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

Registration No. 333-196494

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Amendment No. 3

to

FORM S-1

REGISTRATION STATEMENT

UNDER

THE SECURITIES ACT OF 1933

CareDx, Inc.

(Exact name of Registrant as specified in its charter)

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

3260 Bayshore Boulevard

Brisbane, California 94005

(415) 287-2300

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

Peter Maag, Ph.D.

President and Chief Executive Officer

CareDx, Inc.

3260 Bayshore Boulevard

Brisbane, California 94005

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

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

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

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

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

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

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

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

CALCULATION OF REGISTRATION FEE

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

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

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

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

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

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

PROSPECTUS (Subject to Completion)

Issued July 15, 2014

3,125,000 Shares

CAREDX, INC.
Common Stock

$ per share

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

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

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

Proposed NASDAQ trading symbol: CDNA

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

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

	PRICE $	*A SHARE*

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

[1] See Underwriting for additional information regarding underwriter compensation

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

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

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

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

Piper Jaffray **Leerink Partners**

Raymond James **Mizuho Securities**

, 2014

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

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

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

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

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

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PROSPECTUS SUMMARY

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

CareDx, Inc.

We are a commercial stage company that develops, markets and delivers a diagnostic surveillance solution for heart transplant recipients to help clinicians make personalized treatment decisions throughout a patient s lifetime. Our commercialized testing solution, the AlloMap heart transplant molecular test, or AlloMap, is a blood-based test used to monitor heart transplant recipients for acute cellular rejection. We believe the use of AlloMap, in conjunction with other clinical indicators, can help healthcare providers and their patients better manage long-term care following a heart transplant. In particular, we believe AlloMap can improve patient care by helping healthcare providers to avoid the use of unnecessary, invasive surveillance biopsies and to determine the appropriate dosage levels of immunosuppressants. We believe there is a significant unmet need for non-invasive post-transplant surveillance solutions and we are applying our expertise in transplantation towards the development of additional solutions for organ transplant recipients, including recipients of heart and kidney transplants.

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

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

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

AlloMap is the only non-invasive method recommended in the International Society for Heart and Lung Transplantation, or ISHLT, patient care guidelines for surveillance of heart transplant rejection in non-infants. AlloMap has received 510(k) clearance from the U.S. Food and Drug Administration, or FDA, for marketing and sale as a test to aid in the identification of heart transplant recipients with stable organ function and a low probability of moderate or severe rejection. A 510(k) submission is a premarketing submission made to the FDA. Clearance may be granted by the FDA if it finds the device or test provides satisfactory evidence pertaining to the claimed intended uses and indications for the device or test. Additionally, we have obtained a CE mark, which indicates a product s compliance with European Union, or EU, legislation and enables the sale of such product within the EU market. Since launch in January 2005, we have performed more than 55,000 commercial AlloMap tests, including more than 10,000 tests in 2013, in our Brisbane, California laboratory. In 2013, AlloMap was used in 105 of the approximately 126 heart transplant centers in the United States. We believe that there is a meaningful opportunity for AlloMap outside of the United States, and through recent partnerships we are expanding our AlloMap offering to Europe and Canada.

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

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

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

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

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

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

Recent Developments

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

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

Our Strategy

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

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

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

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

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

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

Care of Organ Transplant Recipients

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

Risks of Organ Rejection and the Side-Effects of Immunosuppression

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

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

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Heart Transplants

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

Kidney Transplants

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

Limitations of Existing Approaches for Surveillance of Transplant Recipients

Surveillance of Heart Transplant Recipients

The historical standard for heart transplant surveillance has been the microscopic examination of heart tissue obtained through an invasive endomyocardial biopsy. In the biopsy procedure, a catheter is inserted into the right internal jugular vein to obtain four pieces of tissue from the wall of the heart. This sample is then sent to a laboratory for examination by a pathologist who uses a microscope to look for evidence of cellular rejection. Limitations of biopsies in the surveillance of heart transplant recipients include:

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

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

Due to these and other limitations, biopsies are not frequently used by clinicians to tailor the use of immunosuppressants. The typical schedule of biopsy surveillance may involve a total of ten to fifteen biopsies within the first year post-transplant. Because repeated biopsies incur cumulative risk and trauma to the recipient, the frequency of biopsy surveillance after one year has been low, despite the fact that

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recipients would benefit from continued monitoring for rejection and management of their immunosuppressive drugs for the rest of their lives. With less biopsy data collected after the first year post-transplant, clinicians have less information upon which to tailor immunosuppression treatment for their recipients.

Surveillance of Kidney Transplant Recipients

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

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

Immunosuppression of Heart and Kidney Transplant Recipients

The risk of rejection in heart and kidney transplant recipients is managed primarily through the use of immunosuppression. Surveillance biopsies are infrequent, especially in kidney and even in heart after the first year, because of invasive procedural risks, discomfort, inconvenience, expense and the low rate of finding moderate to severe grade rejection. As a result, clinicians have limited and infrequent information about an individual recipient s risk of rejection over the months and years following transplant. In the average recipient, the immune system gradually adapts to the organ graft, and the need for immunosuppression declines over time. However, there is meaningful variation in the level of rejection activity and need for immunosuppression among transplant recipients.

Limited insight into the risk profile of the individual recipient often causes clinicians to apply a one-size-fits all approach to immunosuppression to help protect against the severe consequences of rejection. Although typical doses of immunosuppressants result in a low rate of rejection in the transplant population as a whole, many individuals receive more immunosuppressants than they may actually need. Improved post-transplantation diagnostics are necessary to make further gains in the long-term care and health outcomes of heart, kidney and other organ transplant recipients.

The Need for a Better Surveillance Solution

More effective solutions for the surveillance and risk assessment of recipients would improve the clinician s ability to individualize immunosuppression therapy and to reduce the use of invasive biopsies. We believe that core elements of effective surveillance solutions include:

- Highly accurate and quantitative results;
- Non-invasive;
- Easy to administer;

Differentiate rejection from quiescence;

Detect rejection earlier; and

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

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Our Solution

We develop and provide a diagnostic surveillance testing solution for organ transplant recipients. Our commercial testing solution, AlloMap, uses gene expression technology to aid in the identification of heart transplant recipients at low risk of rejection. The test measures the molecular signatures that correlate with biological activity associated with acute cellular rejection. Gene expression may indicate acute cellular rejection well before the evidence of damage is visible from a tissue biopsy sample. AlloMap applies a proprietary mathematical algorithm comprised of the expression values, or RNA levels, of 20 genes and yields a single integer score which determines the probability of moderate to severe acute cellular rejection. A key benefit of the AlloMap score is its negative predictive value, or NPV. The NPV of AlloMap is the likelihood that a heart transplant recipient is at low risk for rejection. The NPV for recipients with an AlloMap score below the threshold range for one or more years post-transplant can be greater than 99% depending on the actual score.

The clinical utility of AlloMap is supported by numerous clinical trials sponsored by us, the results of which have been published in leading peer-reviewed medical journals. AlloMap is the first and only non-invasive method recommended in the ISHLT patient care guidelines for surveillance of heart transplant recipients for rejection in non-infants. AlloMap has obtained 510(k) clearance from the FDA.

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

AlloMap is designed to provide the following benefits:

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

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

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

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

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

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

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

Our Development Pipeline

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

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

Cell-free DNA for Heart Transplants

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

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

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

Cell-free DNA for Kidney Transplants

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

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

Risks Associated with our Business

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

- We have a history of losses, and we expect to incur net losses for the next several years;
- Our financial results are largely dependent on sales of one test, AlloMap, and we will need to generate sufficient revenues from this and other future solutions to grow our business;
- We receive a substantial portion of our revenues from Medicare, and the loss of, or a significant reduction in, reimbursement from Medicare would adversely affect our financial performance;
- The development and commercialization of additional diagnostic solutions is a key to our growth strategy. New test development involves a lengthy and complex process, and we may not be successful in our efforts to develop and commercialize additional diagnostic solutions using cfDNA or other technologies;
- Health insurers and other third-party payers may decide to revoke coverage of our existing test, decide not to cover our future solutions or may provide inadequate reimbursement, which could jeopardize our commercial prospects;
- In order to operate our laboratory, we have to comply with the Clinical Laboratory Improvement Amendments of 1988, or CLIA, and state laws governing clinical laboratories;
- Our competitive position depends on maintaining intellectual property protection;
- We may face intellectual property infringement claims that could be time-consuming and costly to defend and could result in our loss of significant rights and the assessment of treble damages; and
- Our operating results may fluctuate, which could cause our stock price to decrease.

Our Corporate Information

We were originally incorporated in Delaware in December 1998 under the name Hippocratic Engineering, Inc. In April 1999, we changed our name to BioCardia, Inc., in June 2002, we changed our name to Expression Diagnostics, Inc., in July 2007, we changed our name to XDx, Inc., and in March 2014, we changed our name to CareDx, Inc.

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

Office Location

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

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Implications of Being an Emerging Growth Company

We are an emerging growth company, as defined in the Jumpstart Our Business Startups Act, or the JOBS Act, and therefore we may take advantage of certain exemptions from various public company reporting requirements, including not being required to have our internal controls over financial reporting audited by our independent registered public accounting firm pursuant to Section 404 of the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and any golden parachute payments. We may take advantage of these exemptions until we are no longer an emerging growth company. In addition, the JOBS Act provides that an emerging growth company can delay adopting new or revised accounting standards until such time as those standards apply to private companies. We have irrevocably elected not to avail ourselves of this exemption, and, therefore, we will be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies. We will remain an emerging growth company until the earlier of (1) the last day of the fiscal year (a) following the fifth anniversary of this offering, (b) in which we have total annual gross revenue of at least $1.0 billion or (c) in which we are deemed to be a large accelerated filer, which means the market value of our common stock that is held by non-affiliates exceeds $700 million as of the prior June 30th, and (2) the date on which we have issued more than $1.0 billion in non-convertible debt securities during the prior three-year period.

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THE OFFERING

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

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

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

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

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