CareDx, Inc. Form S-1/A July 15, 2014 Table of Contents

Index to Financial Statements

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)

Index to Financial Statements

Michael J. Danaher

Delaware (State or other jurisdiction of incorporation or organization) 8071 (Primary Standard Industrial Classification Code Number) 3260 Bayshore Boulevard 94-3316839 (I.R.S. Employer Identification Number)

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)

Copies to:

Asaf H. KharalGlenn R. PollnerWilson Sonsini Goodrich & Rosati, P.C.Gibson, Dunn & Crutcher LLP650 Page Mill Road200 Park AvenuePalo Alto, California 94304New York, New York 10166(650) 493-9300(212) 351-4000

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 " Non-accelerated filer x (Do not check if a smaller reporting company)

CALCULATION OF REGISTRATION FEE

| Title of each Class of | Proposed Maximum | Amount of |
|---|---|---------------------------------|
| Securities to be Registered | Aggregate Offering Price ⁽¹⁾⁽²⁾ | 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.

Accelerated filer

Smaller reporting company

Index to Financial Statements

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 <u>Risk Factors</u> 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

Index to Financial Statements

Index to Financial Statements

TABLE OF CONTENTS

| Decementus Summer | Page |
|---|------|
| Prospectus Summary | 1 |
| The Offering | 11 |
| <u>Risk Factors</u> | 16 |
| Special Note Regarding Forward-Looking Statements | 54 |
| Market and Industry Data | 55 |
| <u>Use of Proceeds</u> | 56 |
| Dividend Policy | 57 |
| Capitalization | 58 |
| Dilution | 61 |
| Selected Financial Data | 64 |
| Management s Discussion and Analysis of Financial Condition and Results of Operations | 66 |
| Business | 88 |
| Management | 118 |
| Executive Compensation | 126 |
| Certain Relationships and Related Party Transactions | 138 |
| Principal Stockholders | 141 |
| Description of Capital Stock | 144 |
| Shares Eligible for Future Sale | 148 |
| Material U.S. Federal Income Tax Consequences to Non-U.S. Holders of Our Common Stock | 151 |
| Underwriting | 155 |
| Legal Matters | 163 |
| Experts | 163 |
| Additional Information | 163 |
| Index to Financial Statements | F-1 |

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.

Index to Financial Statements

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.

ii

Index to Financial Statements

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*,

Index to Financial Statements

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.

Index to Financial Statements

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.

Index to Financial Statements

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 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.

Index to Financial Statements

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

5

Index to Financial Statements

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 result | 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.

Index to Financial Statements

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

7

Index to Financial Statements

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

Index to Financial Statements

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.

⁹

Index to Financial Statements

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.

¹⁰

Index to Financial Statements

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 |

Index to Financial Statements

Risk factors

Proposed trading symbol

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.

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.

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

12

Index to Financial Statements

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.

13

Index to Financial Statements

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 2012 | Decembo | er 31, 2013 | Т | hree Months I 2013 (unau | | arch 31, 2014 |
|---|----|-----------------|---------|----------------|----|--------------------------------|----|------------------|
| 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

14

Index to Financial Statements

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⁾ (in thousands) (unaudited) | Pro Forma As Adjusted ⁽²⁾⁽³⁾ | | | | |
| 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.

(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.

15

Index to Financial Statements

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

16

Index to Financial Statements

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:

Edgar Filing: CareDx, Inc. - Form S-1/A

failure of the test at the research or development stage;

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

Index to Financial Statements

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

Index to Financial Statements

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;

Edgar Filing: CareDx, Inc. - Form S-1/A

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.

Index to Financial Statements

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.

Index to Financial Statements

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

Index to Financial Statements

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.

Index to Financial Statements

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

Index to Financial Statements

Edgar Filing: CareDx, Inc. - Form S-1/A

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

Index to Financial Statements

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;

Index to Financial Statements

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

Edgar Filing: CareDx, Inc. - Form S-1/A

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.

Index to Financial Statements

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

Index to Financial Statements

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 claims or any judgments, fines or settlement costs arising out of any such claims. Any 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 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



Index to Financial Statements

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 no 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

Index to Financial Statements

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.

Index to Financial Statements

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

Edgar Filing: CareDx, Inc. - Form S-1/A

our partners in Europe may be negatively affected by the financial instability of, and austerity measures implemented by, several countries in Europe.

Index to Financial Statements

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

Index to Financial Statements

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 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.

Index to Financial Statements

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

Edgar Filing: CareDx, Inc. - Form S-1/A

decreased and may decrease further. Any third-party payer may stop or lower payment at any time, which could substantially reduce our revenue.

Index to Financial Statements

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, 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.

Index to Financial Statements

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

Index to Financial Statements

Index to Financial Statements

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

Index to Financial Statements

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

Index to Financial Statements

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 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

Index to Financial Statements

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 swithout undue delays or considerable expenditures. If there are delays in testing or approvals as a result of the failure to

Index to Financial Statements

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

Index to Financial Statements

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

Index to Financial Statements

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.

Edgar Filing: CareDx, Inc. - Form S-1/A

Index to Financial Statements

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 \$150,000) and from \$10,000 to \$100,000 for each knowing failure to report (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 \$150,000) and from \$10,000 to \$100,000 for each knowing failure to report (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 \$150,000) and from \$10,000 to \$100,000 for each knowing failure to report (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 \$10,000 to \$100,000 for each knowing failure to report (up to a maximum per annual report of \$10,000 to \$10,000 to \$100,000 for each knowing failure to report (up to a maximum per annual report of \$

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.

Index to Financial Statements

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. 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

Index to Financial Statements

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

Index to Financial Statements

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, 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 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

Index to Financial Statements

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 or to prevent us from producing or selling some or all of our products, and a failure of the licensors to abide by the terms of a license or to prevent infringement by third parties could 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;

Index to Financial Statements

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

Edgar Filing: CareDx, Inc. - Form S-1/A

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.

Index to Financial Statements

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.

Index to Financial Statements

Nur

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.

| umber 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.

Index to Financial Statements

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.

Index to Financial Statements

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);

Edgar Filing: CareDx, Inc. - Form S-1/A

Index to Financial Statements

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.

Index to Financial Statements

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 of 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

Edgar Filing: CareDx, Inc. - Form S-1/A

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

Index to Financial Statements

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.

Index to Financial Statements

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 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.

Index to Financial Statements

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.

Index to Financial Statements

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.

Index to Financial Statements

| | As of March 31, 2014 | | | ro Forma | | |
|---|----------------------|------------|--------------------------|-----------------------|----------|-------------------------|
| | Actual | | Pro Forma (Unaudited) | | | Adjusted ⁽¹⁾ |
| | | (In thousa | nds, exce | pt share and j | per shar | e 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

Index to Financial Statements

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.

Index to Financial Statements

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

Index to Financial Statements

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 Cons | | | |
|--|------------------|---------|--------------|---------|-----------|---------|
| | | | (amount in t | Aver | age Price | |
| | Number | Percent | Amount | Percent | Pe | r Share |
| 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;

Index to Financial Statements

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.

Index to Financial Statements

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 2012 | Decembe | er 31, 2013 | T | hree Months 2013 (una | | arch 31, 2014 |
|---|----|--------------------|---------|----------------|----|-----------------------------|----|------------------|
| Statements of Operations Data: | | | | | | | ĺ. | |
| 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 |

Edgar Filing: CareDx, Inc. - Form S-1/A

⁽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.

Index to Financial Statements

(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.

| | Decem | December 31, | | | |
|-----------------------------|-----------------|-----------------------------|-----------|--|--|
| | 2012 (in tho | 2012 2013 (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) | | |

Index to Financial Statements

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.

Index to Financial Statements

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.

Index to Financial Statements

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.

Index to Financial Statements

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.

Index to Financial Statements

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.

Index to Financial Statements

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

Index to Financial Statements

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 |

Edgar Filing: CareDx, Inc. - Form S-1/A

Index to Financial Statements

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 vield | % | % | % | % | |

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

Index to Financial Statements

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.

Edgar Filing: CareDx, Inc. - Form S-1/A

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.

Index to Financial Statements

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:

Edgar Filing: CareDx, Inc. - Form S-1/A

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;

Index to Financial Statements

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 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.

Index to Financial Statements

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.

Index to Financial Statements

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) | Marc 2013 | nths Ended ch 31, 2014 ıdited) | Change |
|-----------------------------------|--------------|---|----------|
| 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

Index to Financial Statements

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).

Index to Financial Statements

Comparison of the Years Ended December 31, 2012 and 2013

| | Year Ended I | , | | |
|-----------------------------------|-----------------------------|------------|----------|--|
| | 2012 2013 (in thousands) | | Change | |
| 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

Index to Financial Statements

Index to Financial Statements

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 l 2012 | Year Ended December 31, 2012 2013 | | Months Iarch 31, 2014 dited) |
|--|----------------------|--------------------------------------|----------------|---------------------------------------|
| 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) |
| equivalents | ϕ 5,175 | φ (702) | $\varphi(JJZ)$ | $\varphi(2)1)$ |

Index to Financial Statements

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 of \$0.2 million 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 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 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. 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 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

Index to Financial Statements

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

Index to Financial Statements

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 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 (in thousands) | 3 | 5 Years | More Than 5 Years |
| 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 |

Index to Financial Statements

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

Index to Financial Statements

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.

Index to Financial Statements

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.

Index to Financial Statements

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 \$400 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 \$400 million annually in the United States and over \$400 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.

Index to Financial Statements

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

Index to Financial Statements

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

Index to Financial Statements

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



Index to Financial Statements

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.

Index to Financial Statements

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.

Index to Financial Statements

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

Index to Financial Statements

Edgar Filing: CareDx, Inc. - Form S-1/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.

Index to Financial Statements

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

Edgar Filing: CareDx, Inc. - Form S-1/A

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

Index to Financial Statements

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.

Index to Financial Statements

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 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 and reimbursement for AlloMap through continued development of testing solutions. We intend to build on our success in securing coverage and reimbursement for AlloMap through continued development of testing solutions, 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

Index to Financial Statements

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.

Index to Financial Statements

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.

Index to Financial Statements

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)

Index to Financial Statements

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 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,

Index to Financial Statements

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.

Index to Financial Statements

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 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.

Index to Financial Statements

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

Index to Financial Statements

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,

Index to Financial Statements

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.

Index to Financial Statements

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

Index to Financial Statements

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.

Edgar Filing: CareDx, Inc. - Form S-1/A

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

Index to Financial Statements

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

Index to Financial Statements

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

Index to Financial Statements

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.

Index to Financial Statements

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,

Index to Financial Statements

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 is 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

Edgar Filing: CareDx, Inc. - Form S-1/A

a civil penalty of up to \$100,000 against parties that enter into a scheme to circumvent the Stark Law s prohibition.

Index to Financial Statements

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.

Index to Financial Statements

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

Index to Financial Statements

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.

Index to Financial Statements

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.

Index to Financial Statements

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.

Index to Financial Statements

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

Index to Financial Statements

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 served 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 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. 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 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 receipient 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

Index to Financial Statements

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.

Index to Financial Statements

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

Index to Financial Statements

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.

Index to Financial Statements

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 anniversary after the grant date over the following with the first monthly anniversary after the grant date over 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.

| | Fees | s Earned | | | | | |
|------------------|------|-----------|--------------|--------|------------------------|-----------|--|
| | or | | | Option | | | |
| Name | Paic | d in Cash | Stock Awards | Aw | ards ⁽¹⁾⁽²⁾ | Total | |
| Michael Goldberg | \$ | 100,000 | | \$ | 19,132 | \$119,132 | |
| Ralph Snyderman | | | | \$ | 1,679 | \$ 1,679 | |

Index to Financial Statements

- (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 | Ex Pi | ption cercise rice ⁽¹⁾ r 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.

Index to Financial Statements

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 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

| | | Non-Equity Incentive | | | |
|-----------------------------|------|-------------------------|----------------------------|------------|--|
| Name and Principal Position | Year | Salary | Total | | |
| Peter Maag | 2013 | \$ 350,000 | Compensation \$ 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 | Number of | Number of |
|-------------------------|-------|-----------|-----------|
| | Date | | |

Edgar Filing: CareDx, Inc. - Form S-1/A

| | Vesting Commencement Date | Securities Underlying Unexercised | Securities Underlying Unexercised | ng Price | | Option Expiration Date |
|------------|---|---|--|--|--|--|
| | | Options Exercisable | Options Unexercisable | | | |
| 10/17/2012 | 10/1/2012 | 121,349(1) | 68,589 | \$ | 0.55 | 10/17/2022 |
| 10/25/2006 | 8/8/2006 | 14,598 ⁽²⁾⁽³⁾⁽⁵⁾ | 0 | \$ | 3.43 | 10/25/2016 |
| 9/27/2007 | 1/1/2008 | 29,197 ⁽³⁾⁽⁴⁾⁽⁵⁾ | 0 | \$ | 3.36 | 9/27/2017 |
| 4/8/2010 | 1/1/2010 | 3,649 ⁽³⁾⁽⁴⁾⁽⁵⁾ | 0 | \$ | 3.70 | 4/8/2020 |
| 8/27/2010 | 5/5/2010 | 3,649 ⁽³⁾⁽⁴⁾⁽⁵⁾ | 0 | \$ | 3.97 | 8/27/2020 |
| 1/10/2011 | 8/30/2010 | 3,317 ⁽²⁾⁽³⁾⁽⁵⁾ | 0 | \$ | 3.01 | 1/10/2021 |
| 1/10/2011 | 8/30/2010 | 33,178 ⁽²⁾⁽³⁾⁽⁵⁾ | 0 | \$ | 3.01 | 1/10/2021 |
| | 10/25/2006 9/27/2007 4/8/2010 8/27/2010 1/10/2011 | Interpretended Interpretended 10/17/2012 10/1/2012 10/25/2006 8/8/2006 9/27/2007 1/1/2008 4/8/2010 1/1/2010 8/27/2010 5/5/2010 1/10/2011 8/30/2010 | Commencement Date Underlying Unexercised 10/17/2012 10/1/2012 Options Exercisable 10/17/2012 10/1/2012 121,349 ⁽¹⁾ 10/25/2006 8/8/2006 14,598 ⁽²⁾⁽³⁾⁽⁵⁾ 9/27/2007 1/1/2008 29,197 ⁽³⁾⁽⁴⁾⁽⁵⁾ 4/8/2010 1/1/2010 3,649 ⁽³⁾⁽⁴⁾⁽⁵⁾ 8/27/2010 5/5/2010 3,649 ⁽³⁾⁽⁴⁾⁽⁵⁾ 1/10/2011 8/30/2010 3,317 ⁽²⁾⁽³⁾⁽⁵⁾ | Commencement Date Underlying Unexercised Underlying Unexercised Options Options Exercisable Unexercisable 10/17/2012 10/1/2012 121,349 ⁽¹⁾ 68,589 10/25/2006 8/8/2006 14,598 ⁽²⁾⁽³⁾⁽⁵⁾ 0 9/27/2007 1/1/2008 29,197 ⁽³⁾⁽⁴⁾⁽⁵⁾ 0 4/8/2010 1/1/2010 3,649 ⁽³⁾⁽⁴⁾⁽⁵⁾ 0 8/27/2010 5/5/2010 3,649 ⁽³⁾⁽⁴⁾⁽⁵⁾ 0 1/10/2011 8/30/2010 3,317 ⁽²⁾⁽³⁾⁽⁵⁾ 0 | Commencement Date Underlying Unexercised Underlying Unexercised Options Options Exercisable Unexercisable 10/17/2012 10/1/2012 121,349 ⁽¹⁾ 68,589 \$ 10/25/2006 8/8/2006 14,598 ⁽²⁾⁽³⁾⁽⁵⁾ 0 \$ 9/27/2007 1/1/2008 29,197 ⁽³⁾⁽⁴⁾⁽⁵⁾ 0 \$ 4/8/2010 1/1/2010 3,649 ⁽³⁾⁽⁴⁾⁽⁵⁾ 0 \$ 8/27/2010 5/5/2010 3,649 ⁽³⁾⁽⁴⁾⁽⁵⁾ 0 \$ 1/10/2011 8/30/2010 3,317 ⁽²⁾⁽³⁾⁽⁵⁾ 0 \$ | Commencement Date Underlying Unexercised Underlying Unexercised Price Options Options Price 10/17/2012 10/1/2012 121,349 ⁽¹⁾ 68,589 \$ 0.55 10/25/2006 8/8/2006 14,598 ⁽²⁾⁽³⁾⁽⁵⁾ 0 \$ 3.43 9/27/2007 1/1/2008 29,197 ⁽³⁾⁽⁴⁾⁽⁵⁾ 0 \$ 3.36 4/8/2010 1/1/2010 3,649 ⁽³⁾⁽⁴⁾⁽⁵⁾ 0 \$ 3.70 8/27/2010 5/5/2010 3,649 ⁽³⁾⁽⁴⁾⁽⁵⁾ 0 \$ 3.97 1/10/2011 8/30/2010 3,317 ⁽²⁾⁽³⁾⁽⁵⁾ 0 \$ 3.01 |

footnotes continue on following page

Index to Financial Statements

- (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 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.

Index to Financial Statements

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'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'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's 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'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 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.

Index to Financial Statements

Edgar Filing: CareDx, Inc. - Form S-1/A

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

Index to Financial Statements

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

Index to Financial Statements

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.

Index to Financial Statements

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.

Index to Financial Statements

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.

Index to Financial Statements

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

Index to Financial Statements

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.

Index to Financial Statements

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

Index to Financial Statements

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

Edgar Filing: CareDx, Inc. - Form S-1/A

Index to Financial Statements

determines that the indemnified party is prohibited from receiving indemnification. We believe that these bylaw provisions and indemnification agreements are necessary to attract and retain qualified persons as directors and officers. We also maintain directors and officers liability insurance.

The limitation of liability and indemnification provisions in our amended and restated certificate of incorporation and amended and restated bylaws may discourage stockholders from bringing a lawsuit against directors for breach of their fiduciary duties. They may also reduce the likelihood of derivative litigation against directors and officers, even though an action, if successful, might benefit us and our stockholders. A stockholder s investment may be harmed to the extent we pay the costs of settlement and damage awards against directors and officers pursuant to these indemnification provisions. Insofar as we may provide indemnification for liabilities arising under the Securities Act to our directors, officers, and controlling persons pursuant to the foregoing provisions, or otherwise, we have been advised that, in the opinion of the SEC, such indemnification is against public policy as expressed in the Securities Act, and is, therefore, unenforceable. There is no pending litigation or proceeding naming any of our directors or officers as to which indemnification is being sought, nor are we aware of any pending or threatened litigation that may result in claims for indemnification by any director or officer.

Index to Financial Statements

CERTAIN RELATIONSHIPS AND RELATED PARTY TRANSACTIONS

We describe below transactions and series of similar transactions since January 1, 2011 to which we were a party or will be a party, in which:

the amounts involved exceeded or will exceed \$120,000; and

any of our directors, executive officers, or beneficial holders of more than 5% of any class of our capital stock had or will have a direct or indirect material interest.

Participation in 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. Any shares purchased by these potential investors will be subject to lockup restrictions described under Shares Eligible for Future Sale.

In addition, our directors and executive officers have indicated to us that they currently intend to purchase common stock in the directed share program in this offering at the initial public offering price. These prospective purchasers have the right to purchase these shares, but are under no obligation to purchase any shares in this offering and their interest in purchasing shares in this offering is not a commitment to do so. The underwriters will receive the same discount from shares of our common stock purchased by such directors and officers as they will from other shares of our common stock sold to the public in this offering. Any shares purchased by such directors and officers will be subject to lock-up restrictions described under Shares Eligible for Future Sales.

Private Placement Financings and Registration Rights

Over the past three years, following board and stockholder approval, we sold securities to certain private investors, including our directors and 5% stockholders and persons or entities associated with them. In March 2011 and October 2011, we sold subordinated convertible promissory notes in the second and third closings of a note and warrant financing with certain of our stockholders, pursuant to which we issued subordinated convertible promissory notes in the aggregate principal amount of \$5.3 million. The notes accrued interest at the rate of seven percent (7%) per annum and were due and payable on the one year anniversary of the issue date. Upon the occurrence of a preferred stock financing, the notes were convertible into the series of preferred stock sold in such financing at the lesser of \$21.78 and the lowest price per share paid by other investors in the financing. Pursuant to the terms of the note and warrant purchase agreement, noteholders were also entitled to receive, upon conversion of the subordinated convertible promissory notes, warrants to purchase (1) the number of shares equal to fifty percent (50%) of the aggregate principal value of such note, divided by the note conversion price per share, and (2) if the noteholder purchased greater than its pro rata portion of the notes sold in the note that is greater than the noteholder s pro rata portion, divided by the note conversion price per share. The warrants have a term of the earlier of (a) five years, (b) a Change of Control (as defined in the warrant), or (c) immediately prior to the closing of a firm commitment underwritten initial public offering.

Index to Financial Statements

The following table summarizes purchases since January 1, 2011 of our subordinated convertible promissory notes by our executive officers, directors and holders of more than 5% of our capital stock:

| | Aggregate principal amount of promissory notes | | Aggregate exercise | |
|--|--|-----------|-----------------------|----------------------------|
| Stockholder | p | ourchased | price | of warrants ⁽¹⁾ |
| KPCB Holdings Inc., as nominee ⁽²⁾ | \$ | 1,045,393 | \$ | 1,493,273 |
| Entities affiliated with TPG Biotechnology Partners, L.P. ⁽³⁾ | \$ | 1,010,574 | \$ | 1,444,352 |
| Entities affiliated with Intel Capital Corporation ⁽⁴⁾ | \$ | 629,778 | \$ | 884,787 |
| Entities affiliated with Sprout Capital IX, L.P. ⁽⁵⁾ | \$ | 649,574 | \$ | 979,281 |
| Entities affiliated with Burrill Life Sciences Capital Fund, L.P. ⁽⁶⁾ | \$ | 570,677 | \$ | 821,416 |
| Entities affiliated with DAG Ventures QP, L.P. ⁽⁷⁾ | \$ | 450,230 | \$ | 632,530 |

(1) Not yet exercised.

(2) Brook Byers, a member of our board of directors, is affiliated with KPCB Holdings, Inc., as nominee, which hold these notes and warrants.

(3) The purchasers were (a) TPG BioTech Reinvest AIV, L.P. which purchased notes with an aggregate value of \$704,964.81, (b) TPG Ventures Reinvest AIV, L.P. which purchased notes with an aggregate value of \$305,609.88, (c) TPG Biotechnology Partners, L.P. which received warrants with an aggregate value of \$1,007,624.34, and (d) TPG Ventures L.P. which received warrants with an aggregate value of \$436,728.48. Fred E. Cohen, a member of our board of directors, is affiliated with TPG Biotechnology Partners, L.P., TPG Ventures, L.P., TPG BioTech Reinvest AIV, L.P. and TPG Ventures Reinvest AIV, L.P.
 (4) The purchaser of these notes and warrants was Middlefield Ventures, Inc.

- (5) The purchasers were (a) Sprout Capital IX, L.P. which purchased notes with an aggregate value of \$643,291.32 and received warrants with an aggregate value of \$972,189.60 and (b) Sprout Entrepreneurs Fund, L.P. which purchased notes with an aggregate value of \$6,371.32 and received warrants with an aggregate value of \$7,091.40. Vijay Lathi, a former member of our board of directors who resigned effective as of March 28, 2014, is affiliated with Sprout Capital IX, L.P. and Sprout Entrepreneurs Fund, L.P.
- (6) The purchasers were (a) Burrill Life Sciences Capital Fund, L.P., which purchased notes with an aggregate value of \$526,857.93 and received warrants with an aggregate value of \$762,303.24 and (b) Burrill Indiana Life Sciences Capital Fund, L.P., which purchased notes with an aggregate value of \$43,819.34 and received warrants with an aggregate value of \$59,113.02. G. Steven Burrill, a former member of our board of directors who resigned effective June 19, 2014, is affiliated with Burrill Indiana Life Sciences Capital Fund L.P. and Burrill Life Sciences Capital Fund, L.P., which hold these notes and warrants.
- (7) The purchasers were (a) DAG Ventures QP, L.P. which purchased notes with an aggregate value of \$301,087.10 and received warrants with an aggregate value of \$20,937.12, (b) DAG Ventures I-N, LLC which purchased notes with an aggregate value of \$118,797.66 and received warrants with an aggregate value of \$166,899.12, (c) DAG Ventures, L.P. which purchased notes with an aggregate value of \$15,442.57 and received warrants with an aggregate value of \$21,693.96, and (d) DAG Ventures GP Fund LLC which purchased notes with an aggregate value of \$14,903.33 and received warrants with an aggregate value of \$423,000.42.

In April 2012 we sold in a private placement 708,016 shares of our Series G preferred stock, including issuance of shares of Series G preferred stock upon conversion of all outstanding subordinated convertible promissory notes, at a price per share of \$21.78. In connection with such sale, we also entered into an amendment to our sixth amended and restated investors rights agreement, the terms of which are set forth in Description of Capital Stock Registration Rights.

The following table summarizes purchases since January 1, 2011 of shares of our Series G preferred stock by our executive officers, directors and holders of more than 5% of our capital stock:

| | Shares of Series G | Aggregate purchase |
|--|---------------------|-----------------------|
| | preferred stock | price |
| | purchased with cash | of cash and |
| | or debt | debt |
| Stockholder | cancellation | cancellation |
| KPCB Holdings Inc., as nominee ⁽¹⁾ | 109,845 | \$ 2,392,759 |
| Entities affiliated with TPG Biotechnology Partners, L.P. ⁽²⁾ | 106,236 | \$ 2,314,171 |
| Entities affiliated with Sprout Capital IX, L.P. ⁽³⁾ | 71,350 | \$ 1,554,231 |

Edgar Filing: CareDx, Inc. - Form S-1/A

| Entities affiliated with Intel Capital Corporation ⁽⁴⁾ | 65,253 | \$ 1,421,415 |
|--|--------|--------------|
| Entities affiliated with Burrill Life Sciences Capital Fund, L.P. ⁽⁵⁾ | 60,352 | \$ 1,314,656 |
| Entities affiliated with DAG Ventures QP, L.P. ⁽⁶⁾ | 46,648 | \$ 1,016,169 |

Index to Financial Statements

- ⁽¹⁾ Brook Byers, a member of our board of directors, is affiliated with KPCB Holdings, Inc., which hold these shares.
- (2) The purchasers were (a) TPG Biotechnology Partners L.P. which holds 74,113 shares of preferred stock and (b) TPG Ventures, L.P. which holds 32,123 shares of preferred stock. Fred Cohen, a member of our board of directors, is affiliated with TPG Biotechnology Partners, L.P. and TPG Ventures, L.P.
- (3) The purchasers were (a) Sprout Capital IX, L.P. which holds 70,908 shares of preferred stock and (b) Sprout Entrepreneurs Fund, L.P. which holds 442 shares of preferred stock. Vijay Lathi, a former member of our board of directors who resigned effective as of March 28, 2014, is affiliated with Sprout Capital IX, L.P. and Sprout Entrepreneurs Fund, L.P.
- ⁽⁴⁾ The purchaser was Middlefield Ventures, Inc.
- (5) The purchasers were (a) Burrill Life Sciences Capital Fund, L.P. which holds 55,718 shares of preferred stock and (b) Burrill Indiana Life Sciences Capital Fund, L.P., which holds 4,634 shares of preferred stock. G. Steven Burrill, a former member of our board of directors who resigned effective June 19, 2014, is affiliated with Burrill Indiana Life Sciences Capital Fund L.P. and Burrill Life Sciences Capital Fund, L.P., which hold these shares.
- (6) The purchasers were (a) DAG Ventures QP, L.P. which holds 31,196 shares of preferred stock, (b) DAG Ventures I-N, LL which holds 12,308 shares of preferred stock, (c) DAG Ventures, L.P. which holds 1,600 shares of preferred stock, and (d) DAG Ventures GP Fund LLC which holds 1,544 shares of preferred stock.

Stock Option Grants to Executive Officers

We have granted stock options to our executive officers and certain of our directors. For a description of the options that are currently outstanding, see Executive Compensation 2013 Outstanding Equity Awards at Year End and Management Non-Employee Director Compensation.

Offer Letters

We have entered into offer letters and other arrangements containing compensation, termination and change of control provisions, among others, with certain of our executive officers as described under the caption Executive Compensation Executive Employment Arrangements above.

Other than as described above, there has not been, nor is there any currently proposed, transactions or series of similar transactions to which we have been or will be a party other than compensation arrangements, which are described where required under Executive Compensation.

Indemnification Agreements

We have entered into indemnification agreements with each of our directors and officers. The indemnification agreements and our certificate of incorporation and bylaws that will be in effect upon completion of this offering require us to indemnify our directors and officers to the fullest extent permitted by Delaware law. See Executive Compensation Limitation on Liability and Indemnification Matters.

Policies and Procedures for Related Party Transactions

We have a formal written policy providing that our executive officers, directors, nominees for election as directors, beneficial owners of more than 5% of any class of our common stock, any member of the immediate family of any of the foregoing persons and any firm, corporation or other entity in which any of the foregoing persons is employed, is a general partner or principal or in a similar position, or in which such person has a 5% or greater beneficial ownership interest, is not permitted to enter into a related party transaction with us without the consent of our audit committee.

In approving or rejecting any such proposal, our audit committee is to consider the relevant facts and circumstances available and deemed relevant to our audit committee, including, whether the transaction is on terms no less favorable than terms generally available to an unaffiliated third party under the same or similar circumstances, and the extent of the related party s interest in the transaction.

We believe that we have executed all of the transactions set forth under the section entitled Related Party Transactions on terms no less favorable to us than we could have obtained from unaffiliated third parties. It is our intention to ensure that all future transactions between us and our officers, directors and principal stockholders and their affiliates, are approved by the audit committee of our board of directors, and are on terms no less favorable to us than those that we could obtain from unaffiliated third parties.

Index to Financial Statements

PRINCIPAL STOCKHOLDERS

The following table sets forth certain information with respect to the beneficial ownership of our common stock at June 15, 2014 and as adjusted to reflect the sale of common stock in this offering, for:

each person, or group of affiliated persons, who beneficially owned more than 5% of our common stock;

each of our named executive officers;

each of our directors; and

all of our current directors and executive officers as a group.

We have determined beneficial ownership in accordance with the rules of the SEC, and the information is not necessarily indicative of beneficial ownership for any other purpose. Except as indicated by the footnotes below, we believe, based on information furnished to us, that the persons and entities named in the table below have sole voting and sole investment power with respect to all shares of common stock that they beneficially owned, subject to applicable community property laws.

Applicable percentage ownership prior to the offering is based on 7,060,754 shares of common stock outstanding as of June 15, 2014, giving effect to our issuance of 888,135 shares of preferred stock in connection with our acquisition of ImmuMetrix on June 10, 2014, a one-for-6.85 reverse split of our common and preferred stock effected on July 14, 2014, and the automatic conversion of our convertible preferred stock into common stock. Applicable percentage ownership after the offering is based on 10,504,504 shares of common stock outstanding at June 15, 2014, giving effect to our issuance of 888,135 shares of preferred stock in connection with our acquisition of ImmuMetrix on June 10, 2014, a one-for-6.85 reverse split of our common and preferred stock effected on July 14, 2014, the automatic conversion of our convertible preferred stock into common stock, 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), and 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 common stock price per share of \$16.00). In computing the number of shares of common stock beneficially owned by a person and the percentage ownership of such person, we deemed to be outstanding all shares of common stock subject to options held by the person that are currently exercisable or exercisable within 60 days of June 15, 2014. However, we did not deem such shares outstanding for the purpose of computing the percentage ownership of any other person. In computing the number of shares of common stock beneficially owned by a person and the percentage ownership of such person, we included shares owned by a spouse, minor children and relatives sharing the same home, as well as other entities o

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 information set forth in the table below does not reflect any potential purchases of any shares in this offering by these stockholders or their affiliated entities.

Index to Financial Statements

In addition, the table below assumes that the underwriters do not exercise their option to purchase additional shares and does not reflect any shares of our common stock that our directors and executive officers may purchase in this offering through the directed share program described under Underwriting.

Unless otherwise indicated, the address of each beneficial owner listed in the table below is CareDx, Inc., 3260 Bayshore Boulevard, Brisbane, California 94005.

| | Shares Beneficially | | | |
|--|--------------------------------|-------|---|-------|
| | Owned Prior to the Offering | | Shares Beneficially Owned After the Offering | |
| | Number of | | Number of | |
| Name of Beneficial Owner | Shares | %** | Shares | %** |
| 5% Stockholders | | | | |
| KPCB Holdings, Inc. as nominee ⁽¹⁾ | 1,061,218 | 14.9% | 1,061,218 | 10.0% |
| Entities affiliated with TPG Biotechnology Partners, L.P. ⁽²⁾ | 1,026,396 | 14.4% | 1,026,396 | 9.7% |
| Entities affiliated with Sprout Capital IX, L.P. ⁽³⁾ | 687,054 | 9.7% | 687,054 | 6.5% |
| Entities affiliated with Intel Capital Corporation ⁽⁴⁾ | 631,338 | 8.9% | 631,338 | 6.0% |
| Entities affiliated with Burrill Life Sciences Capital Fund, L.P. ⁽⁵⁾ | 583,577 | 8.2% | 583,577 | 5.5% |
| Entities affiliated with DAG Ventures QP, L.P. ⁽⁶⁾ | 451,334 | 6.4% | 451,334 | 4.3% |
| Mattias Westman ⁽⁷⁾ | 418,207 | 5.9% | 418,207 | 4.0% |
| Named Executive Officers and Directors: | | | | |
| Peter Maag ⁽⁸⁾ | 121,349 | 1.7% | 121,349 | 1.1% |
| James P. Yee ⁽⁹⁾ | 65,691 | * | 65,691 | * |
| Matthew J. Meyer ⁽¹⁰⁾ | 36,495 | * | 36,495 | * |
| George W. Bickerstaff, III ⁽¹⁴⁾ | 0 | * | 0 | * |
| Brook Byers ⁽¹⁾ | 1,061,218 | 14.9% | 1,061,218 | 10.0% |
| Fred E. Cohen ⁽¹¹⁾ | 0 | * | 0 | * |
| Michael Goldberg ⁽¹²⁾ | 64,525 | * | 64,525 | * |
| Ralph Snyderman ⁽¹³⁾ | 26,276 | * | 26,276 | * |
| All current directors and executive officers as a group (10 persons) | 1,492,377 | 19.8% | 1,492,377 | 13.6% |

* Represents beneficial ownership of less than one percent (1%).

** Percentage ownership prior to the offering is based on 7,060,754 shares of common stock outstanding prior to the offering and does not include the 318,750 shares of common stock issuable upon conversion of a subordinated convertible promissory note issued in April 2014 that will convert immediately following the offering. Percentage ownership following the offering includes 3,125,000 shares of common stock to be issued in the offering and 318,750 shares of common stock to be issued upon conversion of the subordinated convertible promissory note.

- (1) All shares are held for convenience in the name of KPCB Holdings, Inc., as nominee, for the accounts of the following individuals and entities, who each exercise their own voting and dispositive control over such shares: (a) 679,371 shares of common stock and 46,910 shares issuable upon exercise of warrants exercisable for shares of common stock held by Kleiner Perkins Caufield & Byers X-A, L.P. (KPCB X-A), (b) 19,034 shares of common stock and 1,323 shares issuable upon exercise of warrants exercisable for shares of common stock held by Kleiner Perkins Caufield & Byers X-B, L.P. (KPCB X-B), (c) 6,957 shares of common stock and 480 shares issuable upon exercise of warrants exercisable for shares of common stock held by Brook Byers, and (d) 287,308 shares of common stock and 19,839 shares issuable upon exercise of warrants exercisable for shares of common stock held by individuals and entities associated with Kleiner Perkins Caufield & Byers. KPCB X Associates, LLC is the general partner of KPCB X-A and KPCB X-B. Brook H. Byers, L. John Doerr, Kevin Compton, Doug Mackenzie, Raymond J. Lane and Theodore E. Schlein are the managers of KPCB X Associates, LLC, and share voting and dispositive control over the shares held by KPCB X-A and KPCB X-B. The address for this stockholder is 2750 Sand Hill Road, Menlo Park, CA 94025.
- (2) Ventures, L.P. (TPG Ventures), (c) 74,113 shares of common stock and 46,257 shares issuable upon exercise of warrants exercisable for shares of common stock held by TPG Biotech Reinvest AIV, L.P. (TPG Biotech Reinvest), and (d) 32,123 shares of common stock and 20,049 shares issuable upon exercise of warrants exercisable for shares of common stock held by TPG Ventures Reinvest AIV, L.P. (TPG Biotech Reinvest AIV, L.P. (TPG Biotech Reinvest AIV, L.P. (TPG Ventures Reinvest and, together with TPG Biotech, TPG Ventures and TPG Biotech Reinvest, the TPG Funds). The general partner of each of TPG Biotech and TPG Biotech Reinvest is TPG Biotechnology GenPar, L.P., whose general partner is TPG Biotechnology GenPar, Advisors, LLC, whose sole member is TPG Holdings I, L.P. The general partner of each of TPG Ventures GenPar Advisors, LLC, whose general partner is TPG Group Holdings (SBS), L.P., whose general partner is TPG Group Holdings (SBS), L.P., whose general partner is TPG Group Holdings (SBS), Advisors, Inc. David Bonderman and James G. Coulter are officers and sole shareholders

footnotes continued on following page

Index to Financial Statements

- of TPG Group Holdings (SBS) Advisors, Inc. and therefore may be deemed to be the beneficial owners of the securities held by the TPG Funds. Messrs. Bonderman and Coulter disclaim beneficial ownership of the securities held by the TPG Funds except to the extent of their pecuniary interest therein. The address of each of the TPG Funds, TPG Group Holdings (SBS) Advisors, Inc. and Messrs. Bonderman and Coulter is c/o TPG Global, LLC, 301 Commerce Street, Suite 3300, Fort Worth, TX 76102.
- Represents (a) 639,798 shares of common stock and 44,630 shares issuable upon exercise of warrants exercisable for shares of common stock held by Sprout
 ⁽³⁾ Capital IX, L.P., and (b) 2,301 shares of common stock and 325 shares issuable upon exercise of warrants exercisable for shares of common stock held by Sprout Entrepreneurs Fund, L.P. DLJ Capital Corporation, a wholly owned subsidiary of Credit Suisse (USA), Inc. (formerly, Credit Suisse First Boston (USA), Inc.) is the Managing General Partner of Sprout Capital IX, L.P. and the sole general partner of Sprout Entrepreneurs Fund L.P. The address for this stockholder is 2500 Sand Hill Road, Suite 203, Menlo Park, CA, 94025.
- (4) Represents (a) 399,346 shares of common stock held by Intel Capital Corporation, (b) 126,121 shares of common stock held by Intel Capital (Cayman), and (c) 65,253 shares of common stock and 40,618 shares issuable upon exercise of warrants exercisable for shares of common stock held by Middlefield Ventures, Inc. Intel Corporation is the parent company of Intel Capital Corporation, Intel Capital (Cayman) Corporation and Middlefield Ventures, Inc., and is deemed to have shared voting and shared dispositive control over the shares of Intel Capital Corporation, Intel Capital (Cayman) and Middlefield Ventures, Inc. The address for each of the stockholders is c/o Intel Corporation, 2200 Mission College Blvd., Attention: Intel Capital Portfolio Manager, M/S RNB 6-59, Santa Clara, CA 95052.
- (5) Represents (a) 503,956 shares of common stock and 34,995 shares issuable upon exercise of warrants exercisable for shares of common stock held by Burrill Life Sciences Capital Fund L.P., and (b) 41,913 shares of common stock and 2,713 shares issuable upon exercise of warrants exercisable for shares of common stock held by Burrill Indiana Life Sciences Capital Fund. Burrill & Company (Life Sciences GP), LLC is the General Manager of Burrill Life Sciences Capital Fund, L.P. G. Steven Burrill is the Managing Member of Burrill & Company (Life Sciences GP) and Burrill & Company (Indiana GP) and may be deemed to hold voting and dispositive control over the share of Burrill Life Sciences Capital Fund L.P. and Burrill Indiana Life Sciences Capital Fund. The address of this stockholder is One Embarcadero Center, Suite 2700, San Francisco, CA 94111.
- (6) Represents (a) 13,978 shares of common stock and 961 shares issuable upon exercise of warrants exercisable for shares of common stock held by DAG Ventures GP Fund LLC, (b) 111,427 shares of common stock and 7,661 shares issuable upon exercise of warrants exercisable for shares of common stock held by DAG Ventures I-N, LLC, (c) 14,483 shares of common stock and 995 shares issuable upon exercise of warrants exercisable for shares of common stock held by DAG Ventures, L.P., and (d) 282,411 shares of common stock and 19,418 shares issuable upon exercise of warrants exercisable for shares of common stock held by DAG Ventures, QP, L.P. DAG Ventures Management, LLC is the Manager of each of DAG Ventures GP Fund LLC and DAG Ventures I-N, LLC and is the General Partner of each of DAG Ventures, L.P. and DAG Ventures QP, L.P. John M. Duff, Jr., R. Thomas Goodrich and John J. Cadeddu, the Managers of DAG Ventures Management, LLC, may be deemed to have voting and dispositive control over the shares of DAG Ventures GP Fund LLC, DAG Ventures I-N, LLC, DAG Ventures, L.P. and DAG Ventures QP, L.P. The address for this stockholder is 251 Lytton Avenue, Suite 200, Palo Alto, CA 94301. Represents shares issued to Mr. Westman in connection with our acquisition of ImmuMetrix, Inc. on June 10, 2014. The address for this stockholder is 28

⁽⁷⁾ Ellerdale Road, London NW3 6BB, United Kingdom.

Represents 121,349 shares subject to options that are immediately exercisable or exercisable within 60 days of June 15, 2014.

(9) of June 15, 2014.

- ⁽¹⁰⁾ Represents 36,495 shares subject to options that are immediately exercisable or exercisable within 60 days of June 15, 2014.
- (11) Dr. Cohen, a member of our board of directors, is a TPG Partner. Dr. Cohen has no voting or investment power over and disclaims beneficial ownership of the securities held by the TPG Funds. Dr. Cohen s business address is c/o TPG Global, LLC, 301 Commerce Street, Suite 3300, Fort Worth, TX 76102.
- ⁽¹²⁾ Represents 64,525 shares subject to options that are immediately exercisable or exercisable within 60 days of June 15, 2014.
- (13) Represents 26,276 shares subject to options that are immediately exercisable or exercisable within 60 days of June 15, 2014.
- ⁽¹⁴⁾ Mr. Bickerstaff was appointed to the board of directors effective on April 8, 2014.

Index to Financial Statements

DESCRIPTION OF CAPITAL STOCK

General

The following is a summary of the rights of our common stock and preferred stock and certain provisions of our amended and restated certificate of incorporation and amended and restated bylaws as they will be in effect upon the completion of this offering. This summary does not purport to be complete and is qualified in its entirety by the provisions of our amended and restated certificate of incorporation and amended and restated and restated bylaws, copies of which have been filed as exhibits to the registration statement of which this prospectus is a part.

Immediately following the completion of this offering, our authorized capital stock will consist of 110,000,000 shares, with a par value of \$0.001 per share, of which:

100,000,000 shares are designated as common stock; and

10,000,000 shares are designated as preferred stock.

As of March 31, 2014, we had outstanding 7,379,302 shares of common stock, held by approximately 194 stockholders of record, and no shares of preferred stock, assuming the automatic conversion of all outstanding shares of our convertible preferred stock into common stock, the issuance of 888,135 shares of common stock in connection with our acquisition of ImmuMetrix, Inc. in June 2014 and 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), each such conversion to be effective immediately upon the completion of this offering. The actual conversion price of the convertible note will be the lower of \$21.78 and the price at which common stock is sold in this offering. In addition, as of March 31, 2014, we had (i) outstanding options to acquire 450,382 shares of our common stock under our 2008 Plan and outstanding options to acquire 97,349 share of our common stock under our 1998 Plan, and (ii) outstanding warrants to acquire 623,803 shares of our common stock.

Common Stock

The holders of common stock are entitled to one vote per share on all matters submitted to a vote of our stockholders and do not have cumulative voting rights. Accordingly, holders of a majority of the shares of common stock entitled to vote in any election of directors may elect all of the directors standing for election. Subject to preferences that may be applicable to any preferred stock outstanding at the time, the holders of outstanding shares of common stock are entitled to receive ratably any dividends declared by our board of directors out of assets legally available. See the section entitled Dividend Policy. Upon our liquidation, dissolution, or winding up, holders of our common stock are entitled to share ratably in all assets remaining after payment of liabilities and the liquidation preference of any then outstanding shares of preferred stock. Holders of common stock have no preemptive or conversion rights or other subscription rights. There are no redemption or sinking fund provisions applicable to the common stock.

Preferred Stock

After the completion of this offering, no shares of preferred stock will be outstanding. Pursuant to our amended and restated certificate of incorporation, our board of directors will have the authority, without further action by the stockholders, to issue from time to time up to 10,000,000 shares of preferred stock in one or more series. Our board of directors may designate the rights, preferences, privileges, and restrictions of the preferred stock, including dividend rights, conversion rights, voting rights, redemption rights, liquidation preference, sinking fund terms, and the number of shares constituting any series or the designation of any series. The issuance of preferred stock could have the effect of restricting dividends on the common stock, diluting the voting power of the common stock, impairing the liquidation rights of

Index to Financial Statements

the common stock, or delaying, deterring, or preventing a change in control. Such issuance could have the effect of decreasing the market price of the common stock. We currently have no plans to issue any shares of preferred stock.

Registration Rights

The holders of 6,048,220 shares of common stock issuable upon conversion of preferred stock, and 541,613 shares of common stock issuable upon conversion of preferred stock which is issuable upon the exercise of outstanding warrants or their permitted transferees are entitled to rights with respect to registration of these shares under the Securities Act following this offering. These rights are provided under the terms of our sixth amended and restated investors rights agreement.

Under these registration rights, holders of the then outstanding registrable securities may require on two occasions that we register their shares for public resale. Such registration requires the election of the holders of registrable securities holding at least 40% of such registrable securities. We are obligated to register these shares only if the requesting holders request the registration of at least the number of shares having an aggregate offering price (prior to deduction for underwriter s discounts and commissions related to the issuance) of at least \$25,000,000.

In addition, holders of registrable securities may request that we register their shares for public resale on Form S-3 or similar short-form registration, if we are eligible to use Form S-3 or similar short-form registration, and the value of the securities to be registered is at least \$1,000,000.

If we elect to register any of our shares of common stock for any public offering, the holders of registrable securities are entitled to include shares of common stock in the registration. However, we may reduce the number of shares proposed to be registered in view of market conditions, provided that we may not reduce the number of registrable securities included in any such registration below 20% of the shares included in the registration (except for a registration relating to our initial public offering, from which all registrable securities may be excluded).

We will pay all expenses in connection with any registration described herein, other than underwriting discounts and commissions. These rights will terminate five years after the closing of this offering and prior to then, a holder of less than two percent of our then-outstanding capital stock shall cease to have registration rights once that holder may sell all of its registrable securities under Rule 144 during any 90 day period.

Anti-Takeover Effects of Delaware Law and Our Certificate of Incorporation and Bylaws

Our amended and restated certificate of incorporation and amended and restated bylaws to be effective upon the completion of this offering will contain provisions that could have the effect of delaying, deferring, or discouraging another party from acquiring control of us. These provisions and certain provisions of Delaware law, which are summarized below, could discourage takeovers, coercive or otherwise. These provisions are also designed, in part, to encourage persons seeking to acquire control of us to negotiate first with our board of directors. We believe that the benefits of increased protection of our potential ability to negotiate with an unfriendly or unsolicited acquirer outweigh the disadvantages of discouraging a proposal to acquire us.

Undesignated Preferred Stock. As discussed above under Preferred Stock, our board of directors will have the ability to designate and issue preferred stock with voting or other rights or preferences that could deter hostile takeovers or delay changes in our control or management.

Limits on Ability of Stockholders to Act by Written Consent or Call a Special Meeting. Our amended and restated certificate of incorporation will provide that our stockholders may not act by written consent. This limit on the ability of stockholders to act by written consent may lengthen the amount of

Index to Financial Statements

time required to take stockholder actions. As a result, the holders of our capital stock will not be able to take stockholder actions, such as actions to amend our certificate of incorporation or bylaws or remove directors without holding a meeting of stockholders called in accordance with the amended and restated bylaws.

In addition, our amended and restated bylaws will provide that special meetings of the stockholders may be called only by the chairman of the board, the chief executive officer, the president (in the absence of a chief executive officer), or our board of directors. A stockholder may not call a special meeting, which may delay the ability of our stockholders to force consideration of a proposal or for holders controlling a majority of our capital stock to take certain actions, or for holders controlling 66 2/3% of the voting power of our capital stock to take certain other actions, including the removal of directors.

Requirements for Advance Notification of Stockholder Nominations and Proposals. Our amended and restated bylaws will establish advance notice procedures with respect to stockholder proposals and the nomination of candidates for election as directors, other than nominations made by or at the direction of our board of directors or a committee of the board of directors. These advance notice procedures may have the effect of precluding the conduct of certain business at a meeting if the proper procedures are not followed and may also discourage or deter a potential acquirer from conducting a solicitation of proxies to elect its own slate of directors or otherwise attempt to obtain control of our company.

Board Classification. Our amended and restated certificate of incorporation provides that our board of directors will be divided into three classes, one class of which is elected each year by our stockholders. The directors in each class will serve for a three-year term. For more information on the classified board of directors, see Management Board Composition. Our classified board of directors may tend to discourage a third party from making a tender offer or otherwise attempting to obtain control of us, because it generally makes it more difficult for stockholders to replace a majority of the directors.

Election and Removal of Directors. Our amended and restated certificate of incorporation and amended and restated bylaws contain provisions that establish specific procedures for appointing and removing members of our board of directors. Under our amended and restated certificate of incorporation and amended and restated bylaws, vacancies and newly created directorships on our board of directors may be filled only by a majority of the directors then serving on the board of directors. Under our amended and restated certificate of incorporation and amended and restated only for cause by the affirmative vote of the holders of at least 66 2/3% in voting power of the shares then entitled to vote at an election of directors.

No Cumulative Voting. The Delaware General Corporation Law provides that stockholders are not entitled to the right to cumulate votes in the election of directors unless our amended and restated certificate of incorporation provides otherwise. Our amended and restated certificate of incorporation and amended and restated bylaws do not expressly provide for cumulative voting. Without cumulative voting, a minority stockholder may not be able to gain as many seats on our board of directors as the stockholder would be able to gain if cumulative voting were permitted. The absence of cumulative voting makes it more difficult for a minority stockholder to gain a seat on our board of directors to influence our board of directors decision regarding a takeover.

Amendment of Charter Provisions. Any amendment of the provisions of the amended and restated certificate of incorporation described above and any amendment of the bylaws would require the approval of holders of at least 66 2/3% of the voting power of our capital stock. These requirements would prevent holders of a majority of the voting power of our capital stock from making changes to our certificate of incorporation and bylaws.

Index to Financial Statements

Delaware Anti-Takeover Statute. We will be subject to the provisions of Section 203 of the Delaware General Corporation Law regulating corporate takeovers. In general, Section 203 prohibits a publicly held Delaware corporation from engaging, under certain circumstances, in a business combination with an interested stockholder for a period of three years following the date the person became an interested stockholder unless:

prior to the date of the transaction, our board of directors approved either the business combination or the transaction that resulted in the stockholder becoming an interested stockholder;

upon completion of the transaction that resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction commenced, excluding for purposes of determining the voting stock outstanding, but not the outstanding voting stock owned by the interested stockholder, (1) shares owned by persons who are directors and also officers and (2) shares owned by employee stock plans in which employee participants do not have the right to determine confidentially whether shares held subject to the plan will be tendered in a tender or exchange offer; or

at or subsequent to the date of the transaction, the business combination is approved by our board of directors and authorized at an annual or special meeting of stockholders, and not by written consent, by the affirmative vote of at least 66 2/3% of the outstanding voting stock that is not owned by the interested stockholder.

Generally, a business combination includes a merger, asset or stock sale, or other transaction resulting in a financial benefit to the interested stockholder. An interested stockholder is a person who, together with affiliates and associates, owns or, within three years prior to the determination of interested stockholder status, did own 15% or more of a corporation s outstanding voting stock. We expect the existence of this provision to have an anti-takeover effect with respect to transactions our board of directors does not approve in advance. We also anticipate that Section 203 may discourage attempts that might result in a premium over the market price for the shares of common stock held by stockholders.

The provisions of Delaware law and the provisions of our amended and restated certificate of incorporation and amended and restated bylaws could have the effect of discouraging others from attempting hostile takeovers and as a consequence, they might also inhibit temporary fluctuations in the market price of our common stock that often result from actual or rumored hostile takeover attempts. These provisions might also have the effect of preventing changes in our management. It is also possible that these provisions could make it more difficult to accomplish transactions that stockholders might otherwise deem to be in their best interests.

Transfer Agent and Registrar

Upon the completion of this offering, the transfer agent and registrar for our common stock will be Computershare Trust Company, N.A. The transfer agent s address is 250 Royall Street, Canton, MA 02021, and its telephone number is (800) 962-4284.

Exchange Listing

We have applied to list our common stock on the NASDAQ Global Market under the symbol CDNA.

Index to Financial Statements

SHARES ELIGIBLE FOR FUTURE SALE

Prior to this offering, there has been no public market for shares of our common stock and we cannot assure you that a liquid trading market for our common stock will develop or be sustained after this offering. Future sales of substantial amounts of shares of common stock, including shares issued upon the exercise of outstanding options, in the public market after this offering, or the possibility of these sales occurring, could adversely affect the prevailing market price for our common stock or impair our ability to raise equity capital.

Upon completion of the offering, the conversion of a subordinated convertible promissory note in the aggregate principal amount of \$5.0 million plus accrued interest into 318,750 shares of common stock (assuming conversion of the note at the common stock price per share of \$16.00, which is the mid-point of the price range on the cover of this prospectus), the issuance of 888,135 shares of our preferred stock upon completion of our acquisition of ImmuMetrix, Inc. in June 2014, and the automatic conversion of all outstanding shares of preferred stock into shares of common stock, such conversion to be effective upon the completion of this offering, a total of 10,504,302 shares of common stock will be outstanding. The actual conversion price of the convertible note will be the lower of \$21.78 and the price at which common stock will be sold in this offering. Of these shares, all 3,125,000 shares of common stock sold in this offering by us, plus any shares sold upon exercise of the underwriters over-allotment option, will be freely tradable in the public market without restriction or further registration under the Securities Act, unless these shares are held by affiliates, as that term is defined in Rule 144 under the Securities Act.

The remaining outstanding shares of our common stock will be deemed restricted securities as defined in Rule 144. Restricted securities may be sold in the public market only if they are registered or if they qualify for an exemption from registration under Rule 144 or Rule 701 under the Securities Act, which rules are summarized below. In addition, holders of substantially all of our equity securities are subject to market stand-off agreements or have entered into lock-up agreements with the underwriters under which they have agreed, subject to specific exceptions, not to sell any of our stock for at least 180 days following the date of this prospectus, as described below. As a result of these agreements and the provisions of our sixth amended and restated investors rights agreement described above under Description of Capital Stock Registration Rights, subject to the provisions of Rule 144 or Rule 701, following the expiration of the lock-up period, all shares subject to such provisions and agreements will be available for sale in the public market only if registered or pursuant to an exemption from registration under Rule 144 or Rule 144 or Rule 701 under the Securities Act.

Rule 144

In general, under Rule 144 as currently in effect, once we have been subject to public company reporting requirements for at least 90 days, a person who is not deemed to have been one of our affiliates for purposes of the Securities Act at any time during the 90 days preceding a sale and who has beneficially owned the shares proposed to be sold for at least six months, including the holding period of any prior owner other than our affiliates, is entitled to sell such shares (subject to the requirements of the lock-up agreements, as described below) without complying with the manner of sale, volume limitation or notice provisions of Rule 144, subject to compliance with the public information requirements of Rule 144. If such a person has beneficially owned the shares proposed to be sold for at least one year, including the holding period of any prior owner other than our affiliates, then such person is entitled to sell such shares (subject to the requirements of subject to the requirements, as described below) without complying with any of the requirements of Rule 144.

Index to Financial Statements

In general, under Rule 144, as currently in effect, our affiliates or persons selling shares on behalf of our affiliates are entitled to sell upon expiration of the lock-up agreements described above, within any three-month period beginning 90 days after the date of this prospectus, a number of shares that does not exceed the greater of:

1% of the number of shares of common stock then outstanding, which will equal approximately 105,043 shares immediately after this offering; or

the average weekly trading volume of the common stock during the four calendar weeks preceding the filing of a notice on Form 144 with respect to such sale.

Sales under Rule 144 by our affiliates or persons selling shares on behalf of our affiliates are also subject to certain manner of sale provisions and notice requirements and to the availability of current public information about us. Notwithstanding the availability of Rule 144, the holders of substantially all of common stock have entered into lock-up agreements as described below, and their restricted securities will become eligible for sale (subject to the above limitations under Rule 144) upon the expiration of the restrictions set forth in those agreements.

Rule 701

Rule 701, as currently in effect, generally allows a stockholder who purchased shares of our common stock pursuant to a written compensatory plan or contract and who is not deemed to have been an affiliate of our company during the immediately preceding 90 days to sell these shares (subject to the requirements of the lock-up agreements, as described below) in reliance upon Rule 144, but without being required to comply with the public information, holding period, volume limitation, or notice provisions of Rule 144. Rule 701 also permits affiliates of our company to sell their Rule 701 shares under Rule 144 without complying with the holding period requirements of Rule 144. However, all holders of Rule 701 shares are required to wait until 90 days after the date of this prospectus (or until such later date that is required by the lock-up agreements, as described below) before selling such shares pursuant to Rule 701.

Lock-Up Agreements

We, all of our directors and officers and the holders of substantially all of our common stock, or securities exercisable for or convertible into our common stock outstanding immediately prior to this offering, have agreed that, without the prior written consent of each of Piper Jaffray & Co. and Leerink Partners LLC, on behalf of the underwriters, we and they will not, during the period ending 180 days after the date of this prospectus:

offer, pledge, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase, lend or otherwise transfer or dispose of, directly or indirectly, any shares of common stock or any securities convertible into or exercisable or exchangeable for shares of common stock; or

enter into any swap or other arrangement that transfers to another, in whole or in part, any of the economic consequences of ownership of our common stock.

whether any such transaction described above is to be settled by delivery of shares of our common stock or such other securities, in cash or otherwise, subject to certain exceptions set forth in section entitled Underwriters.

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

Index to Financial Statements

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 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.

Registration Rights

The holders of 6,048,220 shares of common stock or their transferees will be entitled to various rights with respect to the registration of these shares under the Securities Act. Registration of these shares under the Securities Act would result in these shares becoming fully tradable without restriction under the Securities Act immediately upon the effectiveness of the registration, except for shares purchased by affiliates. See Description of Capital Stock Registration Rights for additional information.

Registration Statements on Form S-8

Upon the completion of this offering, we intend to file a registration statement on Form S-8 under the Securities Act to register all of the shares of common stock issued or reserved for issuance under our stock option plans. Shares covered by this registration statement will be eligible for sale in the public market, upon the expiration or release from the terms of the lock-up agreements and subject to vesting of such shares.

Participation in 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. Any such shares purchased by these potential purchasers could not be resold in the public market immediately following this offering as a result of restrictions under securities laws and lock-up agreements, but would be able to be sold following the expiration of these restrictions, in each case as described above. 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.

In addition, our directors and executive officers have indicated to us that they currently intend to purchase common stock in the directed share program in this offering at the initial public offering price. Any such shares purchased by these potential purchasers could not be resold in the public market immediately following this offering as a result of restrictions under securities laws and lock-up agreements, but would be able to be sold following the expiration of these restrictions, in each case as described above. 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.

¹⁵⁰

Index to Financial Statements

MATERIAL U.S. FEDERAL INCOME TAX CONSEQUENCES TO NON-U.S. HOLDERS

OF OUR COMMON STOCK

The following is a summary of the material U.S. federal income tax consequences to non-U.S. holders (as defined below) of the purchase, ownership and disposition of our common stock, but does not purport to be a complete analysis of all the potential tax considerations relating thereto. This summary is based upon the provisions of the Internal Revenue Code of 1986, as amended, or the Code, Treasury regulations promulgated thereunder, administrative rulings, and judicial decisions, all as of the date hereof. These authorities may be changed, possibly retroactively, so as to result in U.S. federal income tax consequences different from those set forth below.

This discussion is limited to non-U.S. holders that purchase our common stock in this offering and hold our common stock as a capital asset within the meaning of Section 1221 of the Code. This summary does not address the tax considerations arising under the laws of any non-U.S., state or local jurisdiction, or under U.S. federal gift or estate tax laws, except to the limited extent set forth below. In addition, this discussion does not address tax considerations applicable to an investor s particular circumstances or to investors that may be subject to special tax rules, including, without limitation:

banks, insurance companies, or other financial institutions;

tax-exempt organizations or governmental organizations;

controlled foreign corporations, passive foreign investment companies, and corporations that accumulate earnings to avoid U.S. federal income tax;

brokers or dealers in securities or currencies;

traders in securities that elect to use a mark-to-market method of accounting for their securities holdings;

persons that own, or are deemed to own, more than five percent of our capital stock (except to the extent specifically set forth below);

certain U.S. expatriates;

partnerships or entities classified as partnerships for U.S. federal income tax purposes (and investors therein);

persons who hold our common stock as a position in a hedging transaction, straddle, conversion transaction or other risk reduction transaction or integrated investment;

persons who hold or receive our common stock pursuant to the exercise of any employee stock option or otherwise as compensation; or

Edgar Filing: CareDx, Inc. - Form S-1/A

persons deemed to sell our common stock under the constructive sale provisions of the Code.

In addition, if a partnership or entity or arrangement classified as a partnership for U.S. federal income tax purposes holds our common stock, the tax treatment of a partner generally will depend on the status of the partner and upon the activities of the partnership. Accordingly, partnerships that hold our common stock, and partners in such partnerships, should consult their tax advisors.

You are urged to consult your tax advisor with respect to the application of the U.S. federal income tax laws to your particular situation, as well as any tax consequences of the purchase, ownership, and disposition of our common stock arising under the U.S. federal estate or gift tax rules or under the laws of any state, local, non-U.S., or other taxing jurisdiction or under any applicable tax treaty.

Index to Financial Statements

Non-U.S. Holder Defined

For purposes of this discussion, you are a non-U.S. holder if you are any holder other than a partnership (or other entity or arrangement classified as a partnership for U.S. federal income tax purposes) or:

an individual citizen or resident of the United States (for U.S. federal income tax purposes);

a corporation or other entity taxable as a corporation created or organized in the United States or under the laws of the United States or any political subdivision thereof or other entity treated as such for U.S. federal income tax purposes;

an estate whose income is subject to U.S. federal income tax regardless of its source; or

a trust (x) whose administration is subject to the primary supervision of a U.S. court and one or more U.S. persons (within the meaning of Section 7701(a)(3) of the Code) have the authority to control all substantial decisions of the trust or (y) which has in effect a valid election to be treated as a U.S. person.

Distributions

As described in the section entitled Dividend Policy, we have never declared or paid cash dividends on our common stock and do not anticipate paying any dividends on our common stock in the foreseeable future. However, if we do make distributions on our common stock, those payments will generally constitute dividends for U.S. tax purposes to the extent paid from our current or accumulated earnings and profits, as determined under U.S. federal income tax principles. To the extent those distributions exceed both our current and our accumulated earnings and profits, they will constitute a return of capital and will first reduce your basis in our common stock, but not below zero, and then will be treated as gain from the sale of stock as described below under Gain on Disposition of Common Stock.

Subject to the discussion below on effectively connected income, any dividend paid to you generally will be subject to U.S. withholding tax either at a rate of 30% of the gross amount of the dividend or such lower rate as may be specified by an applicable income tax treaty.

Dividends received by you that are treated as effectively connected with your conduct of a U.S. trade or business (and, if required by an applicable income tax treaty, attributable to a permanent establishment maintained by you in the United States) are generally exempt from such withholding tax. In order to obtain this exemption, you must provide us with an IRS Form W-8ECI or other applicable IRS Form W-8 properly certifying such exemption. Such effectively connected dividends, although not subject to withholding tax, are taxed at the same graduated rates applicable to U.S. persons, net of certain deductions and credits. In addition, if you are a corporate non-U.S. holder, dividends you receive that are effectively connected with your conduct of a U.S. trade or business may also be subject to a branch profits tax at a rate of 30% or such lower rate as may be specified by an applicable income tax treaty. You should consult your tax advisor regarding any applicable tax treaties that may provide for different rules.

In order to receive a reduced treaty rate, you must provide us with an IRS Form W-8BEN or other appropriate version of IRS Form W-8 certifying qualification for the reduced rate. A non-U.S. holder of shares of our common stock eligible for a reduced rate of U.S. withholding tax pursuant to an income tax treaty may obtain a refund of any excess amounts withheld by timely filing an appropriate claim for refund with the IRS. If the non-U.S. holder holds the stock through a financial institution or other agent acting on the non-U.S. holder s behalf, the non-U.S. holder will be required to provide appropriate documentation to the agent, which then will be required to provide certification to us or our paying agent, either directly or through other intermediaries.

Index to Financial Statements

Gain on Disposition of Common Stock

Subject to the discussion below regarding legislation related to foreign accounts, you generally will not be required to pay U.S. federal income tax on any gain realized upon the sale or other disposition of our common stock unless:

the gain is effectively connected with your conduct of a U.S. trade or business (and, if required by an applicable income tax treaty, the gain is attributable to a permanent establishment maintained by you in the United States);

you are an individual who is present in the United States for a period or periods aggregating 183 days or more during the calendar year in which the sale or disposition occurs and certain other conditions are met; or

our common stock constitutes a U.S. real property interest by reason of our status as a United States real property holding corporation, or USRPHC, for U.S. federal income tax purposes at any time within the shorter of the five-year period preceding your disposition of, or your holding period for, our common stock.

We believe that we are not currently and will not become a USRPHC. However, because the determination of whether we are a USRPHC depends on the fair market value of our U.S. real property relative to the fair market value of our other business assets, there can be no assurance that we will not become a USRPHC in the future. Even if we become a USRPHC, however, as long as our common stock is regularly traded on an established securities market, such common stock will be treated as U.S. real property interests only if you, directly or indirectly, actually or constructively hold more than five percent of such regularly traded common stock at any time during the shorter of the five-year period preceding your disposition of, or your holding period for, our common stock.

If you are a non-U.S. holder described in the first bullet above, you will generally be required to pay tax on the net gain derived from the sale at the same graduated U.S. federal income tax rates applicable to U.S. persons, and a corporate non-U.S. holder described in the first bullet above also may be subject to the branch profits tax at a 30% rate, or such lower rate as may be specified by an applicable income tax treaty. If you are an individual non-U.S. holder described in the second bullet above, you will generally be required to pay a flat 30% tax (or such lower rate as may be specified by an applicable income tax treaty) on the gain derived from the sale, which tax may be offset by U.S. source capital losses for the same taxable year (provided you have timely filed U.S. federal income tax returns with respect to such losses). You should consult your tax advisor regarding your entitlement to benefits under an applicable income tax or other treaty.

Federal Estate Tax

Our common stock beneficially owned by an individual who is not a citizen or resident of the United States (as defined for U.S. federal estate tax purposes) at the time of the individual s death will generally be includable in the decedent s gross estate for U.S. federal estate tax purposes, unless an applicable estate tax or other treaty provides otherwise, and, therefore, may be subject to U.S. federal estate tax.

Backup Withholding and Information Reporting

Generally, we must report annually to the IRS the gross amount of dividends paid to you, your name and address, and the amount of tax withheld, if any. A similar report will be sent to you. Pursuant to applicable income tax treaties or other agreements, the IRS may make these reports available to tax authorities in your country of residence.

Payments of dividends or of proceeds on the disposition of stock made to you may be subject to information reporting and backup withholding at a current rate of 28% unless you establish an

Index to Financial Statements

exemption, for example, by properly certifying your non-U.S. status on an IRS Form W-8BEN or another appropriate version of IRS Form W-8 and satisfying certain other requirements.

Backup withholding is not an additional tax; rather, the U.S. federal income tax liability of persons subject to backup withholding will be reduced by the amount of tax withheld. If withholding results in an overpayment of taxes, a refund, or credit may generally be obtained from the IRS, provided that the required information is furnished to the IRS in a timely manner.

Foreign Account Tax Compliance

The Foreign Account Tax Compliance Act, or FATCA, imposes withholding tax at a rate of 30% on dividends on and gross proceeds from the sale or other disposition of our common stock paid to foreign financial institutions (as specially defined under these rules), unless such institution enters into an agreement with the U.S. government to withhold on certain payments and to collect and provide to the U.S. tax authorities substantial information regarding the U.S. account holders of such institution (which includes certain equity and debt holders of such institution, as well as certain account holders that are foreign entities with U.S. owners) or otherwise establishes an exemption. The legislation also generally will impose a U.S. federal withholding tax of 30% on dividends on and gross proceeds from the sale or other disposition of our common stock paid to a non-financial foreign entities (as specially defined for purposes of these rules) unless such entity provides the withholding agent with a certification identifying certain substantial direct and indirect U.S. owners of the entity, certifies that there are no such owners or otherwise establishes an exemption. Under certain transition rules, withholding under FATCA on withholdable payments to foreign financial institutions and non-financial foreign entities is expected to apply after December 31, 2016 with respect to gross proceeds from the sale or other disposition of stock in a U.S. corporation, including our common stock, and after June 30, 2014, with respect to dividends on our common stock. An intergovernmental agreement between the United States and an applicable foreign country may modify the requirements described in this paragraph. Non-U.S. holders should consult their own tax advisors regarding the possible implications of this legislation on their investment in our common stock.

Each prospective investor should consult its own tax advisor regarding the particular U.S. federal, state and local and non-U.S. tax consequences of purchasing, holding and disposing of our common stock, including the consequences of any proposed change in applicable laws.

Index to Financial Statements

UNDERWRITING

Piper Jaffray & Co. and Leerink Partners LLC are acting as the representatives of each of the underwriters named below. Subject to the terms and conditions set forth in an underwriting agreement between us and the underwriters, we have agreed to sell to the underwriters, and each of the underwriters has agreed, severally and not jointly, to purchase from us, the number of shares set forth opposite its name below.

| | Number |
|----------------------------------|-----------|
| Underwriter | of Shares |
| Piper Jaffray & Co. | |
| Leerink Partners LLC | |
| Raymond James & Associates, Inc. | |
| Mizuho Securities USA Inc. | |
| | |
| Total | 3,125,000 |

Subject to the terms and conditions set forth in the underwriting agreement, the underwriters have agreed, severally and not jointly, to purchase all of the shares sold under the underwriting agreement if any of these shares are purchased. If an underwriter defaults, the underwriting agreement provides that the purchase commitments of the nondefaulting underwriters may be increased or the underwriting agreement may be terminated.

The underwriters have reserved for sale at the initial public offering price up to 156,250 shares of common stock, or approximately 5% of the shares of being offered by this prospectus, for sale to some of our board members, officers, employees and other parties associated with us in a directed share program. The number of shares of common stock available for sale to the general public in the offering will be reduced to the extent these persons purchase the reserved shares. Any reserved shares of common stock not so purchased will be offered by the underwriters to the general public on the same terms as the other shares.

We have agreed to indemnify the underwriters against certain liabilities, including liabilities under the Securities Act, relating to losses or claims resulting from material misstatements in or omissions from this prospectus, the registration statement of which this prospectus is a part, certain free writing prospectuses that may be used in the offering and in any marketing materials used in connection with this offering and to contribute to payments the underwriters may be required to make in respect of those liabilities.

The underwriters are offering the shares, subject to prior sale, when, as and if issued to and accepted by them, subject to approval of legal matters by their counsel, including the validity of the shares, and other conditions contained in the underwriting agreement, such as the receipt by the underwriters of officer s certificates and legal opinions. The underwriters reserve the right to withdraw, cancel or modify offers to the public and to reject orders in whole or in part.

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.

Index to Financial Statements

Commissions and Discounts

The representatives have advised us that the underwriters propose initially to offer the shares to the public at the public offering price set forth on the cover page of this prospectus and to dealers at that price less a concession not in excess of \$ per share. After the initial offering, the public offering price, concession or any other term of the offering may be changed.

The following table shows the public offering price, underwriting discount and proceeds before expenses to us. The information assumes either no exercise or full exercise by the underwriters of their overallotment option.

| | | Without | | |
|---------------------------------|-----------|---------|-------------|--|
| | Per Share | Option | With Option | |
| Public offering price | \$ | \$ | \$ | |
| Underwriting discount | \$ | \$ | \$ | |
| Proceeds to us, before expenses | \$ | \$ | \$ | |

The underwriting agreement provides that the obligations of the several underwriters to pay for and accept delivery of the shares offered by this prospectus are subject to the approval of certain legal matters by their counsel and to certain other conditions. The underwriters are obligated to take and pay for all of the shares offered by this prospectus if any such shares are taken. However, the underwriters are not required to take or pay for the shares covered by the underwriters over-allotment option described below. If an underwriter defaults, the underwriting agreement provides that the purchase commitments of the non-defaulting underwriters may be increased.

The underwriters initially propose to offer part of the shares directly to the public at the offering price listed on the cover page of this prospectus and part to certain dealers. After the initial offering of the shares, the offering price and other selling terms may from time to time be varied by the representative.

We have granted an option to the underwriters, exercisable for 30 days after the date of this prospectus, to purchase up to additional shares at the public offering price listed on the cover page of this prospectus, less the underwriting discounts and commissions. The underwriters may exercise this option solely to cover any overallotments, if any, made in connection with the offering of the shares offered by this prospectus. If the underwriters exercise this option, each will be obligated, subject to conditions contained in the underwriting agreement, to purchase a number of additional shares proportionate to that underwriter s initial amount reflected in the above table.

The estimated offering expenses payable by us, exclusive of the underwriting discount and commissions, are approximately \$3,000,000, which includes legal, accounting and printing costs and various other fees associated with the registration and listing of our shares. We have also agreed to reimburse the underwriters for certain expenses in an amount up to \$40,000.

The underwriters have informed us that they do not intend sales to discretionary accounts to exceed 5% of the total number of shares of common stock offered by them.

We have applied to list our shares on The NASDAQ Global Market, or NASDAQ, under the symbol CDNA.

No Sales of Similar Securities

We, members of our management board, members of our supervisory board and the holders of substantially all of our shares and other outstanding equity securities have agreed not to sell or transfer any shares or securities convertible into, exercisable or exchangeable for, or that represent the right to receive shares, for 180 days after the date of this prospectus without first obtaining the written consent

Index to Financial Statements

of Piper Jaffray and Leerink Partners. Specifically, we and these other persons have agreed, with certain limited exceptions, not to directly or indirectly:

offer, pledge, announce the intention to sell, sell or contract to sell any shares,

sell any option or contract to purchase any shares,

purchase any option or contract to sell any shares,

grant any option, right or warrant to purchase any shares,

make any short sale or otherwise transfer or dispose of any shares or transfer any shares,

request or demand that we file a registration statement related to the shares,

enter into any swap or other agreement that transfers, in whole or in part, the economic consequence of ownership of any shares whether any such swap or transaction is to be settled by delivery of shares or other securities, in cash or otherwise, or

publicly disclose the intention to do any of the foregoing.

This lock-up provision applies to shares and to securities convertible into, exercisable or exchangeable for or that represent the right to receive shares. It also applies to shares owned now or acquired later by the person executing the agreement or for which the person executing the agreement later acquires the power of disposition.

Listing

We have applied to list our shares on NASDAQ under the symbol CDNA. In order to meet the requirements for listing on that exchange, the underwriters have undertaken to sell a minimum number of shares to a minimum number of beneficial owners as required by that exchange.

Determination of Offering Price

Before this offering, there has been no public market for our shares. The initial public offering price will be determined through negotiations between us and the representatives. In addition to prevailing market conditions, the factors to be considered in determining the initial public offering price are:

the valuation multiples of publicly traded companies in the U.S. that the underwriters believe to be comparable to us,

our financial information,

Edgar Filing: CareDx, Inc. - Form S-1/A

the history of, and the prospects for, our company and the industry in which we compete,

an assessment of our management, its past and present operations, and the prospects for, and timing of, our future revenues,

the present state of our development, and

the above factors in relation to market values and various valuation measures of other companies engaged in activities similar to ours.

An active trading market for our shares listed on NASDAQ may not develop. It is also possible that after the offering the shares will not trade in the public market at or above the initial public offering price.

The underwriters do not expect to sell more than 5% of the shares in the aggregate to accounts over which they exercise discretionary authority.

Index to Financial Statements

Price Stabilization, Short Positions and Penalty Bids

Until the distribution of the shares is completed, SEC rules may limit underwriters and selling group members from bidding for and purchasing our shares. However, the underwriters may engage in transactions that stabilize the price of the shares, such as bids or purchases to peg, fix or maintain that price.

In connection with the offering, the underwriters may purchase and sell our shares in the open market. These transactions may include short sales, purchases on the open market to cover positions created by short sales and stabilizing transactions. Short sales involve the sale by the underwriters of a greater number of shares than they are required to purchase in the offering. Covered short sales are sales made in an amount not greater than the underwriters overallotment option described above. The underwriters may close out any covered short position by either exercising their overallotment option or purchasing shares in the open market. In determining the source of shares to close out the covered short position, the underwriters will consider, among other things, the price of shares available for purchase in the open market as compared to the price at which they may purchase shares through the overallotment option. Naked short sales are sales in excess of the overallotment option. The underwriters must close out any naked short position by purchasing shares in the open market. A naked short position is more likely to be created if the underwriters are concerned that there may be downward pressure on the price of our shares in the open market after pricing that could adversely affect investors who purchase in the offering. Stabilizing transactions consist of various bids for or purchases of shares made by the underwriters in the open market prior to the completion of the offering.

The underwriters may also impose a penalty bid. This occurs when a particular underwriter repays to the underwriters a portion of the underwriting discount received by it because the representatives have repurchased shares sold by or for the account of such underwriter in stabilizing or short covering transactions.

Similar to other purchase transactions, the underwriters purchases to cover the syndicate short sales may have the effect of raising or maintaining the market price of our shares or preventing or retarding a decline in the market price of our shares. As a result, the price of our shares may be higher than the price that might otherwise exist in the open market. The underwriters may conduct these transactions on NASDAQ, in the over-the-counter market or otherwise.

Neither we nor any of the underwriters make any representation or prediction as to the direction or magnitude of any effect that the transactions described above may have on the price of our shares. In addition, neither we nor any of the underwriters make any representation that the representatives will engage in these transactions or that these transactions, once commenced, will not be discontinued without notice.

Electronic Distribution

In connection with this offering, certain of the underwriters or securities dealers may distribute prospectuses by electronic means, such as email.

Other Relationships

The underwriters are full service financial institutions engaged in various activities, which may include securities trading, commercial and investment banking, financial advisory, investment management, principal investment, hedging, financing and brokerage activities. Some of the underwriters and their affiliates have engaged in, and may in the future engage in, investment banking and other commercial dealings in the ordinary course of business with us or our affiliates. They have received, or may in the future receive, customary fees and commissions for these transactions.

Index to Financial Statements

In the ordinary course of their business activities, the underwriters and their affiliates may make or hold a broad array of investments and actively trade debt and equity securities (or related derivative securities) and financial instruments (including bank loans) for their own account and for the accounts of their customers. Such investments and securities activities may involve securities and/or instruments of ours or our affiliates. The underwriters and their affiliates may also make investment recommendations and/or publish or express independent research views in respect of such securities or financial instruments and may hold, or recommend to clients that they acquire, long and/or short positions in such securities and instruments.

Selling Restrictions

Other than in the U.S., no action has been taken by us or the underwriters that would permit a public offering of the securities offered by this prospectus in any jurisdiction where action for that purpose is required. The securities offered by this prospectus may not be offered or sold, directly or indirectly, nor may this prospectus or any other offering material or advertisements in connection with the offer and sale of any such securities be distributed or published in any jurisdiction, except under circumstances that will result in compliance with the applicable rules and regulations of that jurisdiction. Persons into whose possession this prospectus comes are advised to inform themselves about and to observe any restrictions relating to the offering and the distribution of this prospectus. This prospectus does not constitute an offer to sell or a solicitation of an offer to buy any securities offered by this prospectus in any jurisdiction in which such an offer or a solicitation is unlawful.

United Kingdom

This document is only being distributed to and is only directed at (1) persons who are outside the United Kingdom or (2) to investment professionals falling within Article 19(5) of the Financial Services and Markets Act 2000 (Financial Promotion) Order 2005, or the Order, or (3) high net worth entities, and other persons to whom it may lawfully be communicated, falling with Article 49(2)(a) to (d) of the Order (all such persons together being referred to as relevant persons). The securities are only available to, and any invitation, offer or agreement to subscribe, purchase or otherwise acquire such securities will be engaged in only with, relevant persons. Any person who is not a relevant person should not act or rely on this document or any of its contents.

European Economic Area

In relation to each Relevant Member State (Norway and Lichtenstein in addition to the member states of the European Union), from and including the date on which this prospectus was implemented in that Relevant Member State, or the Relevant Implementation Date, an offer of securities described in this prospectus may not be made to the public in that Relevant Member State prior to the publication of a prospectus in relation to the shares which has been approved by the competent authority in that Relevant Member State or, where appropriate, approved in another Relevant Member State and notified to the competent authority in that Relevant Member State, all in accordance with Directive 2003/71/EC as amended by Directive 2010/73/EC, or the E.U. Prospectus Directive, except that, with effect from and including the Relevant Implementation Date, an offer of securities described in this prospectus may be made to the public in that Relevant Member State at any time:

to any legal entity which is a qualified investor as defined under the E.U. Prospectus Directive;

to fewer than 100 or, if the Relevant Member State has implemented the relevant provision of the 2010 PD Amending Directive, 150 natural or legal persons (other than qualified investors as defined in the E.U. Prospectus Directive); or

in any other circumstances falling within Article 3(2) of the E.U. Prospectus Directive, provided that no such offer of securities described in this prospectus shall result in a

Index to Financial Statements

requirement for the publication by us of a prospectus pursuant to Article 3 of the E.U. Prospectus Directive. For the purposes of this provision, the expression an offer of securities to the public in relation to any securities in any Relevant Member State means the communication in any form and by any means of sufficient information on the terms of the offer and the securities to be offered so as to enable an investor to decide to purchase or subscribe for the securities, as the same may be varied in that Member State by any measure implementing the E.U. Prospectus Directive in that Member State. The expression E.U. Prospectus Directive means Directive 2003/71/EC (and any amendments thereto, including the 2010 PD Amending Directive, to the extent implemented in the Relevant Member State) and includes any relevant implementing measure in each Relevant Member State, and the expression 2010 PD Amending Directive means Directive 2001/73/E.U.

Where a claim relating to the information contained in this prospectus is brought before a court in a member state of the E.E.A. or a Relevant Member State, the claimant might, under the national legislation of that Relevant Member State, have to bear the costs of translating this prospectus or any document incorporated by reference herein before the legal proceedings are initiated. Civil liability in relation to this summary attaches to us, but only if this summary is misleading, inaccurate or inconsistent when read together with the other parts of this prospectus (including information incorporated by reference herein).

Canada

The common shares may be sold only to purchasers purchasing as principal that are both accredited investors as defined in National Instrument 45-106 Prospectus and Registration Exemptions and permitted clients as defined in National Instrument 31-103 Registration Requirements, Exemptions and Ongoing Registrant Obligations. Any resale of the common shares must be made in accordance with an exemption from the prospectus requirements and in compliance with the registration requirements of applicable securities laws.

Hong Kong

The shares may not be offered or sold by means of any document other than (1) in circumstances which do not constitute an offer to the public within the meaning of the Companies Ordinance (Cap. 32, Laws of Hong Kong), or (2) to professional investors within the meaning of the Securities and Futures Ordinance (Cap. 571, Laws of Hong Kong) and any rules made thereunder, or (3) in other circumstances which do not result in the document being a prospectus within the meaning of the Companies Ordinance (Cap. 32, Laws of Hong Kong) and no advertisement, invitation or document relating to the shares may be issued or may be in the possession of any person for the purpose of the issue (in each case whether in Hong Kong or elsewhere), which is directed at, or the contents of which are likely to be accessed or read by, the public in Hong Kong (except if permitted to do so under the laws of Hong Kong) other than with respect to shares which are or are intended to be disposed of only to persons outside Hong Kong or only to professional investors within the meaning of the Securities and Futures Ordinance (Cap. 571, Laws of Hong Kong) or any rules made thereunder.

Singapore

This prospectus has not been registered as a prospectus with the Monetary Authority of Singapore. Accordingly, this prospectus and any other document or material in connection with the offer or sale, or invitation for subscription or purchase, of the shares may not be circulated or distributed, nor may the shares be offered or sold, or be made the subject of an invitation for subscription or purchase, whether directly or indirectly, to persons in Singapore other than (1) to an institutional investor under Section 274 of the Securities and Futures Act, Chapter 289 of Singapore (the SFA), (2) to a relevant person pursuant to Section 275(1), or any person pursuant to Section 275(1A), and in accordance with

Index to Financial Statements

the conditions specified in Section 275 of the SFA or (3) otherwise pursuant to, and in accordance with the conditions of, any other applicable provision of the SFA, in each case subject to compliance with conditions set forth in the SFA.

Where the shares are subscribed or purchased under Section 275 of the SFA by a relevant person which is:

a) a corporation (which is not an accredited investor (as defined in Section 4A of the SFA)) the sole business of which is to hold investments and the entire share capital of which is owned by one or more individuals, each of whom is an accredited investor; or

b) a trust (where the trustee is not an accredited investor) whose sole purpose is to hold investments and each beneficiary of the trust is an individual who is an accredited investor,

shares, debentures and units of shares and debentures of that corporation or the beneficiaries rights and interest (howsoever described) in that trust shall not be transferred within six months after that corporation or that trust has acquired the shares pursuant to an offer made under Section 275 of the SFA except:

a) to an institutional investor (for corporations, under Section 274 of the SFA) or to a relevant person defined in Section 275(2) of the SFA, or to any person pursuant to an offer that is made on terms that such shares, debentures and units of shares and debentures of that corporation or such rights and interest in that trust are acquired at a consideration of not less than \$200,000 (or its equivalent in a foreign currency) for each transaction, whether such amount is to be paid for in cash or by exchange of securities or other assets, and further for corporations, in accordance with the conditions specified in Section 275 of the SFA;

b) where no consideration is or will be given for the transfer; or

c) where the transfer is by operation of law.

Switzerland

The shares may not be publicly offered in Switzerland and will not be listed on the SIX Swiss Exchange (the SIX) or on any other stock exchange or regulated trading facility in Switzerland. This document has been prepared without regard to the disclosure standards for issuance prospectuses under art. 652a or art. 1156 of the Swiss Code of Obligations or the disclosure standards for listing prospectuses under art. 27 ff. of the SIX Listing Rules or the listing rules of any other stock exchange or regulated trading facility in Switzerland. Neither this document nor any other offering or marketing material relating to the shares or the offering may be publicly distributed or otherwise made publicly available in Switzerland.

Neither this document nor any other offering or marketing material relating to the offering, or the shares have been or will be filed with or approved by any Swiss regulatory authority. In particular, this document will not be filed with, and the offer of shares will not be supervised by, the Swiss Financial Market Supervisory Authority FINMA, and the offer of shares has not been and will not be authorized under the Swiss Federal Act on Collective Investment Schemes (CISA). Accordingly, no public distribution, offering or advertising, as defined in CISA, its implementing ordinances and notices, and no distribution to any non-qualified investor, as defined in CISA, its implementing ordinances and notices, shall be undertaken in or from Switzerland, and the investor protection afforded to acquirers of interests in collective investment schemes under CISA does not extend to acquirers of shares.

United Arab Emirates

This offering has not been approved or licensed by the Central Bank of the United Arab Emirates (the UAE), Securities and Commodities Authority of the UAE and/or any other relevant licensing authority in the UAE including any licensing authority incorporated under the laws and regulations of any of the free zones established and operating in the territory of the UAE, in particular the Dubai Financial

Index to Financial Statements

Services Authority (DFSA), a regulatory authority of the Dubai International Financial Centre (DIFC). The offering does not constitute a public offer of securities in the UAE, DIFC and/or any other free zone in accordance with the Commercial Companies Law, Federal Law No 8 of 1984 (as amended), DFSA Offered Securities Rules and NASDAQ Dubai Listing Rules, accordingly, or otherwise. The shares may not be offered to the public in the UAE and/or any of the free zones.

The shares may be offered and issued only to a limited number of investors in the UAE or any of its free zones who qualify as sophisticated investors under the relevant laws and regulations of the UAE or the free zone concerned.

France

This prospectus (including any amendment, supplement or replacement thereto) is not being distributed in the context of a public offering in France within the meaning of Article L. 411-1 of the French Monetary and Financial Code (Code monétaire et financier).

This prospectus has not been and will not be submitted to the French Autorité des marchés financiers (the AMF) for approval in France and accordingly may not and will not be distributed to the public in France.

Pursuant to Article 211-3 of the AMF General Regulation, French residents are hereby informed that:

1. the transaction does not require a prospectus to be submitted for approval to the AMF;

2. persons or entities referred to in Point 2°, Section II of Article L.411-2 of the Monetary and Financial Code may take part in the transaction solely for their own account, as provided in Articles D. 411-1, D. 734-1, D. 744-1, D. 754-1 and D. 764-1 of the Monetary and Financial Code; and

3. the financial instruments thus acquired cannot be distributed directly or indirectly to the public otherwise than in accordance with Articles L. 411-1, L. 411-2, L. 412-1 and L. 621-8 to L. 621-8-3 of the Monetary and Financial Code.

This prospectus is not to be further distributed or reproduced (in whole or in part) in France by the recipients of this prospectus. This prospectus has been distributed on the understanding that such recipients will only participate in the issue or sale of our shares for their own account and undertake not to transfer, directly or indirectly, our shares to the public in France, other than in compliance with all applicable laws and regulations and in particular with Articles L. 411-1 and L. 411-2 of the French Monetary and Financial Code.

Index to Financial Statements

LEGAL MATTERS

The validity of the shares of common stock offered hereby will be passed upon for us by Wilson Sonsini Goodrich & Rosati, Professional Corporation, Palo Alto, California. Gibson Dunn & Crutcher LLP, New York, New York, is acting as counsel to the underwriters. Certain members of, and investment partnerships comprised of members of, and persons associated with, Wilson Sonsini Goodrich & Rosati, Professional Corporation, own an aggregate of 34,669 shares of our common stock as of March 31, 2014.

EXPERTS

The financial statements of CareDx, Inc. at December 31, 2012 and 2013, and for the years then ended, appearing in this Prospectus and Registration Statement have been audited by Ernst & Young LLP, independent registered public accounting firm, as set forth in their report thereon appearing elsewhere herein, and are included in reliance upon such report given on the authority of such firm as experts in accounting and auditing.

The financial statements of ImmuMetrix, Inc. at December 31, 2012 and 2013, and for the years then ended, appearing in this Prospectus and Registration Statement have been audited by Frank, Rimerman & Co. LLP, independent registered public accounting firm, as set forth in their report thereon appearing elsewhere herein, and are included in reliance upon such report given on the authority of such firm as experts in accounting and auditing.

ADDITIONAL INFORMATION

We have filed with the SEC a registration statement on Form S-1 under the Securities Act with respect to the shares of common stock offered by this prospectus. This prospectus, which constitutes a part of the registration statement, does not contain all of the information set forth in the registration statement, some of which is contained in exhibits to the registration statement as permitted by the rules and regulations of the SEC. For further information with respect to us and our common stock, we refer you to the registration statement, including the exhibits filed as a part of the registration statement. Statements contained in this prospectus concerning the contents of any contract or any other document are not necessarily complete. If a contract or document has been filed as an exhibit to the registration statement, please see the copy of the contract or document that has been filed. Each statement is this prospectus relating to a contract or document filed as an exhibit is qualified in all respects by the filed exhibit. You may obtain copies of this information by mail from the Public Reference Section of the SEC, 100 F Street, N.E., Room 1580, Washington, D.C. 20549, at prescribed rates. You may obtain information on the operation of the public reference rooms by calling the SEC at 1-800-SEC-0330. The SEC also maintains an Internet website that contains reports, proxy statements, and other information about issuers, like us, that file electronically with the SEC. The address of that website is www.sec.gov.

As a result of this offering, we will become subject to the information and reporting requirements of the Exchange Act and, in accordance with this law, will file periodic reports, proxy statements, and other information with the SEC. These periodic reports, proxy statements, and other information will be available for inspection and copying at the SEC s public reference facilities and the website of the SEC referred to above. We also maintain a website at xdx.com. Upon completion of this offering, you may access these materials free of charge as soon as reasonably practicable after they are electronically filed with, or furnished to, the SEC. Information contained on or that can be accessed through our website is not a part of this prospectus and the inclusion of our website address in this prospectus is an inactive textual reference only.

Index to Financial Statements

CareDx, Inc.

Index to Financial Statements

| Report of Independent Registered Public Accounting Firm | F-2 |
|--|-----|
| Financial Statements | |
| Balance Sheets | F-3 |
| Statements of Operations | F-4 |
| Statements of Convertible Preferred Stock and Stockholders Deficit | F-5 |
| Statements of Cash Flows | F-6 |
| Notes to Financial Statements | F-7 |

F-1

Index to Financial Statements

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

The Board of Directors and Stockholders

CareDx, Inc.

We have audited the accompanying balance sheets of CareDx, Inc. (the Company) as of December 31, 2012 and 2013, and the related statements of operations, convertible preferred stock and stockholders deficit, and cash flows for the years then ended. These financial statements are the responsibility of the Company s management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. We were not engaged to perform an audit of the Company s internal control over financial reporting. Our audits included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company s internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of CareDx, Inc. at December 31, 2012 and 2013, and the results of its operations and its cash flows for the years then ended in conformity with U.S. generally accepted accounting principles.

/s/ Ernst & Young LLP

Redwood City, California

March 31, 2014, except for the last paragraph of Note 1, as to which the date is July 14, 2014.

Index to Financial Statements

CareDx, Inc.

Balance Sheets

(In thousands, except share and per share data)

| | December 31, | | | Pro Forma Stockholders Deficit as of | |
|--|--------------|---------|----|--|-------------------------------------|
| | | 2012 | | 2013 | December 31, 2013 (Unaudited) |
| Assets | | | | | (Chaddhed) |
| Current assets: | | | | | |
| Cash and cash equivalents | \$ | 5,830 | \$ | 5,128 | |
| Accounts receivable | | 952 | | 2,270 | |
| Inventory | | 576 | | 518 | |
| Prepaid and other assets | | 248 | | 255 | |
| Total current assets | | 7,606 | | 8,171 | |
| Property and equipment, net | | 2,118 | | 1,553 | |
| Restricted cash | | 149 | | 147 | |
| Other noncurrent assets | | 3 | | 2 | |
| Total assets | \$ | 9,876 | \$ | 9,873 | |
| Liabilities, convertible preferred stock, and stockholders deficit Current liabilities: | | | | | |
| Accounts payable | \$ | 637 | \$ | 618 | |
| Accrued payroll liabilities | Ŷ | 978 | Ŷ | 1,386 | |
| Accrued royalties | | 1,545 | | -, | |
| Deferred revenue | | 813 | | 80 | |
| Current portion of long-term debt | | 1,455 | | 4,461 | |
| Accrued and other liabilities | | 1,009 | | 1,048 | |
| Total current liabilities | | 6,437 | | 7,593 | |
| Accrued royalties | | | | 2,804 | |
| Deferred rent, net of current portion | | 2,030 | | 1,885 | |
| Deferred revenue, net of current portion | | | | 1,623 | |
| Long-term debt, net of current portion | | 13,410 | | 10,914 | |
| Convertible preferred stock warrant liability | | | | 525 | \$ |
| Total liabilities | | 21,877 | | 25,344 | |
| Commitments and contingencies (Note 8) | | | | | |
| Convertible preferred stock: \$0.001 par value; 6,417,954 shares authorized at | | | | | |
| December 31, 2012 and 2013; 5,155,673 shares issued and outstanding at | | | | | |
| December 31, 2012 and 2013; no shares issued or outstanding, pro forma. | | | | | |
| Liquidation value of \$137,221 at December 31, 2012 and 2013 | | 135,202 | | 135,202 | |
| Stockholders deficit: | | | | | |
| Common stock: \$0.001 par value; 7,737,226 shares authorized at December 31, | | | | | |
| 2012 and 2013; 1,010,499 and 1,010,711 shares issued and outstanding at | | | | | |
| December 31, 2012 and 2013, respectively, and 6,170,796 shares issued and | | | | | _ |
| outstanding, pro forma | | 1 | | 1 | 7 |

Index to Financial Statements

| Additional paid-in capital | 9,410 | 9,482 | 145,203 |
|---|-----------|-----------|-------------|
| Accumulated deficit | (156,614) | (160,156) | (160,156) |
| Total stockholders deficit | (147,203) | (150,673) | \$ (14,946) |
| Total liabilities, convertible preferred stock and stockholders deficit | \$ 9,876 | \$ 9,873 | |

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

Index to Financial Statements

CareDx, Inc.

Statements of Operations

(In thousands, except share and per share data)

| | | Year Ended | December | 31, 2013 |
|---|----|------------|----------|-------------|
| Revenue: | | | | |
| Testing revenue | \$ | 19,730 | \$ | 21,672 |
| Collaboration and license revenue | | 721 | | 426 |
| Total revenue | | 20,451 | | 22,098 |
| Operating expenses: | | | | |
| Cost of testing | | 7,930 | | 9,078 |
| Research and development | | 4,752 | | 3,176 |
| Sales and marketing | | 5,417 | | 5,892 |
| General and administrative | | 4,694 | | 4,809 |
| Total operating expenses | | 22,793 | | 22,955 |
| Loss from operations | | (2,342) | | (857) |
| Interest expense, net | | (2,703) | | (2,149) |
| Other expense, net | | (14) | | (536) |
| Net loss | \$ | (5,059) | \$ | (3,542) |
| Net loss per common share, basic and diluted | \$ | (5.01) | \$ | (3.50) |
| Shares used to compute net loss per common share, basic and diluted | 1 | ,009,236 | 1 | ,010,795 |
| Pro forma net loss per common share, basic and diluted (unaudited) | | | \$ | (0.41) |
| Shares used to compute pro forma net loss per common share, basic and diluted (unaudited) | | | 7 | ,371,515 |

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

Index to Financial Statements

CareDx, Inc.

Statements of Convertible Preferred Stock and Stockholders Deficit

(In thousands, except share data)

| | Convertible Preferred Stock | | Common | Common Stock | | Additional Paid-In Accumulated | | cumulated | Sto | Total ockholders | |
|---|--------------------------------|------------|-----------|--------------|------|-----------------------------------|--------|-----------|-----------|---------------------|-----------|
| | Shares | Amount | Shares | Amo | ount | С | apital | | Deficit | | Deficit |
| Balance at December 31, 2011 | 4,447,657 | \$ 119,837 | 1,007,575 | \$ | 1 | \$ | 9,331 | \$ | (151,555) | \$ | (142,223) |
| Issuance of Series G convertible preferred stock in April | | | | | | | | | | | |
| 2012 for cash, net of issuance costs (Note 9) | 137,722 | 2,941 | | | | | | | | | |
| Conversion of notes payable and interest in April 2012 to | | | | | | | | | | | |
| Series G convertible preferred stock, net of conversion | | | | | | | | | | | |
| costs (Note 10) | 570,294 | 12,424 | | | | | | | | | |
| Issuance of common stock for cash upon exercise of stock | | | | | | | | | | | |
| options | | | 2,924 | | | | 10 | | | | 10 |
| Employee share-based compensation expense | | | | | | | 69 | | | | 69 |
| Net loss | | | | | | | | | (5,059) | | (5,059) |
| | | | | | | | | | | | |
| Balance at December 31, 2012 | 5,155,673 | 135,202 | 1,010,499 | | 1 | | 9,410 | | (156,614) | | (147,203) |
| Issuance of common stock for cash upon exercise of stock | -,, | | ,- , | | | | - / - | | | | |
| options | | | 212 | | | | | | | | |
| Employee share-based compensation expense | | | | | | | 72 | | | | 72 |
| Net loss | | | | | | | | | (3,542) | | (3,542) |
| | | | | | | | | | × / | | |
| Balance at December 31, 2013 | 5,155,673 | \$ 135,202 | 1,010,711 | \$ | 1 | \$ | 9,482 | \$ | (160,156) | \$ | (150,673) |
| | | | | | | | | | | | |

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

Index to Financial Statements

CareDx, Inc.

Statements of Cash Flows

(In thousands)

| | Year Ended D 2012 | December 31, 2013 |
|--|----------------------|----------------------|
| Operating activities | | |
| Net loss | \$ (5,059) | \$ (3,542) |
| Adjustments to reconcile net loss to net cash used in operating activities: | | |
| Depreciation and amortization | 1,072 | 663 |
| Stock-based compensation | 69 | 72 |
| Amortization of deferred revenue | (187) | (193) |
| Amortization of debt discount and noncash interest expense | 634 | 553 |
| Revaluation of warrants to estimated fair value | (2) | 525 |
| Changes in operating assets and liabilities: | | |
| Accounts receivable | (150) | (1,318) |
| Inventory | (152) | 58 |
| Prepaid and other assets | 146 | (4) |
| Accounts payable | (113) | (19) |
| Accrued payroll liabilities | (76) | 408 |
| Accrued royalties | 843 | 1,259 |
| Deferred revenue | 1,000 | 1,083 |
| Accrued and other liabilities | 199 | (91) |
| Net cash used in operating activities | (1,776) | (546) |
| Investing activities | (-,) | (2.10) |
| Purchase of investments | (1,623) | |
| Sales of investments | 383 | |
| Maturities of investments | 2,023 | |
| Purchase of property and equipment | (141) | (98) |
| Net cash provided by (used in) investing activities | 642 | (98) |
| Financing activities | 0.12 | (20) |
| Proceeds from issuance of convertible preferred stock, net of issuance costs | 2,941 | |
| Proceeds from debt, net of issuance costs | 14,650 | |
| Net proceeds from exercise of stock options | 10 | |
| Principal payments on debt | (12,994) | (58) |
| Net cash provided by (used in) financing activities | 4,607 | (58) |
| Net increase (decrease) in cash and cash equivalents | 3,473 | (702) |
| Cash and cash equivalents at beginning of year | 2,357 | 5,830 |
| Cash and cash equivalents at end of year | \$ 5,830 | \$ 5,128 |
| Supplemental disclosures of cash flow information | | |
| Cash paid for interest | \$ 1,966 | \$ 1,506 |
| Supplemental disclosures of noncash investing and financing activities | * 12 | <i>ф</i> |
| Property and equipment purchased under capital leases | \$ 43 | \$ |

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

Index to Financial Statements

CareDx, Inc.

Notes to Financial Statements

1. ORGANIZATION AND DESCRIPTION OF BUSINESS

CareDx, Inc., (the Company or CareDx) was incorporated in the state of Delaware on December 21, 1998, as Hippocratic Engineering, Inc. In April 1999, the Company changed its name to BioCardia, Inc., in June 2002, the Company changed its name to Expression Diagnostics, Inc., in July 2007, the Company changed its name to XDx, Inc. and in March 2014, the Company changed its name to CareDx, Inc. CareDx is 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 transplant patient s lifetime. The Company s commercialized testing solution, the AlloMap heart transplant molecular test (AlloMap), an FDA-cleared test, is a blood-based test used to monitor for acute cellular rejection in heart transplant recipients.

Need for Additional Capital

During the year ended December 31, 2013, the Company incurred a net loss of \$3,542,000 and used \$546,000 of cash in operations. At December 31, 2013, the Company had an accumulated deficit of \$160,156,000. The Company has debt of \$15,375,000 at December 31, 2013, and amounts due under its debt arrangements of \$5,965,000 in 2014. Management believes that cash and cash equivalents at December 31, 2013, together with cash receipts from AlloMap testing revenue, will be sufficient to enable the Company to fund its operations for at least the next 12 months, but not sufficient to accelerate its pipeline development as described below.

The Company s strategy is to accelerate the development of new transplant surveillance solutions and to expand its infrastructure to operate as a public company. Until the Company can generate a sufficient amount of revenue, if ever, it expects to finance future cash needs through private or public equity, such as the proposed initial public offering described below, or debt offerings. Additional capital may not be available on reasonable terms, if at all. If the Company is unable to raise additional capital in sufficient amounts or on terms acceptable to it, the Company will not be able to implement its accelerated development strategy and may have to significantly delay, scale back or discontinue its new test development. If the Company raises additional funds through the issuance of additional debt or equity securities, it could result in dilution to existing stockholders, increased fixed payment obligations and these securities may have rights senior to those of the Company s common stock. These events could significantly harm the Company s business, financial condition and prospects.

Reverse Stock Split

On July 1, 2014, the Company s Board of Directors approved filing an amendment to our Certificate of Incorporation to reflect a 1 for 6.85 reverse stock split (the Reverse Stock Split) of the Company s outstanding common stock and convertible preferred stock. The par value per share was not adjusted as a result of the Reverse Stock Split. All authorized, issued and outstanding shares of common stock, convertible preferred stock, options and warrants to purchase common or preferred stock and related per share amounts contained in the financial statements have been retroactively adjusted to reflect this Reverse Stock Split for all periods presented. The Reverse Stock Split was effected on July 14, 2014.

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES Basis of Presentation

The accompanying financial statements have been prepared in accordance with accounting principles generally accepted in the United States (U.S. GAAP).

Index to Financial Statements

Use of Estimates

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. Significant 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.

Unaudited Pro Forma Financial Information

On March 20, 2014, the Company s board of directors authorized the management of the Company to file a registration statement with the Securities and Exchange Commission (SEC) for the Company to sell shares of its common stock to the public. On March 31, 2014, the Company filed such a registration statement with the SEC as an emerging growth company as defined in the Jumpstart Our Business Startups Act of 2012. The unaudited pro forma stockholders deficit at December 31, 2013, assumes the automatic conversion of all the outstanding convertible preferred stock into shares of common stock and the reclassification of the Company s outstanding warrants to purchase shares of preferred stock from a liability to stockholders deficit, occurring upon the closing of this proposed initial public offering.

Concentration of Credit Risk and Other Risks and Uncertainties

Financial instruments that potentially subject the Company to credit risk consist of cash and cash equivalents, short-term investments, and accounts receivable. The Company s policy is to invest its cash and cash equivalents and short-term investments in money market funds, obligations of U.S. government agencies and government-sponsored entities, commercial paper, and various bank deposit accounts. These financial instruments were held in Company accounts at two financial institutions. The counterparties to the agreements relating to the Company s investments consist of financial institutions of high credit standing. The Company is exposed to credit risk in the event of default by the financial institutions to the extent of amounts recorded on the balance sheets which may be in excess of insured limits.

The Company is also subject to credit risk from its accounts receivable which are derived from revenue earned from AlloMap tests provided for patients located in the U.S. and billed to various third-party payers. For the years ended December 31, 2012 and 2013, approximately 52% and 53%, respectively, of testing revenue was derived from Medicare. At December 31, 2012 and 2013, approximately 64% and 72%, respectively, of accounts receivable were from Medicare. No other payers represented more than 10% of testing revenue for these periods. One other payer represented 12% of accounts receivable at December 31, 2012. No other payers represented more than 10% of accounts receivable at December 31, 2013.

Fair Value of Financial Instruments

Fair value is defined as the price that would be received from selling an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. When determining fair value, the Company considers the principal or most advantageous market in which the Company would transact, and it takes into consideration the assumptions that market participants would use when pricing the asset or liability. The Company s assessment of the significance of a particular input to the fair value measurement of an asset or liability requires management to make judgments and to consider specific characteristics of that asset or liability.

Index to Financial Statements

The carrying amounts of certain of the Company s financial instruments, including cash equivalents, accounts receivable, accounts payable, and accrued liabilities, approximate fair value due to their short maturities. The carrying amount of the convertible preferred stock warrant liability also represents its fair value.

Cash Equivalents

The Company considers all highly liquid investments that are readily convertible into cash having maturities at the time of purchase of three months or less to be cash equivalents. Cash equivalents include money market funds, obligations of U.S. government agencies, and government-sponsored entities which are carried at fair value.

Inventory

Inventory is primarily finished goods which consist of AlloMap reagent plates and raw materials which consist of laboratory supplies and reagents. Inventories are used in connection with tests performed and may also be used for research and product development efforts. Laboratory supplies subsequently designated for research and product development use are expensed. Obsolete or damaged inventories are written off and excluded from the physical inventory. Inventories are stated at the lower of actual cost, which is determined on a first-in, first-out basis or net realizable value.

Property and Equipment

Property and equipment are stated at cost, less accumulated depreciation. Property and equipment are depreciated using the straight-line method over the estimated useful lives of the assets, generally three years for laboratory, computer, and office equipment, and generally seven years for furniture and fixtures. Leasehold improvements are amortized over the shorter of their estimated useful lives or the remaining lease term.

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

The Company capitalizes certain costs incurred for software developed or obtained for internal use. These costs include software licenses, consulting services, and direct materials, as well as employee payroll and payroll-related costs. Capitalized internal-use software costs are depreciated over three years.

Impairment of Long-Lived Assets

The Company evaluates its long-lived assets for indicators of possible impairment when events or changes in circumstances indicate the carrying amount of an asset may not be recoverable. The Company then compares the carrying amounts of the assets with the future net undiscounted cash flows expected to be generated by such asset. Should an impairment exist, the impairment loss would be measured based on the excess carrying value of the asset over the asset s fair value determined using discounted estimates of future cash flows. The Company has not identified any such impairment losses to date.

Restricted Cash

Under lease agreements for certain facilities and an agreement with the State of Florida Medicaid, the Company must maintain letters of credit, minimum collateral requirements, and a surety bond. These agreements are collateralized by cash. The cash which will continue long-term to support these arrangements is classified as restricted cash on the accompanying balance sheets.

Warrants

The Company has freestanding warrants enabling counterparties to purchase shares of its convertible preferred stock and common stock. In accordance with the accounting guidance regarding distinguishing liabilities from equity, freestanding warrants for convertible preferred stock that are contingently

Index to Financial Statements

redeemable are classified as 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 expense, net on the statements of operations. The Company adjusts 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 an initial public 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 Company accounts for its warrants for shares of common stock as equity in accordance with the accounting guidance distinguishing liabilities from equity.

Testing Revenue

The Company operates in one operating segment and derives substantially all its revenue from its AlloMap molecular expression test. The Company currently markets AlloMap to healthcare providers through its 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 the Company provides its testing services are generally not responsible for the payment of these services. The Company generally bills third-party payers upon delivery of an AlloMap score report to the ordering physician. As such, the Company takes the assignment of benefits and the risk of collection from the third-party payer and individual patients.

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. 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, the Company pursues reimbursement on a case-by-case basis. If a reimbursement claim is denied, the Company generally pursues the appeals process for the particular payer.

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

The first criteria is satisfied when a third-party payer makes a coverage decision or enters into a contractual arrangement with the Company for the test. The second criteria is satisfied when the Company performs the test and delivers 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. Such judgments include review of past payment history. AlloMap testing may be considered investigational by some payers and not covered under their reimbursement 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 the Company for tests performed, the Company recognizes revenue on the cash basis in the period in which the payment is received.

Revenue is recognized on the accrual basis net of adjustments for differences between amounts billed and the estimated receipts from payers. The amount the Company expects 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.

Index to Financial Statements

Revenue recognized on an accrual basis is recorded upon delivery of each score report, net of any contractual discount at the amount the Company expects to collect. The Company determines the amount it expects to collect based on a per payer, per contract or arrangement basis, after analyzing historical collection trends.

Occasionally, the Company may receive requests from third-party payers for refunds for previously paid-for tests. The Company maintains a liability for actual overpayments and estimated future refund claims based on historical experience. Accruals for such overpayments and refunds are recorded as a reduction of revenue. For the years ended December 31, 2012 and 2013, the Company paid \$89,000 and \$96,000, respectively, for overpayments and refunds.

Collaboration and License Revenue

The Company generates revenue from collaboration and license agreements. 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. The Company s performance obligations under the collaborations 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. The Company makes judgments that affect the periods over which it recognizes revenue. The Company periodically reviews its estimated periods of performance based on the progress under each arrangement and accounts for the impact of any change in estimated periods of performance on a prospective basis.

The Company recognizes 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. The Company evaluates its 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. The Company uses the following hierarchy in estimating selling price under the relative selling-price method:

(i) vendor-specific objective evidence of fair value of the deliverable, if it exists, (ii) third-party evidence of selling price, if vendor specific objective evidence is not available or (iii) vendor s best estimate of selling price if neither vendor-specific nor third-party evidence is available.

The Company recognizes contingent consideration received from the achievement of a substantive milestone in its entirety in the period in which the milestone is achieved, which the Company believes is more consistent with the substance of its performance under its various license and collaboration agreements. Under the milestone method, a milestone is defined as an event (i) that can only be achieved based in whole or in part on either the Company s performance or on the occurrence of a specific outcome resulting from the Company s performance, (ii) for which there is substantive uncertainty at the date the arrangement is entered into that the event will be achieved, and (iii) that would result in additional payments being due to the Company. A milestone is substantive if the consideration earned from the achievement of the milestone is consistent with the performance required to achieve the milestone or the increase in value to the collaboration resulting from the performance, relates solely to the Company s past performance, and is reasonable relative to all of the other deliverables and payments within the arrangement. The Company did not recognize any milestones during 2012 or 2013.

Cost of Testing

Cost of testing reflects the aggregate costs incurred in delivering the Company s AlloMap test results to clinicians. The components of cost of testing are materials and service costs, direct labor costs, including stock-based compensation, equipment and infrastructure expenses associated with testing samples,

Index to Financial Statements

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 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.

Research and Development Expenses

Research and development expenses represent costs incurred to develop new surveillance solutions as well as continued efforts related to the Company s AlloMap test. These expenses include payroll and related expenses, consulting expenses, laboratory supplies, and certain allocated expenses as well as amounts incurred under certain collaboration and license agreements. Research and development costs are expensed as incurred. The Company records accruals for estimated study costs comprised of work performed by contract research organizations under contract terms.

Stock-Based Compensation

The Company uses the Black-Scholes valuation model, which requires the use of estimates such as stock price volatility and expected option lives, to value employee stock options. The Company estimates the expected option lives using historical data, volatility using data of similar companies in the diagnostics industry, and risk-free rates based on the implied yield currently available in the U.S. Treasury zero-coupon issues with a remaining term equal to the expected option lives, and dividend yield based on the Company s historical data.

The Company uses the straight-line attribution method for recognizing compensation expense. Compensation expense is recognized on awards ultimately expected to vest and reduced for forfeitures that are estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. Forfeitures are estimated based on the Company s historical experience.

Equity instruments granted to nonemployees are valued using the Black-Scholes valuation model and are subject to periodic revaluation over their vesting terms. Nonemployee stock compensation is recognized upon vesting of the stock options which is commensurate with the period over which services are provided.

Income Taxes

The Company accounts for income taxes using the liability method whereby deferred tax asset and liability accounts are determined based on differences between financial reporting and tax bases of assets and liabilities and are measured using the enacted tax rates and laws that are expected to be in effect when the differences are expected to reverse. Valuation allowances are established to reduce deferred tax assets when management estimates, based on available objective evidence, that it is more likely than not that some portion or all of the deferred tax assets will not be realized in the future.

The Company evaluates tax positions for recognition using a more-likely-than-not recognition threshold, and those tax positions eligible for recognition are measured as the largest amount of tax benefit that is greater than 50% likely of being realized upon the effective settlement with a taxing authority that has full knowledge of all relevant information.

Net Loss Per Common Share and Unaudited Pro Forma Net Loss Per Common Share

Basic and diluted net loss per common share are calculated by dividing net loss for the period attributable to common stockholders by the weighted-average number of common shares outstanding during the period. Potentially dilutive securities consisting of convertible preferred stock and options and warrants to purchase stock are considered to be common stock equivalents and were excluded from the

Index to Financial Statements

calculation of diluted net loss per common share because their effect would be antidilutive for all periods presented. In contemplation of an initial public offering, the Company has presented the unaudited pro forma basic and diluted net loss per common share which has been computed to give effect to (i) the conversion of the convertible preferred stock into common stock, (ii) the conversion of Series G preferred stock into common stock issuable in connection with a subordinated convertible promissory note issued in April 2014, and (iii) the conversion of Series G preferred stock into common stock issued in connection with a business combination which is expected to close in June 2014.

Comprehensive Loss

Net loss and comprehensive loss are the same for all periods presented.

Recently Issued Accounting Pronouncements

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

3. NET LOSS PER COMMON SHARE AND UNAUDITED PRO FORMA NET LOSS PER COMMON SHARE

The following table presents the calculations of basic and diluted net loss per common share for the years ended December 31, 2012 and 2013 (in thousands, except share and per share amounts):

| | Year Ended De | cember 31, |
|---|---------------|------------|
| | 2012 | 2013 |
| Net loss | \$ (5,059) | \$ (3,542) |
| Shares used to compute net loss per common share, basic and diluted | 1,009,236 | 1,010,795 |
| Net loss per common share, basic and diluted | \$ (5.01) | \$ (3.50) |

The following outstanding common stock equivalents have been excluded from diluted net loss per common share for the years ended December 31, 2012 and 2013 because their inclusion would be antidilutive:

| | Year Ended D | ecember 31, |
|--|--------------|-------------|
| | 2012 | 2013 |
| Shares of common stock subject to outstanding options | 619,906 | 466,965 |
| Shares of common stock subject to outstanding warrants | 82,190 | 82,190 |
| Shares of common stock subject to conversion from preferred stock | 5,160,085 | 5,160,085 |
| Shares of common stock subject to conversion from preferred stock warrants | 541,613 | 541,613 |
| Total common stock equivalents | 6.403.794 | 6,250,853 |
| Total common stock equivalents | 0,+03,79+ | 0,250,855 |

Index to Financial Statements

The following table sets forth the computation of the Company s unaudited pro forma basic and diluted net loss per common share after giving effect to the conversion of convertible preferred stock. Also, the numerator in pro forma basic and diluted net loss per common share calculation has been adjusted to remove the loss resulting from remeasurement of the warrant liability as these amounts will be reclassified to additional paid-in capital upon a qualifying initial public offering of our common stock (in thousands, except share and per share amounts):

| | | ar Ended ecember 31, 2013 |
|--|----|------------------------------------|
| Net loss | \$ | (3,542) |
| Change in estimated fair value of convertible preferred stock warrant liability | | (525) |
| Net loss used in computing pro forma net loss per common share, basic and diluted | \$ | (3,017) |
| Shares used to compute net loss per common share, basic and diluted | 1 | ,010,795 |
| Pro forma adjustment to reflect assumed conversion of convertible preferred stock | 5 | ,160,085 |
| Pro forma adjustment to reflect assumed conversion of convertible preferred stock issuable in connection with the subordinated convertible promissory note | | 312,500 |
| Pro forma adjustment to reflect assumed conversion of convertible preferred stock issued in connection with the business combination | | 888,135 |
| Shares used to compute pro forma net loss per common share, basic and diluted | 7 | ,371,515 |
| Pro forma net loss per common share, basic and diluted | \$ | (0.41) |

The assumed conversion of Series G convertible preferred stock issuable in connection with the subordinated convertible promissory note was calculated based upon its \$5.0 million principal balance at a conversion price of \$21.78 per share, as provided for in this note. As there is no interest expense related to this note included in the historical net loss, no adjustment to historical net loss is required to compute pro forma net loss per common share, basic and diluted.

The assumed conversion of Series G convertible preferred stock issued in connection with a business combination represents the 888,135 shares of Series G convertible preferred stock (including 75,945 such shares in escrow) issued upon the close of the business combination on June 10, 2014. Shares to be issued upon the achievement of a future milestone are not included in this calculation due to the uncertainty of the Company achieving this performance metric.

4. FAIR VALUE MEASUREMENTS

The Company s financial instruments are measured and recorded at fair value except for its debt, which is recorded at amortized cost. The three levels of inputs that are used to measure fair value are classified into the following hierarchy:

Level 1 Unadjusted quoted prices in active markets for identical assets or liabilities.

Level 2 Unadjusted quoted prices in active markets for similar assets or liabilities, unadjusted quoted prices for identical or similar assets or liabilities in markets that are active, or inputs other than prices that are observable for the assets or liabilities.

Level 3 Unobservable inputs for the assets or liabilities.

Index to Financial Statements

The tables below shows the fair value of the Company s financial assets and liabilities, by level, within the fair value hierarchy that are measured at fair value on a recurring basis at least annually (in thousands):

| | Fair V | Total | | |
|--------------------------------------|-----------|-----------|-----------|----------|
| | (Level 1) | (Level 2) | (Level 3) | Balance |
| Assets | | | | |
| Money market funds | \$ 5,888 | \$ | \$ | \$ 5,888 |
| | | | | |
| Liabilities | | | | |
| Convertible preferred stock warrants | \$ | \$ | \$ | \$ |

| | Fair V | Total | | |
|--------------------------------------|-----------|-----------|-----------|----------|
| | (Level 1) | (Level 2) | (Level 3) | Balance |
| Assets | | | | |
| Money market funds | \$ 5,204 | \$ | \$ | \$ 5,204 |
| | | | | |
| Liabilities | | | | |
| Convertible preferred stock warrants | \$ | \$ | \$ 525 | \$ 525 |

Investments in money market funds are classified within Level 1. At December 31, 2012 and 2013, money market funds were included on the balance sheets in cash and cash equivalents and in restricted cash. At December 31, 2012, \$30,000 of money market funds were also included in prepaid and other assets. The Company s Level 1 assets are valued using quoted prices for identical instruments in active markets. Level 2 assets are typically government-sponsored obligations which mature within 12 months and are valued using broker reports that utilize quoted market prices for similar instruments. There were no transfers between Level 1 and Level 2 categories during the years ended December 31, 2012 and 2013.

The valuation of the convertible preferred stock warrants at December 31, 2012 and 2013, including the methodology and input assumptions used in the valuation, is discussed in Note 11. The Company s convertible preferred stock warrants are classified as Level 3 because they were valued based on unobservable inputs and management s judgment due to the absence of quoted market prices, inherent lack of liquidity and the long-term nature of such financial instruments. These assumptions are inherently subjective and involve significant management judgment. The significant unobservable input used in the fair value measurement of the warrant liability is the fair value of the underlying common stock at the valuation remeasurement date. Generally, increases (decreases) in the fair value of the underlying common stock would result in a directionally similar impact to the fair value measurement of the preferred stock warrants. Any change in estimated fair value is recognized in other income or expense on the statements of operations.

The table below shows the changes in the estimated fair value of the Company s preferred stock warrant liability from December 31, 2011 through December 31, 2013 (in thousands):

| | Significant Unobservable |
|---------------------------------|-----------------------------|
| | Inputs (Level 3) |
| Balance as of December 31, 2011 | \$ 2 |
| Change in fair value | (2) |

| Change in fair value | 525 |
|---------------------------------|-----------|
| Balance as of December 31, 2013 | \$ 525 |

Index to Financial Statements

5. INVENTORY

The following table summarizes the Company s inventory (in thousands):

| | Decen | December 31, | |
|----------------|--------|--------------|--|
| | 2012 | 2013 | |
| Finished goods | \$ 244 | \$ 230 | |
| Raw materials | 332 | 288 | |
| | \$ 576 | \$ 518 | |

6. PROPERTY AND EQUIPMENT

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

| | December 31, | | |
|---|--------------|----------|--|
| | 2012 | 2013 | |
| Laboratory equipment | \$ 3,842 | \$ 3,798 | |
| Leasehold improvements | 4,336 | 4,336 | |
| Furniture and fixtures | 838 | 838 | |
| Computer and office equipment | 3,380 | 3,444 | |
| Construction in progress | 51 | 39 | |
| | | | |
| | 12,447 | 12,455 | |
| Less: accumulated depreciation and amortization | (10,329) | (10,902) | |
| | | | |
| Property and equipment, net | \$ 2,118 | \$ 1,553 | |

Depreciation and amortization expense for the years ended December 31, 2012 and 2013 was \$1,072,000 and \$663,000, respectively.

Unamortized capitalized software costs, included above in computer and office equipment, were \$153,000 and \$0 at December 31, 2012 and 2013, respectively. Related amortization expense, included in depreciation and amortization expense, was \$459,000 and \$153,000 for the years ended December 31, 2012 and 2013, respectively.

Assets purchased under capital leases, included above in laboratory equipment and computer and office equipment, were \$1,439,000 at December 31, 2012 and 2013. Accumulated amortization was \$1,388,000 and \$1,414,000 at December 31, 2012 and 2013, respectively. Related amortization expense, included in depreciation and amortization expense, was \$70,000 and \$26,000 for the years ended December 31, 2012 and 2013, respectively.

7. ACCRUED AND OTHER LIABILITIES

The following table represents the components of accrued and other liabilities (in thousands):

| Professional fees | \$ 333 | \$ 175 |
|-------------------------------------|----------|----------|
| Test sample processing fees | 132 | 195 |
| Accrued overpayments and refunds | 134 | 215 |
| Clinical studies | 24 | 84 |
| Deferred rent current portion | 43 | 145 |
| Capital leases current portion | 58 | 43 |
| Other accrued expenses | 285 | 191 |
| | | |
| Total accrued and other liabilities | \$ 1,009 | \$ 1,048 |

Index to Financial Statements

8. COMMITMENTS AND CONTINGENCIES

Leases

The Company leases its laboratory and office facility in Brisbane, California, under a non-cancelable operating lease agreement expiring in December 2020. The terms of the facility lease provide for rental payments on a graduated scale. The Company recognizes rent expense on a straight-line basis over the lease period and has accrued for rent expense incurred but not paid. In addition, incentives were granted, including allowances to fund leasehold improvements and rent holidays. As such, these allowances have been recorded as deferred rent, and these items are being recognized as reductions to rental expense on a straight-line basis over the term of the lease.

During 2012 and 2013, the Company had leases for blood draw centers under non-cancelable operating leases. Although the Company had subleased some of the blood draw center properties, it remained obligated under the original operating leases. The final lease payment related to the blood draw centers was made in August 2013.

Rent expense under the non-cancelable operating leases was \$1,016,000 and \$1,020,000 for the years ended December 31, 2012 and 2013, respectively. Future minimum lease commitments under these operating and capital leases at December 31, 2013, are as follows (in thousands):

| | Capital | Operating |
|---|---------|-----------|
| | Leases | Leases |
| Years ending December 31: | | |
| 2014 | \$ 48 | \$ 1,178 |
| 2015 | 19 | 1,235 |
| 2016 | | 1,291 |
| 2017 | | 1,348 |
| 2018 and thereafter | | 4,212 |
| Total minimum lease payments | 67 | \$ 9,264 |
| Less: amounts representing interest | (6) | |
| Present value of minimum lease payments | 61 | |
| Less: current portion of obligations under capital leases | (43) | |
| Long-term portion of obligations under capital leases | \$ 18 | |

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

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

Royalty Commitments

In 2004, the Company entered into a license agreement with Roche Molecular Systems, Inc., or Roche, amended in 2006 and 2007, whereby the Company uses licensed technology to perform certain clinical laboratory services. The Company incurs royalty expenses that are based on a mid-single digit percentage of test revenues. Royalties are recorded as a component of cost of testing on the statements of operations.

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

Index to Financial Statements

present, which, based upon the royalty rate currently stated in the license agreement, we would estimate to be an additional \$913,636 through December 31, 2013. 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 statements of operations in the periods to which the royalties relate. The Company does not expect to reach resolution of the arbitration in 2014. As a result, the Company has recorded the \$2.8 million liability balance at December 31, 2013 as a long-term liability on the balance sheet.

Contingencies

The Company is subject to claims and assessments from time to time in the ordinary course of business. The Company s management does not believe that any such matters, individually or in the aggregate, will have a material adverse effect on the Company s business, financial condition, or results of operations.

9. COLLABORATION AND LICENSING AGREEMENTS Laboratory Corporation of America Holdings (LabCorp)

In April 2012, the Company entered into a Collaboration and License Agreement with LabCorp for the purpose of developing a lupus flare predictor test. The Company and LabCorp share equally the costs and expenses of developing the lupus flare predictor test, however LabCorp s share of the development cost subject to certain limits at each stage of the arrangement. LabCorp will be responsible for all costs related to the commercialization of the lupus flare predictor test.

Under this agreement, LabCorp paid the Company a nonrefundable and non-creditable upfront license fee payment of \$1,000,000. The Company also received a nonrefundable and non-creditable payment of \$250,000 for the transfer of certain lupus samples to LabCorp. The Company will receive royalties in the high single digits from LabCorp on net sales of the commercialized flare predictor test or other tests developed using the samples sold.

The Company determined that the transfer of certain lupus samples to LabCorp had stand-alone value, and accordingly, recognized the estimated selling price of \$250,000 in 2012 when the samples were delivered.

For the deliverables under the agreement without stand-alone value, the remaining allocated consideration is being recognized as a combined unit of accounting ratably over the Company s estimated period of performance, which was originally four years for all three stages. The license and cost sharing reimbursements related to research and development services and collaboration committee participation were determined to be one unit of accounting as the services and license do not have value without each other. During 2012, the Company recognized \$437,000 in revenue under this arrangement, which consisted of amortization of the upfront license fee of \$187,000 and reimbursement of research and development expenses of \$250,000. During 2013, the Company recognized \$328,000 in revenue under this arrangement, which consisted of amortization of research and development expenses of \$141,000. Such revenues are included in collaboration and license revenue on the statements of operations.

In late 2013, activities associated with the development of biomarkers concluded and activities moved into confirmation of results, requiring fewer Company resources and expenditures. As a result, the amortization of the upfront license fee was decreased to a much lower rate beginning in September 2013. Stage 1 completion is estimated for March 2014, at which time amortization of the upfront license fee will cease unless or until the project is resumed. The remaining \$626,000 of the upfront license fee is included in deferred revenue at December 31, 2013. This amount will be recognized over the estimated remaining performance period, if and when Stage 2 begins, or if and when the project is terminated.

Index to Financial Statements

Included in research and development expenses were \$499,000 and \$282,000 for the years ended December 31, 2012 and 2013, respectively, for development costs with respect to Stage 1.

As part of the above-referenced transaction, LabCorp purchased 137,722 shares of the Company s Series G preferred stock, resulting in net cash proceeds of \$2,941,000.

Diaxonhit (DHT)

In June 2013, the Company entered into an exclusive Distribution and Licensing Agreement with DHT, a French public company, whereby DHT will have the AlloMap test performed in a French laboratory and commercialize the test in the European Economic Area (EEA). The agreement will expire at the later of the last-to-expire patent in the EEA or ten years from the first commercial sale of the test in the EEA, which is expected to occur in late 2014 or early 2015.

Under this agreement, the Company is responsible for supplying DHT with AlloMap products needed to fulfill commercial sales in the EEA. In addition, throughout the term of the agreement the Company is required to maintain its regulatory approvals, provide limited monthly support to the French laboratory (not to exceed 10 hours per month), and participate on a collaboration committee with DHT. Prior to the first commercial sale of the test in the EEA, the Company must provide specified training to both DHT and the French laboratory.

Consideration under the agreement includes an upfront cash payment of approximately 387,500 (\$503,000) that is designated to offset royalties earned by the Company in the first three years following the first commercial sale. The Company is entitled to receive royalties from DHT on net sales, as defined in the agreement, of AlloMap tests in the mid to high teens. Upon confirmation that the CE mark is in place, the Company also received an initial upfront equity payment of DHT common stock with a value of 387,500 (these shares were promptly sold by the Company in July 2013 for total consideration of \$467,000). Other consideration that may be earned by the Company includes agreed-upon per unit pricing for the supply of AlloMap products, and additional royalties that are payable upon the achievement of various sales milestones by DHT. Approximately 250,000 (\$344,000) of the upfront payments are refundable under certain circumstances.

In this arrangement, there is one combined unit of accounting.

Since commercial sales have not yet begun in the EEA, the Company has yet to deliver AlloMap products or related services to DHT. Accordingly, no revenue from this arrangement has been recognized as of December 31, 2013.

CardioDx-Related Party

In 2005, the Company entered into a services agreement with a related party, CardioDx, Inc. (CDX), whereby the Company provided CDX with biological samples and related data and performed laboratory services on behalf of CDX. Each company granted the other a worldwide license under certain of its intellectual property rights. Pursuant to this agreement, CDX pays royalties to the Company of a low single-digit percentage of the cash collected from sales of CDX licensed products. In 2009, CDX terminated the services portion of this agreement, however, the royalty obligation from CDX continues until the tenth anniversary of the first commercial sale of a CDX licensed product. The first commercial sale of such product by CDX occurred in 2009, therefore the royalty obligation to the Company continues until 2019. The President and Chief Executive Officer of CDX previously served as a member of the Company s Board of Directors, and resigned effective as of March 28, 2014, but remains a stockholder of the Company. Two additional Board members of CDX serve on the Company s Board of Directors and are affiliated with stockholders of the Company. Royalty revenues, recorded when earned, were \$34,000 and \$94,000 in 2012 and 2013, respectively. The Company had receivable balances from CDX of \$21,000 and \$37,000 at December 31, 2012 and 2013, respectively.

Index to Financial Statements

10. DEBT Venture Debt

In August 2012, the Company entered into a \$15,000,000 loan and security agreement (the 2012 Loan), and repaid a loan entered into in 2010 (the 2010 Loan) including principal of \$10,333,833, a termination fee of \$875,000, and other costs associated with the payoff. Prepayment penalties and writeoff of the remaining unamortized costs associated with the 2010 Loan resulted in a charge to interest expense of approximately \$628,000 during the year ended December 31, 2012. These transactions generated net cash proceeds to the Company of \$3,432,260.

In August 2013, the Company amended the 2012 Loan to defer the beginning of repaying principal for six months, to March 1, 2014. To obtain this deferral, there was an additional fee of \$150,000 due at the end of the loan term. The 2012 Loan, as amended, provides for interest-only payments for 18 months followed by 30 equal monthly principal and interest payments of \$566,822 at an annual interest rate of 9.95%. In addition, a final payment of \$1,275,000 will be due at the end of the loan term. The 2012 Loan also included a facility fee of \$75,000.

In connection with the 2012 Loan, the Company issued to the lenders warrants to purchase 167,182 shares of Series G convertible preferred stock or Next Round Stock at \$21.78 per share. The warrants are exercisable until 2019. The estimated fair value of warrants on the date of issuance was negligible. The estimated fair value of the warrants at December 31, 2012 and 2013, including the methodology and input assumptions used in the valuation, is discussed in Note 11.

The 2012 Loan is collateralized by a security interest in all of the Company s assets except intellectual property on which there is a negative pledge, and the loan agreement contains covenants, including a revenue covenant, and restrictions on the Company s ability to pay cash dividends. At December 31, 2013, the Company was in compliance with all loan covenants.

In connection with the 2010 Loan, the Company issued to the lenders warrants to purchase 17,215 shares of Series G convertible preferred stock at \$21.78 per share. The warrants are exercisable until 2017. The estimated fair value of the warrants on the date of issuance of \$8,000 was recorded as a debt discount liability which has been amortized to interest expense over the term of the loan. Amortization of \$4,400 was included in interest expense during the year ended December 31, 2012. The estimated fair value of the warrants at December 31, 2012 and 2013, including the methodology and input assumptions used in the valuation, is discussed in Note 11.

Aggregate annual payments at December 31, 2013 due on the 2012 Loan as amended, are as follows (in thousands):

| | Annual Payments |
|-------------------------------------|--------------------|
| Years ending December 31: | |
| 2014 | \$ 5,917 |
| 2015 | 6,802 |
| 2016 | 5,809 |
| | |
| | 18,528 |
| Less: amounts representing interest | (3,528) |
| | |
| | 15,000 |
| Plus: unamortized premium, net | 357 |
| • | |
| | 15,357 |
| Less: current portion | 4,461 |
| • | , |
| Long-term portion | \$ 10,896 |
| | |

Index to Financial Statements

Convertible Notes

At December 31, 2011, the Company had a liability for \$11,365,000 principal amount of convertible subordinated promissory notes, which had been issued at various times from June 2010 to October 2011 (the 2010 Notes). The 2010 Notes had an annual interest rate of 7%, compounded annually and payable at maturity. Amortization of \$39,000 for an embedded debt discount related to the 2010 Notes is included in interest expense during the year ended December 31, 2012.

In April 2012, the Company converted all the 2010 Notes including principal and interest of \$12,423,000, into 570,294 shares of Series G preferred stock at \$21.78 per share, and issued 357,216 Series G preferred stock warrants exercisable at \$21.78 per share. The estimated fair value of the warrants on the date of issuance was negligible. The estimated fair value of the warrants at December 31, 2012 and 2013, including the methodology and input assumptions used in the valuation, is discussed in Note 11.

11. WARRANTS

At December 31, 2012 and 2013, outstanding convertible preferred stock warrants consisted of:

| | | | | Number of | Dece | mber 31, | |
|---------------|-----|------------------|-----------------------------------|-------------------|--|----------|------------------------------------|
| | | Original Term | Convertible Preferred Stock | Exercise Price | Shares Outstanding Underlying Warrant | | 2013 Estimated Fair Value |
| Issue date: | | | | | | | |
| December 2010 | (a) | 7 years | Series G | \$ 21.78 | 17,215 | \$ | \$ 13,792 |
| April 2012 | (b) | 5 years | Series G | \$ 21.78 | 357,216 | | 217,492 |
| August 2012 | (c) | 7 years | Series G | \$ 21.78 | 167,182 | | 293,369 |
| | | | | | 541,613 | \$ | \$ 524,653 |

(a) Issued to lenders in connection with the 2010 Loan (see Note 10).

(b) Issued to note holders upon the conversion of all of the 2010 Notes (see Note 10).

(c) Issued to lenders in connection with the 2012 Loan (see Note 10).

The convertible preferred stock warrants are exercisable upon issuance and are classified as liabilities on the balance sheets. The Company adjusts the liability for changes in fair value until the earlier of the exercise or expiration of the warrants or the completion of a liquidation event, including the completion of an initial public 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 estimated fair value of the outstanding convertible preferred stock warrants was measured at December 31, 2012, using the Black-Scholes option pricing model with the following assumptions: expected volatility ranging from 44% to 47%, a contractual term equal to the remaining contractual term, risk-free interest rate ranging from 0.5% to 1.2%, underlying common stock price of \$0.34, and dividend yield of 0%.

The estimated fair value of the outstanding convertible preferred stock warrants was measured at December 31, 2013, using the Black-Scholes option pricing model with the following assumptions: expected volatility ranging from 40% to 45%, a contractual term equal to the remaining contractual term, risk-free interest rate ranging from 0.8% to 2.1%, underlying common stock price of \$8.97, and dividend yield of 0%.

In October 2011, a number of preferred stock holders did not purchase their pro rata share of the 2010 Notes, and as a result, 82,190 warrants to purchase Series E, F, and G preferred stock converted to

Index to Financial Statements

warrants to purchase common stock. The strike price of the warrants remained the same. At December 31, 2012 and 2013, outstanding common stock warrants consisted of:

| | Original Term | Exercise Price | Number of Shares Outstanding Underlying Warrants |
|----------------------|------------------|-------------------|--|
| Original issue date: | | | |
| July 2006 | 10 years | \$ 31.72 | 17,656 |
| November 2006 | 10 years | \$ 31.72 | 1,576 |
| February 2008 | 10 years | \$ 35.07 | 22,792 |
| August 2009 | 10 years | \$ 21.78 | 33,472 |
| July 2010 | 9 years | \$ 21.78 | 6,694 |
| | | | 82,190 |

12. CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS DEFICIT

Under the Company s amended and restated certificate of incorporation, the Company s convertible preferred stock is issuable in series. The Company s Board of Directors is authorized to determine the rights, preferences, and terms of each series.

In April 2012, the Company issued 708,038 shares of Series G convertible preferred stock for \$15.4 million, net of offering costs, in addition to 430,973 shares of Series G convertible preferred stock issued in 2009. The price of the Series G convertible preferred stock was \$21.78 per share.

Convertible preferred stock at December 31, 2012 and 2013 consists of the following:

| | Shares | | Carrying | Liquidation | |
|---------|------------|-------------|----------------|----------------|--|
| | Authorized | Outstanding | Value | Value | |
| Series: | | | | | |
| А | 79,708 | 16,930 | \$ 267,000 | \$ 290,000 | |
| В | 145,221 | 16,065 | 826,143 | 853,143 | |
| С | 850,899 | 829,209 | 14,139,373 | 14,200,373 | |
| D | 965,672 | 877,880 | 18,459,000 | 20,024,985 | |
| E | 857,323 | 835,547 | 26,423,000 | 26,499,984 | |
| F | 1,463,859 | 1,441,053 | 50,443,000 | 50,541,097 | |
| G | 2,055,272 | 1,138,989 | 24,644,515 | 24,811,238 | |
| | | | | | |
| Total | 6,417,954 | 5,155,673 | \$ 135,202,031 | \$ 137,220,820 | |

The convertible preferred stock is classified as temporary equity on the Company s balance sheets. These shares are contingently redeemable upon events that are outside of the control of the Company, including a liquidation, sale or transfer of control. The Company has not adjusted the carrying values of its convertible preferred stock to their redemption values since it is uncertain whether or when a redemption event will occur. Subsequent adjustments to increase the carrying values to the ultimate redemption values will be made only when it becomes probable that such a liquidation event will occur.

Dividends

Holders of Series A, Series B, Series C, Series D, Series E, Series F, and Series G convertible preferred stock are entitled to noncumulative dividends of \$1.199, \$3.720, \$1.199, \$1.596, \$2.219, \$2.459, and

Index to Financial Statements

\$1.528 per share, respectively, if and when declared by the Board of Directors. These dividends are to be paid in advance of any distributions to common stockholders. No dividends have been declared to date.

Conversion

At December 31, 2013, each share of Series A, Series C, Series D, Series E, Series F, and Series G convertible preferred stock was convertible, at the option of the holder, into one share of common stock. Each share of Series B convertible preferred stock is convertible at the option of the holder into 0.18611 shares of common stock. The preferred stock converts automatically under certain circumstances or upon the vote of at least $66^{2}/_{3}\%$ of the holders of the outstanding preferred stock. The initial conversion prices for shares of Series A, Series B, Series C, Series D, Series E, Series F, and Series G convertible preferred stock are \$17.12, \$13.43, \$17.12, \$21.78, \$21.78, \$21.78, and \$21.78 per share, respectively.

Liquidation Preference

In the event of the liquidation or dissolution of the Company, the Series A, Series B, Series C, Series D, Series E, Series F, and Series G convertible preferred stock carry liquidation preferences of \$17.12, \$53.09, \$17.12, \$22.81, \$31.72, \$35.07, and \$21.78 per share, respectively, plus all declared but unpaid dividends. Holders of Series D and Series E convertible preferred stock have liquidation preference subsequent to the holders of Series G convertible stock. Holders of Series F convertible preferred stock have liquidation preference subsequent to holders of Series G convertible stock. Holders of Series B, and Series C convertible preferred stock have liquidation preference subsequent to holders of Series D, Series E, Series F, and Series G convertible preferred stock. After liquidation preferences to all convertible preferred stockholders have been paid, the remaining assets of the Company shall be distributed among the holders of common stock.

Voting Rights

Each holder of shares of Series A, Series B, Series C, Series D, Series E, Series F, and Series G convertible preferred stock is entitled to voting rights equivalent to the number of shares of common stock into which their respective shares are convertible. So long as 14,599 shares of Series C convertible preferred stock remain outstanding, the holders of Series C convertible preferred stock are entitled to elect three members to the Company s Board of Directors. So long as 14,599 shares of Series F and Series G convertible preferred stock remain outstanding, the holders of Series F and Series G convertible preferred stock are entitled to elect one member to the Board of Directors. So long as 14,599 shares of Series F and Series G convertible preferred stock are entitled to elect one member to the Company s Board of Directors. The holders of Series A and B convertible preferred stock and the holders of common stock, voting together as a single class, are entitled to elect three members to the Board of Directors.

13. STOCK OPTION PLANS

The Company has one active stock option plan, the 2008 Equity Incentive Plan, and one terminated stock option plan, the 1998 Stock Plan. The 2008 Equity Incentive Plan was approved in November 2008 under which 698,542 shares of the Company s common stock were reserved for future issuance. The 2008 Equity Incentive Plan will terminate in November 2018 unless terminated earlier. The 1998 Stock Plan terminated in December 2008, however options remain outstanding for up to 10 years from their date of grant. Both plans provide that stock options granted may be either incentive stock options or nonstatutory stock options. Incentive stock options may be granted to employees with exercise prices of no less than the estimated fair value of the common stock at the date of the grant. Nonstatutory options may be granted to employees, directors, or consultants at exercise prices of no less than 85% of the estimated fair value of the common stock on the grant date, as determined by the Board of Directors. If the Company grants an option to a recipient who directly or by attribution owns more than 10% of the total combined voting power of all classes of stock of the Company, the option price

Index to Financial Statements

shall be at least 110% of the estimated fair value of the common stock and shall not be exercisable more than five years after the date of grant. Options may be granted with vesting terms as determined by the Board of Directors, which is generally four years.

The following table summarizes option activity under the plans, and related information:

| | | Options Outstanding Weightee | | |
|------------------------------|------------------------|---------------------------------|-------------------|--|
| | Shares | | Average | |
| | Available for Grant | Number of Shares | Exercise Price | |
| Balance at December 31, 2011 | 306,188 | 496,908 | \$ 3.70 | |
| Granted | (211,056) | 211,056 | 0.55 | |
| Exercised | | (2,924) | 3.36 | |
| Forfeited | 32,585 | (32,585) | 3.43 | |
| Expired | 52,549 | (52,549) | 3.49 | |
| Balance at December 31, 2012 | 180,266 | 619,906 | 2.67 | |
| Granted | (4,081) | 4,081 | 0.48 | |
| Exercised | | (212) | 0.55 | |
| Forfeited | 7,247 | (7,247) | 2.33 | |
| Expired | 149,563 | (149,563) | 4.73 | |
| Balance at December 31, 2013 | 332,995 | 466,965 | 1.99 | |

The following table summarizes information about stock options outstanding at December 31, 2013:

| | Options Outstanding and Exercisable at December 31, 2013 | | | Options Vested at December 31, 2013 | |
|--------------------------|---|--------------|-----------|--|-----------|
| | | Weighted- | | | |
| | | Average | Weighted- | | Weighted- |
| | | Remaining | Average | Number | Average |
| | Number | Contractual | Exercise | of | Exercise |
| Range of Exercise Prices | Outstanding | Life (Years) | Price | Options | Price |
| \$0.27 - 0.55 | 205,871 | 8.81 | \$0.55 | 4,373 | \$0.55 |
| \$1.71 - 3.01 | 143,755 | 6.53 | \$2.88 | 111,731 | \$2.81 |
| \$3.36 - 3.97 | 117,339 | 4.30 | \$3.49 | 131,352 | \$3.43 |
| | | | | | |
| | 466,965 | 6.97 | \$1.99 | 247,456 | \$3.15 |

The weighted-average grant-date fair value of options granted during the years ended December 31, 2012 and 2013 using the Black-Scholes valuation model were \$0.27 and \$0.21, respectively.

Options outstanding and exercisable that have vested and are expected to vest at December 31, 2013, are as follows:

| | Number of Shares | A | ighted- /erage cise Price | Weighted- Average Remaining Contractual Life (Years) | Ir | gregate atrinsic Value housands) |
|------------------|---------------------|----|---------------------------------|---|----|---|
| Vested | 247,456 | \$ | 3.15 | 5.14 | \$ | 1,449 |
| Expected to vest | 219,509 | \$ | 0.89 | 9.23 | | 1,775 |
| Total | 466,965 | \$ | 1.99 | 6.97 | \$ | 3,224 |

Index to Financial Statements

In the table above, aggregate intrinsic value represents the difference between the exercise price and the estimated fair value of common stock as of December 31, 2013. There was no intrinsic value as of December 31, 2012.

The Company s results of operations include expense relating to employee and nonemployee share-based payment awards as follows (in thousands):

| | | Year Ended December 31, | | |
|----------------------------|-------|-------------------------|------|--|
| | 2012 | 20 | 2013 | |
| Cost of testing | \$ 2 | \$ | 3 | |
| Research and development | 13 | | 7 | |
| Sales and marketing | 5 | | 3 | |
| General and administrative | 49 | | 59 | |
| | \$ 69 | \$ | 72 | |

No tax benefit was recognized related to share-based compensation expense since the Company has never reported taxable income and has established a full valuation allowance to offset all of the potential tax benefits associated with its deferred tax assets. In addition, no amounts of share-based compensation costs were capitalized for the periods presented.

Valuation Assumptions

The Company s board of directors determines the estimated fair value of its common stock based on assistance from an independent third party valuation. The fair value of stock-based awards was estimated using the Black-Scholes option-pricing model using the following weighted-average assumptions:

| | Year Ended D | Year Ended December 31, | |
|--------------------------|--------------|-------------------------|--|
| | 2012 | 2013 | |
| Risk-free interest rate | 1.01% | 1.21% | |
| Volatility | 46.55% | 45.25% | |
| Expected term (in years) | 6.0 | 6.0 | |
| Expected dividend yield | % | C | |

Risk-free Interest Rate: The Company based 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.

Volatility: The Company used an average historical stock price volatility of comparable public companies that were deemed to be representative of future stock price trends as the Company does not have any trading history for its common stock.

Expected Term: The expected term represents the period for which the Company s 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.

Expected Dividends: The Company has not paid and does not anticipate paying any dividends in the near future.

At December 31, 2013, there was approximately \$37,000 of total unrecognized share-based compensation costs, net of estimated forfeitures, related to nonvested employee stock option awards granted that will be recognized on a straight-line basis over the remaining vesting period of 1.9 years.

Index to Financial Statements

14. 401 (K) PLAN

The Company has a 401 (k) plan that stipulates that eligible employees can elect to contribute to the plan, subject to certain limitations. The Company may make a discretionary contribution to the plan, and the amount of the contribution is determined each year. To date, the Company has made no contributions to the plan.

15. INCOME TAXES

The Company has incurred net operating losses for the years ended December 31, 2012 and 2013, therefore, no provision for income taxes has been recorded for these years. A reconciliation of the difference between the benefit for income taxes and income taxes at the statutory U.S. federal income tax rate is as follows:

| | Year ended Dec | Year ended December 31, | |
|---------------------------------------|----------------|-------------------------|--|
| | 2012 | 2013 | |
| Federal tax benefit at statutory rate | 34.0% | 34.0% | |
| Stock based compensation | 0.0 | (11.4) | |
| Change in valuation allowance | (30.9) | (8.6) | |
| Change in unrecognized tax benefits | 0.0 | (8.4) | |
| Preferred stock warrant revaluation | 0.0 | (5.0) | |
| Interest expense | (2.3) | | |
| Other | (0.8) | (0.6) | |
| | | | |
| Effective income tax rate | % | % | |

Although the Company recorded no benefit for income taxes for 2012 and 2013, there were significant differences in several of the items affecting the rate reconciliation above. These differences primarily relate to the cancellation of stock options for which deferred taxes were previously provided and an increase in unrecognized tax benefits which were netted against the respective deferred tax assets. These items are separately disclosed and not included with the change in the valuation allowance.

The components of net deferred tax assets were as follows (in thousands):

| | Decem | December 31, | |
|----------------------------------|-----------|--------------|--|
| | 2012 | 2013 | |
| Deferred tax assets: | | | |
| Net operating loss carryforwards | \$ 63,080 | \$ 62,863 | |
| Tax credit carryforwards | 4,433 | 3,973 | |
| Accruals | 494 | 1,097 | |
| Property and equipment | 133 | 147 | |
| Other | 511 | 97 | |
| | | | |
| Total deferred tax assets | 68,651 | 68,177 | |
| Valuation allowance | (68,651) | (68,177) | |
| | | | |
| Net deferred tax assets | \$ | \$ | |

The Company has recorded losses from operations since its inception. The Company believes that, based on the history of such losses and other factors, the weight of available evidence indicates that it is more likely than not that it will not be able to realize its deferred tax assets. Accordingly, the net deferred tax assets have been offset by a full valuation allowance. The valuation allowance increased by approximately \$1.7 million and decreased by approximately \$0.5 million for the years ended December 31, 2012 and 2013, respectively.

Index to Financial Statements

At December 31, 2013, the Company had federal and California operating loss carryforwards of \$162.5 million and \$136.3 million, respectively, available to offset future taxable income. The Company also had federal and California tax credit carryforwards of \$3.0 million and \$3.8 million, respectively, available to offset future income tax liabilities. The federal and state net operating losses will expire at various dates beginning in 2018 and 2014, respectively, if not utilized. The federal tax credit carryforward will expire at various dates beginning in 2021, if not utilized. The state tax credit carryforwards do not expire.

Utilization of the Company s net operating loss carryforwards and credits may be subject to a substantial annual limitation due to the ownership change limitations provided by the Tax Reform Act of 1986, as amended and similar state provisions. The annual limitation may result in the expiration of net operating losses and credits before utilization. Based on a preliminary review of our equity transactions since inception, the Company believes its net operating loss carryforwards may be limited due to equity financings which occurred in 2000, 2003 and 2007.

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

| | December 31, | |
|--|--------------|------------|
| | 2012 | 2013 |
| Balance at beginning of year | \$ 1,130 | \$ 1,159 |
| Additions based on tax positions related to current year | 53 | 177 |
| Additions (reductions) based on tax positions related to prior years | (24) | 860 |
| | | |
| Balance at end of year | \$ 1,159 | \$ \$2,196 |

The unrecognized tax benefits, if recognized and in absence of full valuation allowance, would impact the income tax provision by \$0.9 million and \$1.5 million as of December 31, 2012 and 2013, respectively.

The Company has elected to include interest and penalties as a component of tax expense. During the years ended December 31, 2012 and 2013, the Company did not recognize accrued interest and penalties related to unrecognized tax benefits. The Company does not anticipate that the amount of existing unrecognized tax benefits will significantly change during the next 12 months.

Because the Company has not utilized any of its net operating loss carryforwards, its federal and state income tax returns are subject to tax authority examination from inception.

Index to Financial Statements

CareDx, Inc.

Index to Unaudited Interim Condensed Financial Statements

| Unaudited Interim Condensed Financial Statements | |
|---|------|
| Condensed Balance Sheets | F-29 |
| Condensed Statements of Operations | F-30 |
| Condensed Statements of Cash Flows | F-31 |
| Notes to Unaudited Interim Condensed Financial Statements | F-32 |

Index to Financial Statements

CareDx, Inc.

Condensed Balance Sheets

(In thousands, except share and per share data)

| | ember 31, 2013 Note 1) | arch 31, 2014 naudited) | Pro Forma Stockholde Deficit as o March 31 2014 (Unaudited | ers of , |
|--|------------------------------|-------------------------------|---|----------------|
| Assets | | | | |
| Current assets: | | | | |
| Cash and cash equivalents | \$ 5,128 | \$ 4,837 | | |
| Accounts receivable | 2,270 | 2,093 | | |
| Inventory | 518 | 725 | | |
| Prepaid and other assets | 255 | 1,825 | | |
| Total current assets | 8,171 | 9,480 | | |
| Property and equipment, net | 1,553 | 1,466 | | |
| Restricted cash | 147 | 147 | | |
| Other noncurrent assets | 2 | 2 | | |
| Total assets | \$ 9,873 | \$ 11,095 | | |
| Liabilities, convertible preferred stock, and stockholders deficit Current liabilities: | | | | |
| Accounts payable | \$ 618 | \$ 781 | | |
| Accrued payroll liabilities | 1,386 | 826 | | |
| Deferred revenue | 80 | 65 | | |
| Current portion of long-term debt | 4,461 | 5,485 | | |
| Accrued and other liabilities | 1,048 | 3,421 | | |
| Total current liabilities | 7,593 | 10,578 | | |
| Accrued royalties | 2,804 | 3,139 | | |
| Deferred rent, net of current portion | 1,885 | 1,835 | | |
| Deferred revenue, net of current portion | 1,623 | 1,621 | | |
| Long-term debt, net of current portion | 10,914 | 9,591 | | |
| Convertible preferred stock warrant liability | 525 | 1,053 | \$ | |
| Total liabilities | 25,344 | 27,817 | | |
| Commitments and contingencies (Note 6) Convertible preferred stock: \$0.001 par value; 6,417,954 shares authorized at December 31, 2013 and March 31, 2014; 5,155,673 shares issued and outstanding at December 31, 2013 and March 31, 2014; no shares authorized, issued or outstanding, pro forma. Liquidation value of \$137,221 at | | | | |
| December 31, 2013 and March 31, 2014 Stockholders deficit: | 135,202 | 135,202 | | |
| Common stock: \$0.001 par value; 7,737,226 shares authorized at December 31, 2013 and March 31, 2014; 1,010,711 and 1,012,332 shares issued and outstanding at December 31, 2013 and March 31, 2014, respectively; 6,172,417 | | | | |
| shares issued and outstanding, pro forma | 1 | 1 | | 7 |

Edgar Filing: CareDx, Inc. - Form S-1/A

| Additional paid-in capital | 9,482 | 9,535 | 145,784 |
|---|-----------|-----------|-------------|
| Accumulated deficit | (160,156) | (161,460) | (161,460) |
| Total stockholders deficit | (150,673) | (151,924) | \$ (15,669) |
| Total liabilities, convertible preferred stock and stockholders deficit | \$ 9,873 | \$ 11,095 | |

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

Index to Financial Statements

CareDx, Inc.

Condensed Statements of Operations

(unaudited)

(In thousands, except share and per share data)

| | | Three Months March 3 | | | |
|---|----|-------------------------|------|-----------|--|
| | | 2013 | | 2014 | |
| Revenue: | | | | | |
| Testing revenue | \$ | 4,809 | \$ | 5,834 | |
| Collaboration and license revenue | | 172 | | 90 | |
| Total revenue | | 4,981 | | 5,924 | |
| Operating expenses: | | | | | |
| Cost of testing | | 2,124 | | 2,162 | |
| Research and development | | 1,002 | | 720 | |
| Sales and marketing | | 1,569 | | 1,474 | |
| General and administrative | | 1,064 | | 1,795 | |
| Total operating expenses | | 5,759 | | 6,151 | |
| Loss from operations | | (778) |) | (227) | |
| Interest expense, net | | (565) |) | (548) | |
| Other expense, net | | (5) |) | (529) | |
| Net loss | \$ | (1,348) |) | (1,304) | |
| Net loss per common share, basic and diluted | \$ | (1.33) |) \$ | (1.29) | |
| Shares used to compute net loss per common share, basic and diluted | 1 | ,010,684 | | 1,011,980 | |
| Pro forma net loss per common share, basic and diluted | | | § | (0.11) | |
| Shares used to compute pro forma net loss per common share, basic and diluted | | | | 7,372,700 | |

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

Index to Financial Statements

CareDx, Inc.

Condensed Statements of Cash Flows

(unaudited)

(In thousands)

| | Three Months Ended M 2013 | | d March 31, 2014 | |
|---|---------------------------|----|---------------------|--|
| Operating activities | | | | |
| Net loss | \$ (1,348) | \$ | (1,304) | |
| Adjustments to reconcile net loss to net cash (used in) provided by operating activities: | | | | |
| Depreciation and amortization | 251 | | 106 | |
| Stock-based compensation | 19 | | 49 | |
| Amortization of deferred revenue | (63) | | (17) | |
| Amortization of debt discount and noncash interest expense | 150 | | 153 | |
| Revaluation of warrants to estimated fair value | | | 528 | |
| Changes in operating assets and liabilities: | | | | |
| Accounts receivable | (222) | | 177 | |
| Inventory | 85 | | (207) | |
| Prepaid and other assets | (60) | | (1,570) | |
| Accounts payable | 219 | | 163 | |
| Accrued payroll liabilities | (168) | | (560) | |
| Accrued royalties | 294 | | 335 | |
| Accrued and other liabilities | (91) | | 2,327 | |
| Net cash (used in) provided by operating activities Investing activities | (934) | | 180 | |
| Purchase of property and equipment | | | (19) | |
| Net cash used in investing activities | | | (19) | |
| Financing activities | | | () | |
| Proceeds from exercise of stock options | | | 4 | |
| Principal payments on debt | (18) | | (456) | |
| Net cash used in financing activities | (18) | | (452) | |
| Net decrease in cash and cash equivalents | (952) | | (291) | |
| Cash and cash equivalents at beginning of period | 5,830 | | 5,128 | |
| Cash and cash equivalents at end of period | \$ 4,878 | \$ | 4,837 | |
| Supplemental disclosures of cash flow information | | | | |
| Cash paid for interest | \$ 377 | \$ | 375 | |

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

Index to Financial Statements

CareDx, Inc.

Notes to Unaudited Interim Condensed Financial Statements

1. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES Unaudited Interim Financial Statements

The unaudited interim condensed balance sheet as of March 31, 2014 and the statements of operations and cash flows for the three months ended March 31, 2013 and 2014 are unaudited. The unaudited interim condensed financial statements have been prepared on the same basis as the annual audited financial statements and, in the opinion of management, reflect all adjustments, which include only normal recurring adjustments, necessary to present fairly the Company s financial position as of March 31, 2014 and its results of operations and cash flows for the three months ended March 31, 2013 and 2014. The financial data and the other financial information disclosed in these notes to financial statements related to the three month periods are also unaudited. The results of operations for the three months ended March 31, 2014 are not necessarily indicative of the results to be expected for the year ending December 31, 2014 or for any other future annual or interim period. These financial statements should be read in conjunction with the Company s audited financial statements included elsewhere in this prospectus.

Unaudited Pro Forma Stockholders Deficit

On March 20, 2014, the Company s board of directors authorized the management of the Company to file a registration statement with the Securities and Exchange Commission (SEC) for the Company to sell shares of its common stock to the public. On March 31, 2014, the Company filed such a registration statement with the SEC as an emerging growth company as defined in the Jumpstart Our Business Startups Act of 2012. The unaudited proforma stockholders deficit at March 31, 2014, assumes the automatic conversion of all the outstanding convertible preferred stock into shares of common stock and the reclassification of the Company s outstanding warrants to purchase shares of preferred stock from a liability to stockholder s deficit, occurring upon the closing of this proposed initial public offering.

Need for Additional Capital

At March 31, 2014, the Company had an accumulated deficit of \$161.5 million, cash of \$4.8 million and debt of \$15.1 million. In April 2014 the Company received an additional \$5.0 million in proceeds from the issuance of subordinated convertible debt (see note 9, Subsequent Events). Management believes that cash and cash equivalents, together with cash receipts from AlloMap testing revenue, will be sufficient to enable the Company to fund its operations for at least twelve months. However, the Company will need to raise additional capital to fully implement its strategy to accelerate the development of new transplant surveillance solutions and to expand its infrastructure.

Reverse Stock Split

On July 1, 2014, the Company s Board of Directors approved filing an amendment to our Certificate of Incorporation to reflect a 1 for 6.85 reverse stock split (the Reverse Stock Split) of the Company s outstanding common stock and convertible preferred stock. The par value per share was not adjusted as a result of the Reverse Stock Split. All authorized, issued and outstanding shares of common stock, convertible preferred stock, options and warrants to purchase common or preferred stock and related per share amounts contained in the financial statements have been retroactively adjusted to reflect this Reverse Stock Split for all periods presented. The Reverse Stock Split was effected on July 14, 2014.

Index to Financial Statements

Use of Estimates

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 expense during the reporting period. Significant 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 fair value of the Company s common stock, the estimate of differences between amounts billed and estimated receipts from payers, 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 by 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.

Concentration of Credit Risk

The Company is subject to credit risk from its accounts receivable which are derived from revenue earned from AlloMap tests provided for patients located in the U.S. and billed to various third-party payers. For the three months ended March 31, 2013 and 2014, approximately 52% and 50%, respectively, of testing revenue was derived from Medicare. No other payers represented more than 10% of testing revenue for these periods. At March 31, 2014, approximately 74% of accounts receivable were from Medicare. No other payers represented more than 10% of accounts receivable at March 31, 2014.

Cash Equivalents

The Company considers all highly liquid investments that are readily convertible into cash having maturities at the time of purchase of three months or less to be cash equivalents. Cash equivalents include money market funds, obligations of U.S. government agencies, and government-sponsored entities which are carried at fair value.

Deferred Offering Costs

Deferred offering costs, which primarily consist of direct incremental legal and accounting fees relating to the IPO, are capitalized. The deferred offering costs will be offset against IPO proceeds upon the consummation of the offering. In the event the offering is terminated, deferred offering costs will be expensed. As of December 31, 2013 and March 31, 2014, zero and \$1.4 million, respectively, of deferred offering costs were capitalized in prepaid and other assets on the condensed balance sheets.

Testing Revenue

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

The first criteria is satisfied when a third-party payer makes a coverage decision or enters into a contractual arrangement with the Company for the test. The second criteria is satisfied when the Company performs the test and delivers 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. 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.

Index to Financial Statements

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 the Company for tests performed, the Company recognizes revenue on the cash basis in the period in which the payment is received.

Revenue is recognized on the accrual basis net of adjustments for differences between amounts billed and the estimated receipts from payers. The amount the Company expects 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.

Collaboration and License Revenue

The Company generates revenue from collaboration and license agreements. 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. The Company s performance obligations under the collaborations 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. The Company makes judgments that affect the periods over which it recognizes revenue. The Company periodically reviews its estimated periods of performance based on the progress under each arrangement and accounts for the impact of any change in estimated periods of performance on a prospective basis.

The Company recognizes contingent consideration received from the achievement of a substantive milestone in its entirety in the period in which the milestone is achieved, which the Company believes is more consistent with the substance of its performance under its various license and collaboration agreements. The Company did not recognize any milestones during the three months ended March 31, 2013 or 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.

Index to Financial Statements

Transaction costs associated with these 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.

Net Loss Per Common Share and Unaudited Pro Forma Net Loss Per Common Share

Basic and diluted net loss per common share are calculated by dividing net loss for the period attributable to common stockholders by the weighted-average number of common shares outstanding during the period. Potentially dilutive securities consisting of convertible preferred stock and options and warrants to purchase stock are considered to be common stock equivalents and were excluded from the calculation of diluted net loss per common share because their effect would be antidilutive for all periods presented. In contemplation of an IPO, the Company has presented the unaudited pro forma basic and diluted net loss per common share which has been computed to give effect to (i) the conversion of the convertible preferred stock into common stock, (ii) the conversion of Series G preferred stock into common stock issuable in connection with the subordinated convertible promissory note discussed in Note 9, and (iii) the conversion of Series G preferred stock into common stock issued in connection with a business combination which closed on June 10, 2014.

2. NET LOSS PER COMMON SHARE AND PRO FORMA NET LOSS PER COMMON SHARE

The following outstanding common stock equivalents have been excluded from diluted net loss per common share for the periods presented because their inclusion would be antidilutive:

| | Three Months Ended March 31, | | |
|--|------------------------------|-----------|--|
| | 2013 | 2014 | |
| Shares of common stock subject to outstanding options | 529,227 | 547,731 | |
| Shares of common stock subject to outstanding warrants | 82,190 | 82,190 | |
| Shares of common stock subject to conversion from preferred stock | 5,160,085 | 5,160,085 | |
| Shares of common stock subject to conversion from preferred stock warrants | 541,613 | 541,613 | |
| | | | |
| Total shares of common stock equivalents | 6,313,115 | 6,331,619 | |

The following table sets forth the computation of the Company s unaudited pro forma basic and diluted net loss per common share after giving effect to the conversion of convertible preferred stock. Also, the numerator in the pro forma basic and diluted net loss per common share calculation has been adjusted to remove the loss resulting from remeasurement of the warrant liability as these amounts will be reclassified to additional paid-in capital upon a qualifying IPO of our common stock (in thousands, except share and per share amounts):

| | Aonths Ended ch 31, 2014 |
|--|---------------------------------|
| Net loss | \$ (1,304) |
| Change in estimated fair value of convertible preferred stock warrant liability | (528) |
| Net loss used in computing pro forma net loss per common share, basic and diluted | \$ (776) |
| Shares used to compute net loss per common share, basic and diluted | 1,011,980 |
| Pro forma adjustments to reflect assumed conversion of convertible preferred stock | 5,160,085 |
| Pro forma adjustment to reflect assumed conversion of convertible preferred stock issuable in | |
| connection with the subordinated convertible promissory note | 312,500 |
| Pro forma adjustment to reflect assumed conversion of convertible preferred stock issued in connection | |
| with the business combination | 888,135 |
| Shares used to compute pro forma net loss per common share, basic and diluted | 7,372,700 |

Pro forma net loss per common share, basic and diluted

(0.11)

\$

Index to Financial Statements

The assumed conversion of Series G convertible preferred stock issuable in connection with the subordinated convertible promissory note was calculated based upon its \$5.0 million principal balance at a conversion price of \$21.78 per share, as provided for in this note. As there is no interest expense related to this note included in the historical net loss, no adjustment to historical net loss is required to compute net loss per common share, basic and diluted.

The assumed conversion of Series G convertible preferred stock issued in connection with a business combination represents the 888,135 shares of Series G convertible preferred stock (including 75,945 such shares in escrow) issued upon the close of the business combination on June 10, 2014. Shares issuable upon the achievement of a future milestone are not included in this calculation due to the uncertainty of the Company achieving this performance metric.

3. FAIR VALUE MEASUREMENTS

The Company s financial instruments are measured and recorded at fair value except for its debt, which is recorded at amortized cost. The three levels of inputs that are used to measure fair value are classified into the following hierarchy:

Level 1 Unadjusted quoted prices in active markets for identical assets or liabilities.

Level 2 Unadjusted quoted prices in active markets for similar assets or liabilities, unadjusted quoted prices for identical or similar assets or liabilities in markets that are active, or inputs other than prices that are observable for the assets or liabilities.

Level 3 Unobservable inputs for the assets or liabilities.

The tables below shows the fair value of the Company s financial assets and liabilities, by level, within the fair value hierarchy that are measured at fair value on a recurring basis (in thousands):

| | December 31, 2013 Fair Value Measured Using | | Total | |
|--------------------------------------|--|-----------|-----------|----------|
| | (Level 1) | (Level 2) | (Level 3) | Balance |
| Assets | | | | |
| Money market funds | \$ 5,204 | \$ | \$ | \$ 5,204 |
| | | | | |
| Liabilities | | | | |
| Convertible preferred stock warrants | \$ | \$ | \$ 525 | \$ 525 |

| | March 31, 2014 Fair Value Measured Using | | | Total |
|--------------------------------------|---|-----------|-----------|----------|
| | (Level 1) | (Level 2) | (Level 3) | Balance |
| Assets | | | | |
| Money market funds | \$ 4,880 | \$ | \$ | \$ 4,880 |
| | | | | |
| Liabilities | | | | |
| Convertible preferred stock warrants | \$ | \$ | \$ 1,053 | \$ 1,053 |

Investments in money market funds are classified within Level 1. At December 31, 2013 and March 31, 2014, money market funds were included on the balance sheets in cash and cash equivalents and in restricted cash. There were no transfers between Level 1 and Level 2 categories during the periods presented.

Index to Financial Statements

The Company s convertible preferred stock warrants are classified as Level 3 because they were valued based on unobservable inputs and management s judgment due to the absence of quoted market prices, inherent lack of liquidity and the long-term nature of such financial instruments. The significant unobservable input used in the fair value measurement of the warrant liability is the fair value of the underlying common stock at the valuation remeasurement date. Generally, increases (decreases) in the fair value of the underlying common stock would result in a directionally similar impact to the fair value measurement of the preferred stock warrants. Any change in estimated fair value is recognized in other income or expense on the statements of operations.

The table below shows the change in the estimated fair value of the Company s preferred stock warrant liability (in thousands):

| | Significant Unobservable Inputs (Level 3) |
|---------------------------------|---|
| Balance as of December 31, 2013 | \$ 525 |
| Change in fair value | 528 |
| Balance as of March 31, 2014 | \$ 1,053 |

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 \$0.34 and \$12.40 at March 31, 2013 and 2014, respectively, and the following assumptions:

| | Three Months Ended March 31, | | |
|--|------------------------------|-----------------|--|
| | 2013 | 2014 | |
| Risk-free interest rate | 0.6 - 1.0% | 0.9 - 1.7% | |
| Volatility | 42 - 45% | 41 - 42% | |
| Estimated term equal to the remaining contractual term | 4.0 - 6.4 years | 3.0 - 5.4 years | |
| Expected dividend yield | % | % | |

4. INVENTORY

The following table summarizes the Company s inventory (in thousands):

| | December 31, 2013 | | March 31, 2014 | |
|-----------------|----------------------|----|-------------------|--|
| Finished goods | \$ 230 | \$ | 237 | |
| Raw materials | 288 | | 488 | |
| Total inventory | \$ 518 | \$ | 725 | |

Index to Financial Statements

5. ACCRUED AND OTHER LIABILITIES

The following table represents the components of accrued and other liabilities (in thousands):

| | December 31, 2013 | March 31, 2014 |
|-------------------------------------|----------------------|-------------------|
| Deferred IPO costs | \$ | \$ 1,356 |
| Professional fees | 175 | 747 |
| Test sample processing fees | 195 | 283 |
| Accrued overpayments and refunds | 215 | 330 |
| Clinical studies | 84 | 99 |
| Deferred rent current portion | 145 | 159 |
| Capital leases current portion | 43 | 38 |
| Other accrued expenses | 191 | 409 |
| Total accrued and other liabilities | \$ 1,048 | \$ 3,421 |

6. COMMITMENTS AND CONTINGENCIES Royalty Commitments

In 2004, the Company entered into a license agreement with Roche Molecular Systems, Inc., or Roche, amended in 2006 and 2007, whereby the Company uses licensed technology to perform certain clinical laboratory services. The Company incurs royalty expenses that are based on a mid-single digit percentage of test revenues. Royalties are recorded as a component of cost of testing on the statements of operations.

On February 11, 2014 Roche filed a demand for arbitration with the American Arbitration Association seeking a declaration that the Company has 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, the Company estimates to be an additional \$1,248,237 through March 31, 2014. While management believes it has meritorious defenses to these claims, which it plans to fully pursue in the arbitration, the Company has fully reserved the amount of these unpaid royalties has been reflected as an expense in the Company s statements of operations in the periods to which the royalties relate. The Company does not expect to reach resolution of the arbitration within the next twelve months. As a result, the Company has recorded the \$3.1 million liability balance at March 31, 2014 as a long-term liability on the condensed balance sheets.

7. COLLABORATION AND LICENSING AGREEMENTS Laboratory Corporation of America Holdings (LabCorp)

In April 2012, the Company entered into a Collaboration and License Agreement with LabCorp for the purpose of developing a lupus flare predictor test. The Company and LabCorp share equally the costs and expenses of developing the lupus flare predictor test, however LabCorp s share of the development cost subject to certain limits at each stage of the arrangement.

Under this agreement, LabCorp paid the Company a nonrefundable and non-creditable upfront license fee payment of \$1,000,000.

The Company determined that the transfer of certain lupus samples to LabCorp had stand-alone value, and accordingly, recognized the estimated selling price of \$250,000 in 2012 when the samples were delivered.

Edgar Filing: CareDx, Inc. - Form S-1/A

Index to Financial Statements

For the deliverables under the agreement without stand-alone value, the allocated consideration is being recognized as a combined unit of accounting ratably over the Company s estimated period of performance. During the three months ended March 31, 2013, the Company recognized \$163,000 in revenue under this arrangement, which consisted of amortization of upfront license fee of \$63,000 and reimbursement of research and development expenses of \$100,000. During the three months ended March 31, 2014, the Company recognized \$29,000 in revenue under this arrangement, which consisted of upfront license fee of \$15,000 and reimbursement of research and development expenses of \$14,000. Such revenues are included in collaboration and license revenue on the statements of operations.

Phase 1 of the project was completed in the first quarter of 2014. The remaining \$611,000 of the upfront license fee is included in deferred revenue at March 31, 2014. This amount will be recognized over the estimated remaining performance period, if and when Stage 2 begins, or if and when the project is terminated.

Included in research and development expenses were \$201,000 and \$29,000 for the three months ended March 31, 2013 and 2014, respectively, for development costs with respect to Phase 1.

Diaxonhit (DHT)

In June 2013, the Company entered into an exclusive Distribution and Licensing Agreement with DHT, a French public company, whereby DHT will have the AlloMap test performed in a French laboratory and commercialize the test in the European Economic Area (EEA). The agreement will expire at the later of the last-to-expire patent in the EEA or ten years from the first commercial sale of the test in the EEA, which is expected to occur in late 2014 or early 2015.

Consideration under the agreement includes an upfront cash payment of approximately 387,500 (\$503,000) that is designated to offset royalties earned by the Company in the first three years following the first commercial sale. The Company is entitled to receive royalties from DHT as a percent of net sales, as defined in the agreement, of AlloMap tests in the mid to high teens. Approximately 250,000 (\$344,000) of the upfront payments are refundable under certain circumstances. Upon confirmation that the CE mark was in place, the Company also received an equity payment of DHT common stock with a value of 387,500. These shares were promptly sold by the Company in July 2013 for total consideration of \$467,000.

Other consideration that may be earned by the Company includes agreed-upon per unit pricing for the supply of AlloMap products, and additional royalties that are payable upon the achievement of various sales milestones by DHT. In this arrangement, there is one combined unit of accounting.

Since commercial sales have not yet begun in the EEA, the Company has yet to deliver AlloMap products or related services to DHT. Accordingly, no revenue from this arrangement has been recognized as of March 31, 2014.

CardioDx-Related Party

In 2005, the Company entered into a services agreement with a related party, CardioDx, Inc. (CDX), whereby the Company provided CDX with biological samples and related data and performed laboratory services on behalf of CDX. Each company granted the other a worldwide license under certain of its intellectual property rights. Pursuant to this agreement, CDX pays royalties to the Company of a low single-digit percentage of the cash collected from sales of CDX licensed products. In 2009, CDX terminated the services portion of this agreement, however, the royalty obligation from CDX continues until the tenth anniversary of the first commercial sale of a CDX licensed product. The first commercial sale of such product by CDX occurred in 2009, therefore the royalty obligation to the Company

Index to Financial Statements

continues until 2019. The President and Chief Executive Officer of CDX previously served as a member of the Company s Board of Directors, and resigned effective as of March 28, 2014, but remains a stockholder of the Company. Two additional Board members of CDX serve on the Company s Board of Directors and are affiliated with stockholders of the Company. Royalty revenues, recorded when earned, were \$9,000 and \$58,000 in the three months ended March 31, 2013 and 2014, respectively. The Company had receivable balances from CDX of \$37,000 and \$58,000 at December 31, 2013 and March 31, 2014, respectively.

8. STOCK OPTION PLANS

The Company has one active stock option plan, the 2008 Equity Incentive Plan, and one terminated stock option plan, the 1998 Stock Plan. The 2008 Equity Incentive Plan was approved in November 2008 under which 698,542 shares of the Company s common stock were reserved for future issuance.

The following table summarizes option activity and related information during the three months ended March 31, 2014 under the 2008 Equity Incentive Plan and for options which remain outstanding under the 1998 Stock Plan:

| | | Options Outstanding Weighte | | |
|------------------------------|----------------------------------|--------------------------------|---|--|
| | Shares Available for Grant | Number of Shares | Weighted- Average Exercise Price | |
| Balance at December 31, 2013 | 332,995 | 466,965 | \$ 1.99 | |
| Granted | (94,538) | 94,538 | 12.40 | |
| Exercised | | (1,621) | 2.60 | |
| Forfeited | 1,056 | (1,056) | 0.96 | |
| Expired | 11,095 | (11,095) | 3.08 | |
| Balance at March 31, 2014 | 250,608 | 547,731 | 3.77 | |

The weighted-average grant-date fair value of options granted during the three months ended March 31, 2014 using the Black-Scholes valuation model was \$4.45 per share.

Options outstanding and exercisable that have vested and are expected to vest at March 31, 2014 are as follows:

| | Number of Shares | Av | ighted- /erage cise Price | Weighted- Average Remaining Contractual Life (Years) | Ir | ggregate ntrinsic Value housands) |
|------------------|---------------------|----|---------------------------------|---|----|--|
| Vested | 349,930 | \$ | 2.67 | 6.40 | \$ | 3,406 |
| Expected to vest | 197,801 | \$ | 5.69 | 9.01 | | 1,324 |
| Total | 547,731 | \$ | 3.77 | 7.35 | \$ | 4,730 |

In the table above, aggregate intrinsic value represents the difference between the exercise price and the estimated fair value of the Company s common stock of \$12.40 per share, as determined by the Board of Directors, as of March 31, 2014.

Edgar Filing: CareDx, Inc. - Form S-1/A

Index to Financial Statements

The Company s results of operations include expense relating to employee and nonemployee stock-based payment awards as follows (in thousands):

| | | Three Months Ended March 31, | |
|----------------------------|-------|---------------------------------|--|
| | 2013 | 2014 | |
| Cost of testing | \$ 1 | \$ 1 | |
| Research and development | 2 | 1 | |
| Sales and marketing | 1 | 1 | |
| General and administrative | 15 | 46 | |
| | \$ 19 | \$ 49 | |

Valuation Assumptions

The fair value of stock-based awards was estimated using the Black-Scholes option-pricing model using the following weighted-average assumptions:

| | Three Mont March | |
|--------------------------|---------------------|--------|
| | 2013 | 2014 |
| Risk-free interest rate | 1.00% | 1.55% |
| Volatility | 45.82% | 40.69% |
| Expected term (in years) | 6.0 | 4.6 |
| Expected dividend yield | % | % |

At March 31, 2014, there was approximately \$356,000 of total unrecognized stock-based compensation costs, net of estimated forfeitures, related to nonvested employee stock option awards granted that will be recognized on a straight-line basis over the remaining vesting period of 3.8 years.

In April 2014, the Company increased the common stock reserved for future issuance under the 2008 Equity Incentive Plan by 102,189 shares. Also in April 2014, the Company granted 317,549 stock options at an exercise price of \$12.40 per share.

9. SUBSEQUENT EVENTS Subordinated Convertible Promissory Note

In April 2014, the Company issued a \$5.0 million Subordinated Convertible Promissory Note to Illumina, Inc. (2014 Note) which provides for interest at an annual rate of 8.0%. The 2014 Note matures one year following its issuance with principal and unpaid interest due at that time unless the Note is converted into equity prior to the maturity date. Conversion is mandatory in the instance of a Qualified Initial Public Offering or Qualified Financing, as defined in the 2014 Note. Conversion prices are defined in the 2014 Note with regard to mandatory conversion and the holder may convert to Series G preferred stock at any time at \$21.78 per share. If the proposed initial public offering or a qualified financing does not occur before the one-year anniversary of the issuance of the 2014 Note, and the holder does not choose to convert, then the repayment of the principal and unpaid interest totaling approximately \$5.4 million would be due no later than April 2015.

Business Combination

On June 10, 2014, in accordance with an Agreement and Plan of Merger (Agreement), the Company acquired ImmuMetrix, Inc. (IMX), a privately held development stage company working in new technologies using cell-free donor DNA (cfDNA) technology for the diagnosis,

Edgar Filing: CareDx, Inc. - Form S-1/A

treatment and management of transplant rejection, immune disorders and diseases, including the development of a new,

Index to Financial Statements

non-invasive test designed to detect the early stages of solid organ transplant rejection. The Company acquired all IMX assets associated with transplant diagnostics, including related immune repertoire and infectious diseases. IMX retained the limited assets not associated with transplant diagnostics.

The total estimated purchase price is \$19.1 million consisting of i) \$600,000 in cash; ii) 911,364 shares of the Company s Series G convertible preferred stock with an estimated fair value of \$15.9 million, including 23,229 shares of the Company s Series G convertible preferred stock with an estimated fair value of \$0.4 million as a result of the Company s assumption of IMX outstanding stock options; and iii) an additional payment of 227,845 shares of CareDx Series G convertible preferred stock if a future performance milestone is achieved.

The Agreement provides that the milestone will be achieved if the Company completes 2,500 commercial tests involving the measurement of cfDNA in organ transplant recipients in the United States no later than six years after the closing date of the merger. The additional shares to be paid for the achievement of the milestone will be Series G preferred stock, or common stock if the Company is public at the time the milestone is met. The initial estimated fair value of this contingent consideration is \$2.6 million.

Through this acquisition, the Company expects to add to its existing know-how, expertise and intellectual property in applying cfDNA technology to the surveillance of transplant recipients. The intellectual property we expect to acquire includes an exclusive license from Stanford University to a patent relating to the diagnosis of rejection in organ transplant recipients using cfDNA.

The Company has evaluated subsequent events through July 7, 2014, the date these unaudited interim condensed financial statements are considered issued.

Index to Financial Statements

ImmuMetrix, Inc. (A Development Stage Company)

Index to Financial Statements of Acquired Business

| Independent Auditors Report | F-44 |
|--|------|
| Consolidated Financial Statements | |
| Consolidated Balance Sheets | F-46 |
| Consolidated Statements of Operations | F-47 |
| Consolidated Statements of Stockholders Equity (Deficit) | F-48 |
| Consolidated Statements of Cash Flows | F-49 |
| Notes to Consolidated Financial Statements | F-50 |
| Unaudited Condensed Financial Statements | |
| Unaudited Condensed Balance Sheets | F-61 |
| Unaudited Condensed Statements of Operations | F-62 |
| Unaudited Condensed Statements of Cash Flows | F-63 |
| Notes to Unaudited Condensed Financial Statements | F-64 |

Index to Financial Statements

Board of Directors

ImmuMetrix, Inc.

Palo Alto, California

INDEPENDENT AUDITORS REPORT

Report on the Consolidated Financial Statements

We have audited the accompanying consolidated financial statements of ImmuMetrix, Inc. (formerly ImmuMetrix, LLC) (a development stage company) (the Company), which comprise the consolidated balance sheets as of December 31, 2013 and 2012, and the related consolidated statements of operations, stockholders equity (deficit) and cash flows for the years then ended and the period from November 9, 2010 (inception) through December 31, 2013, and the related notes to the consolidated financial statements.

Management s Responsibility for the Consolidated Financial Statements

Management is responsible for the preparation and fair presentation of these consolidated financial statements in accordance with accounting principles generally accepted in the United States of America; this includes the design, implementation, and maintenance of internal control relevant to the preparation and fair presentation of consolidated financial statements th