquisition, technology license, strategic alliance or joint venture.

To finance any acquisitions, we may choose to issue shares of our common stock as consideration, which would dilute your interest in us. If the price of our common stock is low or volatile, we may not be able to acquire other companies using our stock as consideration. Alternatively, it may be necessary for us to raise additional funds for acquisitions through public or private financings. Additional funds may not be available on terms that are favorable to us, or at all.

Defects in AlloMap or other solutions we develop could result in substantial product liabilities or professional liabilities that exceed our resources.

The marketing, sale and use of AlloMap and future solutions could lead to the filing of product liability claims if someone were to allege that our test failed to perform as 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 for us to defend. Although we maintain product and professional liability insurance, our insurance may not fully protect us from the financial impact of defending against product liability or professional liability claims or any judgments, fines or settlement costs arising out of any such claims. Any product liability or professional liability claim brought against us, with or without merit, could increase our insurance rates or prevent us from securing insurance coverage in the future. 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 impact our results of operations.

We rely on sole suppliers for some of our laboratory instruments and testing supplies and may not be able to find replacements or immediately transition to alternate suppliers in the event our sole suppliers no longer supply those instruments or supplies.

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, or CPTs, 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. The universal master mix that is supplied by Thermo Fisher Scientific Inc. is a critical test component needed to perform AlloMap and is being discontinued. At present, we have sufficient master mix material to continue delivering AlloMap through February 2015 and we are engaged in a process that allows for dual sourcing of a replacement for this critical test component.

We have contracted with a third party manufacturer for the development of a custom master mix. As of March 31, 2014, three verification lots were produced at small scale and found to be acceptable for use in AlloMap testing. The contract manufacturer is now engaged in scale up activities and production of

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validation lots which will be tested to determine their suitability for use in AlloMap testing, which scale up and validation have not yet been completed. We recently met with Thermo Fisher and initiated a discussion regarding the possibility of Thermo Fisher also formulating a custom master mix for use in AlloMap testing. In both cases, assuming successful development and scale up of three validation lots of master mix, we do not expect the performance characteristics of the AlloMap solution to change.

In addition, our ABI 7900 Thermocycler, a real time 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 2017. We believe we have secured sufficient instrument inventory to last for the next three to five years and are in the process of validating an alternative instrument. 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 from Qiagen N.V., the quality and quantity of reagents or other supplies, as well as the availability of instruments, 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.

We are involved in legal proceedings with Roche Molecular Systems and may be involved in additional legal proceedings in the future, the results of which could have a material adverse effect on us.

In November 2004, we entered into a license agreement with Roche Molecular Systems, Inc., or Roche, that grants us the right to use PCR and quantitative real-time PCR for use in clinical laboratory services, including for use in connection with AlloMap. This is a non-exclusive license agreement in the United States covering the claims in multiple Roche patents. On February 11, 2014 Roche filed a demand for arbitration with the American Arbitration Association seeking a declaration that we have materially breached the Roche license agreement by failing to report and pay royalties owing to Roche in respect of licensed services performed by us after July 1, 2011. Roche seeks damages in the form of unpaid royalties from July 1, 2011 to March 31, 2013 of $1,805,775 plus interest of $84,928 and royalties in an unspecified amount from April 1, 2013 to present, which, based upon the royalty rate currently stated in the license agreement, we would estimate to be an additional $1,248,237 through March 31, 2014. We responded to the Roche demand on March 14, 2014. A preliminary conference with the arbitration panel was held on June 24, 2014 and a hearing has been scheduled for February 2, 2015. While we believe we have meritorious defenses to these claims, which we plan to fully pursue in the arbitration, we have fully reserved the amount of these unpaid royalties on our balance sheet, and the amount of these unpaid royalties has been reflected as an expense in our income statements in the periods to which the royalties relate.

The agreement provides that if we fail to cure any breach of a material term within 30 days after Roche has given written notice of the breach, Roche would have the right to terminate our agreement. To date, Roche has not communicated to us any intention on its part to terminate the agreement and has not sought a declaration in the arbitration it commenced as to its right to terminate the agreement. If Roche were to seek to terminate our agreement, and we did not cure within the required time period, our license to the unexpired patents licensed thereunder would terminate, and Roche could thereafter initiate litigation seeking damages or injunctive relief on the basis that AlloMap or other of our services infringe Roche patents. We cannot assure you that Roche will not seek to terminate the license agreement, that

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we would ultimately prevail in the arbitration or that in the event that Roche were successful in terminating the license agreement, that it would not thereafter seek to enjoin us from selling AlloMap based upon a claim of patent infringement. If any of these things were to occur, we cannot assure you that we would not be materially adversely affected. Among other things, any inability by us to continue to perform AlloMap would have a material adverse effect on our business, financial condition and results of operations.

We have incurred and expect to continue to incur expenses for legal services related to the Roche matter, and this matter has also required substantial time and attention from our management. An adverse outcome in the Roche arbitration would require us to pay the full amount of accrued royalties plus interest, which amounts have been reserved on our balance sheet, plus associated legal fees to Roche. We may be involved in additional legal proceedings in the future with business partners, customers or suppliers. Adverse outcomes or other developments during the course of such matters may harm our business, financial condition or results of operations, as well as investors perception of our business.

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.

In the ordinary course of our business, we and our third-party billing and collections provider 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. We also 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 face four primary risks relative to protecting this 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 this 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 is 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.

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Any such breach or interruption could compromise our networks or those of our third-party billing and collections provider, 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.

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 commercial agreements for the promotion of AlloMap in Europe and Canada with Diaxonhit SA and LifeLabs Medical Laboratories Services, respectively. 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.

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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

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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 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 and Canada will be conducted through exclusive distribution agreements with a sole collaborator in each region. 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 filing.

Risks Related to Billing and Reimbursement

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 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 only when AlloMap test results are actually paid for. We delivered approximately 10,100 AlloMap results in 2013 and recognized revenue for approximately 8,400 tests; approximately 1,100 of which were for test results delivered prior to 2013.

For new diagnostic solutions, each private and government payer decides whether to cover the test, the amount it will reimburse for a covered test and the specific conditions for reimbursement. Clinicians and recipients may be likely not to order a diagnostic test unless third-party payers pay a substantial portion of the test price. Therefore, coverage determinations and reimbursement levels and conditions are critical to the commercial success of a diagnostic product, and if we are not able to secure positive coverage determinations and reimbursement levels, our business will be materially adversely affected.

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

- not experimental or investigational;
- medically necessary;
- 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 could be limited. Payment for diagnostic tests furnished to Medicare beneficiaries is typically made based on a fee schedule set by the Centers for Medicare & Medicaid Services, or 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.

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Since each payer makes its own decision as to whether to establish a policy to reimburse for a test, seeking payer coverage and other approvals is a time-consuming and costly process. We cannot 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. As of March 31, 2014, we had been reimbursed for approximately 78% of AlloMap results delivered in the twelve months ended September 30, 2013. Coverage policies approving AlloMap have been adopted by many of the largest private payers, including Aetna, Cigna, Humana, Inc., Kaiser Foundation Health Plan, Inc., 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 Centers for Medicare & Medicaid Services, or 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 Clinical Laboratory Fee Schedule, or 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 gapfilling methodology if the Medicare contractor determines the code is payable.

AlloMap has been billed since the inception of the test using an unlisted CPT code. The test also has been granted a second code through a Medicare program for molecular diagnostics, which is included on all Medicare claims. If AlloMap is assigned a different MAAA CPT code in the future, a determination not to pay for such MAAA CPT codes 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. Reimbursement for AlloMap under an MAAA code could also be lower than that currently received when AlloMap is billed under a miscellaneous CPT code.

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We receive a substantial portion of our revenues from Medicare, and the loss of, or a significant reduction in, reimbursement from Medicare would adversely affect our financial performance

To date, we have received a substantial portion of our revenues from Medicare, which has been paid by our California Medicare Administrative Contractor. Payments from Medicare for AlloMap represented approximately 52% of testing revenue for the year ended December 31, 2012 and approximately 53% of testing revenue for the year ended December 31, 2013. We anticipate that Medicare will continue to be the payer for a significant portion of our claims for the foreseeable future. However, we may not be able to maintain or increase our rate of reimbursement by Medicare for a variety of reasons, including:

- changes in the local Medicare Administrative Contractor, or MAC, servicing our jurisdiction, which may result in a change in reimbursement practices for Medicare claims submitted by us or others in California and other states affected by the change;
- any policy level review of our test by the CMS contractors could result in a reduction or denial of coverage and payment for our test; and
- the assignment of a specific billing code to our test by CMS may result in reductions in the per test amount reimbursed for our current and future solutions by Medicare.

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 Nordian 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 could have a significant adverse effect on our revenue and results of operations. Any such decision could also cause affected clinicians treating Medicare covered patients to reduce or discontinue the use of our test.

The assignment of a CPT code to AlloMap could adversely affect future payments for clinical laboratory testing services, including AlloMap and our future solutions.

Currently, AlloMap is paid under a non-specific billing code, which means there is no specific CPT code for our test and therefore, no established payment for the test under the Clinical Laboratory Fee Schedule. The local Medicare contractor processing our claims determines the amount of payment for the tests we bill. If the test is classified under a specific billing code, the payment amount established under the Clinical Laboratory Fee Schedule would be the basis for Medicare payment for AlloMap. We may in the near future apply for a unique CPT code for AlloMap, which would likely take one or more years to be considered and, if granted, would likely result in a change in our reimbursed amount. At this time, we cannot predict whether the classification of AlloMap under a billing code subject to the fee schedule would result in a lower payment amount.

In addition, it is possible that competitive bidding will be applied more broadly to clinical laboratory services under Medicare at some point in the future, which would impact payment for AlloMap. If a competitive bidding program is implemented and includes AlloMap, and if comparable solutions are identified, we may experience a decrease in our reimbursement rates for our clinical laboratory solutions.

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

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certainty as to the outcome of the billing process. In cases where we do receive a fixed fee per test, we may still have disputes over pricing and billing. We receive payment from individual recipients and from a variety of payers, such as commercial insurance carriers and governmental programs, primarily Medicare. Each payer typically has different billing requirements. Among the factors complicating our billing of third-party payers are:

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

Additionally, from time to time, payers change processes that may affect timely payment. These changes may result in uneven cash flow or impact the timing of revenue recognized with these payers. With respect to payments received from governmental programs, factors such as a prolonged government shutdown could cause significant regulatory delays or could result in attempts to reduce payments made to us by federal government healthcare programs. These billing complexities, and the related uncertainty in obtaining payment for AlloMap and future solutions, could negatively affect our revenue, cash flow and profitability.

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 could 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. Beginning in 2013, each medical device manufacturer must pay an excise tax in an amount equal to 2.3% of the price for which such manufacturer sells its medical devices that are listed with the FDA. While we do not believe that we are subject to this excise tax, the FDA has contended that clinical laboratory tests that are developed and validated by a laboratory for its own use, or LDTs, such as our proprietary tests, are medical devices. AlloMap is currently listed with the FDA. We cannot assure you that the tax will not be extended to services such as ours in the future. The Affordable Care Act also provides that payments under the Medicare Clinical Laboratory Fee Schedule are 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 creates a new system of health insurance exchanges , designed to make health policies available to individuals and certain groups though state- or federally-administered marketplaces, beginning in 2014. In connection with such exchanges, certain essential health benefits are intended to be made more consistent across plans, setting basically a baseline coverage level. There is some discretion to the states (and the federal government) in the definition of essential health benefits and we cannot predict at this time whether AlloMap would fall into a benefit category deemed essential for coverage purposes across the plans offered in any or all or the

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exchanges. Failure to be covered by plans offered in the exchanges could have a materially adverse impact on our business.

Moreover, the Affordable Care Act includes payment reductions to Medicare Advantage plans. These cuts have been mitigated in part by a CMS demonstration program set to expire 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 Clinical Laboratory Fee Schedule, or CLFS, by 2%. The Protecting Access to Medicare Act of 2014 introduced a multi-year pricing program for services paid under the CLFS. Under the program, beginning in 2016 laboratories will report to CMS the payment rates paid to the laboratories by commercial third-party payors 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 in the future. 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 payors 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 payor data reported for those tests.

Regardless of the impact 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.

Healthcare Regulatory Risks

In order to operate our laboratory, we have to comply with the Clinical Laboratory Improvement Amendments of 1988, or 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

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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 the Company s business.

We were inspected and recertified under CLIA in February 2014 and we expect the next regular inspection under CLIA to occur in 2016. 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 were to discontinue its policy of enforcement discretion over any future solutions we market as LDTs, we could 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 laboratory-developed tests, or 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 generally 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 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 501(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. The FDA has not yet finalized its previously issued guidance regarding LDTs known as IVDMIAs. As a result, we do not intend to seek clearance or approval for any other uses of AlloMap or for any other LDT solutions we develop, including our planned cell-free DNA solutions for heart, kidney and other organs. If the FDA changes its current policy of enforcement discretion, we may be required to seek FDA clearance or premarket approval for LDTs developed by us in the future.

The FDA held a meeting in July 2010 during which it indicated that it intends to reconsider its current policy of enforcement discretion and to begin drafting an oversight framework for LDTs. In November 2013, the FDA published a list of planned guidance documents that were to be the focus of the agency in its fiscal year 2014, including the finalization of previously issued draft guidance which could include guidance documents addressing FDA regulation of LDTs such as ours. As recently as June 2013, a senior agency official publicly reiterated the FDA s continued interest in such regulation. As of May 2014, the FDA has not finalized its previously issued guidance relating to its exercise of enforcement discretion over IVDMIAs. We cannot predict the extent of the FDA s future regulation and

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policies with respect to LDTs, and there can be no assurance that the FDA will not require us to obtain premarket clearance or approval for some or all portions of our future solutions. If the FDA makes significant changes to the regulation of LDTs, or if Congress were to pass legislation that more actively regulates LDTs, it could restrict our ability to provide our current and future solutions, be reimbursed for our current and future solutions or delay the launch of future solutions. We could also be required to conduct additional clinical trials, submit a pre-market clearance notice or a pre-market approval application with the FDA or limit the labeling claims for our solutions. There can be no assurance that any solutions or additional uses of solutions for which we seek clearance or approval in the future will be cleared or approved on a timely basis, if at all, nor can there be 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, 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 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. A significant change in any of these laws, or the FDA s interpretation of the scope of its enforcement discretion, may require us to change our business model in order to maintain compliance with these laws.

While we qualify all materials used in AlloMap according to CLIA regulations, we cannot be certain that the FDA will not enact rules or issue guidance documents which could impact our ability to purchase materials necessary for the performance of our current and future solutions. Should any of the reagents obtained by us from suppliers and used in conducting our current and future solutions be affected by future regulatory actions, our business could be adversely affected by those actions, including by an increase in the cost of testing or delays, limitations or prohibitions on the purchase of reagents necessary to perform testing. In addition, overlapping regulation of our efforts by CLIA and the FDA creates risk of duplication and inconsistencies in the requirements to which we are subject.

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

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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 solutions under development, 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 and promotion and recordkeeping. 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

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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, currently set at $5,500 to $11,000 per false claim. If our operations are found to be

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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.

The international expansion of our business exposes us to regulatory and operational risks associated with doing business outside of the United States.

As part of our business strategy, we are expanding into international markets, initially the European Union and Canada. Doing business internationally involves a number of risks, including:

- failure by us to obtain regulatory approvals or adequate reimbursement for the use of AlloMap and our solutions under development in various countries;
- logistics and regulations associated with shipping patient samples, including infrastructure conditions and transportation delays;
- limits in our ability to penetrate international markets if we are not able to process AlloMap and our solutions under development locally;
- multiple, conflicting and changing laws and regulations such as tax laws, export and import restrictions, employment laws, regulatory requirements and other governmental approvals, permits and licenses; and
- regulatory and compliance risks that relate to maintaining accurate information and control over sales and distributors activities.

Any of these factors could significantly harm our international expansion and operations and, consequently, our revenues and results of operations. 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.

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.

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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 Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act, or the Affordable Care Act, became law. This law substantially changes the way healthcare is financed by both governmental and private insurers, and significantly impacts our industry. The Affordable Care Act contains a number of provisions that are expected to impact our business and operations, some of which in ways we cannot currently predict, including those governing enrollment in federal healthcare programs, reimbursement changes and fraud and abuse, which will impact existing government healthcare programs and will result in the development of new programs.

Our business will also be affected by the Physician Payment Sunshine Act, or the Sunshine Act. Enacted as part of the Affordable Care Act, it requires all pharmaceutical and medical device manufacturers of products covered by Medicare, Medicaid or the Children s Health Insurance Program to report annually to the Secretary of the Department of Health and Human Services payments or other transfers of value they make, or direct a third party to make, to physicians and teaching hospitals or to third parties on behalf of physicians or teaching hospitals. The payments required to be reported include the cost of meals provided to a physician, travel reimbursements and other transfers of value provided as part of contracted services such as speaker programs, advisory boards, consultation services and clinical trial services. Failure to comply with the reporting requirements can result in significant civil monetary penalties ranging from $1,000 to $10,000 for each payment or other transfer of value that is not reported (up to a maximum per annual report of $150,000) and from $10,000 to $100,000 for each knowing failure to report (up to a maximum per annual report of $1.0 million). Additionally, there are criminal penalties if an entity intentionally makes false statements in such reports. We are subject to the Sunshine Act and the information we disclose may lead to greater scrutiny of our interactions with physicians and teaching hospitals, which may result in modifications to established practices and additional costs. Additionally, similar reporting requirements have also been enacted on the state level domestically, and an increasing number of countries worldwide either have adopted or are considering similar laws requiring transparency of interactions with healthcare professionals.

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 payors 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 payors. While in general it is too early to predict specifically what effect the Affordable Care Act and its implementation 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 Relating 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.

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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 March 31, 2014, we had 16 issued U.S. patents, one pending U.S. patent application, and three pending patent applications outside the United States related to autoimmunity and transplant rejection. We have five issued U.S. patents covering methods of diagnosing transplant rejection using 9 of the 11 informative genes measured in AlloMap. The expiration dates of these patents range from 2021 to 2024. In connection with our acquisition of ImmuMetrix, we expect to succeed to an exclusive license from Stanford University to a patent relating to the diagnosis of rejection in organ transplant recipients using 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 an autoimmune or chronic inflammatory disease, such as lupus, by detecting specific genes. The patent with the longest term expires in 2029. While we have clinical samples and patents covering lupus diagnostics, we do not intend to actively pursue the lupus test opportunity. In cfDNA-based transplant diagnostics, we have submitted a provisional 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 provisional 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 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. 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. It is too early to determine what the effect or impact the AIA will have on the

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operation of our business and the protection and enforcement of our intellectual property. However, the AIA and its implementation could 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 issues 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 this 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

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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 and XDx are registered trademarks of our company in the United States. Our application to register the trademark CareDx in the United States was initially denied based in part on two existing registrations and may not be allowed in a timely fashion or at all. Further consideration of our application may require us to successfully bring a cancellation action against an existing registration that we believe has been abandoned and successfully distinguish our trademark from the second registration. Opposition or cancellation proceedings may be filed against our trademark applications and registrations, and our trademarks may not survive such proceedings. If we do not secure or maintain registrations for our trademarks, we may encounter more difficulty in continuing to use such trademarks or enforcing them against third parties. 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

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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 from third parties technology necessary to develop and commercialize our products. Our most significant license covers PCR technology used in AlloMap and may be required for future solutions we develop. We license this technology from Roche. In connection with our acquisition of ImmuMetrix, we expect to succeed to an exclusive license from Stanford University to a patent relating to the diagnosis of rejection in organ transplant recipients using cfDNA. 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. For more information about a pending arbitration case with Roche to which we are a party, please see the risk factor entitled, We may be subject to legal proceedings that may have an adverse effect on our results of operations as well as the section entitled Business Legal Proceedings.

Risks Related to Our Common Stock and this Offering

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 our share price. 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;

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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;

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. In addition, 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.

If an active, liquid trading market for our common stock does not develop, you may not be able to sell your shares quickly or at or above the initial offering price.

Prior to this offering, there has not been a public market for our common stock. An active and liquid trading market for our common stock may not develop or be sustained following this offering. You may not be able to sell your shares quickly or at or above the initial offering price if trading in our stock is not active. The initial public offering price may not be indicative of prices that will prevail in the trading market. See Underwriting for more information regarding the factors that will be considered in determining the initial public offering price.

Our management will have broad discretion in the use of the net proceeds from this offering, and we may not use these proceeds effectively, which could affect our results of operations and cause our stock price to decline.

Although we currently intend to use the net proceeds from this offering in the manner described in the section entitled Use of Proceeds in this prospectus, our management will have broad discretion over the use of proceeds from this offering and may use the proceeds in ways with which you may disagree. Because we are not required to allocate the net proceeds from this offering to any specific investment or transaction, you

cannot determine at this time the value or propriety of our application of the proceeds. Moreover, you will not have the opportunity to evaluate the economic, financial or other information on which we base our decisions on how to use our proceeds. We may use the proceeds for corporate purposes that do not immediately enhance our prospects for the future or increase the value of your investment. As a result, you and other stockholders may not agree with our decisions.

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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 principal stockholders, and entities affiliated with them, will beneficially own in the aggregate approximately 44% of our common stock following this offering, assuming no purchases in this offering by these parties, who have indicated an interest in purchasing up to an aggregate of approximately 250,000 shares of our common stock at the initial public offering price, and no purchases by such parties in our directed share program. To the extent our existing stockholders purchase additional shares, in this offering or otherwise, this ownership concentration would increase. 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.

We will 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 will 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 Global Market exchange 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 intend to 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 will rely 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 after the completion of this offering, and such 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 ceases coverage of our company, we could lose visibility in the market, which in turn could cause our stock price to decline.

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Future sales of shares by our stockholders could cause the market price of our common stock to drop significantly, even if our business is doing well.

After this offering, we will have outstanding 10,504,302 shares of common stock, based on the number of shares that had been outstanding at March 31, 2014, shares issued upon our acquisition of ImmuMetrix, Inc. in June 2014 and shares issuable upon conversion of the subordinated convertible note issued to Illumina, Inc. in April 2014. This includes the 3,125,000 shares we are selling in this offering, which may be resold in the public market immediately. The remaining 7,379,302 shares will become available for resale in the public market as shown in the chart below.

Number of Restricted Shares	Date of Availability for Resale into the Public Market
2,766,477	180 days (subject to extension in specified circumstances) after the date of this prospectus due to the release of the lock-up agreement these stockholders have with the underwriters
4,612,825	At some point after 180 days (subject to extension in specified circumstances) after the date of this prospectus, subject to the requirements of Rule 144 (subject, in some cases, to volume limitations), or Rule 701

At any time, the underwriters may in their sole discretion release all or some of the securities subject to the lock-up agreements, including securities purchased in the directed shares program described in the Underwriting section of this prospectus. As restrictions on resale end, the market price of our stock could drop significantly if the holders of those shares sell them or are perceived by the market as intending to sell them. In addition, six months after this offering, the holders of 6,048,220 shares of common stock issued upon the conversion of our preferred stock may require us to file a registration statement covering those shares, which may also cause our stock price to decline. These declines in our stock price could occur even if our business is otherwise doing well.

Purchasers in this offering will experience immediate and substantial dilution in the book value of their investment.

The initial public offering price of our common stock is substantially higher than the pro forma net tangible book value per share of our common stock immediately after this offering. In other words, you are paying a price per share that substantially exceeds the value of our assets after subtracting our liabilities. Based on an assumed initial public offering price of $16.00 per share and the pro forma net tangible book value of our common stock at March 31, 2014, your shares will be worth $13.09 less per share than you will pay in the offering. The exercise of outstanding options will result in further dilution of your investment. In addition, if we raise funds by issuing additional shares, the newly issued shares will further dilute your ownership interest.

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, we may in the future become subject to contractual restrictions on, or prohibitions against, the payment of dividends.

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If we are unable to substantially utilize our net operating loss carryforwards, our financial results will be harmed.

As of December 31, 2013, our net operating loss, or NOL, carryforward amounts for U.S. federal income and California tax purposes were $162.5 million and $136.3 million, respectively. Under Section 382 of the Internal Revenue Code, a corporation that undergoes an ownership change may be subject to limitations on its ability to utilize its pre-change NOLs to offset future taxable income. We may have undergone ownership changes in the past, and purchases of our common stock in amounts greater than specified levels in the future, including in connection with this offering, which may be beyond our control, could create additional limitations on our ability to utilize our NOLs in the future. Limitations imposed on our ability to utilize NOLs could cause U.S. federal and state income taxes to be paid earlier than would be paid if such limitations were not in effect and could cause such NOLs to expire unused, in each case reducing or eliminating the benefit of such NOLs. Furthermore, we may not be able to generate sufficient taxable income to utilize our NOLs before they expire. If any of these events occur, we may not derive some or all of the expected benefits from our NOLs.

Our financial controls and procedures may not be sufficient to ensure timely and reliable reporting of financial information, which, as a public company, could materially harm our stock price and exchange listing.

As a public reporting company, we will be required to comply with the Sarbanes-Oxley Act of 2002 and the related rules and regulations of the Securities and Exchange Commission, 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 recently have been upgrading our finance and accounting systems, procedures and controls and will need to continue to implement additional finance and accounting systems, procedures and controls as we grow our business and organization and to satisfy new reporting requirements. If we are unable to complete the required Section 404 assessment as to the adequacy of our internal control over financial reporting, if we fail to maintain or implement adequate controls, or if our independent registered public accounting firm is unable to provide us with an unqualified report as to the effectiveness of our internal control over financial reporting as of the date of our first Form 10-K for which compliance is required, our ability to obtain additional financing could be impaired.

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. In addition, investors could lose confidence in the reliability of our internal control over financial reporting and in the accuracy of our periodic reports filed under the Securities Exchange Act. A lack of investor confidence in the reliability and accuracy of our public reporting could cause our stock price to decline.

As a public company, we will require greater financial resources than we have had as a private company. We cannot provide you with assurance that our finance department has or will maintain adequate resources to ensure that we will not have any future material weaknesses in our system of internal controls. 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 fail to have effective controls and procedures for financial reporting in place, we could be unable to provide timely and accurate financial information and may be subject to NASDAQ Global Market delisting, SEC investigation and civil or criminal sanctions.

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In reviewing our preliminary purchase accounting and supporting analyses relating to our acquisition of ImmuMetrix, Inc., we identified a material weakness in our internal control over financial reporting.

In reviewing our preliminary purchase accounting and supporting analyses related to our acquisition of ImmuMetrix, Inc., we identified a material weakness in our internal control over financial reporting. The material weakness related to our internal controls over financial reporting pertaining to business combinations processes that were not adequately designed and therefore not operating effectively. A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected and corrected on a timely basis. The material weaknesses involved aspects of our proposed purchase accounting for our ImmuMetrix acquisition that required adjustment, including adjustments to valuation of in-process technology, deferred income tax liability related to acquired in-process technology, goodwill, share based compensation and recording of transaction costs.

We are in the process of implementing measures designed to improve our internal control over financial reporting to strengthen our internal control over financial reporting. These measures include the hiring of additional accounting staff, including a controller with experience preparing periodic reports to be filed under the Securities Exchange Act, the recent hiring of Ken Ludlum, a chief financial officer with experience preparing periodic reports to be filed under the Securities Exchange Act, and continued training of our accounting staff on accounting processes and procedures, including those relating to business combinations. We cannot assure you that the measures we have taken to date, or any measures we may take in the future, will be sufficient to remediate the material weakness in our internal control over financial reporting or to avoid potential future material weaknesses.

In future periods, if during the evaluation and testing process, we identify any other material weaknesses in our internal control over financial reporting, we may be unable to assert that our internal control over financial reporting is effective. If we are unable to assert that our internal control over financial reporting is effective, we could lose investor confidence in the accuracy and completeness of our financial reports, which could cause the price of our common stock to decline.

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 that will be in effect upon completion of this offering and Section 203 of the Delaware General Corporation Law 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 will be authorized, without prior stockholder approval, to create and issue preferred stock which could be used to implement anti-takeover devices;
- advance notice will be required for director nominations or for proposals that can be acted upon at stockholder meetings;
- our board of directors will be 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 will be prohibited;
- special meetings of the stockholders will be permitted to 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);

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stockholders will not be permitted to cumulate their votes for the election of directors; and

stockholders will be permitted to 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 Delaware General Corporation Law. 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, if we decide to comply only with 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 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 shareholder approval of any golden parachute payments not previously approved. We will continue to be an emerging growth company until the earlier of (1) the last day of the fiscal year (a) following the fifth anniversary of the completion of this 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 June 30th, and (2) 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 if we choose to rely 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 have irrevocably elected not to avail ourselves of this exemption from new or revised accounting standards following the completion of this offering, and therefore, we will be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies.

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SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus, including the sections entitled Prospectus Summary, Risk Factors, Use of Proceeds, Management s Discussion and Analysis of Financial Condition and Results of Operations, Business and Executive Compensation, contains forward-looking statements. The words believe, may, will, potentially, estimate, continue, anticipate, intend, could, would, project, plan, predict, expect and similar e uncertainty of future events or outcomes are intended to identify forward-looking statements.

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

- our ability to generate revenue from sales of AlloMap and future solutions, if any, and our ability to increase the commercial success of AlloMap;
- our plans and ability to develop and commercialize new solutions, including cell-free DNA, or cfDNA, solutions for the surveillance of heart and kidney transplant recipients;
- our ability to achieve, maintain and expand reimbursement coverage from payers for AlloMap and future solutions, if any;
- the outcome or success of our clinical trial collaborations or observational studies;
- our compliance with federal, state and foreign regulatory requirements;
- the continuing favorable review of AlloMap test in peer-reviewed publications, and receipt of favorable review of future solutions, if any;
- our ability to protect and enforce intellectual property rights and our strategies regarding filing additional patent applications to strengthen our intellectual property rights;
- our anticipated cash needs and our estimates regarding our capital requirements and our needs for additional financing; and
- anticipated trends and challenges in our business and the markets in which we operate.

These forward-looking statements are subject to a number of risks, uncertainties and assumptions, including those described in the section entitled Risk Factors and elsewhere in this prospectus. 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 prospectus 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. We undertake no obligation to update publicly any forward-looking statements for any reason after the date of this prospectus to conform these statements to actual results or to changes in our expectations, except as required by law.

You should read this prospectus and the documents that we reference in this prospectus and have filed with the SEC as exhibits to the registration statement of which this prospectus is a part with the

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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.

MARKET AND INDUSTRY DATA

Unless otherwise indicated, information contained in this prospectus concerning our industry and the markets in which we operate, including our general expectations and market position, market opportunity and market size, is based on information from various sources including industry publications and reports, on assumptions that we have made that are based on those data and other similar sources and on our knowledge of the markets for our products and services. We are responsible for all of the disclosure in this prospectus. The future performance of the industry in which we operate is necessarily subject to a high degree of uncertainty and risk due to a variety of factors, including those described in the section entitled Risk Factors and elsewhere in this prospectus. These and other factors could cause results to differ materially from those expressed in these publications and reports.

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USE OF PROCEEDS

We estimate that the net proceeds from the sale of our common stock in this offering will be approximately $43.5 million, based upon an assumed initial public offering price of $16.00 per share, the midpoint of the price range set forth on the cover page of this prospectus, and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. If the underwriters option to purchase additional shares is exercised in full, we estimate that we will receive net proceeds of approximately $50.5 million, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

Each $1.00 increase (decrease) in the assumed initial public offering price of $16.00 per share would increase (decrease) the net proceeds to us from this offering by approximately $2.9 million, assuming the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. Similarly, each increase (decrease) of 1,000,000 shares in the number of shares of common stock offered by us would increase (decrease) the net proceeds to us from this offering by approximately $14.9 million, assuming that the assumed initial public offering price remains the same, and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

We currently intend to use the net proceeds from this offering as follows:

- approximately $20.2 million for research and development, including research aimed at expanding the clinical utility of AlloMap and the development of new solutions for the surveillance of heart and kidney transplant recipients;
- approximately $13.3 million for sales and marketing activities, including expansion of our sales force to support the ongoing commercialization of our products; and
- the remainder for general and administrative expenses (including personnel related costs and the costs of operating as a public company), and for working capital and other general corporate purposes.

The expected use of proceeds from this offering represents our intentions based on our current plans and business conditions. The amounts and timing of our actual expenditures may vary depending on numerous factors, including the progress of our commercialization efforts, the status of additional payer reimbursement coverage determinations for our AlloMap solution and the results of our research and development efforts. If our research and development of new solutions for the surveillance of heart and kidney transplants requires more time or resources than we currently anticipate or if we encounter unforeseen difficulties in securing reimbursement for our AlloMap solution or future surveillance solutions, we may allocate additional proceeds of this offering to our research and development efforts. If our research and development efforts progress faster than we currently expect, we may elect to reallocate a portion of the proceeds of this offering from research and development to sales and marketing activities to support the launch and commercialization of our new solutions. We may also use a portion of the net proceeds from this offering for the acquisition of, or investment in, technologies, solutions or businesses that complement our business. However, except for our proposed acquisition of ImmuMetrix, Inc., which is described elsewhere in this prospectus, we have no present commitments or agreements to enter into any such acquisitions or investments. Pending these uses, we intend to invest the net proceeds from this offering in short-term, investment-grade interest-bearing securities such as money market funds, certificates of deposit, commercial paper and guaranteed obligations of the U.S. government.

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DIVIDEND POLICY

We have never declared or paid cash dividends on our common stock. We currently intend to retain all available funds and any future earnings for use in the operation of our business and do not anticipate paying any dividends on our common stock in the foreseeable future. Any future determination to declare dividends will be made at the discretion of our board of directors and will depend on our financial condition, operating results, capital requirements, general business conditions and other factors that our board of directors may deem relevant. Further, our Loan and Security Agreement with Oxford Finance, LLC and Silicon Valley Bank restricts our ability to pay dividends while amounts remain outstanding under that facility.

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CAPITALIZATION

The following table sets forth our cash and cash equivalents and capitalization as of March 31, 2014 on:

- an actual basis;
- a pro forma basis, giving effect to the issuance of an aggregate of 888,135 shares of Series G Preferred Stock upon completion of our acquisition of ImmuMetrix, Inc. in June 2014, the automatic conversion of all outstanding shares of our convertible preferred stock into 6,048,220 shares of common stock, the automatic conversion of all outstanding convertible preferred stock warrants into warrants for 541,613 shares of common stock and the effectiveness of our amended and restated certificate of incorporation and amended and restated bylaws as of immediately prior to the completion of this offering, as if such conversions had occurred and our amended and restated certificate of incorporation had become effective on March 31, 2014; and
- a pro forma as adjusted basis, giving effect to the pro forma adjustments, the issuance and conversion of a subordinated convertible promissory note issued in April 2014 in the aggregate principal amount of $5.0 million plus accrued interest into 318,750 shares of common stock (assuming conversion of the note on July 15, 2014 at a common stock price per share of $16.00, which is the mid-point of the price range on the cover of this prospectus), and the sale of 3,125,000 shares of common stock by us in this offering, based on an assumed initial public offering price of $16.00 per share, the mid-point of the price range reflected on the cover page of this prospectus, after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us.

The pro forma as adjusted information set forth in the table below is illustrative only and will be adjusted based on the actual initial public offering price and other terms of this offering determined at pricing.

You should read this table together with Management s Discussion and Analysis of Financial Condition and Results of Operations and our audited and unaudited financial statements and related notes included elsewhere in this prospectus.

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	As of March 31, 2014		
	Actual	Pro Forma (Unaudited)	Pro Forma as Adjusted[1]
	(In thousands, except share and per share data)		
Cash and cash equivalents	$ 4,837	$ 4,437	$ 53,008
Convertible preferred stock warrant liability	$ 1,053	$	$
Convertible preferred stock: $0.001 par value; 6,417,954 shares authorized, 5,155,673 shares issued and outstanding, actual; no shares authorized, issued and outstanding, pro forma and pro forma as adjusted	135,202		
Stockholders equity (deficit):			
Preferred Stock, par value $0.001; no shares authorized, issued and outstanding, actual; 10,000,000 shares authorized, no shares issued and outstanding, pro forma and pro forma adjusted			
Common stock: $0.001 par value; 7,737,226 shares authorized, 1,012,332 shares issued and outstanding, actual; 100,000,000 shares authorized, 6,172,417 shares issued and outstanding, pro forma; 100,000,000 shares authorized, 10,504,302 shares issued and outstanding, pro forma as adjusted	1	8	11
Additional paid-in capital	9,535	161,720	210,317
Accumulated deficit	(161,460)	(159,860)	(159,860)
Total stockholders equity (deficit)	(151,924)	1,868	50,468
Total capitalization	$ (15,669)	$ 1,868	$ 50,468

(1) Each $1.00 increase (decrease) in the assumed initial public offering price of $16.00 per share, the midpoint of the price range set forth on the cover page of this prospectus, would increase (decrease) our pro forma as adjusted cash and cash equivalents, additional paid-in capital, total stockholders equity and total capitalization by approximately $2.9 million, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us.

The number of shares of our common stock that will be outstanding immediately after this offering is based on 6,172,417 shares outstanding as of March 31, 2014, 888,135 shares issued upon completion of our acquisition of ImmuMetrix, Inc. in June 2014 and 318,750 shares issuable upon conversion of a subordinated convertible promissory note issued by us in April 2014. The number of outstanding shares excludes:

- 450,382 shares of common stock issuable upon the exercise of options outstanding under our 2008 Equity Incentive Plan as of March 31, 2014, at a weighted average exercise price of $3.90 per share;
- 97,349 shares of common stock issuable upon the exercise of options outstanding pursuant to the 1998 Stock Plan as of March 31, 2014, at a weighted average exercise price of $3.14 per share;
- 623,803 shares of common stock issuable upon the exercise of warrants outstanding as of March 31, 2014, on an as-converted basis and at a weighted average exercise price of $22.58 per share;
- 838,695 shares of common stock reserved for future issuance under our 2014 Equity Incentive Plan (which consist of (1) 803,418 shares of common stock initially reserved for issuance under the 2014 Equity Incentive Plan; and (2) 35,277 shares of common stock reserved for issuance under our 2008 Equity Incentive Plan, which shares will be added to the shares reserved under the 2014 Equity Incentive Plan upon its effectiveness), which will become effective upon the execution and delivery of the

underwriting agreement for this

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offering; and up to 865,252 additional shares as of immediately prior to this offering that may be added to the 2014 Equity Incentive Plan upon the expiration, termination, forfeiture or other reacquisition of any shares of common stock issuable upon the exercise of stock awards outstanding under the 2008 Equity Incentive Plan and any automatic increases in the number of shares of common stock reserved for future issuance under the 2014 Equity Incentive Plan;

89,269 shares of common stock to be reserved for issuance under our 2014 Employee Stock Purchase Plan, to be effective in connection with this offering, as well as any automatic increases in the number of shares of common stock reserved for future issuance under this plan;

227,845 shares of common stock issuable to the former stockholders of ImmuMetrix upon achievement of a performance milestone; and

23,229 shares of our preferred stock issuable upon the exercise of options assumed upon completion of our acquisition of ImmuMetrix, Inc. in June 2014, all of which shall be converted into options for common stock immediately prior to the closing of this offering.

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DILUTION

If you invest in our common stock, your interest will be diluted to the extent of the difference between the amount per share paid by purchasers of shares of common stock in this initial public offering and the pro forma as adjusted net tangible book value per share of common stock immediately after this offering.

As of March 31, 2014, our pro forma net tangible book value was approximately $(18.0) million, or $(2.55) per share of common stock. Our pro forma net tangible book value per share represents the amount of our total pro forma tangible assets reduced by the amount of our pro forma total liabilities and divided by the total number of shares of our common stock outstanding as of March 31, 2014, assuming the conversion of all outstanding shares of our convertible preferred stock into 6,048,220 shares of common stock, which includes 888,135 shares issued upon completion of our acquisition of ImmuMetrix, Inc. in June 2014.

After giving effect to our sale in this offering of 3,125,000 shares of our common stock, at an assumed initial public offering price of $16.00 per share, the midpoint of the price range set forth on the cover page of this prospectus, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us and after giving effect to the conversion of a subordinated convertible note issued in April 2014 in the aggregate principal amount of $5.0 million, plus interest through July 15, 2014 at $16.00 per share, our pro forma, as adjusted, net tangible book value as of March 31, 2014 would have been approximately $30.6 million, or $2.91 per share of our common stock. This represents an immediate increase in pro forma net tangible book value of $5.46 per share to our existing stockholders and an immediate dilution of $13.09 per share to investors purchasing shares of common stock in this offering and the holder of the convertible subordinated note.

The following table illustrates this dilution:

Assumed initial public offering price per share		$ 16.00
Pro forma net tangible book value per share as of March 31, 2014	$ (2.55)	
Increase per share attributable to conversion of subordinated convertible note issued in April 2014	0.80	
Increase per share attributable to this offering	4.66	
Pro forma net tangible book value, as adjusted to give effect to this offering and conversion of the subordinated convertible note		2.91
Dilution in pro forma net tangible book value per share to new investors in this offering and the holder of the convertible subordinated note		$ 13.09

The dilution information discussed above is illustrative only and will change based on the actual initial public offering price and other terms of this offering determined at pricing. Each $1.00 increase (decrease) in the assumed initial public offering price of $16.00 per share, the midpoint of the price range set forth on the cover page of this prospectus, would increase (decrease) our pro forma net tangible book value, as adjusted to give effect to this offering and conversion of the subordinated convertible note, by $0.28 per share, would increase (decrease) the dilution in pro forma as adjusted net tangible book value per share to new investors in this offering and conversion of the subordinated convertible note by $0.72 per share, assuming the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting estimated underwriting discounts and commissions and estimated expenses payable by us.

If the underwriters exercise their over-allotment option in full, the pro forma net tangible book value per share of our common stock after giving effect to this offering and conversion of the subordinated

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convertible note would be $3.42 per share, and the immediate dilution in net tangible book value per share to investors in this offering and conversion of the subordinated convertible note would be $12.58 per share.

The following table summarizes, on a pro forma as adjusted basis as of March 31, 2014, after giving effect to (1) the automatic conversion of all of our convertible preferred stock into common stock, the issuance of 888,135 shares upon completion of our acquisition of ImmuMetrix, Inc. in June 2014, the conversion of a subordinated convertible promissory note issued in April 2014 in the aggregate principal amount of $5.0 million plus accrued interest into 318,750 shares of common stock (assuming conversion of the note on July 15, 2014 at a price per share equal to $16.00, which is the mid-point of the price range on the cover of this prospectus), and the effectiveness of our amended and restated certificate of incorporation and amended and restated bylaws and (2) this offering on an assumed initial public offering price of $16.00 per share, the midpoint of the price range reflected on the cover page of this prospectus, the difference between existing stockholders and new investors with respect to the number of shares of common stock, purchased from us, the total consideration paid to us, and the average price per share paid, before deducting estimated underwriting discounts and commissions and estimated offering expenses:

	Shares Purchased		Total Consideration (amount in thousands)		Average Price Per Share
	Number	Percent	Amount	Percent	
Existing stockholders	7,060,552	67%	$ 167,157	75%	$ 23.67
New public investors and the holder of the subordinated convertible note	3,443,750	33	55,100	25	16.00
Total	10,504,302	100%	$ 222,257	100%	

The information discussed above is illustrative only and will change based on the actual initial public offering price and other terms of this offering determined at pricing. Each $1.00 increase (decrease) in the assumed initial public offering price of $16.00 per share, the midpoint of the price range set forth on the cover page of this prospectus, would increase (decrease) total consideration paid by new investors and total consideration paid by all stockholders by approximately $2.9 million, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us.

Except as otherwise indicated, the above discussion and tables assume no exercise of the underwriters over-allotment option. If the underwriters exercise their over-allotment option in full, our existing stockholders would own 64% and our new investors would own 36% of the total number of shares of our common stock outstanding upon the completion of this offering.

The number of shares of our common stock that will be outstanding immediately after this offering is based on 6,172,417 shares outstanding as of March 31, 2014, 888,135 shares issued in connection with our acquisition of ImmuMetrix, Inc. in June 2014 and 318,750 shares issuable upon conversion of a subordinated convertible promissory note issued by us in April 2014. The number of outstanding shares excludes:

- 450,382 shares of common stock issuable upon the exercise of options outstanding under our 2008 Equity Incentive Plan as of March 31, 2014, at a weighted average exercise price of $3.90 per share;

- 97,349 shares of common stock issuable upon the exercise of options outstanding pursuant to the 1998 Stock Plan as of March 31, 2014, at a weighted average exercise price of $3.14 per share;

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623,803 shares of common stock issuable upon the exercise of warrants outstanding as of March 31, 2014, on an as-converted basis and at a weighted average exercise price of $22.58 per share;

838,695 shares of common stock reserved for future issuance under our 2014 Equity Incentive Plan (which consist of (1) 803,418 shares of common stock initially reserved for issuance under the 2014 Equity Incentive Plan; and (2) 35,277 shares of common stock reserved for issuance under our 2008 Equity Incentive Plan as of immediately prior to the completion of this offering, which shares will be added to the shares reserved under the 2014 Equity Incentive Plan upon its effectiveness), which will become effective upon the execution and delivery of the underwriting agreement for this offering; and up to 865,252 additional shares as of immediately prior to the completion of this offering that may be added to the 2014 Equity Incentive Plan upon the expiration, termination, forfeiture or other reacquisition of any shares of common stock issuable upon the exercise of stock awards outstanding under the 2008 Equity Incentive Plan and any automatic increases in the number of shares of common stock reserved for future issuance under the 2014 Equity Incentive Plan;

89,269 shares of common stock to be reserved for issuance under our 2014 Employee Stock Purchase Plan, to be effective in connection with this offering, as well as any automatic increases in the number of shares of common stock reserved for future issuance under this benefit plan;

227,845 shares of common stock issuable to the former stockholders of ImmuMetrix upon achievement of a performance milestone; and

23,229 shares of our preferred stock issuable upon the exercise of options that were assumed in connection with our acquisition of ImmuMetrix, Inc. in June 2014, and the conversion of such options into options for common stock immediately prior to the closing of this offering.

Certain of our existing stockholders and their affiliated entities have indicated an interest in purchasing up to an aggregate of approximately 250,000 shares of our common stock in this offering at the initial public offering price. However, because indications of interest are not binding agreements or commitments to purchase, these stockholders may determine to purchase fewer shares than they have indicated an interest in purchasing or not to purchase any shares in this offering. It is also possible that these stockholders could indicate an interest in purchasing more shares of our common stock. In addition, the underwriters could determine to sell fewer shares to any of these stockholders than the stockholders have indicated an interest in purchasing or not to sell any shares to these stockholders. The foregoing discussion and tables do not reflect any potential purchases of any shares in this offering by these stockholders or their affiliated entities.

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SELECTED FINANCIAL DATA

You should read the following selected financial data together with our audited financial statements and the related notes included elsewhere in this prospectus and the information under the caption Management s Discussion and Analysis of Financial Condition and Results of Operations.

We derived the selected statements of operations data for the years ended December 31, 2012 and 2013 and the balance sheet data as of December 31, 2012 and 2013 from our audited financial statements included elsewhere in this prospectus. We derived the selected statements of operations data for the three months ended March 31, 2013 and 2014 and the selected balance sheet data as of March 31, 2014 from our unaudited interim condensed financial statements and the related notes included elsewhere in this prospectus. The following summary financial data should be read together with our audited and unaudited financial statements and the related notes, as well as the section entitled Management s Discussion and Analysis of Financial Condition and Results of Operations included elsewhere in this prospectus. Our unaudited interim condensed financial statements were prepared on the same basis as our audited financial statements and include, in our opinion, all adjustments, consisting of normal recurring adjustments that we consider necessary for a fair presentation of the financial information set forth in those financial statements. Our historical results presented below are not necessarily indicative of the results that may be achieved in future periods, and results of interim periods are not necessarily indicative of results for the entire year.

(in thousands, except share and per share data)	Year Ended December 31, 2012	2013	Three Months Ended March 31, 2013	2014
			(unaudited)	
Statements of Operations Data:				
Revenue:				
Testing revenue	$ 19,730	$ 21,672	$ 4,809	$ 5,834
Collaboration and license revenue	721	426	172	90
Total revenue	20,451	22,098	4,981	5,924
Operating expenses:				
Cost of testing	7,930	9,078	2,124	2,162
Research and development	4,752	3,176	1,002	720
Sales and marketing	5,417	5,892	1,569	1,474
General and administrative	4,694	4,809	1,064	1,795
Total operating expenses	22,793	22,955	5,759	6,151
Loss from operations	(2,342)	(857)	(778)	(227)
Interest expense, net	(2,703)	(2,149)	(565)	(548)
Other expense, net	(14)	(536)	(5)	(529)
Net loss	$ (5,059)	$ (3,542)	$ (1,348)	$ (1,304)
Net loss per common share, basic and diluted[1]	$ (5.01)	$ (3.50)	$ (1.33)	$ (1.29)
Shares used to compute net loss per common share, basic and diluted[1]	1,009,236	1,010,795	1,010,684	1,011,980
Pro forma net loss per common share, basic and diluted (unaudited)[1][2]		$ (0.41)		$ (0.11)
Shares used to compute pro forma net loss per common share, basic and diluted (unaudited)[1][2]		7,371,515		7,372,700

(1) Basic and diluted net loss per common share is calculated by dividing net loss for the period by the weighted average number of common shares outstanding during the period. See Notes 2 and 3 to our audited financial statements and Note 2 to our unaudited interim condensed financial statements included elsewhere in this prospectus.

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(2) We have presented pro forma net loss per common share information for the year ended December 31, 2013 and three months ended March 31, 2014 to (i) reflect the issuance of 888,135 shares of our preferred stock upon completion of our acquisition of ImmuMetrix, Inc. in June 2014, (ii) the issuance of 312,500 shares of our preferred stock upon conversion of a subordinated convertible promissory note issued in April 2014 in the aggregate principal amount of $5.0 million at an assumed conversion price per share of $16.00, (iii) reflect the conversion of all of our outstanding shares of convertible preferred stock into an aggregate of 6,048,220 shares of common stock, and (iv) the reclassification to equity of our convertible preferred stock warrant liability in connection with the conversion of our outstanding convertible preferred stock warrants into common stock warrants. The numerator has been adjusted to remove the loss resulting from remeasurement of the warrant liability, as these amounts will be reclassified as equity upon the closing of this offering.

	December 31,		As of March 31, 2014
	2012	2013	(unaudited)
	(in thousands)		
Balance Sheet Data:			
Cash and cash equivalents	$ 5,830	$ 5,128	$ 4,837
Working capital	1,169	578	(1,098)
Total assets	9,876	9,873	11,095
Total debt	14,865	15,375	15,076
Convertible preferred stock	135,202	135,202	135,202
Total stockholders deficit	(147,203)	(150,673)	(151,924)

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MANAGEMENT S DISCUSSION AND ANALYSIS

OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

You should read the following discussion and analysis of our financial condition and results of operations together with the financial statements and related notes that are included elsewhere in this prospectus. This discussion and other parts of this prospectus contain forward-looking statements based upon current plans, expectations and beliefs that involve risks and uncertainties. Our actual results may differ materially from those discussed in these forward-looking statements as a result of various factors, including in the section entitled Risk Factors and in other parts of this prospectus.

Business Overview

We are a commercial stage company that develops, markets and delivers a diagnostic surveillance solution for heart transplant recipients to help clinicians make personalized treatment decisions throughout a patient s lifetime. Our commercialized testing solution, the AlloMap heart transplant molecular test, is a blood-based test used to monitor heart transplant recipients for acute cellular rejection. 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 to avoid the use of unnecessary, invasive surveillance biopsies and to determine the appropriate dosage levels of immunosuppressants. We believe that there is a significant unmet need for post-transplant surveillance solutions and are applying our expertise in transplantation towards the development of additional solutions for other organ transplant recipients, including recipients of heart and kidney transplants.

Since the launch of AlloMap in January 2005 we have performed more than 55,000 commercial AlloMap tests, including approximately 10,100 tests in 2013 and approximately 2,800 tests in first quarter of 2014, in our Brisbane, California laboratory. In 2013, the test was used in 105 of the approximately 126 U.S. heart transplant management centers in the U.S. We believe that there is a meaningful opportunity for AlloMap outside of the U.S. and through recent partnerships we have expanded the AlloMap offering to Europe and Canada. We believe that we are not currently capacity constrained and that our current facility can support a substantial increase in testing volume.

Reimbursement for AlloMap tests comes primarily from Medicare, private third party payers such as insurance companies and managed care organizations, hospitals and state Medicaid programs. Tests performed on patients covered by Medicare represented 40% and 39% of all AlloMap tests in 2012 and 2013, respectively. Tests performed on patients covered by Medicare represented 40% and 36% of all AlloMap tests in the quarters ended March 31, 2013 and 2014, respectively. A number of payers have adopted coverage policies approving AlloMap tests 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 the appeals process for the particular payer.

Forty-three payers, including Medicare, insured recipients that accounted for approximately 90% of the tests we delivered in 2013. Forty-six payers, including Medicare, insured recipients that accounted for approximately 90% of the tests we delivered in the first quarter of 2014. Many of these, including Medicare, have adopted coverage policies approving AlloMap for reimbursement. We continue to pursue adoption of positive coverage policies by other private and Medicaid payers. The rate at which our tests are covered and reimbursed has, and is expected to continue to vary by payer. Reimbursement performance is reviewed using a lagging metric of six months, as any period less than this is considered not to be reflective of future performance, as the reimbursement process can take six months or more to complete, depending on the payer. Similarly, as of March 31, 2014, we had been reimbursed for approximately 78% of AlloMap results delivered in the twelve months ended September 30, 2013.

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Since our inception, we have generated significant net losses. As of March 31, 2014, we had an accumulated deficit of $161 million. We incurred net losses of $5.1 million and $3.5 million in the years ended December 31, 2012 and 2013, respectively and $1.3 million in the three months ended March 31, 2014. Together with our cash and cash equivalents, cash receipts from our AlloMap testing and net proceeds from this offering, we expect to be able to accelerate the development of new transplant surveillance solutions, such as our planned cell-free DNA, or cfDNA, solution for heart and kidney, using both our proprietary and third party libraries of blood samples from multiple organs.

Financial Operations Overview

Testing Revenue

Our testing revenue is derived from AlloMap tests which represented 97% of our total revenue in 2012 and 98% of our total revenue in 2013. AlloMap tests represented 97% and 99% of our total revenue in the three months ended March 31, 2013 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 March 31, 2014, 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.

As of December 31, 2012 and 2013, the number of tests for which results were delivered and billed, but for which the associated revenue had not been recognized because our revenue recognition criteria were not met, and taking into account claim status and possibility of collection, was approximately 3,800 and 3,900, respectively. As of March 31, 2013 and March 31, 2014, the number of such tests was approximately 3,800 and 4,100 respectively. We cannot provide any assurance as to when, if ever, or to what extent any of these amounts will be collected.

Collaboration and License Revenue

Revenue from our collaboration and license agreements was less than 5% of total revenue for each period presented. Collaboration and license agreements may include non-refundable upfront payments, partial or complete reimbursement of research and development costs, contingent payments based on the occurrence of specified events under the agreements, license fees and royalties on sales of products or product candidates if they are successfully commercialized. Note 9 to our audited financial statements included elsewhere in this prospectus includes descriptions of these agreements. 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.

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Cost of Testing

Cost of testing reflects the aggregate costs incurred in delivering our AlloMap 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, shipping, logistics and specimen processing charges to collect and transport samples and allocated overhead including rent, information technology, equipment depreciation and utilities and royalties. 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 included in cost of testing are associated with a license from Roche Molecular Systems, Inc., or Roche. In February 2014, we received a demand for arbitration from Roche regarding our claim that the royalty rate being assessed under the Roche license should be reduced. See the Business Section Legal Proceedings included elsewhere in this prospectus regarding this arbitration. Liabilities recorded on our balance sheets of $1.5 million, $2.8 million and $3.1 million as of December 31, 2012, December 31, 2013 and March 31, 2014, respectively, reflect the full amount of royalties owed at the stated royalty rate set forth in the agreement, plus interest. Our obligation under the Roche agreement expires on the date of the last to expire of the relevant patents included within the licensed technology that covers our tests.

We expect cost of testing to increase, in absolute dollars, as the number of tests we perform increases. However, due to the fixed nature of expenses associated with direct labor, equipment and infrastructure, we expect the cost per test will decrease over time as volume increases. Logistics, supplies and royalties are generally variable in nature and we expect these expenses to increase as test volume increases.

Research and Development Expenses

Research and development expenses represent costs incurred to develop new surveillance solutions as well as continued efforts related to our AlloMap test. 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.

Sales and Marketing Expenses

Sales and marketing expenses represent costs incurred to sell, promote and increase awareness of our AlloMap test to both clinicians and payers, including education of patients, clinicians and payers. 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 quarterly or semi-annual commissions or bonuses based on the achievement of predetermined sales goals or other management objectives. We have infrastructure in place to cover most of the key transplant centers in the United States both for offerings of our existing AlloMap product as well as future products. We may increase our product range and our geographic reach in the future which would lead to an expansion of our sales and marketing efforts.

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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 incur additional expenses as a result of operating as a public company, including expenses related to compliance with the rules and regulations of the Securities and Exchange Commission and The NASDAQ Global Market, additional insurance expenses, investor relations activities and other administrative and professional services. We also expect our general and administrative expenses will increase in absolute dollars related to anticipated testing volume and collections growth.

Interest Expense, Net

Interest expense, net is associated with borrowings under our loan agreements.

Other Expense, Net

Other expense, net is primarily associated with the remeasurement of the estimated fair value of the warrants to purchase shares of our convertible preferred stock.

Critical Accounting Policies and Significant Judgments and Estimates

Our management s discussion and analysis of our financial condition and results of operation is based on our financial statements, which have been prepared in accordance with United States generally accepted accounting principles or U.S. GAAP. The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenue and expenses during the reporting period. Items subject to estimates based on judgments include, but are not limited to: revenue recognition, the valuation of warrants to purchase convertible preferred stock, the determination of the valuation allowance associated with deferred tax assets, the determination of the accruals for clinical studies, the determination of estimated refunds to be requested from third-party payers, any impairment of long-lived assets and legal contingencies. Actual results could differ from these estimates and such differences could affect the results of operations in future periods.

Our significant accounting policies are described in Note 2 to our audited financial statements included elsewhere in this prospectus. 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 criteria is satisfied when a third-party payer makes a coverage decision or enters into a contractual arrangement with us for the test. The second criteria is satisfied when we perform the test and deliver the test result to the ordering physician. The third criteria is satisfied if the third-party payer s coverage decision or reimbursement contract specifies a price for the test. The fourth criteria is satisfied based on management s judgments regarding the collectability of the fees charged under the arrangement.

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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 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 2012 and 2013, approximately 56% and 64%, respectively, of our testing revenue was recognized on the accrual basis. In the three months ended March 31, 2013 and March 31, 2014, approximately 63% and 62%, 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,		Three Months Ended March 31,	
	2012	2013	2013	2014
AlloMap tests delivered	8,300	10,100	2,200	2,800
AlloMap tests for which revenue was recognized	7,500	8,400	1,900	2,200
AlloMap tests for which revenue was recognized which were delivered prior to the period presented	1,800	1,100	700	800

We did not recognize revenue for the remaining tests because either there was no contract, no coverage policy in place, insufficient payment history or we had not received payment for those tests from a payer. We will continue to make requests for payment from payers and patients and/or appeal payment decisions made by third-party payers. As a result, we may receive payment for a portion of these tests. However, a portion of our requests for payments could be denied or only partially satisfied. If third-party payers agree to pay us for these tests in the future, we will recognize revenue for such tests in the period in which all of our revenue recognition criteria are met. This will continue to affect the comparability of our revenues from period to period. We regularly review to determine if payers meet our revenue recognition criteria and account for the impact of any change on a prospective basis.

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

Collaboration and License Revenue

Revenue from our collaboration and license agreements was less than 5% of total revenue for each period presented. Collaboration and license agreements may include non-refundable upfront payments, partial or complete reimbursement of research and development costs, contingent payments based on the occurrence of specified events under the agreements, license fees and royalties on sales of products or product candidates if they are successfully commercialized.

We recognize collaboration and license revenue based upon the relative-selling price method which is used to allocate arrangement consideration to all of the units of accounting in an arrangement. We evaluate our collaboration and license agreements to identify the deliverables, determine if the deliverables have stand-alone value, to identify the units of accounting and to allocate arrangement consideration to each unit of accounting based on relative best estimate selling price.

We recognize contingent consideration received from the achievement of a substantive milestone in its entirety in the period in which the milestone is achieved, which we believe is more consistent with the substance of our performance under our various license and collaboration agreements. We did not recognize any milestones during 2012 or 2013 or during the quarter ended March 31, 2014.

Business Combinations

In accordance with ASC 805, *Business Combinations*, the Company determines and allocates the purchase price of an acquired business to the tangible and identifiable intangible assets acquired and liabilities assumed based on their estimated fair values as of the business combination date, including identifiable intangible assets which either arise from a contractual or legal right or are separable from goodwill. The Company bases the estimated fair value of identifiable intangible assets acquired in a business combination on independent valuations that use information and assumptions provided by management, which consider management s best estimates of inputs and assumptions that a market participant would use. The Company allocates any excess purchase price over the estimated fair value assigned to the net tangible and identifiable intangible assets acquired and liabilities assumed to goodwill. The use of alternative valuation assumptions, including estimated revenue projections, growth rates, royalty rates, cash flows, discount rates, estimated useful lives and probabilities surrounding the achievement of contingent milestones, could result in different purchase price allocations and amortization expense in current and future periods.

In those circumstances where an acquisition involves a contingent consideration arrangement that meets the definition of a liability under ASC 480, *Distinguishing Liabilities from Equity*, the Company recognizes a liability equal to the fair value of the contingent payments the Company expects to make as of the acquisition date. The Company remeasures this liability each reporting period and records changes in the fair value as a component of operating expenses.

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

Warrant Liability

We have freestanding warrants enabling counterparties to purchase shares of our convertible preferred stock. In accordance with the accounting guidance regarding distinguishing liabilities from equity, freestanding warrants for convertible preferred stock that are contingently redeemable are classified as

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liabilities on the balance sheets and recorded at their estimated fair value. These warrants are remeasured at each balance sheet date and any change in estimated fair value is recognized in other income or expense on the statements of operations. We adjust the liability for changes in estimated fair value until the earlier of the exercise or expiration of the warrants or the completion of a liquidation event, including the completion of this offering, at which time all preferred stock warrants would be converted into warrants to purchase common stock, and, accordingly, the liability would be reclassified to equity. The then-current aggregate fair value of these warrants, after a final remeasurement of fair value, will be reclassified from liabilities to additional paid-in capital, a component of stockholders equity, and we will cease to record any related periodic fair value adjustments.

The estimated fair value of the convertible preferred stock warrant liability was determined using the Black-Scholes option pricing model using an underlying common stock price of $8.97 and $12.40 at December 31, 2013 and March 31, 2014, respectively, and the following assumptions:

	As of December 31, 2013	As of March 31, 2014 (unaudited)
Risk-free interest rate	0.8 - 2.1%	0.9 - 1.7%
Volatility	40 - 45%	41 - 42%
Estimated term equal to the remaining contractual term	3.3 - 5.6 years	3.0 - 5.4 years
Expected dividend yield	%	%

We recorded $0.5 million for the year ended December 31, 2013 and $0.5 million for the three months ended March 31, 2014 to other expense, net on the statements of operations, to reflect increases in the estimated fair value of the preferred stock warrants.

Stock Based Compensation

We recognize compensation costs related to stock options granted to employees based on the estimated fair value of the awards on the date of grant, net of estimated forfeitures. We estimate the grant date fair value, and the resulting stock-based compensation expense, using the Black-Scholes option-pricing model. The grant date fair value of the stock-based awards is expensed on a straight-line basis over the vesting period of the respective award.

Information regarding our stock option grants, along with the estimated fair value per share of the underlying common stock for stock options granted from 2012 to May 2014 is summarized below:

Grant Date	Number of Shares Granted	Exercise Price Per Share	Estimated Fair Value Per Share of Common Stock
October 17, 2012	210,036	$ 0.55	$ 0.55
November 14, 2012	656	0.55	0.55
December 12, 2012	364	0.55	0.55
January 23, 2013	656	0.55	0.55
May 16, 2013	2,333	0.55	0.55
July 17, 2013	72	0.55	0.55
September 24, 2013	291	0.27	0.27
December 3, 2013	729	0.27	0.27
March 31, 2014	94,538	12.40	12.40
April 8, 2014	317,549	12.40	12.40
May 1, 2014	2,334	12.40	12.40

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We did not grant stock-based awards to non-employees during 2012 or 2013. During the first quarter of 2014, we granted 13,339 fully vested stock options to a former member of our Board of Directors, who now provides services to us as a consultant.

As a result of our Black-Scholes option fair value calculations, we recognized employee stock-based compensation expense of $69,000 and $72,000 during the years ended December 31, 2012 and 2013, respectively. We recognized employee and non-employee stock-based compensation expense of $19,000 and $49,000 during the three months ended March 31, 2013 and 2014, respectively. As of March 31, 2014, total compensation cost related to unvested employee stock options not yet recognized in the financial statements was approximately $356,000 and the weighted average period over which this cost is expected to be recognized is 3.8 years. We expect to continue to grant stock options in the future, and to the extent that we do, our stock-based compensation expense recognized in future periods will likely increase. Following the consummation of this offering, stock option award values will be determined based on the quoted market price of our common stock.

The Black-Scholes option pricing model requires the use of highly subjective and complex assumptions which help us determine the estimated fair value of stock-based awards, including the expected term and the price volatility of the underlying stock. These assumptions include:

Expected Term: The expected term represents the period for which our stock-based awards are expected to be outstanding and is based on analyzing the vesting and contractual terms of the options and the holders historical exercise patterns and termination behavior.

Volatility: We used an average historical stock price volatility of comparable public companies that were deemed to be representative of future stock price trends as we do not have any trading history for our common stock.

Risk-Free Interest Rate: We base the risk-free interest rate over the expected term of the options based on the constant maturity rate of U.S. Treasury securities with similar maturities as of the date of grant.

Expected Dividends: We have not paid and do not anticipate paying any dividends in the near future.

In addition to the assumptions used in the Black Scholes option-pricing model, we must also estimate a forfeiture rate to calculate the stock-based compensation for our awards. We will continue to use judgment in evaluating the expected volatility, expected terms and forfeiture rates utilized for our stock based compensation calculations on a prospective basis.

The estimated grant date fair values of the employee and non-employee stock options were based on the following weighted-average assumptions:

	Year Ended December 31,		Three Months Ended March 31,	
	2012	2013	2013	2014
			(unaudited)	
Risk-free interest rate	1.01%	1.21%	1.00%	1.55%
Volatility	46.55%	45.25%	45.82%	40.69%
Expected term (in years)	6.0	6.0	6.0	4.6
Expected dividend yield	%	%	%	%

We are also required to estimate the fair value of the common stock underlying our stock-based awards when performing the fair value award calculations using the Black-Scholes option-pricing model. The estimated fair value of the common stock underlying our stock-based awards was determined on each grant date by our board of directors, with input from management. Our board of directors is comprised

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of a majority of non-employee directors with significant experience investing in and operating companies in the molecular diagnostics industry. As such, we believe that our board of directors has the relevant experience to determine a fair value of our common stock on each respective grant date. Given the absence of a public trading market of our common stock, and in accordance with the American Institute of Certified Public Accountants, or AICPA, Practice Aid, *Valuation of Privately-held-Company Equity Securities issued as Compensation (the AICPA Practice Aid)* our board of directors exercised reasonable judgment and considered numerous objective and subjective factors to determine the best estimate of the fair value of our common stock.

Significant Factors, Assumptions and Methodologies Used in Determining the Estimated Fair Value of Our Common Stock

To assist our board of directors with the determination of the exercise price of our stock options and the estimated fair value of the common stock underlying the options, we obtained third-party valuations of our common stock as of December 31, 2012, December 31, 2013 and March 26, 2014. The independent valuations performed by unrelated third-party specialists were utilized by our board of directors to assist with the valuation of the common stock. The board of directors utilized the fair values of the common stock derived in the third party valuations as a factor to set the exercise prices for options granted, however management and our board of directors assume full responsibility for the estimates. Our board of directors determined the estimated fair value of our common stock on the date of each grant based on a number of objective and subjective factors, including:

- the superior rights and preferences of the convertible preferred stock relative to those of our common stock, including the liquidation preferences of the convertible preferred stock;
- our operating results and financial condition, including our levels of available capital resources;
- material risks related to our business;
- the lack of liquidity of our common stock as a private company and the state of the initial public offering market for similarly situated private companies;
- the estimated likelihood of achieving a liquidity event such as an initial public offering and valuation conditions on our ability to go public;
- the results of research and development activities;
- external market conditions affecting the life sciences industry sector;
- the valuation of publicly traded companies in the life sciences and medical diagnostics sectors;
- valuations performed by an independent third party; and
- general U.S. economic conditions, including stock volatility and interest rates.

Our board of directors intended all options granted to be exercisable at a price per share not less than fair market value of the shares of our stock underlying those options on their respective dates of grant.

There are significant judgments and estimates inherent in the determination of the estimated fair value of our common stock. These judgments and estimates include assumptions regarding our future operating performance, the time to a liquidity event, such as an initial public offering, or other event and the determination of the appropriate valuation methods. If we had made different assumptions, our stock-based compensation expense, net loss and net loss per share could have been significantly different.

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December 31, 2012 Valuation

During the year ended December 31, 2012, we granted 211,056 stock options to employees at an exercise price of $0.55 per share.

In accordance with the AICPA Practice Aid, for the valuation at December 31, 2012, we used the discounted cash flow method of the income approach to calculate our enterprise value. The discounted cash flow method derives the equity value of a business by estimating future returns discounted by its cost of capital. We also performed comparable public company and comparable acquisition analyses. We then considered various methods for allocating the enterprise value across our classes and series of capital stock to determine the estimated fair value of our common stock and determined that the option pricing method, or OPM, was the appropriate model to use. The OPM treats common stock and preferred stock as call options on the total equity value of a company, with exercise prices based on the liquidation preferences of the preferred stock. The OPM uses the Black-Scholes option pricing model to price the call options. This model defines the securities fair values as functions of the current enterprise value of a company and uses assumptions such as the anticipated timing of a potential liquidity event, the risk-free interest rate as of the valuation date and the estimated volatility of the equity securities. Under this method, the common stock has value only if the funds available for distribution to stockholders exceeds the value of the liquidation preference at the time of a liquidity event. Additionally, because our common stock is unregistered and the holder of a minority interest in the common stock may not influence the timing of a liquidity event, we also applied a discount for lack of marketability.

On July 5, 2013, we received a report from an independent third party valuing our common stock as of December 31, 2012. The resulting fair value of the common stock at December 31, 2012 was $0.27 per share, a decrease from the prior estimated fair value of $0.55 per share at December 31, 2011. The decrease in the common stock value was primarily due to more Preferred Series G shares outstanding and therefore greater liquidation preferences and more common shares outstanding on a fully diluted basis in 2012 than in 2011.

December 31, 2013 Valuation

During the year ended December 31, 2013, we granted 4,081 stock options to employees at a weighted average exercise price of $0.48 per share.

The valuation of our common stock in 2013 was based on several factors, including the following:

- our financial condition and results of operations;
- our negative cash flows and need for additional financing;
- offers received from unrelated third parties regarding a potential acquisition of our company;
- the rights and preferences, including liquidation preferences of our preferred stock;
- the valuation performed by an independent third party as of December 31, 2012; and
- our estimates of the relative probability of a sale or initial public offering of our company.

In late December 2013, it was becoming clearer that the feasibility of an initial public offering and the potential valuation of our company were improving due to our improved business performance and the sustained appreciation in the capital markets. In particular, the following factors contributed to our business improvement in late December 2013:

visibility into our results of operations for the fourth quarter of 2013;

reductions in personnel in the fourth quarter of 2013, which reduced costs and improved efficiencies;

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achievement of modest income from operations, for the fourth quarter of 2013; and

increasing valuations and successful initial public offerings among our peer group of companies.

It was not clear prior to very late in 2013 that a possible exit outcome for our company was an initial public offering. Additionally, during the second and third quarters of 2013, our company was negotiating an offer from a private company that, considering liquidation preferences, supported our option grant prices.

In accordance with the AICPA Practice Aid, for the valuation as of December 31, 2013, we used the probability-weighted expected return method, or PWERM, to calculate our enterprise value. We switched to PWERM as more certainty developed regarding possible exit outcomes, including the possibility of an initial public offering. Under the PWERM, share value is derived from the probability weighted present value of expected future investment returns, considering possible outcomes available to us, as well as the economic and control rights of each share class. Our December 31, 2013 valuation considered time to liquidity and various types of liquidity events, including the following scenarios: (1) an initial public offering; (2) a sale or merger of the Company in the near-term; (3) a sale or merger of the Company at a later date; and (4) dissolution. The December 31, 2013 valuation assigned the following weighting to the four scenarios: 55% for an initial public offering, 20% for a sale of the Company in the near-term; 20% for a sale of the Company longer term and 5% for dissolution.

On March 20, 2014, we received a report from an independent third party valuing our common stock as of December 31, 2013. The resulting estimated fair value of the common stock at December 31, 2013 was $8.97 per share reflecting our improved business performance, continued significant appreciation in the capital markets, and a significant new weighting of a probable initial public offering. It was not until very late in 2013 that it was becoming clearer that the feasibility of an initial public offering and the related potential valuation of our company were improving due to improved business performance, new surveillance strategy and sustained appreciation in the capital markets. Selection of underwriters and our organizational meeting to formally begin the process for this offering, including the registration statement drafting process, began in February 2014.

March 26, 2014 Valuation

During the quarter ended March 31, 2014, we granted 94,538 stock options at an exercise price of $12.40 per share.

The valuation of our common stock for the first quarter of 2014 was based on several factors, including the following:

our financial condition and results of operations;

our negative cash flows and need for additional financing;

the rights and preferences, including liquidation preferences of our preferred stock; and

our estimates of the relative probability of a sale or initial public offering of our company.

In accordance with the AICPA Practice Aid, for the valuation as of March 26, 2014, we used the probability-weighted expected return method, or PWERM, to calculate our common stock value. Under the PWERM, share value is derived from the probability weighted present value of expected future investment returns, considering possible outcomes available to us, as well as the economic and control rights of each share class. Our March 26, 2014 valuation considered time to liquidity and various types of liquidity events, including the following scenarios: (1) an initial public offering; (2) a sale or merger of our company in the near-term; (3) a sale or merger of our company at a later date; and (4) a dissolution.

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The March 26, 2014 valuation assigned the following weighting to the four scenarios: 75% for an initial public offering, 10% for a sale of our company in the near-term; 10% for a sale of our company in the longer term and 5% for a dissolution.

On March 31, 2014, we received a report from an independent third party valuing our common stock as of March 26, 2014. The resulting estimated fair value of the common stock at March 26, 2014 was $12.40 per share. The increase from the December 31, 2013 valuation primarily reflected the increase in our weighting of an initial public offering from 55% to 75%.

Emerging Growth Company Status

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

Factors Affecting Our Performance

The Number of AlloMap Tests We Receive and Report

The growth of our business is tied to the number of AlloMap tests we receive and report. Historically, less than two percent of tests received are not reported due to improper sampling or damage in transit or other causes. We incur costs of collecting and shipping all samples and a portion of the costs where we cannot ultimately issue a score report. As a result, the number of samples received largely directly correlates to the number of score reports.

How We Recognize Revenue

Medicare and certain other payers with agreed upon reimbursement rates and a predictable history of collections allows us to recognize the related revenue on an accrual basis. In 2012, 2013 and in the first quarter of 2014, 44%, 36% and 38%, respectively, of our revenue was recognized when cash was received. Until we achieve our revenue recognition criteria for a larger number of payers, we will continue to recognize a large portion of our revenue when cash is received. Because we often need to appeal prior to being paid for certain tests, it can take over a year for a test to result in revenue being recorded, and for a portion of our tests, we may never realize revenue.

Additionally, as we commercialize new products, we will need to achieve our revenue recognition criteria for each payer for each new product prior to being able to recognize the related revenue on an accrual basis. Because the timing and amount of cash payments received from payers is difficult to predict, we expect our revenue may fluctuate significantly in any given quarter. In addition, even if we begin to accrue larger amounts of revenue related to AlloMap, when we introduce new products, we do not expect we will be able to recognize revenue from new products on an accrual basis for some period of time.

Continued Adoption of and Reimbursement for AlloMap

Our reimbursement rate has steadily increased over time since the launch of AlloMap, as payers adopt coverage policies and fewer payers consider AlloMap as experimental and investigational. The rate at which our tests are covered and reimbursed has, and is expected to continue to vary by payer. As of March 31, 2014, we had been reimbursed for approximately 78% of AlloMap results delivered in the twelve months ended September 30, 2013. Reimbursement performance is reviewed using a lagging metric of six months as any period less than this is considered not to be reflective of future performance, as the reimbursement process can take six months or more to complete depending on the payer. Revenue growth depends on our ability to achieve broader reimbursement from third party payers, to expand the number of tests per patient and the base of ordering physicians.

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Development of Additional Products

We rely on sales of AlloMap to generate the majority of our revenue. Our product development pipeline includes other surveillance solutions for organ transplant recipients to help clinicians make personalized treatment decisions throughout a transplant patient s lifetime. Accordingly, we expect to invest in research and development in order to develop additional products. Our success in developing new products will be important in our efforts to grow our business by expanding the potential market for our products and diversifying our sources of revenue.

Timing of Research and Development Expenses

Our spending on experiments may vary substantially from quarter to quarter. We also spend to secure clinical samples that can be used in discovery, product development, clinical validation, utility and outcome studies. The timing of these research and development activities is difficult to predict. If a substantial number of clinical samples are acquired in a given quarter or if a high-cost experiment is conducted in one quarter versus the next, the timing of these expenses can affect our financial results. We conduct clinical studies to validate our new products as well as on-going clinical and outcome studies to further the published evidence to support our commercialized AlloMap test. Spending on research and development for both experiments and studies, may vary significantly by quarter depending on the timing of these various expenses.

Results of Operations

Comparison of the Three Months Ended March 31, 2013 and 2014

(in thousand)	Three Months Ended March 31, 2013	2014	Change
	(unaudited)		
Revenue:			
Testing revenue	$ 4,809	$ 5,834	$ 1,025
Collaboration and license revenue	172	90	(82)
Total revenue	4,981	5,924	943
Operating expenses:			
Cost of testing	2,124	2,162	38
Research and development	1,002	720	(282)
Sales and marketing	1,569	1,474	(95)
General and administrative	1,064	1,795	731
Total operating expenses	5,759	6,151	392
Loss from operations	(778)	(227)	551
Interest expense, net	(565)	(548)	17
Other expense, net	(5)	(529)	(524)
Net loss	$ (1,348)	$ (1,304)	$ 44

Testing Revenue

Testing revenue increased by $1.0 million, or 21%, in the three months ended March 31, 2014 compared to the same period of 2013. The increase reflects additional volume of tests performed for accrual payers of $0.6 million, as well as improved collections from cash payers due to increased volume of tests during the three months ended March 31, 2014 of $0.4 million. There was an increase to our average revenue per test in the three months ended March 31, 2014 of approximately 3% over the three months ended March 31, 2013 reflecting normal variation in amounts recognized due to payer mix and payment

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amounts. Revenue recognized in the three months ended March 31, 2014 as the result of a payer meeting accrual criteria rather than remaining on the cash basis, was approximately $0.3 million as compared to approximately $0.2 million in the three months ended March 31, 2013.

Collaboration and License Revenue

Collaboration and license revenue decreased by $0.1 million, or 48%, in the three months ended March 31, 2014 compared to the three months ended March 31,2013 primarily due to decreased activity associated with our LabCorp collaboration.

Cost of Testing

Cost of testing was flat in the three months ended March 31, 2014 compared to the three months ended March 31, 2013. While the variable costs for specimen processing and royalty fees increased with the volume and revenue increase, respectively, in the three months ended March 31, 2014, these increased costs were offset by decreases in headcount and shipping costs.

Research and Development

Research and development expenses decreased by $0.3 million, or 28%, in the three months ended March 31, 2014 compared with the three months ended March 31, 2013. The decrease reflects lower payroll and related costs of $0.2 million due to reduced headcount in the three months ended March 31, 2014, and reduced consulting of $0.1 million in the three months ended March 31, 2014, primarily related to decreases in activity on the LabCorp collaboration. 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 new tests, when developed.

Sales and Marketing

Sales and marketing decreased by $0.1 million, or 6%, in the three months ended March 31, 2014 compared with the three months ended March 31, 2013 primarily as a result of decreased marketing activities such as fewer physician and nurse advisory boards.

General and Administrative

General and administrative expenses increased $0.7 million, or 69%, in the three months ended March 31, 2014 compared with the three months ended March 31, 2013 primarily due increased headcount costs, including recruiting of $0.3 million, increased tax and audit fees of $0.3 million and $0.1 million for increased legal fees, both general corporate and intellectual property in the three months ended March 31, 2014.

Other Expense, Net

We recorded other expense of $0.5 million for the three months ended March 31, 2014, compared to a negligible amount for the three months ended March 31, 2013. This increase was due to our remeasurement of the estimated fair value of the warrants to purchase shares of our convertible preferred stock (see Note 3 to our unaudited interim condensed financial statements included elsewhere in this prospectus).

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Comparison of the Years Ended December 31, 2012 and 2013

	Year Ended December 31, 2012	2013	Change
	(in thousands)		
Revenue:			
Testing revenue	$ 19,730	$ 21,672	$ 1,942
Collaboration and License revenue	721	426	(295)
Total revenue	20,451	22,098	1,647
Operating expenses:			
Cost of testing	7,930	9,078	1,148
Research and development	4,752	3,176	(1,576)
Sales and marketing	5,417	5,892	475
General and administrative	4,694	4,809	115
Total operating expenses	22,793	22,955	162
Loss from operations	(2,342)	(857)	1,485
Interest expense, net	(2,703)	(2,149)	554
Other expense, net	(145)	(536)	(522)
Net loss	$ (5,059)	$ (3,542)	$ 1,517

Testing Revenue

Testing revenue increased by $1.9 million or 10%, in 2013 compared to 2012 primarily due to additional volume and to a lesser extent, an increase in payers meeting revenue recognition criteria. There was no material change year over year to our average revenue per test. Revenue recognized in 2013 as a result of payers meeting accrual criteria rather than remaining on the cash basis was approximately $0.3 million. Testing volume increased approximately 21% in 2013, as compared to 2012. The percentage increase in testing revenue was less than the percentage increase in testing volume due to the timing of the tests performed and our ability to recognize related revenue until the revenue recognition criteria were met.

Collaboration and License Revenue

Collaboration and license revenue decreased by $0.3 million or 41% in 2013 compared to 2012 primarily due to lower revenues from a collaboration agreement. Under the agreement, in 2012, we provided certain samples to the collaboration partner for $250,000; no such samples were provided under the agreement in 2013.

Cost of Testing

Cost of testing increased $1.1 million, or 14% in 2013 compared to 2012 reflecting our 21% testing volume growth in 2013. These increases included payroll and related expenses of $1.0 million, specimen processing of $0.2 million, licensing fees of $0.1 million and expired reagents of $0.2 million, partially offset by decreased depreciation of $0.4 million as certain lab equipment and software became fully depreciated. Royalty expense, included in cost of testing, was $1.1 million in 2012 and $1.2 million in 2013.

Research and Development

Research and development expenses decreased by $1.6 million, or 33%, in 2013 compared with 2012. The decrease reflects lower payroll and related costs of $1.0 million due to reduced headcount primarily in our informatics, clinical and regulatory groups. In addition, there was a reduction of approximately $0.5 million in depreciation and facilities-related expenses. During 2013, we focused our efforts on

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stabilizing and enhancing our current AlloMap business, choosing not to spend our limited resources on new product development. 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 new tests, when developed.

Sales and Marketing

Sales and marketing increased by $0.5 million, or 9% in 2013 compared with 2012 primarily as a result of increased commissions of $0.3 million and increased marketing activities such as physician and nurse advisory boards and speaker programs of $0.2 million.

General and Administrative

General and administrative expenses increased $0.1 million, or 2%, in 2013 compared with 2012 primarily due to 2013 expenses of $0.3 million in connection with the evaluation of strategic alternatives, increased payroll and related costs of $0.2 million, partially offset by a reduction in costs associated with reporting capabilities for executive management of $0.3 million, and decreased outside services of $0.1 million.

Interest Expense, Net

Interest expense, net decreased by $0.6 million, or 20%, in 2013 compared with 2012. In April 2012, we converted all of our convertible subordinated promissory notes of $12.4 million principal and interest which had been issued in 2010, into preferred stock and preferred stock warrants (see Note 10 to our audited financial statements included elsewhere in this prospectus). Interest expense on these notes recorded in 2012 was $0.4 million. In August 2012, we entered into a $15.0 million loan, and repaid at that time an existing loan with a principal balance of $10.3 million. Prepayment penalties and writeoff of the remaining unamortized costs associated with the paid off loan resulted in a charge to interest expense in 2012 of $0.6 million. The reduction in interest expense in 2013 compared to 2012 was partially offset by a higher effective interest rate on the $15.0 million loan compared to the previous $10.3 million loan.

Other Expense, Net

We recorded other expense of $0.5 million, for the year ended December 31, 2013 compared to a negligible amount for the year ended December 31, 2012. This change is due to the remeasurement of the estimated fair value of the warrants to purchase shares of our convertible preferred stock (see Notes 2 and 11 to our audited financial statements included elsewhere in the prospectus).

Cash Flows for the Years Ended December 31, 2012 and 2013 and for the Three Months Ended March 31, 2013 and 2014

The following table summarizes the primary sources and uses of cash for each of the periods presented:

(in thousands)	Year Ended December 31, 2012	2013	Three Months Ended March 31, 2013	2014
			(unaudited)	
Net cash provided by (used in):				
Operating activities	$ (1,776)	$ (546)	$ (934)	$ 180
Investing activities	642	(98)		(19)
Financing activities	4,607	(58)	(18)	(452)
Net increase (decrease) in cash and cash equivalents	$ 3,473	$ (702)	$ (952)	$ (291)

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Operating Activities

Net cash (used in) provided by operating activities consisted of net losses adjusted for certain non-cash items and changes in operating assets and liabilities.

Net cash provided by operating activities for the three months ended March 31, 2014 was $0.2 million and reflected (i) the net loss of $1.3 million, (ii) net non-cash items of $0.8 million, including $0.5 million revaluation of warrants to estimated fair value, amortization of debt discount and non-cash interest expense of $0.2 million and depreciation and amortization of $0.1 million, and (iii) a net cash inflow from changes in balances of operating assets and liabilities of $0.7 million. The most significant item comprising the changes in balances of operating assets and liabilities was a higher balance of accrued and other liabilities of $2.4 million, primarily representing deferred initial public offering costs and increased legal, accounting, consulting and recruiting expenses. Other significant items comprising the changes in balances of operating assets and liabilities were increased royalties of $0.3 million, offset by an increase of $1.6 million of prepaid and other assets relating primarily to deferred initial public offering costs and a decrease in accrued payroll liabilities of $0.6 million, reflecting the payment of year-end bonuses.

Net cash used in operating activities for the three months ended March 31, 2013 was $0.9 million and reflected the net loss of $1.3 million and net non-cash items of $0.4 million consisting primarily of depreciation and amortization of $0.3 million and amortization of debt discount and non-cash interest expense of $0.1 million.

The largest contributors to the $1.2 million decrease in net cash used in operating activities in 2013, compared with 2012, were a lower net loss of $1.5 million and a higher change in total liabilities of $0.8 million, partially offset by a higher change in accounts receivable of $1.2 million.

Net cash used in operating activities for the year ended December 31, 2013 was $0.5 million and reflected (i) the net loss of $3.5 million, (ii) net non-cash items of $1.6 million, consisting primarily of depreciation and amortization of $0.7 million, amortization of debt discount and non-cash interest expense of $0.5 million and revaluation of warrants to estimated fair value of $0.5 million, and (iii) a net cash inflow from changes in balances of operating assets and liabilities of $1.4 million. The significant items comprising the changes in balances of operating assets and liabilities were a higher balance of accrued royalties of $1.3 million and a higher deferred revenue balance of $1.1 million, partially offset by an increased accounts receivable balance of $1.3 million. The increased accounts receivable balance was due to increased volume of approximately $0.7 million, the change in our Medicare contractor effective October 2013, resulting thus far, in slower payments for Medicare tests of approximately $0.3 million, and more payers meeting our revenue recognition criteria of approximately $0.3 million. Our experience with Medicare contractor changes in the past has shown initially slower payments, which resolve after the new contractor is in place for some period.

Net cash used in operating activities for the year ended December 31, 2012 was $1.8 million and reflected the net loss of $5.1 million, net non-cash items of $1.6 million, consisting primarily of depreciation and amortization of $1.1 million and amortization of debt discount and non-cash interest expense of $0.6 million, and a net cash inflow from changes in balances of operating assets and liabilities of $1.7 million. The significant items comprising the changes in balances of operating assets and liabilities were a higher balance of accrued royalties of $0.8 million and a higher deferred revenue balance of $1.0 million.

Cash flow from operations in 2013 and 2012 and in the first three months of 2014 and 2013 was aided by our suspension of royalty payments under our license agreement with Roche Molecular Systems, Inc., or Roche. As described in the Business Legal Proceedings included elsewhere in this prospectus, we

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have had past dialogue with Roche regarding the appropriate amount of royalties to be paid under this agreement and are now in arbitration proceedings. The $2.8 million accrual at December 31, 2013, and $3.1 million accrual at March 31, 2014 reflects the full amount of royalties owed at the stated royalty rate set forth in the agreement, plus interest at those respective dates. We do not expect to reach resolution of the arbitration within the next twelve months. As a result, we have recorded the $3.1 million liability balance at March 31, 2014 and the $2.8 million liability balance at December 31, 2013 as long-term liabilities on our balance sheets.

Investing Activities

Our investing activities have consisted primarily of maturities and sales of short-term investments, net of purchases, and purchases of property and equipment. During the three months ended March 31, 2014 and 2013, we had a negligible amount of purchases of property and equipment. Net cash used in investing activities for the year ended December 31, 2013 of $0.1 million consisted of purchases of property and equipment. Net cash provided by investing activities for the year ended December 31, 2012 of $0.6 million consisted of net maturities of short-term investments of $0.8 million, partially offset by $0.2 million of purchases of property and equipment.

We expect capital expenditures to increase modestly in 2014 and beyond as we expand our research and discovery work to develop new transplant surveillance solutions. We believe that we are not currently capacity constrained and that our current facility can support a substantial increase in testing volume and support new surveillance solutions currently being developed.

Financing Activities

Net cash used in financing activities for the three months ended March 31, 2014 of $0.5 million was for principal payments on debt and capital leases.

Net cash used in financing activities for the year ended December 31, 2013 of $0.1 million consisted of principal payments on capital leases. Net cash provided by financing activities for the year ended December 31, 2012 of $4.6 million consisted of net proceeds from the issuance of debt of $14.7 million and net proceeds from the issuance of convertible preferred stock of $2.9 million. At the time we issued the debt above, we repaid a previous loan and, together with principal payments on that loan, used $13.0 million for principal payments on debt in 2012.

Liquidity and Funding Requirements

Since our inception, substantially all of our operations have been financed through the issuance of our convertible preferred stock, the incurrence of debt and cash received from testing revenues. Through March 31, 2014, we had received net proceeds of $151 million from the issuances of preferred stock, including preferred stock issued on conversion of promissory notes, which preferred stock has a carrying value of $135 million, $15.0 million in proceeds from a venture debt loan and approximately $111 million from testing revenues. As of March 31, 2014, we had cash and cash equivalents of $4.8 million and $15.1 million of debt outstanding on our venture debt loan and capital lease obligations.

In April 2014, we issued a $5.0 million subordinated convertible promissory note, or convertible note, to Illumina, Inc., which provides for interest at an annual rate of 8.0%. The convertible note matures one year following its issuance with principal and unpaid interest due at that time unless the convertible note is converted prior to the maturity date (see Note 9, Subsequent Events, to our unaudited interim condensed financial statements included elsewhere in this prospectus). Conversion is mandatory in the event of a qualified initial public offering or qualified financing. The convertible note will automatically convert into shares of our common stock upon the effectiveness of the offering described in this prospectus at a conversion price per share equal to the lesser of the price at which shares of common

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stock are sold in this offering and $21.78 per share. If the proposed initial public offering or another qualified financing does not occur before the one-year anniversary of the issuance of the convertible note, and the holder chooses not to convert the note into shares of our capital stock, then the repayment of the principal and unpaid interest totaling approximately $5.4 million would be due at that time.

We currently expect to use the net proceeds from this offering for research and development, including research aimed at expanding the clinical utility of AlloMap and the development of new solutions for the surveillance of heart and kidney transplant, sales and marketing activities, general and administrative expenses and for working capital and other general corporate purposes. As of the date of this prospectus, we cannot predict with certainty all of the particular uses for the proceeds of this offering or the amounts that we will actually spend on the uses set forth above. The amount and timing of actual expenditures may vary depending upon a number of factors, such as the progress of our product development, regulatory requirements, commercialization efforts, the amount of cash used by operations and progress in reimbursement. If our research and development of new solutions for the surveillance of heart and kidney transplants requires more time or resources than we currently anticipate or if we encounter unforeseen difficulties in securing reimbursement for our AlloMap solution or future surveillance solutions, we may allocate proceeds of this offering to our research and development efforts. If our research and development progress faster than we currently expect, we may elect to reallocate a portion of the proceeds of this offering from research and development to sales and marketing activities to support the launch and commercialization of our new solutions. A portion of the net proceeds may also be used to acquire or invest in complementary businesses, technologies, services or products. Except for our proposed acquisition of ImmuMetrix, Inc. in exchange for shares of our Series G Preferred Stock, we have no current agreements or commitments with respect to any such acquisition or investment.

We currently anticipate that our cash and cash equivalents, cash receipts from AlloMap testing, and net proceeds from this offering, will be sufficient to enable us to fund our operations for at least the next 24 months. We cannot be certain that any of our development of new transplant surveillance solutions will be successful or that we will be able to raise sufficient additional funds, if necessary, to see these programs through to a successful result.

If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we may have to significantly delay, scale back or discontinue our new test development. If we raise additional funds through the issuance of additional debt or equity securities, it could result in dilution to our existing stockholders, increased fixed payment obligations and these securities may have rights senior to those of our common stock. These events could significantly harm our business, financial condition and prospects.

Our forecast of the period of time through which our financial resources will be adequate to support our operations is a forward-looking statement and involves risk and uncertainties, and actual results could vary as a result of a number of factors. We have based this estimate on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we currently expect.

Contractual Obligations

The following table summarizes our significant contractual obligations as of March 31, 2014 and the effect those obligations are expected to have on our liquidity and cash flows in future periods:

	Payments due by Period				
	Total	Less Than 1 Year	1 3 Years	3 5 Years	More Than 5 Years
			(in thousands)		
Debt obligations	$ 17,713	$ 6,802	$ 10,911	$	$
Operating lease obligations	8,969	1,193	2,554	2,737	2,485
Capital lease obligations	210	91	115	4	
Total contractual obligations	$ 26,892	$ 8,086	$ 13,580	$ 2,741	$ 2,485

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In August 2012, we entered into a $15.0 million loan and security agreement maturing in August 2016. As of March 31, 2014, we had an aggregate principal amount of $14.6 million outstanding. The loan provided for interest-only payments through February 2014. Beginning March 2014, the loan provides for 30 equal monthly principal and interest payments of $566,822 at a stated annual interest rate of 9.95%. In addition, a final payment of $1,275,000 is due at the end of the loan term. The loan is collateralized by a security interest in all of our assets except intellectual property on which there is a negative pledge, and the loan agreement contains covenants, including a revenue covenant, and restrictions on our ability to pay cash dividends. At March 31, 2014, we believe we were in compliance with all loan covenants.

Upon any prepayment of the loan, we would incur a prepayment fee and accelerate recording the amortization of debt discount and non-cash interest expense. This prepayment fee is 4% of the then outstanding principal amount, or approximately $0.5 million for prepayment prior to August 31, 2014 and such percentage drops to 2%, or approximately $0.2 million for prepayment on August 31, 2014. For example, if the loan were prepaid on August 31, 2014, there would be cash payments of approximately $13.8 million representing the then principal balance of $12.3 million, an end-of-term payment of $1.3 million and a prepayment fee of $0.2 million. Additionally, there would be non-cash charges recorded of approximately $0.6 million representing the acceleration of amortization of debt discount and interest expense.

Our non-cancelable operating lease obligations consist of the lease for our laboratory and office facility in Brisbane, California expiring in December 2020.

Our capital lease obligations consist of equipment financing arrangements with vendors. The contractual obligations table above includes two capital leases entered into in April 2014.

In November 2004, we entered into a license agreement with Roche. The agreement, which was amended in January 2007, in July 2007 and October 2008, grants us the non-exclusive right to use polymerase chain reaction, or PCR, and quantitative real-time PCR technology for use in clinical laboratory services in the United States. Under the terms of the agreement, we are required to report and pay royalties on a quarterly basis that are based on a mid-single digit percentage of test revenues using the licensed intellectual property. Our obligation under the Roche agreement expires on the date of the last to expire of the relevant patents included within the licensed technology that covers our tests. We have had past dialogue with Roche regarding the appropriate amount of royalties to be paid under this agreement and are now in arbitration proceedings. Since beginning this dialogue, we have suspended payment of royalties. We have recorded a liability on our balance sheets of $3.1 million at March 31, 2014 which reflects the full amount of royalties owed at the stated royalty rate set forth in the agreement, plus interest. Refer to Business Legal Proceedings included elsewhere in this prospectus regarding arbitration of our claim that the royalty rate being assessed under our license agreement with Roche be reduced.

Recent Developments

On June 10, 2014, we acquired ImmuMetrix, Inc. for 888,135 shares of our Series G preferred stock, assumed options that will be exercisable for 23,229 shares of Series G preferred stock and $600,000 in cash, of which $400,000 was paid by us on May 19, 2014. All such shares of Series G preferred stock and options to acquire Series G preferred stock will convert into common stock and options to acquire common stock immediately prior to the closing of the offering contemplated by this prospectus. ImmuMetrix is a privately held development-stage company working on cfDNA-based solutions in transplantation and other fields. Through this acquisition, we added to our existing know-how, expertise and intellectual property in applying cfDNA technology to the surveillance of transplant recipients. The intellectual property rights of ImmuMetrix include an exclusive license from Stanford University to a patent relating to the diagnosis of rejection in organ transplant recipients using cfDNA. In connection

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with this acquisition, we entered into a consulting agreement with ImmuMetrix founder and Stanford University professor Dr. Stephen Quake.

Prior to the closing of this acquisition, ImmuMetrix transferred to a newly formed company, Lineage Biosciences, Inc., certain intellectual property, records and tangible and intangible assets of ImmuMetrix related to cfDNA detection and immune system profiling technologies for the diagnosis or clinical management of cancer, or conditions that are a precursor to cancer, and for other applications and purposes. Lineage Biosciences is owned by the former stockholders of ImmuMetrix and is not a subsidiary of ImmuMetrix. ImmuMetrix retained intellectual property rights, records and tangible and intangible assets related to the development, commercialization, licensing, marketing or sale of products or services that utilize cfDNA detection or immune system profiling technologies specifically for the diagnosis and clinical management of solid organ and bone marrow transplant recipients or pre-transplant patients who are on a designated transplant waiting list.

The agreement pursuant to which we acquired ImmuMetrix provides that if we complete 2,500 commercial tests involving the measurement of cfDNA in organ transplant recipients within six years of the acquisition closing date, we will issue an additional 227,845 shares of our common stock to the former stockholders of ImmuMetrix. Such shares will be issuable whether or not ImmuMetrix technology is included in such commercial tests. cfDNA tests performed without charge in parallel with a commercialized test will be considered commercial tests for this purpose.

The acquisition has been accounted for using the purchase method of accounting. Under the purchase method of accounting, the total purchase price presented in the accompanying unaudited pro forma condensed combined financial statements was allocated to the assets acquired and liabilities assumed based on their estimated fair values as of the acquisition date, including identifiable intangible assets which either arise from a contractual or legal right or are separable from goodwill. The excess of the purchase price over the estimated fair value assigned to the net tangible and identifiable intangible assets acquired and liabilities assumed is considered goodwill.

Internal Control over Financial Reporting

Prior to this offering, we were a private company with limited accounting personnel and other resources with which to address our internal controls and procedures. In reviewing our preliminary purchase accounting and supporting analyses related to our pending acquisition of ImmuMetrix, Inc., we identified a material weakness in our internal control over financial reporting. The material weakness related to our internal controls over financial reporting pertaining to business combinations processes that were not adequately designed and therefore not operating effectively. A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected and corrected on a timely basis. The material weaknesses involved aspects of our proposed purchase accounting for our ImmuMetrix acquisition that required adjustment, including adjustments to valuation of in-process technology, deferred income tax liability related to acquired in-process technology, goodwill, share based compensation and recording of transaction costs.

We are in the process of implementing measures designed to improve our internal control over financial reporting. Among other things, we recently hired a new Chief Financial Officer, we added George Bickerstaff, an experienced finance executive to our audit committee, and we have identified several potential candidates with experience preparing periodic reports under the Securities Exchange Act for the position of our controller. While we believe that our efforts will be sufficient to remediate the material weakness and prevent further internal control deficiencies, we cannot assure you that our remediation efforts will be successful.

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We will be required to disclose changes made in our internal control and procedures on a quarterly basis. However, our independent registered public accounting firm will not be required to formally attest to the effectiveness of our internal control over financial reporting pursuant to Section 404 until the later of the year following our first annual report required to be filed with the SEC, or the date we are no longer an emerging growth company as defined in the Jumpstart our Business Startups Act of 2012, or JOBS Act. At such time, our independent registered public accounting firm may issue a report that is adverse in the event that such firm is not satisfied with the level at which our controls are documented, designed or operating. As a result, we may need to undertake various actions, such as implementing new internal controls and procedures and hiring accounting or internal audit staff. Our remediation efforts may not enable us to avoid a material weakness in the future.

Off-Balance Sheet Arrangements

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

Quantitative and Qualitative Disclosures About Market Risk

We are exposed to market risks in the ordinary course of our business. These risks primarily relate to interest rates. We had cash and cash equivalents of $4.8 million at March 31, 2014, which consist of bank deposits and money market funds. Such interest-bearing instruments carry a degree of risk; however, we have not been exposed to, nor do we anticipate being exposed to, material risks due to changes in interest rates. A hypothetical 10% change in interest rates during any of the periods presented would not have had a material impact on our financial statements.

All of our revenues are recognized in U.S. dollars. Upfront payments received from the collaboration agreement in the European Union (see Note 9 to our audited financial statements included elsewhere in this prospectus) were paid in foreign currency and converted to U.S. dollars. As a result, factors such as changes in foreign currency exchange rates or weak economic conditions in foreign markets will affect our financial results. Although the impact of currency fluctuations on our financial results has been immaterial to date, there can be no guarantee the impact of currency fluctuations related to our international activities will not be material in the future.

Recent Accounting Pronouncements

There are no new accounting pronouncements issued that are expected to significantly impact our financial statements or results of operations.

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BUSINESS

Company Overview

We are a commercial stage company that develops, markets and delivers a diagnostic surveillance solution for heart transplant recipients to help clinicians make personalized treatment decisions throughout a patient s lifetime. Our first commercialized testing solution, the AlloMap heart transplant molecular test, or AlloMap, is a blood-based test used to monitor heart transplant recipients for acute cellular rejection. 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 to avoid the use of unnecessary, invasive surveillance biopsies and to determine the appropriate dosage levels of immunosuppressants. We believe there is a significant unmet need for non-invasive post-transplant surveillance solutions and we are applying our expertise in transplantation towards the development of additional solutions for organ transplant recipients, including recipients of heart and kidney transplants.

Transplant recipients are among the highest cost patients in the healthcare system as they require significant healthcare services immediately before, during and after transplantation. Transplant recipients face lifelong risks of illness and death from organ rejection and/or organ failure, and these risks vary significantly among transplant recipients. In order to reduce the risk of organ rejection, drug therapy is used to suppress the recipient s immune system response to the transplanted organ. This immunosuppression therapy can have serious side-effects including infections, cancers, kidney failure and new onset diabetes. Current solutions for the surveillance of organ transplant recipients provide only limited and infrequent information on the presence or absence of rejection. As a result, clinicians tend to administer a relatively high levels of immunosuppression therapy to control rejection risk, which may be more than required for an individual recipient. 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. Long-term survival rates for heart and kidney transplant recipients did not improve significantly between 1997 and 2007, and mortality rates for heart transplant and kidney recipients within the first ten years post-transplant remain at approximately 44% and 32%, respectively.

We believe that better post-transplant surveillance solutions that provide objective, personalized and actionable data can help clinicians control rejection risk while reducing the risk of side-effects of immunosuppression for organ transplant recipients. Effective transplant surveillance solutions must be both sensitive enough to detect the early signs of rejection and be non-invasive to allow for frequent testing and timely delivery of information to clinicians. We believe that such solutions can meaningfully improve the care of the approximately 285,000 organ transplant recipients living in the United States and the approximately 285,000 organ transplant recipients living in Europe. Based on published annual transplant data, including the *OPTN & Scientific Registry of Transplant Recipients Data Report 2011*, survival rates for transplant recipients, published and estimated testing protocols, reimbursement rates for AlloMap and our estimate of reimbursement rates for our solutions under development, we estimate the total potential market for post-transplant surveillance of heart and kidney transplant recipients to be over $1 billion annually in the United States and over $500 million annually in Europe, with the total potential market for AlloMap alone to be over $90 million annually in the United States and over $40 million annually in Europe, and we estimate the total potential market for a post-transplant kidney surveillance solution to be over $900 million annually in the United States and over $450 million annually in Europe.

AlloMap is the only non-invasive method recommended in the International Society for Heart and Lung Transplantation, or ISHLT, patient care guidelines for surveillance of heart transplant rejection in non-infants. 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 rejection. A 510(k) submission is a premarketing submission made to the FDA.

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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. Additionally, we have obtained a CE mark, which indicates a product s compliance with European Union, or EU, legislation and enables the sale of such product within the EU. Since launch in January 2005, we have performed more than 55,000 commercial AlloMap tests, including more than 10,000 tests in 2013, in our Brisbane, California laboratory. In 2013, AlloMap was used in 105 of the approximately 126 heart transplant centers in the United States. We believe that there is a meaningful opportunity for AlloMap outside of the United States, and through recent partnerships we are expanding our AlloMap offering to Europe and Canada.

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. and WellPoint. In the aggregate, payers with positive coverage decisions represented approximately 50 million covered lives as of December 31, 2006, 65 million covered lives as of December 31, 2010 and 177 million covered lives as of March 31, 2014. In addition, these payers, when taken together with payers from whom we do not have a formal coverage decision but who have been paying a majority of claims for AlloMap, represent approximately 220 million covered lives as of March 31, 2014. We believe our success in achieving reimbursement confirms the value proposition of AlloMap to our key constituents. As of March 31, 2014, we had been reimbursed for approximately 78% of AlloMap results delivered in the twelve months ended September 30, 2013.

We have successfully completed a number of landmark clinical trials in the transplant field demonstrating the clinical utility of AlloMap for surveillance of heart transplant recipients. We initially established the analytical and clinical validity of AlloMap on the basis of our *Cardiac Transplanted Organ Rejection Gene expression Observational* (Crespo-Leiro M et al., AM. J. Transplantation, 2012), or CARGO, study, which was published in the American Journal of Transplantation. A subsequent 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.

By developing and commercializing AlloMap, we have gained deep insights into working with transplant centers, transplant clinicians, post-transplant care teams, transplant recipients and payers in the field of managing transplant recipients. Additionally, by conducting numerous clinical trials in transplantation, we have honed our ability to design and execute large trials that have helped to establish the clinical utility of our products. We have also created a proprietary database and blood sample repository over the course of 10 years from over 25 transplant centers containing proprietary, longitudinal samples with clinical outcomes and other data from heart transplant recipients (more than 2,000 recipients with more than 16,000 study visits yielding more than 37,000 samples) and other organ transplant recipients (more than 100 kidney transplant recipients with more than 300 study visits yielding more than 1,000 samples). We believe this proprietary database and sample repository provide us with a significant competitive advantage in the development and validation of solutions for post-transplantation surveillance of organs.

We believe our success in developing and commercializing AlloMap, combined with our database and sample repository, will accelerate our efforts to develop additional testing solutions in the heart transplant market and new testing solutions in other organ transplant markets. For instance, we believe we can apply next generation sequencing platforms to detect genetic differences between cell-free DNA, or cfDNA, in the blood stream emanating from the donor heart and cfDNA emanating from the transplant recipient. We are currently developing a research use only cfDNA-based solution for heart transplant recipients. If successful, we intend to offer the cfDNA solution for research use only for heart transplant patients who are also being tested with AlloMap pursuant to a research protocol agreement

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with participating clinicians. We expect this solution to help determine rejection-specific activity manifested as cell damage in the transplanted heart.

We expect our scientific rationale and understanding of cfDNA to monitor rejection in heart to further our efforts to provide surveillance solutions for additional organs with an initial focus on using a similar cfDNA technology for monitoring kidney transplant recipients.

Recent Developments

On June 10, 2014, we acquired ImmuMetrix, Inc., a development-stage company working on cfDNA-based solutions in transplantation and other fields. Through this acquisition, we added to our existing know-how, expertise and intellectual property in applying cfDNA technology to the surveillance of transplant recipients. The intellectual property rights of ImmuMetrix include an exclusive license from Stanford University to a patent relating to the diagnosis of rejection in organ transplant recipients using cfDNA. In connection with this acquisition, we entered into a consulting agreement with ImmuMetrix founder and Stanford University professor, Dr. Stephen Quake.

On April 17, 2014, we issued a subordinated convertible promissory note to Illumina, Inc. in connection with a $5.0 million investment by Illumina in our company. The convertible note provides for interest at an annual rate of 8.0% and matures one year following its issuance. The convertible note will automatically convert into shares of our common stock upon the effectiveness of the offering described in this prospectus at a conversion price per share equal to the lesser of the price at which shares of common stock are sold in this offering and $21.78 per share.

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., in June 2002, we changed our name to Expression Diagnostics, Inc., in July 2007, we changed our name to XDx, Inc., and in March 2014, we changed our name to CareDx, Inc. 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. Our principal executive offices are located at 3260 Bayshore Boulevard, Brisbane, California. As of March 31, 2014, all of our testing revenue has come from the United States and all of our assets and operations are located in the United States.

Care of Organ 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, 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, with a significant percentage of this cost due to dialysis costs after renal transplant failure, increased rates of severe infections and cancer. Waiting lists for organ transplants in the United States and internationally continue to grow while the number of available donor organs has remained stable. This situation underscores the need for improvements in post-transplant surveillance and care to help ensure that the limited supply of donor organs provides prolonged benefits to transplant recipients.

Transplant Populations

In the United States, approximately 28,900 patients received a heart, kidney or other organ transplant in 2013, and we believe the total population of organ transplant recipients living in the United States

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remained steady at approximately 285,000, and there are approximately 285,000 organ transplant recipients living in Europe.

According to the Organ Procurement and Transplant Network, or OPTN, in 2013, there were approximately 2,500 new heart transplants in the United States, and we believe the total population of heart transplant recipients living in the United States remained steady at approximately 25,000. We believe that there are approximately 126 centers performing heart transplants in the United States.

According to the OPTN, in 2013 there were approximately 16,900 kidney transplants performed in the United States, and we believe that there were approximately 180,000 kidney transplant recipients living in the United States. We believe that there are approximately 230 centers managing kidney transplant recipients in the United States, many of which are the same centers that manage heart transplant recipients.

According to the European Union Organ Transplant Database, in 2012 approximately 30,000 organ transplants, including 2,000 heart transplants and 19,000 kidney transplants, were performed in the European Union across more than 150 transplant centers, and we believe there were approximately 24,000 heart transplant recipients and 180,000 kidney transplant recipients living in the European Union.

Risks of Organ Rejection and the Side-Effects of Immunosuppression

Post-transplant recipient care focuses on the life-long management of immunosuppressive drug regimens to prevent or treat rejection. An immunosuppressive drug regimen is necessary to prevent or treat the recipient s immune system from reacting against and rejecting the donor organ. In the case of transplantation of non-self organs, or transplanted organs, the recipient s immune system recognizes the transplanted organ to be foreign to the body and activates various mechanisms to reject the transplanted organ. It is necessary to medically suppress this normal immune system response to prevent rejection of the transplanted organ. Lymphocytes are a cell type that is important to proper immune function and they are the main cell type involved in the rejection of an organ transplant. Medical immunosuppression of transplant recipients involves the administration of a drug regimen that blocks lymphocyte activation or response pathways or depletes lymphocytes. Immunosuppressive drugs are administered most intensively beginning at the time of transplantation, reduced to maintenance levels in the first year post-transplant and continued throughout the recipient s life.

Immunosuppressive therapy, or drug treatments that are used to decrease the body s immune response to the transplanted organ, has serious short-term and long-term adverse side effects. Since lymphocytes play a major role in defending the body from malignant cells and infections, immunosuppressive therapy increases susceptibility of an individual to cancers and infections. Other unwanted consequences of immunosuppressive drugs include kidney failure, new onset diabetes, imbalances of blood lipid levels, hypertension and osteoporosis. Steroids are a type of immunosuppressant with very overt side-effects including fluid retention, weight gain, mood disturbances and metabolic imbalances. As reported in *Cancer Incidence and Risk Factors after Organ Transplantation* (Vajdic CM et al., Int. J. Cancer, 2009), or the Cancer Report, a combined analysis of five population-based studies demonstrated a three-fold increased risk of cancer in organ transplant recipients compared with the general population matched for age, sex and calendar period. According to the Cancer Report, this widespread increase in cancer risk after transplantation strongly implicates immunosuppression as a primary cause of the increased cancer

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risk. The following graphic illustrates the serious consequences of both under-immunosuppression and over-immunosuppression for a particular transplant recipient.

Heart Transplants

Immunosuppressive therapy may cause serious adverse side effects in heart transplant recipients. According to the *OPTN & Scientific Registry of Transplant Recipients Data Report 2011*, close to 18% of heart transplant recipients die within three years post-transplant and approximately 44% of recipients die within ten years post transplant. According to *ISHLT s 30th Adult Heart Transplantation Report 2012* (Lund LH et. al., J. Heart and Lung Transplantation, 2013), or ISHLT Report, the median survival rate for recipients of heart transplants between 1982 and June 2011 was approximately 11 years. The leading causes of death after a heart transplant are graft failure, acute rejection, cardiac transplanted organ vasculopathy (CAV), which is a form of chronic rejection, infection, cancer and renal failure. CMV (cytomegalovirus) is a common form of latent viral infection found in up to 75% of transplant recipients or donor organs. As illustrated by the graphic below, non-CMV infections, cancer and renal failure from all causes, including immunosuppression regimens, account for 27% of deaths in the first three years after transplantation and 41% of deaths five to ten years from transplantation.

Source: The Registry of the International Society for Heart and Lung Transplantation: 30th Official Adult Heart Transplant Report; 2012

Over time, acute organ rejection becomes a less prevalent cause of death among heart transplant recipients. As indicated in the figure below, by the fourth year following transplantation, cancer becomes a major cause of death in heart transplant recipients. In addition, infections are also a major cause of death in transplant recipients and, over time, like cancer, cause more deaths in heart transplant recipients than deaths due to rejection. According to the ISHLT Report, there is a clear need for better methods to enable physicians to individualize treatment and minimize the intensity of immunosuppression while still avoiding rejection, as a significant amount of deaths are due to infection or malignancy.

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Source: Journal of Heart and Lung Transplantation Online October 2013

Kidney Transplants

Although short-term survival rates for kidney transplant recipients are generally good, the long-term survival rates and health of kidney transplant recipients remains considerably inferior to that of the general population. According to *Outcomes of Kidney and Pancreas Transplantation* (Srinivas T R et. al., Kidney and Pancreas Transplantation: A Practical Guide, 2010), as of 2008, between 64% and 47% of transplant recipients survive ten years or more following the transplant, which equates to a median survival rate for kidney transplant recipients of approximately 10 years. The leading causes of death among these recipients include cardiovascular disease, chronic renal failure, cancer and infection. As reported in the *Diabetes Mellitus after Kidney Transplantation in the United States* (Kasiske B L et al., Am. J. Transplantation, 2003), kidney transplant recipients are highly prone to hypertension and lipid metabolism disorders, and 24% of kidney transplant recipients develop diabetes within three years post-transplant. The National Kidney Foundation reports that immunosuppressive drugs commonly used in the treatment of post-transplant kidney recipients cause or exacerbate cardiovascular disorders, renal failure, cancer, infection, diabetes and other metabolic disorders. The potentially severe side-effects of immunosuppressive drugs in kidney transplantation highlights the need to provide clinicians with more effective diagnostic tools to help them better understand a recipient s risk profile and better manage the risks of rejection and risks of disease or illness caused by immunosuppression.

In addition to the health consequences to recipients, the failure of kidney transplants results in significant increased costs in the healthcare system. According to the United States Renal Data System, or the USRDS, the average annual cost per person to Medicare for a kidney transplant recipient in 2012 was $32,914, and the average annual costs per person for a recipient receiving hemodialysis therapy was $87,561. This amounts to an average annual increase in costs to Medicare of approximately $54,000 when a kidney transplant fails and a recipient returns to hemodialysis therapy. According to the USRDS, approximately 5,600 recipients with kidney transplant failure returned to dialysis in 2012.

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Limitations of Existing Approaches for Surveillance of Transplant Recipients

Surveillance of Heart Transplant Recipients

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. Limitations of biopsies in the surveillance of heart transplant recipients include:

- Pathologist evaluations are subjective and dependent upon visual assessment and qualitative interpretation;
- If cellular rejection is at an early stage, it may not be visually apparent. Accordingly, biopsies may not be effective at detecting early stages of rejection;
- Negative biopsy results do not necessarily prove a lack of rejection activity, or quiescence, because of possible sampling errors;
- As reported in *The Limited Utility of Endomyocardial Biopsy in the first year after Heart Transplantation* (Hamour I M et al., Transplantation, 2008), serious complications such as arrhythmias, perforation of the heart, or injury to the tricuspid valve of the heart occur in 2% of biopsies;
- Biopsies present radiation related risks associated with the x-ray imaging used in biopsies. According to *Radiation Exposure After Heart Transplantation: Trends and Significance* (Noor M et al., J. Heart and Lung Transplantation, 2011), a single heart transplant recipient may undergo enough biopsies in the decade following transplant to be exposed to an effective radiation dose of 84 mSv, which is equivalent to 4,000 chest X-rays. This contributes to the increased prevalence of cancers in transplant recipients; and
- Biopsies involve surgical procedures that require recipients to be admitted to a hospital or other transplant center, where recipients often spend more than half a day in preparation, procedure and recovery.

Due to these and other limitations, biopsies 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.

According to a 2005 article, *The Economic Implications of Noninvasive Molecular Testing for Cardiac Transplanted Organ Rejection* (Evans RW et al., Am. J. Transplantation, 2005), biopsies performed on heart transplant recipients are estimated to have an average reimbursement rate of approximately $4,140 from private payers and $3,581 from Medicare. Actual costs of biopsies, including fees billed to and actually paid by the recipient, are generally higher.

Surveillance of Kidney Transplant Recipients

Kidney transplant recipients are typically monitored using clinical laboratory tests that measure kidney function but are not necessarily indicative of rejection. The main clinical test indicator of transplanted kidney dysfunction is an increase in serum creatinine levels above a

baseline value. Although widely used, literature suggests that changes in serum creatinine levels may be nonspecific and only detected late, after significant renal function loss has occurred.

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The use of renal biopsies for surveillance of kidney transplants is limited due to the risks associated with such biopsies. As reported in the *Timing of Complications in Percutaneous Renal Biopsy* (Whittier W L et al., J. Am. Soc. Nephrol, 2004), overt complications, most related to bleeding, occur in up to 13% of the cases, with half of those complications considered major. Following a renal biopsy, a recipient must often remain under medical supervision and on bed rest for four to six hours due to the risk of bleeding. Complications from bleeding may require blood transfusion or an invasive procedure (radiographic or surgical) to identify the location of the bleeding and control it. Accordingly, renal biopsy is generally used only when kidney rejection is suspected.

Immunosuppression of Heart and Kidney Transplant Recipients

The risk of rejection in heart and kidney transplant recipients is managed primarily through the use of immunosuppression. Surveillance biopsies are infrequent, especially in kidney and even in heart 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 make 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, without creating risks to the recipient;
- Easy to administer;
- Differentiate rejection from quiescence;
- Detect rejection earlier; and
- Timing and frequency of results that allow informed and effective treatment decisions.

Our Solution

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. Our AlloMap solution addresses the varied needs of constituents across healthcare, including:

Patients

Better Patient Care. AlloMap is designed to be performed using a sample of the patient s blood. Blood draws are relatively painless and the process is familiar to anyone who has had a blood test. By comparison, biopsies are invasive procedures that are uncomfortable, sometimes painful, time-consuming and present risk of complications. Some patients, particularly those who don t show symptoms, may

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choose to avoid recommended biopsies. Avoiding recommended surveillance can be especially dangerous in heart transplant patients, where rejection can begin at a cellular level without any noticeable symptoms or discomfort. We believe our testing solution will be attractive to patients who today may not be fully compliant with their prescribed testing protocol.

More Personalized Care. By providing patients and their care providers with timely, accurate and quantitative information about a patient s risk of rejection activity, AlloMap is intended to help improve the quality and effectiveness of patient care in the post-transplant period. Information provided by our solution, together with other factors and information, is intended help tailor the level of invasive testing and immunosuppression therapy to a particular patient s needs. Our goal is to help physicians increase the level of intervention and immunosuppression when the risk of rejection is high and reduce the level of immunosuppression and its associated risks when the risk of rejection is low.

Providers

Novel, Clinically Actionable Information. AlloMap may be used instead of a surveillance heart biopsy to rule out acute cellular rejection in heart transplant recipients. In addition, *The Utility of Gene Expression Profiling Score Variability to Predict Clinical Events in Heart Transplant Recipients* (Deng M et al., Transplantation, 2014), or the Deng Study, demonstrated the potential for AlloMap score patterns (specifically the variability of scores within a patient over time) to provide information about the patient s risk for future graft dysfunction or death. This new information has the potential to further guide personalized immunosuppressant treatment. We designed AlloMap to provide further insights into immune status including earlier detection of heart rejection signals. Because AlloMap is non-invasive, patients can be monitored through more frequent testing that is impractical using more invasive methods.

Quantitative Results. AlloMap uses a molecular approach that provides clinicians with a reproducible, quantitative assessment and an associated numerical score. The molecular nature of AlloMap scores are highly objective and can be compared to scores for the same patient over time to identify increases or decreases in the likelihood that the patient is experiencing rejection. In contrast, tissue biopsies rely on visual and qualitative interpretation by pathologists and cannot provide precise or repeatable results given their inherent subjectivity.

Rapid Turnaround. Rapid, high quality results are essential to enable timely implementation of treatment options. For approximately 95% of patients, we return AlloMap results to the clinician within three business days after the blood draw.

Payers

Providing Members with Better Care. Payers seek to differentiate themselves by offering their insured the best care available. By providing recipients with timely, accurate and quantitative information about their risk of rejection activity, AlloMap is intended to help improve the quality of recipient care through improved tailoring of immunosuppression therapy and biopsies to the recipient s individual needs.

Reduce Healthcare Costs and Resource Usage. Long-term care of transplant recipients is costly. Providing timely, accurate and non-invasive surveillance data for heart transplant recipients would help clinicians make more informed decisions on use of biopsies and optimal immunosuppression therapy. Enhanced surveillance using AlloMap has the potential to reduce overall healthcare costs by avoiding unnecessary biopsies and their associated risks, reducing the use and adverse effects of immunosuppression therapy and potentially reducing the rate of heart transplant rejection.

We are designing our future surveillance solutions to provide benefits similar to AlloMap by helping clinicians to regularly monitor for organ rejection throughout the life of the recipient, modulate the use of immunosuppression and make more personalized treatment decisions, thereby improving recipient care and health outcomes.

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Business Strategy

We are dedicated to providing novel, clinically actionable and timely information to improve the lifelong care of recipients with organ transplants. Key elements of our strategy include:

Develop and Commercialize Post-Transplant Surveillance Solutions to Improve Recipient Outcomes. We are applying our expertise in the surveillance of heart transplant recipient to develop additional solutions for heart and new solutions for other organs by leveraging our development team, experience in transplant surveillance, research in cfDNA and significant clinically-annotated patient sample libraries. Our objective is to develop non-invasive diagnostic solutions that become the clinical standard of care by enabling clinicians to make more informed and personalized treatment decisions. We believe we can improve the lives of recipients by providing timely and clinically actionable data to help clinicians optimize the frequency of biopsies and personalize immunosuppression dosing to reduce risks and improve recipient outcomes.

Increase Utilization of AlloMap. We are pursuing broad-based adoption of AlloMap through encouraging its regular and clinically appropriate use in transplant recipients to improve monitoring and outcomes. In 2013, AlloMap was used in 105 of the 126 heart transplant centers in the United States, 54 of which have included AlloMap in their treatment protocols to encourage consistent use of AlloMap throughout their patient population. We continue to support transplant centers in establishing and adhering to testing protocols, including the use of AlloMap, because we believe that establishing these standards for surveillance are critical in personalizing a recipient s treatment. We expect to build upon our marketing and medical education programs and leverage our transplant-focused sales and marketing team that interacts directly with clinicians, nurses, laboratory and pathology personnel.

Expand the Clinical Utility and Actionability of our Current and Future Solutions. A key driver for the adoption of our current and future solutions is our ability to substantiate clinical utility and actionability through completed trials and peer-reviewed publications. Completed post-marketing trials, including IMAGE, the *Early Invasive Monitoring Attenuation through Gene Expression*, or EIMAGE, and the European-based CARGO trial, or CARGO II, have been designed to evaluate the further clinical utility and actionability of AlloMap and are an integral part of our business strategy and marketing programs. We intend to continue to invest in clinical trials to expand the utility and rate of adoption of our current and future solutions. Many of the investigators in our sponsored trials are well recognized key opinion leaders in the field and contribute to the education of their peers by way of publications, presentations of their clinical knowledge and experience with developing AlloMap.

Build Upon our Reimbursement Success. 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., and WellPoint. In the aggregate, these payers represent approximately 177 million covered lives. In addition, these payers, when taken together with payers with whom we do not have a formal coverage decision but who have been paying at least a majority of claims for AlloMap, represent approximately 220 million covered lives in the aggregate. We believe the clinical utility and actionability of AlloMap, combined with our experience and deep knowledge of the factors needed to gain payer reimbursement in the transplant market will enable us to expand coverage of AlloMap and will improve our ability to obtain reimbursement for future solutions. We intend to build on our success in securing coverage and reimbursement for AlloMap through continued development of testing solutions that become part of routine clinic practice, basing our solutions on rigorous science, including clinical trials and peer-reviewed publications, and educating payers regarding the clinical value of our current solution and its potential to reduce the overall cost of care.

Strategically Offer AlloMap Internationally. We believe there is a meaningful market opportunity internationally for AlloMap and have recently begun our international expansion through select partners. We recently signed distribution agreements with Diaxonhit SA to offer AlloMap in Europe, and with

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LifeLabs Medical Laboratory Services to offer AlloMap in Canada. We intend to continue to investigate partnerships for our offerings in other regions.

AlloMap Molecular Testing for Heart Transplant Recipients

Overview

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 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 values, or RNA levels, of 20 genes and yields a single AlloMap score. AlloMap may be used for heart transplant recipients 15 years of age or older after 55 days post transplant.

AlloMap provides a single integer score ranging from 0 to 40 and determines the probability 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 utility of AlloMap is well established. AlloMap is the first and only non-invasive method recommended in the 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 (IVDMIA). In addition, the clinical utility of AlloMap is supported by numerous clinical trials sponsored by us, the results of which have been published in leading peer-reviewed medical journals.

To date, we have performed commercial AlloMap tests for more than 13,000 recipients, and we have performed more than 55,000 commercial AlloMap tests in total. We estimate that there are approximately 126 centers performing heart transplants in the United States. In 2013, AlloMap was used in 105 of these centers, 54 of which have included AlloMap in their treatment protocols to encourage consistent use of AlloMap throughout their patient population.

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Through March 31, 2014, the average number of AlloMap tests per heart transplant recipient using our solution has been 4.2 AlloMap tests. The following chart shows the usage of AlloMap among heart transplant recipients in the United States during the first year post-transplant and subsequent years as a whole. In 2013, nearly half of all newly transplanted heart recipients in the United States were tested with AlloMap.

In 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 is well positioned as a high value test in the surveillance of heart transplant recipients. We believe this positioning is demonstrated by the adoption and usage rates discussed above and the reimbursement rate for AlloMap, which, as of March 31, 2014, was approximately 78% of the AlloMap tests performed in the twelve months ended September 30, 2013.

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The following chart shows the number of AlloMaps performed on an annual and quarterly basis in the periods indicated.

Clinical Trials of AlloMap

The utility of AlloMap is supported by a number of major clinical trials involving more than 2,000 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 and clinical development and marketing programs. In heart transplantation, two major observational trials, CARGO and CARGO II, enabled the initial development, validation and further validation by us of AlloMap to detect and monitor acute cellular rejection in heart transplant recipients. Blood samples and clinical data from these two trials, and other trials of lung and kidney transplant recipients have been preserved. 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.

CARGO

The *Cardiac Transplanted Organ Rejection Gene expression Observational* trial (Crespo-Leiro M et al., Am. J. Transplantation, 2012), or CARGO, demonstrated that AlloMap can detect when there is a low probability of acute cellular rejection in cardiac transplanted organ recipients. This multicenter longitudinal trial involved nine leading United States transplant centers, with over 4,900 blood samples collected from more than 700 heart transplant recipients between 2001 and 2005. This trial provided the materials and data used for the initial analytical and clinical validation of AlloMap.

CARGO II

The European-based *Cardiac Transplanted Organ Rejection Gene Expression Observational* trial (Crespo-Leiro M et al., Transplantation, 2012), or CARGO II, confirmed the AlloMap performance characteristics previously established in the first CARGO study. Between 2006 and 2011, 741 heart transplant recipients from 17 participating transplant centers (13 in Europe and four in North America)

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were observed longitudinally. The trial collected over 6,900 blood samples and study visits that included surveillance biopsies, AlloMap results and other clinical observations.

IMAGE

The *Invasive Monitoring Attenuation through Gene Expression* (Pham M X et al., N. Eng. J. Med, 2010), or IMAGE, trial is a landmark trial in the field of surveillance of transplanted organs for rejection. This prospective, randomized trial demonstrated that AlloMap is noninferior to biopsy in the routine monitoring of recipients between six months and 60 months after heart transplant. The study observed outcome events of 602 heart transplant recipients over two years. The IMAGE trial received priority review and publication in the *New England Journal of Medicine* in April 2010 and is a major foundation of recommended use of AlloMap as a non-invasive surveillance method in the ISHLT patient care guidelines issued in 2011.

EIMAGE

Between 2009 and 2011, The *Early Invasive Monitoring Attenuation through Gene Expression* (Kobahigawa J et al., J. Heart and Lung Transplantation, 2013), or EIMAGE, trial observed 60 recipients at the Cedars-Sinai Heart Institute beginning in the second month following transplant through the first year after transplant. The EIMAGE trial showed that clinical outcomes for patients managed with AlloMap were similar to outcomes of patients managed with biopsy for rejection surveillance and steroid tapering. The EIMAGE trial was presented at the Montreal ISHLT 2013 and manuscript submission for this presentation is planned for the second quarter of 2014. The trial also suggests that AlloMap may be useful in guiding immunosuppression dosage reduction.

AlloMap Score Variability Studies

We have completed two studies analyzing data from earlier trials to observe how the variability in AlloMap scores over time may be useful in predicting the risk of rejection and graft dysfunction. One study, the *Utility of Gene Expression Profiling Score Variability to Predict Clinical Events In Heart Transplant Recipients*, was published on February 7, 2014 in the Deng Study in the journal *Transplantation*, based on data from 369 recipients from the IMAGE trial. The other study, currently published as an abstract, *Utility of Gene Expression Profiling Test (GEP) Score Variability to Predict Future Clinical Outcomes in Heart Transplant: Recipients* (Deng M et al., Transplantation, 2014), used data from a subgroup of 108 recipients in the CARGO II recipient set. The two studies independently corroborate that an individual recipient s AlloMap score variability over time may prospectively predict future risk of transplanted organ dysfunction or death. This information is independent of the probability of acute cellular rejection at the time of testing that is rendered from a single AlloMap score and provides additional data for clinicians to use in making treatment decisions.

Outcomes AlloMap Registry

We are sponsoring a multi-year, multi-center registry, which we refer to as the Outcomes AlloMap Registry, or OAR. OAR will prospectively observe the long-term clinical management and outcomes of heart transplant recipients with regular AlloMap testing. Because protocols for testing and treatment of heart transplant recipients vary from center to center and sometimes vary among the clinicians within a single center, we believe this multi-center study of a large numbers of recipients will increase our understanding of various recipient care practices and associated clinical outcomes. We estimate that this study will involve over 2,000 patients and over 8,000 samples.

Our Development Pipeline

Our development pipeline is focused on further expanding the clinical utility of AlloMap through additional research and analysis of our database and samples acquired from previously completed trials, developing new solutions for the surveillance of organ transplants by applying donor derived cell-free DNA as a biomarker,

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and potential in-licensing or acquisition of new products and technologies that further enhance our portfolio of solutions to improve the long-term care of organ transplant recipients.

cfDNA as a Biomarker for Organ Rejection

We believe donor derived cfDNA may be useful as a biomarker for the detection of rejection related organ damage in organ transplant recipients. cfDNA are short fragments of DNA that are released into the blood stream when cells die. cfDNA assays have 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 genetic identity can be used to distinguish between cfDNA in the blood stream emanating from the donor organ and cfDNA emanating from the recipient.

Initial studies including the *Heart transplants are genome transplants: Universal Noninvasive detection of organ transplant rejection* (Snydev 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 cfDNA may be a universally applicable marker for rejection, not only for heart, but for kidney, liver and lung as well. Our initial studies and other outside studies have reported that the proportions of donor derived cfDNA in heart transplant recipients increase as much as five-fold during rejection episodes. Measuring the level and changes in the relative amount of donor derived cfDNA in the blood stream may be a useful new method to detecting rejection. This technique involves measuring the cfDNA released by dying cells from the donor organ into the recipient s blood stream. The level of donor specific 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 cfDNA level. The rationale for this approach arises from the observation that both acute and chronic rejection processes are associated with cell death within the transplanted organ.

We are pursuing novel strategies to detect donor specific cfDNA using next generation sequencing. Whole genome sequencing (WGS) has been used to detect donor specific cfDNA in published studies. However, the complexity and cost of the analysis required by WGS limits its application as a surveillance tool. If successful, we believe our sequencing approach will potentially enable us to achieve the turnaround time and cost-efficiency required for practical commercial use in clinical surveillance. We believe our existing repository of specimens suitable for product development in heart will provide us with a competitive advantage in developing and establishing our cfDNA solution in heart and extending our approach to kidney and other organs.

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cfDNA for Heart Transplants

We are seeking to develop a cfDNA-based solution for heart transplant recipients. AlloMap relies on gene expression testing to determine the relative state of quiescence, or lack of rejection activity, in the recipient s immune system and is a well established test to rule-out rejection when the AlloMap score is below a threshold level. We believe that a cfDNA-based solution for heart transplant recipients would provide additional value to clinicians, particularly in situations where a recipient s AlloMap score does not suggest a low probability of rejection activity. We believe it is possible to apply next-generation sequencing platforms and strategies to detect genetic differences between cfDNA in the blood stream emanating from the donor organ and cfDNA emanating from the recipient. Initial studies published in the Proceedings of the National Academy of Sciences and the Journal of American Cardiology have reported that the proportion of donor derived cfDNA in heart transplant recipients increases as much as five-fold during rejection episodes. These studies report that the percentage of donor derived cfDNA in the blood stream indicated the likelihood of rejection in over 90% of the cases where moderate or severe rejection was found in an associated biopsy specimen. We believe a cfDNA solution for heart would help enable 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 believe our proprietary database and blood sample repository and our extensive experience working with transplant centers, transplant clinicians, post-transplant care teams, recipients and payers in the field of managing transplant recipients provide us with competitive advantages in the development, validation and commercialization of a cfDNA solution for heart transplant recipients. Our proprietary database and blood sample repository collected by us over the course of 10 years from over 25 transplant centers contains proprietary, longitudinal samples with clinical outcomes and other data from heart transplant recipients including more than 2,000 recipients with more than 16,000 study visits yielding more than 37,000 samples.

We have completed internal studies to define methods to be used to test our collection of samples as well as additional samples to be acquired by us. We have established our proprietary strategy for quantification of donor specific cfDNA and we have completed initial proof of concept studies. We have defined a strategy to efficiently utilize our sample repository to enable further development and validation of our cfDNA solution. We have further defined a series of experiments to be conducted in the third quarter of 2014 with the objective of developing a research use only version of our cfDNA solution as early as the end of 2014.

Other steps in our development process for a cfDNA solution in heart include publication of an abstract on the results of the clinical performance of our cfDNA solution for heart based on our CARGO II sample and data repository, and publication of abstracts from our initial clinical experience with our research use only test. Timing of these events will depend on the success of our development efforts. If we are successful in developing a cfDNA solution for heart transplant recipients, we expect that it would be made available without additional charge to participating clinicians as a research use only solution pursuant to a research protocol agreement. Accordingly, the cfDNA solution would not generate additional standalone revenue for us. To further our research and development and ensure comparability to our other data, we expect the RUO cfDNA solution for heart to be made available to participating clinicians who order AlloMap using a blood sample taken at the same time as the sample for AlloMap. We do not expect to market or sell a cfDNA solution for heart as a commercial diagnostic product, and we do not intend to seek 510(k) clearance from the FDA for the research use only distribution of our cfDNA test. We believe that a RUO cfDNA-based solution for heart transplant recipients, if developed by us, would provide validation of cfDNA as a meaningful biomarker for post-transplant surveillance, provide us with further insight and expertise in the development of cfDNA-based solutions for the surveillance of organ transplants and enhance our relationships within the heart transplant community through ongoing dialogue.

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cfDNA for Kidney Transplants

We intend to apply the expertise we gain in developing our heart transplant cfDNA solution towards developing cfDNA solutions for other organ transplants, beginning with kidney transplants. We have a proprietary library of longitudinal blood samples from kidney transplant recipients obtained from the University of California at San Francisco. The library consists of more than 1,000 samples from 101 subjects that had 325 study visits and includes blood, plasma and urine samples. These samples were acquired during the course of our Kidney Transplanted Organ Rejection Gene expression Observational Study, or KARGO. KARGO was designed with an intent to discover and develop new non-invasive diagnostics solutions for the surveillance of kidney transplant recipients for rejection. We have begun to utilize the KARGO sample repository for aspects of our cfDNA biomarker research. We are seeking 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. If we are successful in developing a research use only version of our cfDNA-based kidney solution, we plan to move this solution into a lab compliant with the Clinical Laboratory Improvement Amendments of 1988, or CLIA, to complete the analytical validation required to commercialize a solution for use in kidney transplant recipients. If developed, we expect to commercialize this solution as a Laboratory Developed Test, or LDT, under CLIA. 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 not finalized by the FDA and, at present, we do not anticipate seeking 510(k) clearance from the FDA for our cfDNA-based kidney solution. 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 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 cfDNA test for heart transplants and the time required to acquire sufficient samples. We are aiming to initiate a prospective clinical outcomes study in kidney transplant recipients applying a cfDNA-based test as early as the second half of 2015.

Research and Development

We endeavor to stay at the cutting edge of organ transplant surveillance solutions by continuously exploring and developing new clinically-relevant approaches to our products. Our ongoing research and development efforts include:

- further refinement of the AlloMap product line;
- undertaking additional studies to expand the clinical utility of AlloMap and generate additional data to enhance clinical understanding of transplant rejection;
- new product development in other areas of transplant surveillance, such as the use of cell-free DNA technology as a biomarker for rejection; and
- technology platform development to increase efficiency and lower costs in our testing and laboratory operations.

Our research and development efforts are not limited to specific technology platforms, biomarkers or methodologies. We aim to leverage current and future innovations in biomarker identification and measurement in developing future solutions. During the development of AlloMap we focused on the use of genomic technologies, especially gene expression, as a promising area for the discovery of biological signals that could be built into multivariate genomic solutions. We are now engaged in discovery and development efforts using cfDNA to develop additional post-transplant diagnostic solutions, with a focus on a test for heart rejection followed by a test for kidney rejection.

We have a proprietary database and blood sample repository from our clinical trials and research collaborations. Our archives contain proprietary, longitudinal samples with clinical outcomes and other data from heart transplant recipients (more than 2,000 recipients with more than 16,000 study visits yielding more than 37,000 samples) and other organ transplant recipients (more than 100 kidney

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recipients with more than 300 study visits yielding more than 1,000 samples). We have already used our sample archives and data sets to assess how the variability in AlloMap scores over time may correlate with risk of rejection.

Our research and development team includes leading scientists in the field of organ transplant surveillance. We believe our technology base, combined with our know-how and experience, especially that gained from our work on AlloMap, should facilitate our development and commercialization of future organ transplant surveillance solutions.

As of December 31, 2013, we had six employees engaged in research and development functions. Our research and development expenses for the years ended December 31, 2012 and 2013 were $4.8 million and $3.2 million, respectively.

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. As of March 31, 2014, we had been reimbursed for approximately 78% of AlloMap results delivered in the twelve months ended September 30, 2013.

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 the appeals process for the particular payer.

Forty-three payers, including Medicare, insured recipients that accounted for approximately 90% of the tests we delivered in 2013. Many of these, including Medicare, have adopted coverage policies approving AlloMap for reimbursement. We continue to pursue adoption of positive coverage policies by other private and Medicaid payers.

AlloMap has been billed since the inception of the test using an unlisted CPT code. This approach is consistent with the billing approach for many diagnostic tests.

Medicare

We are reimbursed for a substantial portion of our tests performed on recipients covered by Medicare. These represented 40% and 39% of all AlloMap tests in 2012 and 2013, respectively. Approximately 52% and 54% of all testing revenue was derived from Medicare reimbursements for the years ended December 31, 2012 and 2013. Medicare reimbursement for AlloMap began in 2006 and has continued through three successive Medicare Administrative Contractors, which are the local organizations that make most coverage decisions for Medicare.

Private Payers and Medicaid Payers

We are reimbursed for a substantial portion of the tests we perform on patients covered by private payers and Medicaid payers. For example, we have been reimbursed to date for approximately 63% of the tests performed in the twelve months ended June 30, 2013 where the patient had private insurance or Medicaid coverage.

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., WellPoint,

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

About 7% of our tests for which we have recognized revenue were reimbursed by hospitals in 2013. These hospitals have chosen to retain responsibility for dealing with third party payers.

Europe and Canada

Our Canadian partner, Lifelabs Medical Laboratory Services, pays us directly for the tests we perform for them and is responsible for obtaining reimbursement from payers in their territory. In Europe, we receive revenue in two ways. First, through our sale of testing materials to our partner, Diaxonhit SA, and second, through royalties on Diaxonhit SA s net sales of AlloMap in Europe.

Testing and Lab Operations

The AlloMap process is comprised of a pre-analytical phase conducted at trained blood draw and processing sites, the testing phase conducted in our laboratory in Brisbane, California, and a reporting phase whereby AlloMap recipient test results are provided to healthcare providers managing a heart transplant recipient.

When AlloMap is ordered by a clinician, a blood sample is drawn, processed to isolate the white blood cells, which are subsequently broken down, frozen and sent via overnight courier to our Brisbane, California laboratory, which is certified under the Clinical Laboratory Improvement Amendment of 1988, or CLIA.

All recipient blood samples are tested in triplicate and results are reported to the ordering clinician by fax within 1-2 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.

AlloMap Testing Process

We believe that our laboratory capacity will be adequate to meet demand for AlloMap for the next several years. We intend to expand our laboratory facility as we move into other areas of organ transplant surveillance.

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We rely solely on single suppliers to provide certain laboratory instruments and 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 periodically forecast our needs to these sole source suppliers and enter into standard purchase orders based on these forecasts. The universal master mix that is supplied by Thermo Fisher Scientific Inc. is a key test component needed to perform AlloMap and is being discontinued. At present, we believe that we have sufficient master mix material to continue delivering AlloMap through February 2015 and we are engaged in a process that allows for dual sourcing of a replacement for this critical test component.

We have contracted with a third party manufacturer for the development of a custom master mix. As of March 31, 2014, three verification lots were produced at small scale and found to be acceptable for use in AlloMap testing. The contract manufacturer is now engaged in scale up activities and production of validation lots which will be tested to determine their suitability for use in AlloMap testing, which production and testing have not yet been completed. We recently met with Thermo Fisher and initiated a discussion regarding the possibility of Thermo Fisher also formulating a custom master mix for use in AlloMap testing. In both cases, assuming successful development and scale up of three validation lots of master mix, we do not expect the performance characteristics of the AlloMap solution to change.

Sales and Marketing

Our sales approach to the heart transplant market in the United States focuses on the clinical and economic benefits of AlloMap and the scientific validation that supports our test. As of December 31, 2013, our sales and marketing team consisted of 20 employees, including transplant account sales executives, reimbursement account managers, medical science liaisons and patient service center and customer service personnel. All personnel are field based except for customer service, which are based in our California headquarters. Our account team structure is designed to match the transplant medical team structure based on areas of interest, i.e. new technology knowledge, clinical application and reimbursement/coverage knowledge. All of our sales personnel have prior experience in the field of transplantation.

Our sales approach is highly technical and our account team is trained to address the sales, medical and reimbursement issues inherent in selling a test like AlloMap. Our account team focuses on educating and selling to the transplant team, which consists of clinicians, nurses, laboratory and pathology personnel, finance administrators and social workers.

Our team covers all aspects of the transplantation channel, including sales, medical science, reimbursement, customer service and field laboratory/draw site support. In 2013, AlloMap was used in 105 of the approximately 126 heart transplant centers in the United States Our sales 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 and to increase the number of tests ordered per clinician. In addition, we are actively pursuing additional treatment centers to establish protocols and procedures for ordering our test and to encourage clinicians at those centers to incorporate our test into their standard clinical practice. We continue to use new clinical data on AlloMap to demonstrate additional clinical utility for AlloMap, including data that show the utility for the test in long-term recipient management by monitoring the longitudinal AlloMap score variability of a specific recipient.

We intend to leverage our relationships with heart transplant centers to commercialize our planned kidney transplant test, assuming successful completion of development, as many heart transplant

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management centers also manage kidney transplant recipients. Of the 105 heart transplant centers that have used our test in 2013, nearly all also manage kidney transplant recipients. We estimate that there are approximately 230 centers managing kidney transplant recipients in the United States. A significant portion of kidney transplant recipients eventually are managed by community-based nephrologists. If we are successful in developing a diagnostic solution for kidney transplant recipients, we expect that the full commercialization of our kidney transplant diagnostic solution would require us to increase the size of our sales and support team or enter into marketing relationships with third parties, or both.

Internationally, we have commercial agreements in Europe and Canada that provide for exclusive rights to promote AlloMap in those territories. In Europe, Diaxonhit SA is our commercial partner. Diaxonhit SA is a French, publicly traded specialty diagnostics company with activities in France, Switzerland and Belgium. Diaxonhit SA 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 will provide Diaxonhit SA with training and a license to perform AlloMap and Diaxonhit SA, through a third party laboratory, has agreed to perform AlloMap in Europe to facilitate the turnaround time and cost effectiveness of the test process. Diaxonhit SA will pay royalties to us on the net sales, as defined in the agreement, of AlloMap tests, in the mid to high teens. Diaxonhit SA made an upfront payment to us in cash of approximately 387,500 ($503,000) and Diaxonhit SA s publicly traded common stock with a value at the time of 387,000 following execution of the agreement. The cash portion of this upfront payment will offset the royalties payable to us upon the satisfaction of certain milestones in the first three years following the first commercial sale. Diaxonhit SA is also obligated to pay additional royalties based on certain milestones, up to a maximum of 1,450,000, and some of the royalty payments may be made pursuant to the issuance to us of Diaxonhit SA s publicly traded common stock. We expect to begin offering our test in Europe through Diaxonhit SA in late 2014 or early 2015.

In Canada, LifeLabs Medical Laboratories Services, the largest Canadian reference laboratory, is our commercial partner and currently offers AlloMap in Ontario. Under this arrangement, LifeLabs Medical Laboratories Services sends blood samples to our laboratory in Brisbane, California for testing. LifeLabs Medical Laboratories Services will pay us on a per test basis. They also made an upfront payment to us following execution of the agreement that is available to offset test fees up to the amount of the upfront payment in the first year. Under the terms of our agreement, we will provide LifeLabs Medical Laboratories Services with training and marketing materials. LifeLabs Medical Laboratories Services has an option to expand its rights to commercialize AlloMap in all other Canadian provinces. We first began performing tests under our arrangement with LifeLabs Medical Laboratories Services in the fourth quarter of 2013. We recognized minimal revenue from this agreement in 2013 and we do not expect revenues from this agreement for 2014 and 2015 to exceed 5% of our total revenues in each year.

Competition

We believe the principal competitive factors in our target markets include:

- quality and strength of clinical and analytical validation data;
- confidence in diagnostic results;
- the extent of reimbursement;
- inclusion in practice guidelines;
- cost-effectiveness; and
- ease of use.

We believe we compete favorably on the factors described above.

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

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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 post-transplant surveillance to increase as there are numerous 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 or our development pipeline. 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 have knowledge of cfDNA technology, have indicated they are considering this market.

Many transplant centers are located within hospitals that have their own laboratory facilities and have capacity to conduct various tests. If we are unable to keep pace with diagnostic developments in areas for which we have developed solutions or if hospitals are able to conduct alternate tests more cost-effectively in their own laboratories, hospitals may choose to rely on internally developed and/or internally performed surveillance and diagnostic tests.

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. Others may develop products with prices lower than ours that could be viewed by clinicians and payers as functionally equivalent to 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 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 March 31, 2014, we have 16 issued United States patents, one pending United States patent application, and three pending patent applications outside the United States related to transplant

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rejection and autoimmunity. We have five issued United States patents covering methods of diagnosing transplant rejection using 9 of the 11 informative genes measured in AlloMap. The expiration dates of these patents range from 2021 to 2024. We have six issued United States patents covering a method of diagnosing or monitoring an autoimmune or chronic inflammatory diseases, such as lupus, by detecting specific genes. The patent with the longest term expires in 2029. While we have clinical samples and patents covering lupus diagnostics, we do not intend to actively pursue the lupus test opportunity.

In the area of cell-free DNA-based transplant diagnostics, we have filed a provisional patent application to cover some of our initial research and development work in this field. In connection with our acquisition of ImmuMetrix, we expect to succeed to an exclusive license from Stanford University to a patent relating to the diagnosis of rejection in organ transplant recipients using cfDNA.

AlloMap and XDx are registered trademarks of our company in the United States. Our application to register the trademark CareDx in the United States was initially denied based in part on two existing registrations and may not be allowed in a timely fashion or at all. Further consideration of our application may require us to successfully bring a cancellation action against an existing registration that we believe has been abandoned and successfully distinguish our trademark from the second registration. Opposition or cancellation proceedings may be filed against our trademark applications and registrations, and our trademarks may not survive such proceedings. If we do not secure or maintain registrations for our trademarks, we may encounter more difficulty in continuing to use such trademarks or enforcing them against third parties.

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 PCR measurements, and in the analysis of genomic data and algorithm development.

See Risk Factors Risks Relating to Our Intellectual Property.

License Agreements

In November 2004, we entered into a license agreement with Roche Molecular Systems, Inc., or Roche, which was amended in January 2007, July 2007 and October 2008, that grants us the right to use PCR and quantitative real-time PCR for use in clinical laboratory services. This is a non-exclusive license agreement in the United States covering the claims in multiple Roche patents. The term of the agreement runs until such time as the last patent subject to the agreement which contains at least one valid claim covered by the licenses granted pursuant to the agreement expires. We may terminate the agreement without cause upon 30 days written notice. Under the terms of the agreement, 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. We have disputed the royalty rate Roche seeks to charge under the agreement, and we have been withholding payment of such royalties pending resolution of this matter. Among other things, we believe that Roche failed to adequately consult with us, as required under the agreement, prior to setting the royalty rate and that the royalty rate fails to properly reflect the value contributed by the licensed services. On February 13, 2014, we received a demand for arbitration from Roche seeking a declaration that we have materially breached the Roche license agreement by failing to report and pay royalties owing to Roche in respect of licensed services performed by us after July 1, 2011. See the section entitled Legal Proceedings below.

In connection with of our acquisition of ImmuMetrix, we succeeded to the exclusive license granted by Stanford University to a patent relating to the diagnosis of rejection in organ transplant recipients using cfDNA. This amended and restated license agreement with Stanford University, or Stanford, grants us the exclusive worldwide right to the patent and a non-exclusive license to related technology provided by Stanford. The term of the exclusive license to the patent runs until such time as the patent expires, which will be November 5, 2030, while the non-exclusive license to the related technology continues beyond the expiration of the patent. Subject to various rights of extension, we are required to achieve certain

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development and commercialization milestones set forth in the license agreement. Failure to achieve such milestones after expiration of any extensions could result in termination of the license agreement by Stanford. Under the terms of the license agreement, 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. We may terminate this agreement with 30 days advance notice. Stanford may terminate this agreement upon written notice and failure by us to take remedial action within a specified time period if we are delinquent on any report or payment, we are not diligently developing or commercializing products using the licensed technology, we fail to achieve the milestones set forth in the agreement after expiration of applicable extension periods or we otherwise breach the agreement.

Prior to the closing of our acquisition of ImmuMetrix, ImmuMetrix transferred to a newly formed company, Lineage Biosciences, Inc., certain intellectual property, records and tangible and intangible assets of ImmuMetrix related to cfDNA detection and immune system profiling technologies for the diagnosis or clinical management of cancer, or conditions that are a precursor to cancer, and for other applications and purposes. Lineage Biosciences is owned by the former stockholders of ImmuMetrix and is not a subsidiary of ImmuMetrix. ImmuMetrix retained intellectual property rights, records and tangible and intangible assets related to the development, commercialization, licensing, marketing or sale of products or services that utilize cfDNA detection or immune system profiling technologies specifically for the diagnosis and clinical management of solid organ and bone marrow transplant recipients or pre-transplant patients who are on a designated transplant waiting list. ImmuMetrix granted to Lineage Biosciences a sublicense to the Stanford patent in the field of detection, diagnosis or clinical management of cancer, or conditions that are a precursor to cancer and all other applications and purposes outside the field of transplantation described above, including products that are used outside the field of transplantation but also have utility within transplantation. This sublicense is exclusive for the detection, diagnosis or clinical management of cancer, or conditions that are a precursor to cancer, and all applications and purposes outside the use of cfDNA detection or immune system profiling to diagnose and clinically manage solid organ and bone marrow human transplant recipients.

Regulation

Clinical Laboratory Improvement Amendments of 1988

As a clinical laboratory, we are required to hold certain federal, state and local licenses, certifications and permits to conduct our business. Under the Clinical Laboratory Improvement Amendments of 1988, or CLIA, administered by the Centers for Medicare & Medicaid Services, or 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 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 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 and recertified under CLIA in February 2014. We expect the next regular inspection under CLIA to occur in 2016.

California Laboratory Licensing

In addition to federal certification requirements of laboratories under 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.

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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. It is possible that still other states will have such requirements in the future. If we identify any other state with such requirements or if we are contacted by any other state advising us of such requirements, we intend to follow instructions from the state regulators as to how we should comply with such requirements.

Food and Drug Administration

The U.S. Food and Drug Administration 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. The FFDCA defines medical devices to mean, among other things, an instrument, apparatus...in vitro reagent, or other similar or related article...intended for use in the diagnosis of disease or other conditions.... This broad definition includes in vitro diagnostic test kits, which are packaged with all necessary elements and instructions so they may be performed outside of the laboratory. The FDA has also asserted that it has the authority to regulate laboratory-developed tests, known as 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 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 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. However, we may not seek clearance or approval for any other uses of AlloMap or for any other tests we develop, including our planned cell-free DNA tests for heart, kidney and other organs.

The FDA held a meeting in July 2010 during which it indicated that it intends to reconsider its current policy of enforcement discretion and to begin drafting an oversight framework for LDTs. In October 2012, the FDA published a list of planned guidance documents that were to be the focus of the agency in its fiscal year 2013, including the finalization of previously issued draft guidance which could include guidance documents addressing FDA regulation of LDTs such as ours. As recently as June 2013, a senior agency official publicly reiterated the FDA s continued interest in such regulation. As of March 2014, the FDA has not issued any of these planned guidance documents.

If the FDA changes its current policy of enforcement discretion, we may be required to seek FDA clearance or premarket approval LDTs developed by us in the future. We have also obtained the CE mark which indicates a product s compliance with European Union, or EU, legislation and is needed to market AlloMap in the European Community as well.

From the time that our device entered commercial distribution, numerous regulatory requirements apply. These include the Quality System Regulation, or QSR, which imposes extensive design, testing, control,

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documentation and other quality assurance requirements on the manufacturers of medical devices; labeling regulations; the FDA s general prohibition against promoting products for unapproved or off-label uses; and the Medical Device Reporting regulation, which requires that manufacturers report to the FDA if their device may have caused or contributed to a death or serious injury or malfunctioned in a way that would likely cause or contribute to a death or serious injury if it were to reoccur. The FDA has broad post-market and regulatory and enforcement powers. Failure to comply with applicable United States medical device regulatory requirements could result in, among other things, warning letters, fines, injunctions, consent decrees, civil penalties, repairs, replacements, refunds, recalls or seizures of products, total or partial suspension of production, the FDA s refusal to grant future premarket clearances or approvals, withdrawals or suspensions of current product applications, and criminal prosecution.

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 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, commonly known as 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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These self-referral prohibitions apply regardless of the reasons for the financial relationship and the referral. No finding of intent to violate the Stark Law is required to commit a violation. In addition, knowing violations of the Stark Law may also serve as the basis for liability under the Federal False Claims Act.

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. While we have attempted to comply with the Stark Law, PORA and similar laws of other states, it is possible that some of our financial arrangements with physicians could be subject to regulatory scrutiny at some point in the future, and we cannot provide an assurance that we will be found to be in compliance with these laws following any such regulatory review.

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, which we refer to collectively as 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.

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.

The Anti-Kickback Statute is broad and prohibits many arrangements and practices that are otherwise lawful in businesses outside of the healthcare industry. Recognizing that the Anti- Kickback Statute is broad and may technically prohibit many innocuous or beneficial arrangements, Congress authorized the Office of Inspector General (OIG) of the HHS to issue a series of regulations known as safe harbors. These safe harbors set forth provisions that, if all their applicable requirements are met, will assure healthcare providers and other parties that they will not be prosecuted under the Anti-Kickback Statute. The failure of a transaction or arrangement to fit precisely within one or more safe harbors does not necessarily mean that it is illegal or that prosecution will be pursued. However, conduct and business arrangements that do not fully satisfy on applicable safe harbor may result in increased scrutiny by government enforcement authorities such as OIG.

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.

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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, action 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 law 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 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.

While we are unaware of any current matters alleging we have violated the False Claims Act, we are unable to predict whether we will be subject to actions under the False Claims Act or similar state laws, or the impact of such actions. The costs of defending such claims, as well as any sanctions imposed, could significantly affect our financial performance.

The Sunshine Act

The Physician Payment Sunshine Act, or the Sunshine Act, which was enacted as part of the Affordable Care Act, requires all pharmaceutical and medical device manufacturers of products covered by Medicare, Medicaid or the Children s Health Insurance Program to report annually to the Secretary of the Department of Health and Human Services payments or other transfers of value made by that entity, or by a third party as directed by that entity, to physicians and teaching hospitals or to third parties on behalf of physicians or teaching hospitals. The payments required to be reported include the cost of meals provided to a physician, travel reimbursements and other transfers of value provided as part of contracted services such as speaker programs, advisory boards, consultation services and clinical trial services. The final rule implementing the Sunshine Act required data collection on payments to begin on August 1, 2013. The first required report, comprised of aggregate payment data collected from August 1, 2013 to December 31, 2013, was due on March 31, 2014, with a full report of payments to covered recipients during the same period due by June 30, 2014. The statute requires the federal government to make reported information available to the public starting September 2014. Failure to comply with the reporting requirements can result in significant civil monetary penalties ranging from $1,000 to $10,000

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for each payment or other transfer of value that is not reported (up to a maximum per annual report of $150,000) and from $10,000 to $100,000 for each knowing failure to report (up to a maximum per annual report of $1.0 million). Additionally, there are criminal penalties if an entity intentionally makes false statements in such reports. We are subject to the Sunshine Act and the information we disclose may lead to greater scrutiny of our interactions with physicians and teaching hospitals, which may result in modifications to established practices and additional costs. Additionally, similar reporting requirements have also been enacted on the state level domestically, and an increasing number of countries worldwide either have adopted or are considering similar laws requiring transparency of interactions with healthcare professionals.

Foreign Corrupt Practices Act

The Foreign Corrupt Practices Act, or FCPA, prohibits any United States individual or business from paying, offering, or authorizing payment or offering of anything of value, directly or indirectly, to any foreign official, political party or candidate for the purpose of influencing any act or decision of the foreign entity in order to assist the individual or business in obtaining or retaining business. The FCPA also obligates companies whose securities are listed in the United States to comply with accounting provisions requiring us to maintain books and records that accurately and fairly reflect all transactions of the corporation, including international subsidiaries, and to devise and maintain an adequate system of internal accounting controls for international operations.

International Laws

In Europe various countries have adopted anti-bribery laws providing for severe consequences, in the form of criminal penalties and/or significant fines, for individuals and/or companies committing a bribery offence. Violations of these anti-bribery laws, or allegations of such violations, could have a negative impact on our business, results of operations and reputation. For instance, in the United Kingdom, under the Bribery Act 2010, which went into effect in July 2011, a bribery occurs when a person offers, gives or promises to give a financial or other advantage to induce or reward another individual to improperly perform certain functions or activities, including any function of a public nature. Bribery of foreign public officials also falls within the scope of the Bribery Act 2010. Under the new regime, an individual found in violation of the Bribery Act of 2010, faces imprisonment of up to 10 years. In addition, the individual can be subject to an unlimited fine, as can commercial organizations for failure to prevent bribery.

The Corruption of Foreign Public Officials Act, or CFPOA, prohibits Canadian businesses and individuals from giving or offering to give a benefit of any kind to a foreign public official, or any other person for the benefit of the foreign public official, where the ultimate purpose is to obtain or retain a business advantage. Under the CFPOA, companies may be liable for the actions of their employees or third-party agents.

Employees

As of March 31, 2014, we had a total of 55 employees, including 20 employees in sales and marketing and eight employees in research and development. From time to time we also employ independent contractors, consultants and temporary employees to support our operations. 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.

Properties

Our headquarters in Brisbane, California comprise approximately 46,000 square feet of leased space, which includes office space, our clinical laboratory and our research and development laboratories. The lease agreement for the Brisbane facility expires on December 31, 2020. 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.

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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. We cannot predict how changes in laws or new regulations will affect our business, operations or the cost of compliance.

Legal Proceedings

From time to time, we may be party to lawsuits and other legal proceedings in the ordinary course of business.

In November 2004, we entered into a license agreement with Roche Molecular Systems, Inc., or Roche, that grants us the right to use PCR and quantitative real-time PCR for use in clinical laboratory services, including for use in connection with AlloMap. This is a non-exclusive license agreement in the United States covering the claims in multiple Roche patents. We have disputed the royalty rate Roche seeks to charge under the agreement, and we have been withholding payment of such royalties pending resolution of this matter. Among other things, we believe that Roche failed to adequately consult with us, as required under the agreement, prior to setting the royalty rate and that the royalty rate fails to reflect the value contributed by the licensed services. On February 11, 2014 Roche filed a demand for arbitration with the American Arbitration Association seeking a declaration that we have materially breached the Roche license agreement by failing to report and pay royalties owing to Roche in respect of licensed services performed by us after July 1, 2011. Roche seeks damages in the form of unpaid royalties from July 1, 2011 to March 31, 2013 of $1,805,775 plus interest of $84,928 and royalties in an unspecified amount from April 1, 2013 to present, which, based upon the royalty rate currently in the license agreement, we would estimate to be an additional $1,248,237 through March 31, 2014. We responded to the Roche demand on March 14, 2014. A preliminary conference with the arbitration panel was held on June 24, 2014 and a hearing has been scheduled for February 2, 2015. While we believe we have meritorious defenses to Roche s claims, which we plan to fully pursue in the arbitration, we have fully reserved the amount of these unpaid royalties on our balance sheets, and the amount of these unpaid royalties has been reflected as an expense in our income statements in the periods to which the royalties relate.

The agreement provides that if we fail to cure any breach of a material term within 30 days after Roche has given written notice of the breach, Roche would have the right to terminate our agreement. To date, Roche has not communicated to us any intention on its part to terminate the agreement and has not sought a declaration in the arbitration it commenced as to its right to terminate the agreement. If Roche were to seek to terminate our agreement, and we did not cure within the required time period, our license to the unexpired patents licensed thereunder would terminate, and Roche could thereafter initiate litigation seeking damages or injunctive relief on the basis that AlloMap or other of our services infringe Roche patents. We cannot assure you that Roche will not seek to terminate the license agreement, that we would ultimately prevail in the arbitration or that in the event that Roche were successful in terminating the license agreement, that it would not thereafter seek to enjoin us from selling AlloMap based upon a claim of patent infringement. If any of these things were to occur, we cannot assure you that we would not be materially adversely affected. Among other things, any inability by us to continue to perform AlloMap would have a material adverse effect on our business, financial condition and results of operations.

Other than the arbitration proceeding with Roche, we are not a party to any legal proceedings that we believe are material to our business, financial condition or results of operations.

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MANAGEMENT

Executive Officers and Directors

The following table provides information regarding our executive officers and directors as of June 25, 2014:

Name	Age	Position
Executive Officers		
Peter Maag, Ph.D	47	President, Chief Executive Officer, and Director
James P. Yee, M.D., Ph.D.	65	Chief Medical Officer
Matthew J. Meyer	44	Chief Business Officer
Ken Ludlum	61	Chief Financial Officer
Mitchell J. Nelles, Ph.D.	61	Chief Operating Officer
Non-Employee Directors		
George W. Bickerstaff, III[3]	58	Director
Brook Byers[1]	68	Director
Fred E. Cohen, M.D., D. Phil.[1]	57	Director
Michael Goldberg[1][3]	56	Director, Chairman of the Board
Ralph Snyderman, M.D.[2]	74	Director

(1) Member of compensation committee.
(2) Member of nominating and governance committee.
(3) Member of audit committee.

Executive Officers

Peter Maag, Ph.D. has served as our President and Chief Executive Officer since October 2012 and as a member of our board of directors since November 2012. Prior to joining the Company, Dr. Maag held numerous positions with increasing responsibility at Novartis International AG, a global healthcare company from September 2001 to April 2012, including Global Head of Novartis Diagnostics from 2009 to 2012, a business unit of Novartis A.G. Dr. Maag also served as Country President for Novartis Pharma AG in Germany from 2006 to 2008, Country President for Novartis Korea operations from 2003 to 2005, and the Head of Strategy for the pharmaceutical division of Novartis A.G. from 2001 to 2002. Dr. Maag also worked at McKinsey & Company, focusing on healthcare and globalization from 1995 to 2001. Dr. Maag also serves on the board of directors at Phoenix Pharmahandel GmbH & Co KG and Molecular MD. Dr. Maag studied pharmaceutical sciences at the University of Heidelberg and University of London and received his Ph.D. from the University of Berlin, Germany. Our board of directors has concluded that Dr. Maag should serve on our board of directors due to his position as President and Chief Executive Officer of the Company as well as his extensive experience in the pharmaceuticals and life sciences industries.

James P. Yee, M.D., Ph.D. has served as our Chief Medical Officer since August 2006. From January 2003 to June 2006, Dr. Yee was Vice President and Head of Development for Celera Genomics, Inc., a diagnostics company. From June 1995 to December 2002, he was Vice President of Preclinical and Clinical Development at Roche Bioscience, a division of F. Hoffmann-La Roche Ltd. Earlier in his career, Dr. Yee held a variety of research and development positions of increasing responsibility at Syntex Corporation, including Vice President and Director of the Institute for Clinical Medicine from 1989 to 1992. Dr. Yee is certified in internal medicine by the American Board of Internal Medicine. Dr. Yee holds a B.S. in Electrical Engineering and Computer Science and a Ph.D. in Biophysics from the University of California at Berkeley, and an M.D. from the University of California, Los Angeles School of Medicine.

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Matthew J. Meyer has served as our Chief Business Officer since February 2012. Prior to that, he served as our Vice President of Corporate Development and Legal Affairs since August 2010. Mr. Meyer has over 15 years of business development, marketing, legal and commercial experience in the global life sciences industry. Prior to joining CareDx, Mr. Meyer was Vice President, Business Development and General Counsel at Cerimon Pharmaceuticals from January 2008 to August 2010, where he led the in-license and partnering of prescription pharmaceuticals in the fields of pain and inflammation. Prior to that, Mr. Meyer held senior management positions at Draeger Medical Systems, the U.S. subsidiary of the German-based global medical device company, most recently serving as Vice President and General Counsel from September 2006 to December 2007. Prior to Draeger, from July 2004 to August 2006 Mr. Meyer held positions of increasing responsibility at Novartis Pharma AG in Basel, Switzerland, including serving as Head of Global Marketing Channel Innovations, a role in which he helped foster greater marketing and sales effectiveness through the use of innovative technology-based initiatives. Previously, from January 2000 to June 2004 Mr. Meyer was the Vice President, Global Business Development and Legal Affairs at RxCentric, Inc. which was acquired by Allscripts Healthcare Solutions, Inc. in 2003 and integrated into its Physician s Interactive division, which was a leader in online life science marketing programs to physicians. Prior to that, Mr. Meyer served as a commercial and transactional attorney at Pfizer Inc. from 1995 to 2000, working in the U.S. headquarters and the United Kingdom. Mr. Meyer graduated cum laude and Phi Beta Kappa with a Bachelor of Arts degree from Cornell University. He earned his Juris Doctor degree from Villanova University School of Law.

Ken Ludlum has served as our Chief Financial Officer since March 2014. From April 2011 to October 2013, Mr. Ludlum served as Vice President and Chief Financial Officer, Head of Operations for Endogastric Solutions, Inc. From December 2009 to March 2011, Mr. Ludlum provided consulting and advisory services to a number of private biotechnology companies. From April 2008 to November 2009, he served as Senior Vice President Finance & Administration, CFO for Paracor Medical Inc. Mr. Ludlum has over 30 years of business and financial experience working with healthcare and biotech companies, including service as CFO for two other publicly-held companies, Perclose, Inc, from 1995 to 2000, and Alteon, Inc., from 1992 to 1994. Mr. Ludlum currently serves on the board of directors for another publicly held company, NATUS Medical, Inc. He has also served on the board of directors of several public and private medical or biotechnology companies. Mr. Ludlum holds a B.S. in Business Administration from Lehigh University and a M.B.A. from Columbia University Graduate School of Business.

Mitchell J. Nelles, Ph.D. has served as our Chief Operating Officer since January 2012. Prior to that, he served as our Vice President, Research and Development and Technical Operations since December 2006. From August 2003 to October 2006, Dr. Nelles was Vice President of North America Research and Development at bioMérieux, Inc., an *in vitro* diagnostics company. From December 2001 to July 2003, Dr. Nelles was Vice President of Research and Development at TriPath Oncology, a subsidiary of TriPath Imaging Inc., a company that develops, manufactures, markets and sells solutions to improve the clinical management of cancer. Dr. Nelles holds a B.A. in Biological Sciences from Rutgers College, a Ph.D. in BioMedical Sciences (Immunology) from the University of Texas, Health Sciences Center at Dallas, and has completed postdoctoral training in Immune Regulation at Brandeis University.

Non-Employee Directors

George W. Bickerstaff, III has served as a member of our board of directors since April 2014. Mr. Bickerstaff is currently the Managing Director of M.M. Dillon & Co., LLC, which he joined in 2005. Prior to joining M.M. Dillon & Co., LLC, Mr. Bickerstaff held various positions with Novartis International AG, a global leader in pharmaceuticals and consumer health, including Chief Financial Officer of Novartis Pharma AG from October 2000 to May 2005. From December 1999 to September 2000, Mr. Bickerstaff served as Executive Vice President and Chief Financial Officer of Workscape, Inc. a provider of employee-related information services. From July 1998 to December 1999, Mr. Bickerstaff

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served as Executive Vice President and Chief Financial Officer of Uniscribe Professional Services, Inc., a nationwide provider of paper and technology-based document management solutions. From January 1998 to June 1998, Mr. Bickerstaff served as Executive Vice President and Chief Financial Officer of Intellisource Group, Inc., a provider of information technology solutions to the federal, state and local government and utility markets. From July 1997 to December 1997, Mr. Bickerstaff served as Vice President of Finance of Cognizant Corporation, a global business information services company. From January 1990 to June 1997, Mr. Bickerstaff served in various senior finance roles, including Chief Financial Officer of IMS Healthcare, a global business information services company in the healthcare and pharmaceutical industries. Prior to that, Mr. Bickerstaff held various finance, audit and engineering positions with the Dun & Bradstreet Corporation from 1985 to 1989 and General Electric Company from 1978 to 1985. Mr. Bickerstaff s non-profit activities include serving on the board of directors of the International Vaccine Institute, the International Centre for Missing and Exploited Children, The Center for Disease Dynamics, Economics & Policy and The Global Alliance For Vaccines and Immunization. Mr. Bickerstaff received a Bachelor of Science degree in engineering and a Bachelor of Arts degree in business administration from Rutgers University in 1978. Our board of directors has concluded that Mr. Bickerstaff possesses specific attributes that qualify him to serve as a member of our board of directors, including his substantial financial experience in the healthcare industry and substantial experience with organ transplant markets.

Brook Byers has served as a member of our board of directors since January 2003. Mr. Byers has been a venture capital investor since 1972 and is a Managing Partner of Kleiner Perkins Caufield & Byers, or KPCB, a venture capital firm, which he joined in 1977. He has been closely involved with more than sixty new technology-based ventures, many of which have subsequently become public companies. He formed the first life sciences practice group in the venture capital profession in 1984 and led KPCB to become a premier venture capital firm in the medical, healthcare and biotechnology sectors. Mr. Byers is currently on the board of directors of Foundation Medicine, Inc., Pacific Biosciences, Inc., Veracyte, Inc. and a number of private companies. Mr. Byers is on the Board of Trustees of Stanford University and serves as a board member for the University of California, San Francisco Medical Foundation and the New Schools Foundation. Mr. Byers received the UCSF Medal, its honorary degree equivalent, in 2007. In 2008, Mr. Byers was elected a fellow of the American Academy of Arts and Scientists. Mr. Byers received the Lifetime Achievement Award from the National Venture Capital Association in 2009, and in 2010 he received an honorary Ph.D. from Georgia Institute of Technology. Mr. Byers received an M.B.A. from Stanford University and received a B.S. in Electrical Engineering from Georgia Institute of Technology. Our board of directors has concluded that Mr. Byers possesses specific attributes that qualify him to serve as a member of our board of directors, including his experience with growing numerous companies in the life sciences industry and his leadership in personalized medicine initiatives.

Fred E. Cohen, M.D., D. Phil. has served as a member of our board of directors since January 2003. Dr. Cohen is a Partner at TPG, a global private equity firm. Dr. Cohen joined TPG in 2001, and serves as head of TPG s biotechnology group. Dr. Cohen continues to serve as an Adjunct Professor of Cellular and Molecular Pharmacology at the University of California, San Francisco, where he has taught since 1988. Dr. Cohen has played a role on the boards of directors or scientific advisory boards of a variety of biotechnology companies. He currently serves on the board of directors of Genomic Health Inc., Quintiles Transnational Holdings, Inc., BioCryst Pharmaceuticals, Inc., CardioDx, Inc., Five Prime Therapeutics, Inc., Tandem Diabetes Care, Inc. and Veracyte, Inc., as well as multiple other private companies. He received his M.D. from Stanford University, his D.Phil. in Molecular Biophysics from Oxford University as a Rhodes Scholar, and his B.S. in Molecular Biophysics and Biochemistry from Yale University. Dr. Cohen was elected to the Institute of Medicine of the National Academics in 2004 and the American Academy of Arts and Sciences in 2008. Dr. Cohen also serves as a fellow of the American College of Physicians since 1989, a member of the American Society for Clinical Investigation and the Association of American Physicians, and is the recipient of several awards and honors including the Burroughs-Wellcome New Initiatives in Malaria Award, the LVMH Science Pour L Art Price (shared with Stanley Prusiner), a Searle Scholars Award and Young Investigator Awards from the Endocrine Society and the Western Society for

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Clinical Investigation. Our board of directors has concluded that Dr. Cohen possesses specific attributes that qualify him to serve as a member of our board of directors, including his significant leadership experience in the medical and finance fields, his background as an M.D. and a venture capitalist, his extensive technical expertise relevant to our business, and his service as an investor in and director of numerous life sciences and healthcare companies.

Michael Goldberg has served as a member and chairman of our board of directors since November 2011. Mr. Goldberg has served as a director and chairman of the board of Nodality, Inc., a private molecular diagnostics company, and as an advisor to other private life science companies since May 2011. Mr. Goldberg has also served on the board of directors for eHealth, Inc. since 1999. From January 2005 to May 2011, Mr. Goldberg was a partner at Mohr Davidow Ventures, a venture capital firm, where he led life sciences investments in the area of molecular diagnostics, personalized medicine and wireless healthcare. From October 2000 to December 2004, Mr. Goldberg operated a management and financial consultancy business. In 1995, Mr. Goldberg founded OnCare, Inc., an oncology disease management company, and served as its chairman until August 2001 and as its chief executive officer until March 1999. In 1987, Mr. Goldberg founded Axion, Inc., a cancer treatment services company, and served as its chief executive officer until its sale in 1995. Prior to Axion, Mr. Goldberg was a partner at the venture capital firm of Sevin Rosen Management Company from 1985 to 1987, where he established the firm s life science practice, and director of corporate development at Cetus Corporation from 1981 to 1985. Mr. Goldberg has served as a member of the board of directors of numerous companies in the biotech and health sciences industry, and currently serves as executive chairman of DNAnexus, Inc. and Nodality, Inc. Mr. Goldberg has served on boards and advisory boards of a number of industry, academic and public policy institutions in biotechnology and finance, including the Board of the Independent Citizens Oversight Committee, which is the governing board for the California Institute for Regenerative Medicine, the Board of the Western Association of Venture Capitalists, the Advisory Boards for the Harvard Center for Genetics and Genomics, the Berkeley Center for Law and Technology, and the UCSF Center for Translational and Policy Research on Personalized Medicine. Mr. Goldberg holds a B.A. from Brandeis University and an M.B.A. from the Stanford Graduate School of Business. Our board of directors has concluded that Mr. Goldberg possesses specific attributes that qualify him to serve as a member of our board, including his experience as a senior executive, board member and venture capital investor with numerous companies in the life sciences industry and in personalized medicine and genomics.

Ralph Snyderman, M.D. has served as a member of our board of directors since May 2005. Dr. Snyderman has held the position of Chancellor Emeritus and James B. Duke Professor of Medicine at Duke University since July 2004. From January 1989 to June 2004, he served as Chancellor for Health Affairs at the Duke University School of Medicine and was the founding CEO and President of the Duke University Health System. From January 2006 to November 2009, he consulted for New Enterprise Associates, a venture capital firm, as a venture partner. He previously served on the boards of directors of The Procter and Gamble Company, Pharmaceutical Product Development, LLC (PPD), Trevena, Inc., Crescendo Bioscience, Inc. and Targacept, Inc. He currently serves on the boards of Nodality, Inc., Press Ganey Associates, Inc., and Liquida Technologies, Inc. Dr. Snyderman is a member of the Association of American Physicians, where he served as president from 2003 to 2004, the Association of American Medical Colleges, where he served as chair from 2001 to 2002, the Institute of Medicine and the American Academy of Arts & Sciences. Dr. Snyderman holds a B.S. in Pre-Medical Studies from Washington College, an M.D. from the State University of New York, Downstate Medical Center, and completed an internship and residency in Medicine at Duke University. Our board of directors has concluded that Mr. Snyderman possess specific attributes that qualify him to serve as a member of our board of directors, including his strong background in personalized medicine and broad experience in the healthcare industry.

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Board Composition

Our board of directors consists of six members.

Following the completion of this offering, our amended and restated certificate of incorporation and amended and restated bylaws will provide for a classified board of directors, with each director serving a three year term.

- Our Class I directors will be George W. Bickerstaff, III and Ralph Snyderman, and their terms will expire at the first annual meeting of stockholders following the date of this prospectus;
- Our Class II directors will be Fred E. Cohen and Brook Byers, and their terms will expire at the second annual meeting of stockholders following the date of this prospectus; and
- Our Class III directors will be Michael Goldberg and Peter Maag, and their terms will expire at the third annual meeting of stockholders following the date of this prospectus.

The division of our board of directors into three classes with staggered three-year terms may delay or prevent a change of our management or a change of control. Under our amended and restated certificate of incorporation, our directors may be removed for cause by the affirmative vote of the holders of at least 66 2/3% in voting power of our voting stock.

Director Independence

In connection with this offering, we have applied to list our common stock on The NASDAQ Global Market, or NASDAQ. Under the rules of NASDAQ, independent directors must comprise a majority of a listed company s board of directors within a specified period of the completion of this offering. In addition, the rules of NASDAQ require that, subject to specified exceptions, each member of a listed company s audit, compensation and nominating and corporate governance committees be independent. Under the rules of NASDAQ, a director will only qualify as an independent director if, in the opinion of that company s board of directors, that person does not have a relationship that would interfere with the exercise of independent judgment in carrying out the responsibilities of a director. Audit committee members must also satisfy the independence criteria set forth in Rule 10A-3 under the Exchange Act.

Our board of directors has undertaken a review of its composition, the composition of its committees and the independence of each director. Our board of directors has determined that, other than Dr. Maag, by virtue of his position as our President and Chief Executive Officer, none of our directors has a relationship that would interfere with the exercise of independent judgment in carrying out the responsibilities of a director and that each is independent as that term is defined under the applicable rules and regulations of the SEC and the listing requirements and rules of NASDAQ. Accordingly, a majority of our directors are independent, as required under applicable NASDAQ rules. In making this determination, our board of directors considered the current and prior relationships that each non-employee director has with the Company and all other facts and circumstances our board of directors deemed relevant in determining their independence, including the beneficial ownership of our capital stock by each non-employee director.

Board Leadership Structure

Our board of directors has an independent Chairman, Mr. Goldberg, who has authority, among other things, to preside over board of directors meetings, including meetings of the independent directors, and to call special meetings of the board. Accordingly, the Chairman has substantial ability to shape the work of our board of directors. We currently believe that separation of the roles of Chairman and Chief Executive Officer reinforces the independence of our board of directors in its oversight of the business and affairs of our Company. In addition, we currently believe that having an independent Chairman

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creates an environment that is more conducive to objective evaluation and oversight of management s performance, increasing management accountability and improving the ability of our board of directors to monitor whether management s actions are in the best interests of the Company and its stockholders. However, no single leadership model is right for all companies and at all times. Our board of directors recognizes that depending on the circumstances, other leadership models, such as combining the role of Chairman with the role of Chief Executive Officer, might be appropriate. Accordingly, our board of directors may periodically review its leadership structure.

Committees of the Board of Directors

Our board of directors has an audit committee, a compensation committee and a nominating and corporate governance committee, each of which will have the composition and responsibilities described below upon completion of this offering. Members serve on these committees until their resignation or until otherwise determined by our board of directors.

Audit Committee. George W. Bickerstaff, III, Fred Cohen and Michael Goldberg serve on our audit committee. George W. Bickerstaff, III is the chair of this committee. Our audit committee oversees our corporate accounting and financial reporting process and assists our board of directors in oversight of the integrity of our financial statements, our compliance with legal and regulatory requirements, our independent auditor s qualifications, independence and performance, and our internal accounting and financial controls. Our audit committee is responsible for the appointment, compensation, retention and oversight of our independent auditors. Each member of our audit committee meets the financial literacy requirements of the current NASDAQ listing standards. We expect to satisfy the member independence requirements for the audit committee prior to the end of our transition period provided under current NASDAQ listing standards and SEC rules and regulations for companies completing their initial public offering. Our board of directors has determined that George W. Bickerstaff, III is an audit committee financial expert, as defined by the rules promulgated by the SEC, and has the requisite financial sophistication as defined under the applicable rules and regulations of NASDAQ.

Compensation Committee. Brook Byers, Fred Cohen and Michael Goldberg serve on our compensation committee. Brook Byers is the chair of this committee. Our compensation committee oversees our compensation policies, plans and benefits programs and assists our board of directors in meeting its responsibilities with regard to oversight and determination of executive compensation. In addition, our compensation committee reviews and makes recommendations to our board of directors with respect to our major compensation plans, policies and programs and assesses whether our compensation structure establishes appropriate incentives for officers and employees.

Nominating and Corporate Governance Committee. Brook Byers and Ralph Snyderman serve on our nominating and corporate governance committee. Ralph Snyderman is the chair of this committee. Our nominating and corporate governance committee is responsible for making recommendations to our board of directors regarding candidates for directorships and the size and composition of the board of directors and its committees. In addition, our nominating and corporate governance committee is responsible for reviewing and making recommendations to our board of directors on matters concerning corporate governance and conflicts of interest.

Codes of Business Conduct and Ethics

In connection with this offering, our board of directors will adopt a code of business conduct and ethics that applies to all of our employees, officers and directors, including those officers responsible for financial reporting. Upon completion of this offering, our code of business conduct and ethics will be available on our website at *www.caredxinc.com*. We intend to disclose any amendments to the code, or any waivers of its requirements, on our website to the extent required by the applicable rules and exchange requirements. The inclusion of our website address in this prospectus does not include or incorporate by reference into this prospectus the information on or accessible through our website.

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Compensation Committee Interlocks and Insider Participation

In the past three years, none of the members of our compensation committee is or has in the past served as an officer or employee of our company. None of our executive officers currently serves, or in the past year has served, as a member of a board of directors or compensation committee of any entity that has one or more executive officers serving on our board of directors or compensation committee.

Non-Employee Director Compensation

Directors who are employees do not receive any additional compensation for their service on our board of directors. We reimburse our non-employee directors for their reasonable out-of-pocket costs and travel expenses in connection with their attendance at board of directors and committee meetings. In 2013, certain of our non-employee directors received cash compensation and options to purchase shares of our common stock pursuant to our 2008 Stock Plan as set forth below.

Following the closing of this offering, our non-employee directors will receive an annual cash retainer of $30,000 for their service on our board of directors and any committee thereof. Members of our audit committee, compensation committee and nominating and corporate governance committee, other than the chair of each such committee, will receive an additional annual cash retainer of $10,000, $6,000 and $4,000, respectively. The chair of our audit committee, compensation committee and nominating and corporate governance committee will each receive an additional annual cash retainer of $20,000, $12,000 and $8,000, respectively. Additionally, the individual acting as Chairman of the Board will receive an additional annual cash retainer of $65,000. All annual cash retainers will be payable quarterly and pro-rated for partial service in any year. We will also continue to reimburse our non-employee directors for their reasonable out-of-pocket costs and travel expenses in connection with their attendance at board of directors and committee meetings in accordance with our travel policy.

Following the closing of this offering, nondiscretionary, automatic grants of nonstatutory stock options will be made to our non-employee directors. Any non-employee director who first joins our board of directors on or after the effective date of our 2014 Equity Incentive Plan will be automatically granted an initial stock option to purchase 75,000 shares of our common stock at an exercise price equal to the fair market value of our common stock on the date of grant. The options will vest and become exercisable in equal monthly installments beginning with the first monthly anniversary after the grant date over the following three years. On the first business day after each annual meeting of our stockholders, each non-employee director who continues to serve on our board of directors will be automatically granted an option to purchase 36,000 shares of our common stock at an exercise price equal to the fair market value of our common stock on the date of grant. Each of these options will vest and become exercisable in equal monthly installments beginning with the first monthly anniversary after the grant date over the following one year. The vesting of the options described above will accelerate in full upon a change in control as defined in our 2014 Equity Incentive Plan.

The following table sets forth the compensation accrued or paid by us to certain non-employee directors during the year ended December 31, 2013, for service on our board of directors. We did not pay or accrue any compensation for directors Brook Byers and Fred Cohen during the year ended December 31, 2013.

Name	Fees Earned or Paid in Cash	Stock Awards	Option Awards[1][2]	Total
Michael Goldberg	$ 100,000		$ 19,132	$ 119,132
Ralph Snyderman			$ 1,679	$ 1,679

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(1) Amounts represent the aggregate fair value of the option awards computed as of the grant date of each option award in accordance with FASB ASC Topic 718, rather than amounts paid to or realized by the named individual. Our assumptions with respect to the calculation of these values are set forth above in Management s Discussion and Analysis of Financial Condition and Results of Operations Critical Accounting Policies Stock-Based Compensation . There can be no assurance that option awards will be exercised (in which case no value will be realized by the individual) or that the value on exercise will approximate the fair value as computed in accordance with FASB ASC Topic 718.

(2) The following table sets forth outstanding equity awards held by non-employee directors as of March 31, 2014:

Name	Equity Award Grant Date	Number of Securities Underlying Unexercised Options Exercisable	Option Exercise Price[1] Per Share	Option Expiration Date
David Levison[2]	10/27/2004	5,839	$ 2.33	10/27/2014
David Levison[2]	3/31/2014	13,339	$ 12.40	3/20/2016
Ralph Snyderman, M.D.	4/27/2005	11,678	$ 2.33	4/27/2015
Ralph Snyderman, M.D.	4/8/2010	14,598	$ 3.70	4/8/2020
Michael Goldberg	11/16/2011	64,525	$ 2.95	11/16/2021

(1) The grant date fair value of the common stock underlying these option awards is equal to the option exercise price on the date of grant.

(2) Mr. Levison resigned as a member of our board of directors effective as of March 28, 2014.

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EXECUTIVE COMPENSATION

As an emerging growth company, we have opted to comply with the executive compensation disclosure rules applicable to smaller reporting companies, as such term is defined in the rules promulgated under the Securities Act of 1933, as amended, or the Securities Act, which require compensation disclosure for our principal executive officer and the two most highly compensated executive officers other than our principal executive officer. Our named executive officers for the year ended December 31, 2013, which consist of the three executive officers listed in the Summary Compensation Table, are:

Peter Maag, our President and Chief Executive Officer;

James Yee, our Chief Medical Officer; and

Matthew Meyer, our Chief Business Officer.

Throughout this prospectus, these three executive officers are referred to as our named executive officers.

The Summary Compensation Table below sets forth information regarding the compensation awarded to or earned by the named executive officers listed below during the year ended December 31, 2013.

2013 Summary Compensation Table

Name and Principal Position	Year	Salary	Non-Equity Incentive Plan Compensation	Total
Peter Maag	2013	$ 350,000	$ 190,000	$ 540,000
James Yee	2013	$ 365,650	$ 146,260	$ 511,910
Matthew Meyer	2013	$ 308,250	$ 123,300	$ 431,550

Non-Equity Incentive Plan Compensation

Each of our named executive officers is eligible for cash annual incentive payments. For 2013, Dr. Maag had a target annual incentive of $150,000, as contractually set forth in his Chief Executive Employment Agreement described below. Each other named executive officer is eligible for a target annual incentive of 30% to 40% of his base salary.

Payment of an incentive is based on our performance against certain key performance indicators. For 2013, our key performance indicators included patients served, our profits, our partnering relationships, our pipeline, and our performance culture. We measure our actual performance against our budgeted goals, and then determine an incentive payout.

2013 Outstanding Equity Awards at Year-End

The following table presents information concerning all outstanding equity awards held by each of our named executive officers as of December 31, 2013.

Named Executive Officer	Grant Date	Number of	Number of

		Vesting Commencement Date	Securities Underlying Unexercised Options Exercisable	Securities Underlying Unexercised Options Unexercisable	Option Exercise Price	Option Expiration Date
Peter Maag	10/17/2012	10/1/2012	121,349[1]	68,589	$ 0.55	10/17/2022
James Yee	10/25/2006	8/8/2006	14,598[2][3][5]	0	$ 3.43	10/25/2016
James Yee	9/27/2007	1/1/2008	29,197[3][4][5]	0	$ 3.36	9/27/2017
James Yee	4/8/2010	1/1/2010	3,649[3][4][5]	0	$ 3.70	4/8/2020
James Yee	8/27/2010	5/5/2010	3,649[3][4][5]	0	$ 3.97	8/27/2020
Matthew Meyer	1/10/2011	8/30/2010	3,317[2][3][5]	0	$ 3.01	1/10/2021
Matthew Meyer	1/10/2011	8/30/2010	33,178[2][3][5]	0	$ 3.01	1/10/2021

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(1) The shares subject to the stock option vest as follows: 2/48th of the total shares vest each month on the monthly anniversary of the vesting commencement date for twelve (12) months, and, thereafter, 1/36th of the remaining shares vest in equal monthly installments, subject to executive s continued employment on each applicable vesting date.

(2) The shares subject to the stock option vest as follows: 1/4th of the total shares vest on the one year anniversary of the vesting commencement date, and, thereafter, 1/48th of the total shares vest in equal monthly installments, subject to executive s continued employment on each applicable vesting date.

(3) The stock option is subject to accelerated vesting as to the unvested portion of the option upon a qualifying termination of the executive s employment with us following a change of control, as described under Potential Payments and Benefits upon Termination or Change in Control.

(4) The shares subject to the stock option vest as follows: 1/48th of the total shares vest in equal monthly installments on the monthly anniversary of the vesting commencement date, subject to executive s continued employment on each applicable vesting date.

(5) The option is exercisable as to unvested shares, provided that any unvested shares are subject to a repurchase right upon a termination of service.

Offer Letters and Employment Arrangements

We have entered into letter agreements with each of our named executive officers. The letter agreements generally provide for at-will employment and set forth the named executive officer s initial base salary, eligibility for employee benefits and severance benefits upon a qualifying termination of employment. In addition, each of our named executive officers has executed a form of our standard confidential information and invention assignment agreement. The key terms of the letter agreements with our named executive officers are described below. Any potential payments and benefits due upon a qualifying termination of employment or a change in control are further described below under Potential Payments and Benefits upon Termination or Change in Control. These compensation arrangements will not change as a result of this offering.

Agreement with Dr. Maag. We entered into a Chief Executive Employment Agreement with Dr. Maag, dated September 19, 2012, under which Dr. Maag serves as our President and Chief Executive Officer. The agreement provides for at-will employment and sets forth certain agreed upon terms and conditions of employment. Dr. Maag s current annual base salary is $350,000, and he is currently eligible for a target annual bonus of up to $150,000.

Agreement with Dr. Yee. We entered into an offer letter with Dr. Yee, dated July 31, 2006, under which Dr. Yee serves as our Chief Medical Officer. The agreement provides for at-will employment and sets forth certain agreed upon terms and conditions of employment. Dr. Yee s current annual base salary is $365,650, and he is currently eligible for a target annual bonus of up to 40% of his base salary.

Agreement with Mr. Meyer. We entered into an offer letter with Mr. Meyer, dated July 19, 2010, under which Mr. Meyer serves as our Chief Business Officer. The agreement provides for at-will employment and sets forth certain agreed upon terms and conditions of employment. Mr. Meyer s current annual base salary is $308,250, and he is currently eligible for a target annual bonus of up to 40% of his base salary.

Potential Payments and Benefits upon Termination or Change of Control

Dr. Maag. Pursuant to Dr. Maag s Change of Control and Severance Agreement, dated May 1, 2014, if within two months prior to, or twelve months following a change of control, we or our successor terminate Dr. Maag s employment without cause, Dr. Maag will be entitled to (a) twelve months severance, (b) acceleration of vesting equal to 100% of any unvested options, (c) a lump sum payment equal to Dr. Maag s annual bonus, and (d) twelve months of continued benefits, *provided, that* such reimbursement will cease on the date that Dr. Maag becomes covered under a similar plan of a new employer. Pursuant to the agreement, if we or a successor terminate Dr. Maag s employment without cause and such termination occurs outside of a change of control event, Dr. Maag will be entitled to (a) twelve months severance, and (b) twelve months of continued benefits, *provided, that* such reimbursement will cease on the date that Dr. Maag becomes covered under a similar plan of a new employer.

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Dr. Yee. Pursuant to Dr. Yee s Change of Control and Severance Agreement, dated May 1, 2014, if within two months prior to, or twelve months following a change of control, we or our successor terminate Dr. Yee s employment without cause, Dr. Yee will be entitled to (a) twelve months severance, (b) acceleration of vesting equal to 100% of any unvested options, (c) a lump sum payment equal to Dr. Yee s annual bonus and (d) twelve months of continued benefits, *provided, that* such reimbursement will cease on the date that Dr. Yee becomes covered under a similar plan of a new employer. Pursuant to the agreement, if we or a successor terminate Dr. Yee s employment without cause and such termination occurs outside of a change of control event, Dr. Yee will be entitled to (a) six months severance, and (b) six months of continued benefits, *provided, that* such reimbursement will cease on the date that Dr. Yee becomes covered under a similar plan of a new employer.

Mr. Meyer. Pursuant to Mr. Meyer s Change of Control and Severance Agreement, dated May 1, 2014, if within two months prior to, or twelve months following a change of control, we or our successor terminate Mr. Meyer s employment without cause, Mr. Meyer will be entitled to (a) twelve months severance, (b) acceleration of vesting equal to 100% of any unvested options, (c) a lump sum payment equal to Mr. Meyer s annual bonus and (d) twelve months of continued benefits, *provided, that* such reimbursement will cease on the date that Mr. Meyer becomes covered under a similar plan of a new employer. Pursuant to the agreement, if we or a successor terminate Mr. Meyer s employment without cause and such termination occurs outside of a change of control event, Mr. Meyer will be entitled to (a) six months severance, and (b) six months of continued benefits, *provided, that* such reimbursement will cease on the date that Mr. Meyer s becomes covered under a similar plan of a new employer.

For purposes of the change of control agreements, cause means generally:

- executive s material failure to perform his stated duties after a notice of failure and a cure period of ten days;
- executive s material violation of our policies or any written agreement or covenant with us;
- executive s conviction of, or entry of a plea of guilty or *nolo contendere* to, a felony;
- a willful act by executive that constitutes gross misconduct and which is injurious to us;
- executive s commission of any act of fraud, embezzlement, dishonesty or any other willful misconduct that has caused or is reasonably expected to result in material injury to us;
- the unauthorized use or disclosure by executive of any of our proprietary information or trade secrets or any other party to whom he owes an obligation of nondisclosure as a result of his relationship with us; or
- executive s willful failure to cooperate with an investigation by a governmental authority.

Employee Benefit and Stock Plans

2014 Equity Incentive Plan

Our board of directors adopted our 2014 Equity Incentive Plan, or the 2014 Plan, in March 2014, and we expect our stockholders will approve it prior to the completion of this offering. Subject to stockholder approval, the 2014 Plan will be effective immediately prior to the completion of this offering and is not expected to be utilized until after the completion of this offering. Our 2014 Plan provides for the grant of incentive stock options, within the meaning of Section 422 of the Internal Revenue Code, to our employees and any of our parent and subsidiary corporations employees, and for the grant of nonstatutory stock options, restricted stock, restricted stock units, stock appreciation rights, performance units and performance shares to our employees, directors and consultants, and our parent and subsidiary corporations employees and consultants.

Authorized Shares. A total of 838,695 shares of our common stock are reserved for issuance pursuant to the 2014 Plan, of which no awards are issued or outstanding. The shares reserved for issuance under

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our 2014 Plan include 35,277 shares reserved but unissued under our 2008 Plan (as defined below) as of the effective date described above and will also include shares returned to our 2008 Plan as the result of expiration or termination of options (provided that the maximum number of shares that may be added to the 2014 Plan hereunder is 865,252 shares). The number of shares available for issuance under the 2014 Plan will also include an annual increase on the first day of each year beginning in 2014, equal to the least of:

357,075 shares;

4.0% of the outstanding shares of common stock as of the last day of our immediately preceding year; or

such other amount as our board of directors may determine.

Our compensation committee will administer our 2014 Plan after the completion of this offering. In the case of options intended to qualify as performance-based compensation within the meaning of Section 162(m) of the Internal Revenue Code, the committee will consist of two or more outside directors within the meaning of Section 162(m).

Plan Administration. Subject to the provisions of our 2014 Plan, the administrator has the power to determine the terms of the awards, including the exercise price, the number of shares subject to each such award, the exercisability of the awards, and the form of consideration, if any, payable upon exercise. The administrator also has the authority to amend existing awards to reduce their exercise price, to allow participants the opportunity to transfer outstanding awards to a financial institution or other person or entity selected by the administrator and to institute an exchange program by which outstanding awards may be surrendered in exchange for awards with a higher or lower exercise price.

Stock Options. The exercise price of options granted under our 2014 Plan must at least be equal to the fair market value of our common stock on the date of grant. The term of an incentive stock option may not exceed ten years, except that with respect to any participant who owns more than 10% of the voting power of all classes of our outstanding stock, the term must not exceed five years and the exercise price must equal at least 110% of the fair market value on the grant date. Subject to the provisions of our 2014 Plan, the administrator determines the term of all other options.

After the termination of service of an employee, director or consultant, he or she may exercise his or her option or stock appreciation right for the period of time stated in his or her award agreement. Generally, if termination is due to death or disability, the option or stock appreciation right will remain exercisable for 12 months. In all other cases, the option or stock appreciation right will generally remain exercisable for three months following the termination of service. However, in no event may an option be exercised later than the expiration of its term.

Stock Appreciation Rights. Stock appreciation rights may be granted under our 2014 Plan. Stock appreciation rights allow the recipient to receive the appreciation in the fair market value of our common stock between the exercise date and the date of grant. Subject to the provisions of our 2014 Plan, the administrator determines the terms of stock appreciation rights, including when such rights become exercisable and whether to pay any increased appreciation in cash or with shares of our common stock, or a combination thereof, except that the per share exercise price for the shares to be issued pursuant to the exercise of a stock appreciation right will be no less than 100% of the fair market value per share on the date of grant.

Restricted Stock. Restricted stock may be granted under our 2014 Plan. Restricted stock awards are grants of shares of our common stock that vest in accordance with terms and conditions established by the administrator. The administrator will determine the number of shares of restricted stock granted and

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may impose whatever conditions to vesting it determines to be appropriate (for example, the administrator may set restrictions based on the achievement of specific performance goals or continued service to us). The administrator, in its sole discretion, may accelerate the time at which any restrictions will lapse or be removed. Shares of restricted stock that do not vest are subject to our right of repurchase or forfeiture.

Restricted Stock Units. Restricted stock units may be granted under our 2014 Plan. Restricted stock units are bookkeeping entries representing an amount equal to the fair market value of one share of our common stock. The administrator determines the terms and conditions of restricted stock units, including the number of units granted, the vesting criteria (which may include accomplishing specified performance criteria or continued service to us), and the form and timing of payment. The administrator, in its sole discretion, may accelerate the time at which any restrictions will lapse or be removed.

Performance Units and Performance Shares. Performance units and performance shares may be granted under our 2014 Plan Performance units and performance shares are awards that will result in a payment to a participant only if performance goals established by the administrator are achieved or the awards otherwise vest. The administrator will establish organizational or individual performance goals in its discretion, which, depending on the extent to which they are met, will determine the number and/or the value of performance units and performance shares to be paid out to participants. After the grant of a performance unit or performance share, the administrator, in its sole discretion, may reduce or waive any performance objectives or other vesting provisions for such performance units or performance shares. The administrator, in its sole discretion, may pay earned performance units or performance shares in the form of cash, in shares, or in some combination thereof.

Non-Employee Directors. Our 2014 Plan provides that all non-employee directors will be eligible to receive all types of awards (except for incentive stock options) under the 2014 Plan. Please see the description of our non-employee director compensation above under Management Non-Employee Director Compensation.

Non-Transferability of Awards. Unless the administrator provides otherwise, our 2014 Plan generally does not allow for the transfer of awards, and only the recipient of an award may exercise an award during his or her lifetime.

Certain Adjustments. In the event of certain changes in our capitalization, to prevent diminution or enlargement of the benefits or potential benefits available under the 2014 Plan, the administrator will adjust the number and class of shares that may be delivered under the 2014 Plan and/or the number, class and price of shares covered by each outstanding award, and the numerical share limits set forth in the 2014 Plan.

Merger or Change in Control. Our 2014 Plan provides that in the event of a merger or change in control, as defined in the 2014 Plan, each outstanding award will be treated as the administrator determines, including that the successor corporation or its parent or subsidiary will assume or substitute an equivalent award for each outstanding award. The administrator is not required to treat all awards similarly. If there is no assumption or substitution of outstanding awards, the awards will fully vest, all restrictions will lapse, all performance goals or other vesting criteria will be deemed achieved at 100% of target levels and the awards will become fully exercisable.

2014 Employee Stock Purchase Plan

Our board of directors adopted, and we expect our stockholders will approve, our 2014 Employee Stock Purchase Plan, or ESPP, in March 2014. The ESPP will become effective upon completion of this offering. However, our ESPP will not be made available to our employees until a later date to be determined by our compensation committee.

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Authorized Shares. A total of 89,269 shares of our common stock will be made available for sale under the ESPP. In addition, our ESPP provides for annual increases in the number of shares available for issuance under the plan on the first day of each year beginning in 2014, equal to the least of:

- $1\ ^1/_2\%$ of the outstanding shares of our common stock on the first day of such year;
- 133,900 shares; or
- such amount as determined by our board of directors.

Plan Administration. Our compensation committee administers the ESPP, and has full and exclusive authority to interpret the terms of the plan and determine eligibility to participate, subject to the conditions of the plan as described below.

Eligibility. Generally, all of our employees are eligible to participate if they are employed by us, or any participating subsidiary, for at least 20 hours per week and more than five months in any calendar year. However, an employee may not be granted rights to purchase stock under the ESPP if such employee:

- immediately after the grant would own stock possessing 5% or more of the total combined voting power or value of all classes of our capital stock; or
- hold rights to purchase stock under all of our employee stock purchase plans that accrue at a rate that exceeds $25,000 worth of stock for each calendar year.

Offering Periods. Our ESPP is intended to qualify under Section 423 of the Code. Each offering period includes purchase periods, which will be the approximately six months commencing with one exercise date and ending with the next exercise date. No offering periods under the ESPP have been scheduled and the first offering period will be determined by our compensation committee following this offering.

Our ESPP permits participants to purchase shares of common stock through payroll deductions of up to 15% of their eligible compensation. A participant may purchase a maximum of 3,000 shares during a six-month period.

Exercise of Purchase Right. Amounts deducted and accumulated by the participant are used to purchase shares of our common stock at the end of each six month purchase period. The purchase price of the shares will be 85% of the lower of the fair market value of our common stock on the first trading day of each offering period or on the exercise date. If the fair market value of our common stock on the exercise date is less than the fair market value on the first trading day of the offering period, participants will be withdrawn from the current offering period following their purchase of shares on the purchase date and will be automatically re-enrolled in a new offering period. Participants may end their participation at any time during an offering period and will be paid their accrued contributions that have not yet been used to purchase shares of common stock. Participation ends automatically upon termination of employment with us.

Non-Transferability. A participant may not transfer rights granted under the ESPP. If the compensation committee permits the transfer of rights, it may only be done by will, the laws of descent and distribution, or as otherwise provided under the ESPP.

Merger or Change in Control. In the event of our merger or change in control, as defined under the ESPP, a successor corporation may assume or substitute each outstanding purchase right. If the successor corporation refuses to assume or substitute for the outstanding purchase right, the offering period then in progress will be shortened, and a new exercise date will be set. The administrator will notify each participant that the exercise date has been changed and that the participant s option will be exercised automatically on the new exercise date unless prior to such date the participant has withdrawn from the offering period.

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Certain Adjustments. In the event of certain changes in our capitalization, to prevent dilution or enlargement of the benefits or potential benefits available under the ESPP, the administrator will adjust the number and class of shares that may be delivered under the ESPP, the purchase price per share and the number of shares covered by each option and the numerical share limits set forth in the ESPP.

Amendment; Termination. Our ESPP will automatically terminate in 2034, unless we terminate it sooner. Our board of directors has the authority to amend, suspend, or terminate our ESPP, except that, subject to certain exceptions described in the ESPP, no such action may adversely affect any outstanding rights to purchase stock under our ESPP.

2008 Equity Incentive Plan

Our board of directors adopted our 2008 Equity Incentive Plan, or the 2008 Plan, in November 2008 and our stockholders approved the 2008 Plan in July 2009. The 2008 Plan provided for the grant of incentive stock options, nonstatutory stock options, stock appreciation rights, restricted stock, and restricted stock units. Incentive stock options could be granted to our employees and employees of our qualifying parent and subsidiary corporations. Nonstatutory stock options, stock appreciation rights, restricted stock, and restricted stock units could be granted to our employees, consultants and directors and the employees, consultants and directors of certain of our parent and subsidiary entities.

The 2008 Plan will be terminated in connection with this offering and we will not grant any awards under the 2008 Plan following the consummation of this offering. However, the 2008 Plan will continue to govern the terms and conditions of the outstanding awards previously granted under it.

Authorized Shares. A total of 706,425 shares of our common stock were authorized for issuance under our 2008 Plan. As of March 31, 2014, options to acquire a total of 450,382 shares of our common stock were issued and outstanding, and a total of 5,367 shares of our common stock had been issued upon the exercise of options granted under the plan that had not been repurchased by us.

Plan Administration. The 2008 Plan will be administered by our compensation committee after the completion of this offering. The administrator also has the authority, subject to the terms of the 2008 Plan, to amend existing awards to reduce their exercise price, to allow participants the opportunity to transfer outstanding awards to a financial institution or other person or entity selected by the administrator, to institute an exchange program by which outstanding awards may be surrendered in exchange for awards that may have different exercise price and terms, to construe and interpret the plan, to prescribe rules and to extend the post-termination exercisability of certain awards.

Stock Options. The exercise price of a stock option may not be less than 100% of the fair market value of the underlying share on the date of grant (or 110% in the case of incentive stock options granted to certain significant stockholders), except with respect to certain substitute options granted in connection with a corporate transaction. The term of a stock option may not be longer than ten years (or five years in the case of incentive stock options granted to certain significant stockholders). Vesting conditions determined by the administrator may apply to stock options and may include continued service, performance and/or other conditions.

Stock Appreciation Rights. Stock appreciation rights, or SARs, entitle their holder, upon exercise, to receive from us an amount equal to the appreciation of the shares subject to the award between the grant date and the exercise date. The exercise price of a SAR may not be less than 100% of the fair market value of the underlying share on the date of grant and the term of a SAR may not be longer than ten years. Vesting conditions determined by the administrator may apply to SARs and may include continued service, performance and/or other conditions.

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Restricted Stock. Restricted stock awards are grants of shares of our common stock that are subject to various restrictions, including restrictions on transferability and forfeiture provisions. Shares of restricted stock will vest and the restrictions on such shares lapse, in accordance with terms and conditions established by the administrator. Such terms may include, among other things, vesting upon the achievement of specific performance goals determined by the administrator and/or continued service to us. Recipients of restricted stock awards will have voting and dividend rights with respect to such shares upon grant without regard to vesting; provided, however, that the administrator, in its sole discretion, may accelerate the time at which any restrictions will lapse or be removed. Shares of restricted stock that do not vest for any reason will be forfeited by the recipient and will revert to us.

Restricted Stock Units. Each restricted stock unit granted is a bookkeeping entry representing an amount equal to the fair market value of one share of our common stock. The administrator determined the terms and conditions of restricted stock units including the vesting criteria, which may include accomplishing specified performance criteria and/or continued service to us, and the form and timing of payment. Notwithstanding the foregoing, the administrator, in its sole discretion may accelerate the time at which any restrictions will lapse or be removed.

Nontransferability. Generally, awards granted under the 2008 Plan are not transferable by a participant other than by will or by the laws of descent and distribution.

Plan Amendment. Our board of directors may amend the 2008 Plan at any time subject to obtaining stockholder approval to the extent necessary under applicable laws; provided that no amendment may impair the rights of a participant without the affected participant s consent.

Adjustments. The administrator has broad discretion to equitably adjust the provisions of the 2008 Plan, as well as the terms and conditions of existing awards, to prevent the dilution or enlargement of intended benefits and facilitate necessary or desirable changes in the event of certain transactions and events affecting our common stock, such as stock dividends, stock splits, mergers, consolidations, reorganizations, asset sales and other corporate transactions.

Merger or Change in Control. Our 2008 Plan provides that in the event of a merger or change in control, as defined in the 2008 Plan, each outstanding award will be treated as the administrator determines, including that the successor corporation or its parent or subsidiary will assume or substitute an equivalent award for each outstanding award. The administrator is not required to treat all awards similarly. If there is no assumption or substitution of outstanding awards, the awards will fully vest, all restrictions will lapse, all performance goals or other vesting criteria will be deemed achieved at 100% of target levels and the awards will become fully exercisable.

1998 Stock Plan

Our board of directors adopted the 1998 Stock Plan in December 1998 and our stockholders approved the 1998 Stock Plan in January 1999. Since the adoption of our 2008 Equity Incentive Plan, our board of directors has not granted and will not grant any additional options or stock purchase rights under the 1998 Stock Plan. However, the plan will continue to govern the terms and conditions of the outstanding options previously granted under the plan.

A total of 97,349 shares of our common stock remain authorized for issuance under the 1998 Stock Plan. As of March 31, 2014, options to acquire a total of 97,349 shares of our common stock were issued and outstanding, and a total of 411,257 shares of our common stock had been issued upon the exercise of options granted under the plan that had not been repurchased by us.

The plan provides for the grant of nonstatutory stock options and stock purchase rights to our employees, consultants, and directors and for the grant of incentive stock options within the meaning of

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Section 422 of the Internal Revenue Code to our employees. Our board of directors administers the 1998 Stock Plan. The administrator has the authority to determine the terms and conditions of the options granted under the plan.

In the event of a merger with another corporation or a sale of substantially all of our assets in which the outstanding options or stock purchase rights are not assumed, or if the successor corporation does not replace such options or stock purchase rights with equivalent rights, the outstanding awards will become fully vested and exercisable. If an option or a stock purchase right becomes fully vested and exercisable in lieu of assumption or substitution, the administrator will notify the optionee and provide a fifteen (15) day exercise period and the option or stock purchase right will terminate on the expiration of such period.

Shares covered by outstanding grants under the 1998 Stock Plan, as well as the exercise price per share of stock covered by outstanding grants will be proportionately adjusted for any increase or decrease in the number of issued shares of common stock resulting from a stock split, reverse stock split, stock dividend, or any other increase or decrease in number of issued shares of common stock effected without receipt of consideration.

In the event of our proposed liquidation or dissolution, the administrator will notify each optionee as soon as practicable prior to the effective date of such proposed transaction and may provide an optionee the right to exercise his or her option or stock purchase right as to all shares subject to the award until fifteen (15) days prior to such transaction. To the extent it has not been previously exercised, an option or stock purchase right will terminate immediately prior to the consummation of such proposed action.

ImmuMetrix, Inc. 2013 Equity Incentive Plan

In connection with our acquisition of ImmuMetrix, Inc. in June 2014, we assumed options issued under the ImmuMetrix, Inc. 2013 Equity Incentive Plan, or the ImmuMetrix Plan, and converted them into options to purchase our capital stock. The ImmuMetrix Plan was terminated on the closing of the acquisition, but the ImmuMetrix Plan will continue to govern the terms of options we assumed in the acquisition.

Authorized Shares. Upon the closing of the offering described in this prospectus, 23,229 shares of our common stock are expected to be subject to outstanding stock options under the ImmuMetrix Plan.

Plan Administration. The ImmuMetrix Plan will be administered by our compensation committee after the completion of this offering. The administrator also has the authority, subject to the terms of the ImmuMetrix Plan, to amend existing awards to reduce their exercise price, to allow participants the opportunity to transfer outstanding awards to a financial institution or other person or entity selected by the administrator, to institute an exchange program by which outstanding awards may be surrendered in exchange for awards that may have different exercise price and terms, to construe and interpret the plan, to prescribe rules and to extend the post-termination exercisability of certain awards.

Stock Options. The exercise price of a stock option may not be less than 100% of the fair market value of the underlying share on the date of grant (or 110% in the case of incentive stock options granted to certain significant stockholders), except with respect to certain substitute options granted in connection with a corporate transaction. The term of a stock option may not be longer than ten years (or five years in the case of incentive stock options granted to certain significant stockholders). Vesting conditions determined by the administrator may apply to stock options and may include continued service, performance and/or other conditions.

Nontransferability. Generally, awards granted under the ImmuMetrix Plan are not transferable by a participant other than by will or by the laws of descent and distribution.

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Plan Amendment and Termination. Our board of directors may amend the ImmuMetrix Plan at any time subject to obtaining stockholder approval to the extent necessary under applicable laws; provided that no amendment may impair the rights of a participant without the affected participant s consent. The ImmuMetrix Plan has been terminated and we will not grant any additional awards under the ImmuMetrix Plan.

Adjustments. The administrator has broad discretion to equitably adjust the provisions of the ImmuMetrix Plan, as well as the terms and conditions of existing awards, to prevent the dilution or enlargement of intended benefits and facilitate necessary or desirable changes in the event of certain transactions and events affecting our common stock, such as stock dividends, stock splits, mergers, consolidations, reorganizations, asset sales and other corporate transactions.

Merger or Change in Control. The ImmuMetrix Plan provides that in the event of a merger or change in control, as defined in the ImmuMetrix Plan, each outstanding award will be treated as the administrator determines, including that the successor corporation or its parent or subsidiary will assume or substitute an equivalent award for each outstanding award. The administrator is not required to treat all awards similarly. If there is no assumption or substitution of outstanding awards, the awards will fully vest, all restrictions will lapse, all performance goals or other vesting criteria will be deemed achieved at 100% of target levels and the awards will become fully exercisable.

Executive Incentive Compensation Plan

Our compensation committee has adopted an Executive Incentive Compensation Plan, or the Bonus Plan. The Bonus Plan allows our compensation committee to provide cash incentive awards to selected employees, including our named executive officers, based upon performance goals established by our compensation committee.

Under the Bonus Plan, our compensation committee determines the performance goals applicable to any award, which goals may include, without limitation: attainment of research and development milestones; sales bookings; business divestitures and acquisitions; cash flow; cash position; contract awards or backlog; customer renewals; customer retention rates from an acquired company, business unit, or division; earnings (which may include earnings before interest, taxes, depreciation and amortization, earnings before taxes, and net earnings); earnings per share; net income; net profit; net sales; operating expenses; operating income; operating margin; overhead or other expense reduction; product defect measures; product release timelines; productivity; profit; return on assets; return on capital; return on equity; return on investment; return on sales; revenue; revenue growth; sales results; sales growth; stock price; time to market; total stockholder return; working capital; and individual objectives such as peer reviews or other subjective or objective criteria. Performance goals that include our financial results may be determined in accordance with GAAP or such financial results may consist of non-GAAP financial measures and any actual results may be adjusted by the compensation committee for one-time items or unbudgeted or unexpected items when performance goals that include our financial results may be determined in accordance with GAAP, or such financial results may consist of non-GAAP financial measures, and any actual results may be adjusted by the compensation committee for one-time items or unbudgeted or unexpected items when determining whether the performance goals have been met. The goals may be on the basis of any factors the compensation committee determines relevant, and may be adjusted on an individual, divisional, business unit or company-wide basis. The performance goals may differ from participant to participant and from award to award.

Our compensation committee may, in its sole discretion and at any time, increase, reduce or eliminate a participant s actual award, and/or increase, reduce or eliminate the amount allocated to the bonus pool for a particular performance period. The actual award may be below, at or above a participant s target award, in the compensation committee s discretion. Our compensation committee may determine the

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amount of any reduction on the basis of such factors as it deems relevant, and it is not required to establish any allocation or weighting with respect to the factors it considers.

Actual awards are paid in cash only after they are earned, which usually requires continued employment through the date a bonus is paid.

Our compensation committee has the authority to amend, alter, suspend or terminate the Bonus Plan provided such action does not impair the existing rights of any participant with respect to any earned bonus.

401(k) Plan

Our retirement plan, which we refer to as the 401(k) plan, is qualified under Section 401 of the Internal Revenue Code. Eligible employees, including all of our full-time employees, may elect to reduce their current compensation by an amount no greater than the statutorily prescribed annual limit and may have that amount contributed to the 401(k) plan. Matching contributions may be made to the 401(k) plan at the discretion of our board. To date, we have not made any contributions to the 401(k) plan.

Limitation on Liability and Indemnification Matters

Our amended and restated certificate of incorporation and amended and restated bylaws, each to be effective upon the completion of this offering, will provide that we will indemnify our directors and officers, and may indemnify our employees and other agents, to the fullest extent permitted by the Delaware General Corporation Law, which prohibits our amended and restated certificate of incorporation from limiting the liability of our directors for the following:

- any breach of the director s duty of loyalty to us or to our stockholders;
- acts or omissions not in good faith or that involve intentional misconduct or a knowing violation of law;
- unlawful payment of dividends or unlawful stock repurchases or redemptions; and
- any transaction from which the director derived an improper personal benefit.

If Delaware law is amended to authorize corporate action further eliminating or limiting the personal liability of a director, then the liability of our directors will be eliminated or limited to the fullest extent permitted by Delaware law, as so amended. Our amended and restated certificate of incorporation does not eliminate a director s duty of care and in appropriate circumstances, equitable remedies, such as injunctive or other forms of non-monetary relief, remain available under Delaware law. This provision also does not affect a director s responsibilities under any other laws, such as the federal securities laws or other state or federal laws. Under our amended and restated bylaws, we will also be empowered to purchase insurance on behalf of any person whom we are required or permitted to indemnify.

In addition to the indemnification required in our amended and restated certificate of incorporation and amended and restated bylaws, we plan to enter into indemnification agreements with each of our current directors and officers before the completion of this offering. These agreements will provide indemnification for certain expenses and liabilities incurred in connection with any action, suit, proceeding, or alternative dispute resolution mechanism, or hearing, inquiry, or investigation that may lead to the foregoing, to which they are a party, or are threatened to be made a party, by reason of the fact that they are or were a director, officer, employee, agent, or fiduciary of our company, or any of our subsidiaries, by reason of any action or inaction by them while serving as an officer, director, agent, or fiduciary, or by reason of the fact that they were serving at our request as a director, officer, employee, agent, or fiduciary of another entity. In the case of an action or proceeding by, or in the right of, our company or any of our subsidiaries, no indemnification will be provided for any claim where a court