

Invitae Corp  
Form 10-K  
March 30, 2015

Use these links to rapidly review the document

[TABLE OF CONTENTS](#)

[ITEM 8. Financial Statements And Supplementary Data.](#)

[Table of Contents](#)

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

**Form 10-K**

(Mark One)

**ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES  
EXCHANGE ACT OF 1934**

For the fiscal year ended December 31, 2014

**TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES  
EXCHANGE ACT OF 1934**

For the transition period from \_\_\_\_\_ to \_\_\_\_\_  
Commission File No. 001-36847

**Invitae Corporation**

(Exact name of the registrant as specified in its charter)

**Delaware**  
(State or other jurisdiction of  
incorporation or organization)

**27-1701898**  
(I.R.S. Employer  
Identification No.)

**458 Brannan Street, San Francisco, California 94107**  
(Address of principal executive offices, Zip Code)

**(415) 374-7782**  
(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act:

**Title of each class:**

Common Stock, par value \$0.0001 per share

**Name of each exchange on which registered:**

The New York Stock Exchange

Securities registered pursuant to Section 12(g) of the Act: **None**

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes  No

## Edgar Filing: Invitae Corp - Form 10-K

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act. Yes  No

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes  No

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes  No

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K.

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, 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       Smaller reporting company   
(Do not check if a smaller reporting company)

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes  No

The registrant's common stock was not publicly traded as of the last business day of the registrant's most recently completed second fiscal quarter.

The number of shares of the registrant's Common Stock outstanding as of February 28, 2015 was 31,813,353.

---

Table of Contents**TABLE OF CONTENTS**

<b>Item No.</b>		<b>Page No.</b>
<b><u>PART I</u></b>		
<u>Item 1.</u>	<u>Business</u>	<u>1</u>
<u>Item 1A.</u>	<u>Risk Factors</u>	<u>31</u>
<u>Item 1B.</u>	<u>Unresolved Staff Comments</u>	<u>57</u>
<u>Item 2.</u>	<u>Properties</u>	<u>57</u>
<u>Item 3.</u>	<u>Legal Proceedings</u>	<u>58</u>
<u>Item 4.</u>	<u>Mine Safety Disclosure</u>	<u>58</u>
<b><u>PART II</u></b>		
<u>Item 5.</u>	<u>Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities</u>	<u>59</u>
<u>Item 6.</u>	<u>Selected Financial Data</u>	<u>61</u>
<u>Item 7.</u>	<u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	<u>63</u>
<u>Item 7A.</u>	<u>Qualitative and Quantitative Disclosures About Market Risk</u>	<u>75</u>
<u>Item 8.</u>	<u>Financial Statements and Supplementary Data</u>	<u>76</u>
<u>Item 9.</u>	<u>Changes in and Disagreements with Accountants on Accounting and Financial Disclosure</u>	<u>103</u>
<u>Item 9A.</u>	<u>Controls and Procedures</u>	<u>103</u>
<u>Item 9B.</u>	<u>Other Information</u>	<u>103</u>
<b><u>PART III</u></b>		
<u>Item 10.</u>	<u>Directors, Executive Officers and Corporate Governance</u>	<u>104</u>
<u>Item 11.</u>	<u>Executive Compensation</u>	<u>112</u>
<u>Item 12.</u>	<u>Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters</u>	<u>114</u>
<u>Item 13.</u>	<u>Certain Relationships and Related Transactions, and Director Independence</u>	<u>117</u>
<u>Item 14.</u>	<u>Principal Accountant Fees and Services</u>	<u>119</u>
<b><u>PART IV</u></b>		
<u>Item 15.</u>	<u>Exhibits, Financial Statement Schedules</u>	<u>120</u>
<b><u>SIGNATURES</u></b>		<u>123</u>

Table of Contents

**PART I**

**ITEM 1. Business.**

This report contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. All statements in this report other than statements of historical fact, including statements identified by words such as "believe," "may," "will," "estimate," "continue," "anticipate," "intend," "expect" and similar expressions, are forward-looking statements. Forward-looking statements include, but are not limited to, statements about:

our views regarding the future of genetic testing and its role in mainstream medical practice;

strategic plans for our business, products and technology, including our ability to expand our assay and develop new assays while maintaining attractive pricing, further enhance our genetic testing process and the related user experience, build interest in and demand for our tests (including by driving traffic to our website) and attract potential partners;

our expectations with respect to our near-term plan of operation;

the implementation of our business model;

the rate and degree of market acceptance of our tests and genetic testing generally;

our ability to scale our infrastructure and operations in a cost-effective manner;

the timing of and our ability to introduce improvements to our genetic testing platform and to expand our current assay to include additional genes;

our expectations with respect to future hirings;

the timing and results of studies with respect to our tests;

developments and projections relating to our competitors and our industry;

the degree to which individuals will share genetic information generally, as well as share any related potential economic opportunities with us;

our commercial plans, including our sales and marketing expectations;

our ability to obtain and maintain adequate reimbursement for our tests;

regulatory developments in the United States and foreign countries;

## Edgar Filing: Invitae Corp - Form 10-K

our ability to retain key scientific or management personnel;

our expectations regarding our ability to obtain and maintain intellectual property protection and not infringe on the rights of others;

our expectations regarding the time during which we will be an emerging growth company under the JOBS Act;

our ability to obtain funding for our operations;

our financial performance; and

our expectations regarding our future revenue, cost of revenue, operating expenses and capital expenditures, and our future capital requirements.

Forward-looking statements are subject to a number of risks and uncertainties that could cause actual results to differ materially from those expected. These risks and uncertainties include, but are not limited to, those risks discussed in Item 1A of this report. Although we believe that the expectations and assumptions reflected in the forward-looking statements are reasonable, we cannot

# Edgar Filing: Invitae Corp - Form 10-K

## Table of Contents

guarantee future results, level of activity, performance or achievements. In addition, neither we nor any other person assumes responsibility for the accuracy and completeness of any of these forward-looking statements. Any forward-looking statements in this report speak only as of the date of this report. We expressly disclaim any obligation or undertaking to update any forward-looking statements.

This report contains statistical data and estimates that we obtained from industry publications and reports. These publications typically indicate that they have obtained their information from sources they believe to be reliable, but do not guarantee the accuracy and completeness of their information. Some data contained in this report is also based on our internal estimates. Although we have not independently verified the third-party data, we believe it to be reasonable.

In this report, all references to "Invitae," "we," "us," "our," or "the company" mean Invitae Corporation.

Invitae and the Invitae logo are trademarks of Invitae Corporation. We also refer to trademarks of other corporations and organizations in this report.

## **Overview**

Invitae's mission is to bring comprehensive genetic information into mainstream medical practice to improve the quality of healthcare for billions of people. Our goal is to aggregate most of the world's genetic tests into a single service with higher quality, faster turnaround time and lower price than many single gene tests today. We were founded on four core principles:

Patients should own and control their own genetic information;

Healthcare professionals are fundamental in ordering and interpreting genetic information;

Driving down the price of genetic information will increase its clinical and personal utility; and

Genetic information is more valuable when shared.

As the price of DNA sequencing has declined, the amount of genetic information that can be generated per dollar has increased exponentially, enabling the generation, analysis and storage of more comprehensive genetic information than ever before. According to OMIM, there are more than 4,000 inherited genetic conditions for which the scientific and medical community has already identified specific genes and variants useful for diagnosis or treatment planning. By aggregating large numbers of currently available genetic tests into a single service, we can achieve great economies of scale that allow us to not only provide primary single gene or multi-gene tests but also to generate and store additional genetic information on behalf of the patient for future use. We refer to the service of managing genetic information over the course of disease or the lifetime of a patient as "genome management." In addition, as more individuals gain access to their genetic information, we believe that sharing genetic information will provide an economic opportunity for patients and us to participate in advancing the understanding and treatment of disease. We believe that our ongoing investment in building our infrastructure and attracting talent across a range of disciplines to generate, interpret and manage genetic information will position us to be a leader in the field of genetic testing and genome management.

In the near term, we plan to focus on the immediate market for symptomatic disease with the goal to aggregate testing for large numbers of genetic diseases into a single low-cost service. In the future, we plan on expanding our efforts in carrier and newborn testing markets and later into the health and

Table of Contents

wellness market. As our market share grows we expect that our business will develop in three stages over the longer term:

**Genetic testing:** making genetic testing more affordable and more accessible with faster turnaround time than ever before. We believe that there is a significant market opportunity for high volume, low cost genetic testing that can allow us to serve a large number of clients.

**Genome management:** building a secure and trusted genome management infrastructure. By generating and storing large amounts of individualized genetic information for every patient sample, we believe we can create value over the course of disease or lifetime of a client.

**Genome network:** sharing genetic information on a global scale to advance science and medicine. We plan to help patients share their genetic information in a way that benefits them and us by acting as a permission-based broker on their behalf.

The fundamental challenge of the first stage of our business (genetic testing) is to deliver sufficiently comprehensive and quality content at a cost that makes sense for broad healthcare adoption and reimbursement. We believe we are well positioned to address this challenge over time given our investment in infrastructure that will allow us to perform these complex tests in high volume at low cost. This infrastructure includes the scientific curation of individual genetic disorders, genes and variants a rapidly advancing area of science. It also includes large-scale laboratory processes and information systems to store, analyze and manage the data; a knowledge database that allows us to aggregate the role genetic variations play in diseases and drug responses; and software tools to help generate reports for physicians and their patients while reducing the time required by our genetic specialists for interpretation and report sign-out.

We are headquartered in San Francisco, California, where we have offices and a CLIA-certified, CAP-accredited facility. We also have offices in Palo Alto, California as well as a second laboratory in Santiago, Chile. We launched our first commercial offering in late November 2013 with an assay of 216 genes comprising 85 different genetic disorders and 17 targeted panels, and began selling and marketing our panels with a focused effort on hereditary cancers. We charge \$1,500 per sample in most cases, which allows our clients to receive test results on any or all genes in a specific indication or multi-gene panel. Importantly, we are providing turnaround time of less than three weeks for the substantial majority of our tests. Our volume has grown rapidly since commercial launch, and in 2014 we delivered more than 3,600 billable tests, including more than 1,800 billable tests in the fourth quarter of 2014. We expect our rate of growth in delivered billable tests to slow in periods leading up to commercial releases of our expanding platform, including the period in 2015 leading up to the first planned expansion of our current assay of 216 genes. We have a multi-disciplinary team of 161 people as of December 31, 2014, including bioinformaticians, clinical and medical geneticists, commercial and managed care experts, genetic counselors, scientists, software engineers, web developers, graphic designers and lab automation specialists, as well as administrative and corporate personnel. We believe that creating a strong team is a competitive advantage, and we strive to foster a motivating and unique culture in which our people can thrive.

We believe that the keys to our future success will be to steadily reduce the costs we incur in providing test results, increase the amount of genetic content we offer in the form of an expanded test menu for the same or lower prices, increase the volume of tests we deliver, and improve our collections from our customers, particularly third-party healthcare payors such as insurance companies.

**The global opportunity for genetic testing**

We believe that genes are a fundamental particle of modern medicine and that genetic testing has the potential to affect billions of people. Every individual has a unique genome and we believe that comprehensive knowledge of this genetic makeup will be foundational to the future practice of

Table of Contents

medicine. We also believe that eventually many individuals in a modern healthcare system will have their genome sequenced at birth or during the course of their lives, resulting in the potential for dramatic improvements in health and wellness and an overall reduction in healthcare costs through preventive care.

Virtually everyone is carrying loss of function mutations in their genome, recessive genetic conditions that may affect their extended family or genetic mutations that may affect their response to various drugs or therapies. For example, approximately 2.0% of the population has a genetic variant in one of 52 genes identified by the American College of Medical Genetics as important incidental findings that should be reported to patients in part because they are medically actionable. In addition, approximately 0.4% of the population has a cardiac genetic condition that may lead to early onset cardiovascular disease, and approximately 0.5-5.0% of the population has a factor V Leiden variant that increases the genetic risk for blood clots.

The genetic testing market is a rapidly growing global market. According to UnitedHealth Group, the U.S. genetic testing and molecular diagnostics market in 2010 was estimated to be approximately \$5 billion, of which approximately 60%, or \$3 billion, was genetic testing. As of December 2014, genetests.org estimated that there were more than 40,000 different genetic tests available from over 650 laboratories. These tests can identify a person's predisposition to a particular disease (predictive testing), detect whether a person has a disease (diagnostic testing), predict the potential effectiveness of a therapy or drug (pharmacogenetic testing), or assess risk of disease progression (prognostic testing). Based on UnitedHealth's estimates for the growth of the genetic testing and molecular diagnostics market and our assumption that genetic testing's share of this market will be held constant at approximately 60% between 2010 and 2021, we expect the U.S. genetic testing market to grow to at least \$9 billion by 2021.

An example of this rapid growth is in the area of hereditary genetic testing for cancer. The two most commonly tested genes for hereditary risk of breast and ovarian cancer, BRCA1 and BRCA2, were identified about two decades ago. Since their discovery, the market in the United States for testing those two genes alone has grown to over \$600 million per year. In addition, the availability of low cost DNA sequencing has resulted in the discovery of multiple new genes that may cause hereditary forms of breast and ovarian cancer, resulting in a rapid shift in the marketplace toward multi-gene panels. We believe that the rapid growth of the genetic testing market for hereditary cancer and the rapid evolution of multi-gene panels is evidence of the potential for rapid market adoption of new genetic information.

While adoption of genetic testing has been increasing for certain medical applications, there remain a number of primary barriers limiting broader adoption. The cost of genetic testing has been prohibitively high for broad market adoption and use in routine medical practice. Under current pricing, payors generally restrict reimbursement of genetic testing to limited patient populations that meet specific criteria. In a survey by UnitedHealth, approximately 78% of physicians identified cost of tests and reimbursement as a barrier to incorporating genetic tests in their practice. We believe advances in DNA sequencing, information technology and capacity for analysis and high-throughput data processing will be key drivers for reducing the cost of genetic testing in the future.

Adoption of genetic testing also has been constrained by an inefficient testing process with long turnaround times. The growing availability of genetic tests that are specific to a single disease has created a serial retesting process commonly referred to as a diagnostic odyssey in cases where initial tests return negative results or where patients require testing for more than one condition. The retesting process is costly and time consuming, and it commonly fails to reach a conclusive clinical diagnosis. The challenges with sequential retesting are further exacerbated by long and unpredictable turnaround times. Currently, patients and providers can wait more than a month to receive each



Table of Contents

genetic testing result, which limits clinical applicability of genetic testing for patients who are in need of pressing follow-up treatment.

An example of this diagnostic odyssey is the genetic testing process for Bardet-Biedl syndrome, or BBS, a progressive multi-systemic disorder that begins to manifest in early childhood. Individuals with BBS can present with a variety of symptoms including obesity, degeneration of the retina, extra fingers or toes, kidney dysfunction and cognitive impairment. BBS is difficult and expensive to diagnose; patients have historically undergone testing for each individual gene. With over 15 genes implicated in the hereditary disease, sequential testing of individual genes, starting with the most common cause of the disease, could easily take up to a year and cost over \$10,000. With a multi-gene panel, we are now able to evaluate the majority of BBS genes in a single test for a price of \$1,500, while providing reports to physicians usually within three weeks.

In addition, the market for genetic tests was constrained by the existence of patent protection for certain naturally-occurring nucleic acids. However, recent U.S. Supreme Court cases, including *Mayo Collaborative Services v. Prometheus Laboratories, Inc. (2012)*, have clarified that naturally occurring DNA sequences are natural phenomena which should not be patentable. These recent cases have ushered in an era of broader participation in the market for genetic testing services.

Finally, we believe the limited number of geneticists and genetic counselors has forced many physicians to navigate the complexities associated with diagnosis and treatment of genetic disease with insufficient expert assistance. In the same survey by UnitedHealth cited above, 49% of physicians identified a lack of familiarity with genetic tests as a barrier to greater adoption in their practice. We believe the growth of the number of genetic tests available has exacerbated this problem, and makes it more challenging for physicians to identify the appropriate tests and interpret their results. To help address these needs, our strategy is to make the process of ordering genetic tests and understanding the results easier, not only for patients and physicians, but for the broader universe of healthcare professionals.

**Our solution for genetic testing**

We are focused on making comprehensive genetic testing more affordable and more accessible than ever before, pursuing a large and rapidly growing market with a focus on price and quality. We aim to do so for the majority of genetic tests, consolidating most of them into a single offering at a price below the typical prices of many single gene or multi-gene panels.

***Our products today***

We launched our first commercial offering in late November 2013, an assay of 216 genes comprising 85 different genetic disorders and 17 targeted panels, and began selling and marketing our multi-gene panels with a focused effort on hereditary cancers, including breast, colon and pancreatic cancer. We charge \$1,500 per sample in most cases, which allows our clients to receive test results on any or all genes in a specific indication or multi-gene panel. We also currently offer a free re-requisition of additional data within the same indication when ordered within 90 days of the date of service. In addition, clients may obtain test results on genes that are in other indications or panels, or genes within the same indication or panel more than 90 days after the date of initial service, for an additional fee. Importantly, we are providing turnaround time of less than three weeks for the substantial majority of our tests. Since our initial launch, we have marketed additional panels addressing other genetic conditions based on the same assay of 216 genes.

We have developed a value proposition called "the Invitae Advantage," which articulates part of our competitive advantage as follows:

**More affordable than ever before.** One price. Any test.

Table of Contents

**Faster time to answers.** From sample to results in three weeks on average.

**Flexible test options.** Design your own test or select a curated panel.

**Deeper genetic insights.** Choose multi-gene panels or order a free re-requisition.

**Confidence and quality.** Our team of genetic experts delivers high-quality test results.

Since our commercial launch, approximately 80% of our orders have been for indications associated with hereditary cancer. Our hereditary cancer panel options include BRCA1 and BRCA2, a high-risk hereditary breast cancer panel of seven genes, a hereditary colon cancer panel of 14 genes, a hereditary pancreatic cancer panel of 17 genes, or a more comprehensive hereditary cancer panel of 29 cancer genes. Any one or more cancer genes, up to the entire 29-gene panel, is typically available for \$1,500. We are growing our volume rapidly and, during 2014, we delivered more than 3,600 billable tests. Sales of our tests have grown significantly in 2014 from over 200 tests in the first quarter of 2014 to over 1,800 tests in the fourth quarter of 2014, which we believe is evidence that our value proposition is attractive to our clients. As the market for our billable tests develops, we expect that competitors will release offerings with broader content that is clinically relevant to particular patients. We thus expect our rate of growth in delivered billable tests to slow in periods leading up to commercial releases of our expanding platform, including the period in 2015 leading up to the first planned expansion of our current assay of 216 genes. We estimate that the U.S. market for hereditary cancer tests is greater than \$650 million per year and thus represents a key growth opportunity for us. More broadly, it is estimated that approximately 5-10% of all cancers are likely to have a hereditary basis. Today only a subset of individuals are eligible for BRCA1 and BRCA2 testing covered by third-party health insurance plans. However, clinical studies have established that a significant percentage of individuals with breast cancer who would not have qualified for testing based on prior family history may test positive for BRCA1 and BRCA2 mutations. We believe that the market for hereditary breast and ovarian cancer could continue to expand as lower-cost testing becomes available, allowing healthcare systems to test larger populations more cost-effectively.

We plan to substantially increase our sales and marketing effort in oncology in 2015 as well as expand our sales efforts beyond cancer. Since our initial commercialization, we have marketed additional panels involved in multiple different genetic disorders, including cardiology, hematology, neurology and pediatric panels. For example in the field of neurology, we have recently started to market Charcot-Marie Tooth and Spastic Paraplegia panels. Charcot-Marie Tooth, or CMT, is one of the most common inherited neurological genetic disorders in the United States and affects approximately 1 in 2,500 individuals. We include 29 genes in our CMT panel, providing what we believe is one of the most comprehensive offerings for CMT at one of the lowest prices and one of the fastest turn-around times on the market.

In cardiology we have recently begun to offer panels for hypertrophic cardiomyopathy, long QT syndrome, short QT syndrome and Brugada syndrome. Long QT syndrome affects approximately 1 in 2,500 individuals, resulting in significant risk of developing an irregular heartbeat and potential for sudden cardiac death. In addition, the presence of long QT syndrome can result in significant side effects to some commonly prescribed drugs. Hypertrophic cardiomyopathy, or HCM, is the leading cause of sudden cardiac death in people under 30 years old and is believed to be prevalent in about 0.2% of the population. HCM may not present with symptoms until it results in sudden cardiac death. Thus, lower cost of testing for multiple genes which cause HCM could be useful for screening otherwise healthy individuals and their families for a potentially lethal condition.

We also offer panels for pediatric conditions such as Noonan spectrum disorders and ciliopathies. Noonan syndrome is found in approximately 1 in 2,000 individuals and results in numerous congenital problems including congenital heart defects, short stature, learning problems and impaired blood clotting. Ciliopathies are a broad class of genetic diseases that include diseases such as BBS,

## Edgar Filing: Invitae Corp - Form 10-K

### Table of Contents

Joubert syndrome, polycystic kidney disease and others that involve a large number of genes and have been historically hard to diagnose in a cost effective and timely manner.

The foregoing are just some of the inherited genetic conditions included in our current assay of 216 genes. The table below lists disorders that are covered by our 216 gene assay. Some genes are involved in more than one disorder and many disorders may be associated with multiple genes. For a number of disorders in our current panel, we may provide some but not all of the genes that we believe are necessary to provide a comprehensive genetic test. Nonetheless, the low price of our assay allows physicians to conduct an initial screen for the genes which we do cover at prices that we believe are attractive for screening purposes. For example, while we do not cover all BBS genes, we do cover the majority of the genes and at a price we believe is highly attractive for such a test. When we believe that our gene coverage for a given disorder is broad enough to be considered comprehensive by generally accepted medical practice, we classify it as a panel. Within each gene, disorder and panel there may also be certain technical limitations of our assay for specific mutations or types of mutations that we appropriately identify for ordering physicians and note in our clinical reports.

Table of Contents

**Clients can order based on gene, disorder or panel (in bold):**



Table of Contents

*Our genetic testing process*

We have designed our service to be simple for our clients to use. Our clients send a sample to us and in turn receive a test report. Behind this streamlined user experience, however, is a sophisticated, highly automated infrastructure that we have developed in order to scale in a cost effective manner.

Starting from the client requisition and patient sample, through the report delivery, we have invested heavily in tools and technologies at each step in the process:

**Client portal, logistics and sample management:**

We have built an online, easy to use catalog and web portal to enable convenient online test ordering by healthcare providers. This web portal can be entered directly or through one of our other client tools, for example the digital Invitae Family History Tool available online and as an iPad application. Clients can use our web portal to place orders, track progress of the client sample through our system, contact client support, download reports and order further tests. In addition, we are dedicated to providing the highest level of client service, enhanced by technology wherever possible. We plan to continue to invest in online tools that can help support our clients' workflow and create a world class client experience.

**Sample processing and sequencing:**

We have developed a highly automated laboratory process for receiving and tracking samples, extracting genomic DNA, isolating targeted DNA sequences from each genome and sequencing the targeted genes using state-of-the-art next generation DNA sequencing technology. In addition, our fully integrated information and automation systems enable us to track every step from receiving and processing a sample to delivery of a clinical report. The data generated by our integrated sample processing infrastructure allow us to reduce the labor required, increase the amount of data used in our quality systems and reduce the raw costs of sequencing. We plan to continue to invest in this infrastructure to enable further scaling in volume and in breadth of the content we offer.

**Bioinformatics pipeline:**

We integrate standard and proprietary bioinformatics analyses in our workflow. This, combined with our integrated sample processing infrastructure, allows us to optimize our processes for variant detection with clinical sensitivity and specificity, especially for variant types that are difficult to resolve with current technologies. For example, we are able to offer certain types of complex variant analysis without having to run additional laboratory tests. Any pathogenic variants detected by our next generation DNA sequencing and analysis process are currently confirmed in a second laboratory test before reporting to a physician.

**Clinical reporting:**

We have invested significantly in scientific curation, bioinformatics, software infrastructure and tools to build a knowledge base about genetic conditions, genes and variants. This knowledge base and the software toolkit, which we refer to as our clinical report optimization platform, or CROP, that delivers the information to our clinical team enables them to view relevant information in a dashboard, which allows us to provide high quality genetic interpretation of test results to physicians and their patients. Each report is typically reviewed by a Ph.D. scientist, a genetic counselor and a licensed medical professional. Variants are classified in accordance with American College of Medical Genetics guidelines as benign, likely benign, variants of uncertain significance, likely pathogenic or pathogenic. We believe our investment in improved tools for genetic interpretation of test results also allows us to greatly increase the reporting throughput while at the same time standardize the variant identification and reporting process. By heavily investing in scalable software tools to execute the sample-to-report process, we believe that our clinical analysis costs will decline as our experience grows, even while assay and panel sizes increase.

Table of Contents

**Analyzing genomes requires a major investment in software and data analysis:**

One of our competitive advantages is the way in which we generate and deliver clinical reports to our clients. While our approach is enabled by recent advances in next generation sequencing technology, delivery of an individual, industry standard, clinical report that matches the clinical sensitivity and specificity of the various tests being ordered requires us to address a number of challenges. In order to do so, we have invested in solving four key areas of complexity:

**Genetic complexity:** Multiple genes and pathways can be implicated in genetic disorders, and overlapping networks of genes and symptoms can make genetic diagnosis ever more complicated for physicians to assess. Given the intensity of scientific and clinical research in the role of genes in disease process, the available information associating genes with clinically relevant outcomes is rapidly evolving.

To address this complexity, we expect to continue to release new genetic content and provide healthcare professionals with the flexibility to customize their orders by genes, disorders or multi-gene panels.

**Disparate, non-standardized clinical information:** Many of the clinicians and researchers in the field of genetics use information taken from clinical research literature and multiple public databases in disparate repositories hosted around the world. However, many of the public databases are subject to errors and inconsistencies, subjective outcome determinations, unclear condition boundaries and genes and variants with multiple aliases. In addition, the physical mapping to the genome or to the appropriate transcript is in some cases incorrect.

With the goal of ensuring the quality of information we are using to annotate variants identified by our assay, we employ geneticists to evaluate available literature and correct errors before incorporating the information in our knowledge base. We also contribute to public understanding by publishing anonymized variant information from our tests in Clinitae, a database of clinically-observed genetic





Table of Contents

variants aggregated from public sources that we operate and make freely available, and Clinvar, a similar database operated by the National Center for Biotechnology Information.

**Limitations of next generation sequencing to determine complex variants:** While recent advances in sequencing technologies have been impressive, use of these technologies to consolidate testing for many genetic disorders requires additional work when clinically important variants are complex and less amenable to standard sequencing technologies. Current next generation sequencing technologies typically divide DNA into relatively short strands, or "reads," for sequencing in a highly parallel manner. The process then uses software to assemble these short reads back into sequences that represent one or more genes. This process works very well when the variant involves a change in one or more single bases, or points, in the gene's structure. It works less well when the variant involves a more complex variation, such as a large insertion, deletion or duplication.

One way to address this challenge is to use a different technology to identify these variants. While we take this approach on occasion, it increases test costs and turnaround time, as it requires the management of multiple processes, often sequentially. In many cases the alternative technologies are not easily scalable, which means they are costly and labor intensive. As a consequence, we have invested in integrated sample preparation and software analysis processes that allow us to identify certain of these variant types using our next generation sequencing platform without having to resort to alternative technologies. This allows us to deliver high quality reports that identify many of these complex variants at reasonable cost and turnaround times.

**Clinical interpretation at scale:** As sequencing costs decline and the amount of available raw DNA sequence data and genes analyzed per individual sample grows, we expect the cost to interpret the data to increase. Unless addressed systematically, analysis and interpretation of the sheer volume of DNA sequence information available for each patient will require increasing amounts of medical professionals' time.

We have invested significantly in scientific curation, bioinformatics and software infrastructure and tools to build a knowledge base about genetic conditions, genes and variants. This knowledge base and the software toolkit that delivers the information to our clinical team enables them to view relevant information in a dashboard, which allows us to provide high quality genetic interpretation of test results to physicians and their patients. We can thus significantly increase the reporting throughput while at the same time standardizing the variant identification and reporting process, which allows us to deliver a simple, easy to interpret, clinical report to the ordering physician.

Table of Contents

**We have developed a standardized clinical report for clients' ease of use:**

To build the infrastructure that enables us to pursue consolidation of the rapidly growing global market for genetic testing will require significant research and development resources. Our research and development expenses were \$22.1 million, \$16.0 million and \$5.6 million in 2014, 2013 and 2012, respectively.

**Commercializing our genetic tests**

We have developed an offering that enables healthcare professionals to customize a test, receive rapid test results and pay a single price at requisition. Currently, we also offer a free re-requisition for the same indication within 90 days of the date of service. We believe that our investments in our research and development to enable lower prices, the value propositions associated with our service offering and our commercial approach will allow us to accelerate market adoption of our genetic tests.

Currently, we primarily target genetic counselors and geneticists, who we believe are early adopters and can influence broader clinical acceptance of new diagnostics, including multi-gene panels. We intend to expand our reach to include oncologists, neurologists, cardiologists and other healthcare professionals as we expand our offering and our commercial organization.

In order to reach current and future potential clients, our strategy is designed to expand our brand awareness, increase the availability of genetic content, increase traffic to our website, deliver an excellent user experience and attract partners. By offering a compelling value proposition and a comprehensive menu of genetic content at competitive prices, we seek to increase the number of clients that order a test, to encourage repeat orders and to extend client retention.

Table of Contents

We employ a variety of commercial strategies to achieve these goals:

**Our model incorporates a smaller sales force than is typical for other diagnostic companies.** Because we are aggregating large numbers of genetic tests into a single service, our offering will in most cases replace an existing test already offered by a third party. Where our test is replacing an existing test already offered by a third party, clinical utility of the tests that our service might replace is generally well established and accepted in medical practice, thus requiring a targeted sales force that manages relationships with our clients with the support of our in-house client services team.

**We are building a sophisticated client services team.** We strive to deliver an enhanced customer experience and have hired a team with deep clinical and scientific expertise designed to ensure our clients receive quality information. To supplement our client services team, we provide our clients access to our lab directors and genetic counselors for support as needed. We believe that this approach will allow us to maintain existing client relationships, allowing our sales force to focus on generating new accounts and extending the reach within existing accounts.

**Payors may emerge as a sales channel.** Given our commitment to making genetic information as affordable and accessible as possible, we see price as a competitive advantage that we expect will be particularly appealing to payors seeking to control healthcare costs. We believe that with equal or better turnaround time and quality payors will be supportive of our products and encourage their coverage universe to utilize them. We have recently begun to implement a reimbursement strategy and plan to focus on establishing broad coverage for the long term.

**We use innovative sales solutions.** We have built an advanced web portal for healthcare professionals and their patients to enhance and streamline their user experience, which we believe will encourage them to become loyal clients of Invitae. We are also committed to utilizing innovative technology to complement our sales and marketing effort and reduce the overall cost of client acquisition. For example, our Invitae Family History Tool is a family history collection tool available in the Apple app store, which enables genetic counselors to quickly and easily build, modify, share and save their patients' family histories. This tool also helps drive awareness of Invitae and helps to facilitate online ordering. We plan to continue to build innovative sales solutions capitalizing on the expertise of our extensive team of software developers.

**We employ an integrated marketing approach.** Our marketing strategy is focused on driving adoption and educating healthcare professionals on the value of multi-gene panel testing for hereditary cancers, cardiac conditions and other genetic diseases. We work closely with national and regional patient advocacy groups and medical professional societies to promote the awareness and benefits of genetic testing. Our marketing activities include presenting at medical conferences and scientific meetings, advertising on leading websites and other media, contributing to social media, conducting public relations campaigns, developing business alliances and partnerships and sponsoring continuing medical education.

Internationally, we are securing distribution arrangements in select territories to drive awareness and adoption. We currently have distribution agreements in Brazil, Israel, Mexico and other geographies and will work with our partners to develop our go-to market strategy and to create brand awareness, lead generation and client engagement activities in those markets. We intend to continue to build this network to increase our global presence and to make affordable genetic testing available to patients around the world.

Increased sales and marketing efforts may be required to compete with competitors who are more established in the market and have larger direct sales forces than we do. To this end, we plan to further staff in this area to expand our reach into new markets, develop educational information for patients, and engage with our target audience.

Table of Contents

The goal of our integrated, global sales and marketing approach is to develop and build multiple channels that drive adoption and growth, enabling us to bring low cost genetic testing into routine medical practice to improve the quality of healthcare for billions of people.

**Securing reimbursement**

By focusing on affordability, comprehensive genetic content, flexible ordering and quality, we designed our service offering to provide benefits to payors. Because we are aggregating large numbers of genetic tests into a single service, our near-term offering will in most cases replace an existing test already offered by a third party. Where our test is replacing an existing test already offered by a third party, the clinical utility of the tests that our service might replace is generally well established and accepted in medical practice.

We receive payment for our services from three categories of payors: patients, institutions and third-party payors. Given the relatively low cost of our test, a small but consistent percentage of patients whose physicians order our tests elect to pay for the tests themselves. Institutions, which are typically hospitals or foreign healthcare providers, account for a meaningful percentage of our test orders. We bill these organizations for our services, and they are responsible for paying those bills and seeking reimbursement where applicable. In the case of third party distributors, we may discount our price in exchange for marketing and sales services provided by the distributor in the geographic market where it operates.

Third-party payors are responsible for paying for the largest percentage of tests we deliver. Currently, these third-party payors consist exclusively of private health insurers. We believe that establishing coverage from the Centers for Medicare and Medicaid Services, or CMS, is an important factor in gaining adoption by healthcare providers, and we have been accepted as a Medicare provider. Further, we have entered into reimbursement contracts with Blue Shield of California and SelectHealth.

Third-party payors, including private insurers and CMS, require us to identify the test for which we are seeking reimbursement using a Current Procedural Terminology, or CPT, code set maintained by the American Medical Association, or AMA. Where we offer a multi-gene panel and there is no CPT code for the full panel, but the panel includes a gene for which the AMA has an established CPT code, we identify the test provided under that CPT code when billing a third party payor for that test. In cases where there is not a specific CPT code, our test may be billed under a miscellaneous code for an unlisted molecular pathology procedure. Because this miscellaneous code does not describe a specific service, the insurance claim must be examined to determine what service was provided, whether the service was appropriate and medically necessary, and whether payment should be rendered. This may require a letter of medical necessity from the ordering physician and it may result in a delay in processing the claim, a lower reimbursement amount or denial of the claim. Given the changing CPT coding environment, our practices regarding billing may change over time.

Additionally, we are targeting Innovation Centers within select payor organizations to establish pilot programs in order to demonstrate the utility of multi-gene panels. One such program is underway with a major U.S. healthcare provider. We also have an agreement with MultiPlan, a large PPO Network, which provides for adjudication and payment of claims for tests we deliver to members of their network in cases where we have not yet contracted with the payors in whose plans the test patients are members.

**Supporting clinical data**

We do not typically develop new biomarkers but rather aggregate already known genetic tests into our genetic testing platform. However, generating supporting clinical data is a priority for us as we seek to expand the gene content and adoption of our panels and provide supporting information to

Table of Contents

healthcare professionals. We conduct clinical studies to confirm the analytical validity and, when appropriate, clinical utility of our genetic testing platform. These data are used in marketing materials, whitepapers, scientific presentations and publications as appropriate.

Some panels we offer interrogate known genes that may be used in a novel clinical context, for example, the testing of genes that are known to cause certain cancers but have not been reported in other types of cancer. In these cases additional clinical utility data may influence both adoption and reimbursement. We thus also participate in studies to examine issues such as prevalence of genetic findings in different clinical populations and clinical actionability of these findings. We have developed research collaborations with key opinion leaders and leading academic medical centers with patient-care expertise and the appropriate patient populations for clinical studies.

In April 2014, a team of researchers from Stanford University and Invitae published the initial results of such a collaboration in the *Journal of Clinical Oncology*. The study utilized a panel of 42 cancer risk genes selected for clinical and research relevance that were tested by us on bio-banked germline DNA from 198 women who had been referred for hereditary breast and ovarian cancer testing to the Stanford University Medical Center. These individuals had been previously tested for BRCA1 and BRCA2 by an independent laboratory. Of the patients who participated in this study, 174 had breast cancer and 57 carried pathogenic germline variants in BRCA1 and BRCA2. The study found that BRCA1 and BRCA2 results from our panel were highly concordant with prior BRCA testing results on these individuals. Among the 141 BRCA-negative women, our panel identified additional risk variants in the MLH1, CDH1, NBN, ATM, MUTYH, CDKN2A, SLX4, BLM and PRSS1 genes. Based on the identification of new risk variants in genes beyond BRCA1 and BRCA2, Stanford's clinical staff determined that about 10% of participants warranted re-contact and additional counseling based on this new information. Stanford provided personalized recommendations for additional screening and other potential changes in care were provided as appropriate. The Stanford team found that this counseling was both feasible and was appreciated by the patients.

One of the patients described above is a woman who had been diagnosed with unilateral breast cancer in her mid-30s. At the time of her original diagnosis, the patient received a negative BRCA1 and BRCA2 test report from an independent laboratory, and consented to have her DNA banked. In this study, the patient was found to have a pathogenic variation in the gene MLH1 associated with Lynch syndrome. Following Institutional Review Board-approved protocol, the patient was re-contacted and the MLH1 results independently confirmed and communicated to her. In the time between the BRCA1 and BRCA2 and gene panel tests, the patient had been diagnosed with endometrial cancer. Following communication of her MLH1 status, she underwent an early colonoscopy and a polyp was found and removed. Thus, the tubular adenoma was caught years earlier than if no broad genetic test had been performed.

More recently, our scientists collaborated with two medical centers to test 600 patients indicated for BRCA1 and BRCA2 testing under National Comprehensive Cancer Network guidelines. Each of these patients had also previously received BRCA1 and BRCA2 test results from another, well-established laboratory employing traditional diagnostic techniques. Our test detected all BRCA1 and BRCA2 mutations that had been previously detected and independently confirmed. This list includes sequence variants of varying sizes and complexities, as well as deletions and duplications. All pathogenic variants detected by our assay were confirmed in the reference data. We observed 99.8% agreement between our clinical interpretations of pathogenic variants and those reported by the other lab. For the subset of patients in the study who had full sequence data for both BRCA1 and BRCA2 from both Invitae and from the reference lab, we reported a variant of uncertain significance, or VUS, in 6% of the patients, while 4% of the patients had a VUS from the other lab. For this count, we excluded patients who received limited testing (e.g., an Ashkenazi mutation panel or single-site testing) as such tests can never produce a VUS and artificially reduce VUS rates. We believe that sharing data on clinically-interpreted genetic variants benefits the medical and scientific communities by making

Table of Contents

knowledge more accessible, reducing VUS rates, and enabling independent verification of genetic test results. We are committed to sharing our clinically-interpreted variants along with the supporting evidence. This study has been expanded to over 900 patients and we expect the full study results to be available in 2015.

Clinical data from our various research and development efforts have been accepted for presentation at major conferences, including those sponsored by the Association for Molecular Pathology, the American College of Medical Genetics and Genomics, the American Society of Clinical Oncology, the American Society of Human Genetics, and the National Society of Genetic Counselors. Additional data have been submitted for publication and new studies in complementary clinical areas are in process.

**Expanding genetic testing content**

Aggregating multiple genetic tests into one test menu and one laboratory and medical interpretation process provides economies of scale and greater efficiency. We are focused on delivering a wide variety of genetic content through our CLIA-certified laboratory, and plan to release an increasing menu of content over time. By providing large numbers of different but related tests, such as multiple genes associated with a broad genetic condition like hereditary cancer or cardiovascular disorders, we provide physicians with choice and flexibility in ordering tests for individual genes, panels of genes or custom sets of genes at the physician's discretion. In addition, by adding genes relevant to new diseases, we are able to expand our offering to address new markets for genetic testing services.

In the first quarter of 2015, we introduced a substantial improvement to our genetic testing platform which allows us to sequence certain genes with features that are more difficult to analyze and to include additional genes in our offering. In addition, we plan to introduce in the second half of 2015 an expansion of our current offering to over 500 genes. This expanded offering would double the amount of genetic content we are able to provide at a fixed cost, which would further drive down the cost per reportable gene.

We expect to expand the amount of genetic information we provide over time to include all of the clinically-indicated genes currently known more than 4,000 according to genetests.org and eventually the whole genome. The long list of disorders for which clinicians currently order these tests highlights the opportunity at hand in aggregating the "long tail" of genetic tests.

**We plan to steadily increase the release of genetic content while driving down the cost per gene:**

We are developing an integrated portfolio of laboratory processes, software tools and informatics capabilities that allow us to process DNA-containing samples, analyze information about patient-specific genetic variation and generate test reports for physicians and their patients. In addition, we are optimizing web technologies for efficient and productive interactions with physicians and patients using our service. We are investing heavily in systems that we believe will allow us to deliver individual clinical reports for physicians and patients from an expanding menu of content at increasing speed while decreasing costs per reportable gene over time.

Table of Contents

**The evolution of our business**

We believe there is a substantial opportunity for genetic tests and information to be aggregated and then ultimately captured in comprehensive genome management services. We envision that this shift will enable the medical community to use genetic information on an ongoing basis, as part of mainstream medical practice, to improve patient care.

***Genome management***

We are building a genome data management infrastructure to provide clients, including patients and healthcare professionals, with an ongoing resource for pertinent genetic information over the course of disease or life of a patient. In the future we plan to work with healthcare providers to establish a system where this genetic information is linked at the point of care for appropriate use as needs arise.

The decreasing cost of DNA sequencing is allowing us to provide an increasing amount of genetic information at a decreasing price per gene and thus aggregate an expanding number of genes into a single service. As a result, our laboratory process captures more genetic information than the physician may initially request. Only those genes that are requisitioned by the ordering physician are analyzed by our medical team and reported to the ordering physician and patient. The additional information is stored electronically on behalf of the patient should their physician request any of it in the future. Currently, we allow re- requisition of data for additional genes within the same indication at no additional charge within 90 days of the date of service.

As the amount of information available for each patient expands, we plan to initiate a genome management program to provide patients and their healthcare providers with access to that additional information to answer healthcare questions as they arise. We expect to make additional genetic content accessible to physicians and their patients along with educational materials on the conditions, genes and variants. Because the raw DNA sequence information has already been derived from our laboratory processes, the cost of delivering an additional clinical report will involve only information management and clinical interpretation, and as a consequence will be significantly lower than running a new test.

Ultimately, we believe we can significantly improve patient care by offering comprehensive genetic testing, where reports for large numbers of genetic conditions can be available for additional charges over the lifetime of a patient. For example, a patient whose whole genome has been sequenced could have that information linked to an electronic medical records system or available via Invitae systems for a variety of applications. Using this information, we may be able to provide a surgical team with genetic information about a patient's predisposition to complications associated with anesthesia, post-operative medication and bleeding or clotting. We may also be able to provide prospective parents with carrier testing for possible genetic conditions. As another example, in the case of patients undergoing chemotherapy we may be able to provide the treating clinicians with information about other genetic conditions that might result in complications during treatment.

***The genome network***

As our genetic testing and genome management offerings grow in scale, we intend to continue to invest in informatics solutions that enable sharing of genetic information to improve healthcare and clinical outcomes. Participants in our genome network may include patients, family members, healthcare professionals, payors, industry professionals, researchers and clinical trial sponsors.

For example, patients will be able to share information regarding their health and test results with family members and future generations to help them understand their own health, enabling targeted testing and potentially reducing common health issues. Parents of children with the same rare genetic conditions can come into contact with each other to compare treatment options, educational choices, and provide emotional support. Physicians could access easily navigated databases that show the latest

Table of Contents

scientific data, including variants, and connect them with other physicians to discuss diagnoses and treatment options for similar patients. Patients could donate their genetic information to the research community. Pharmaceutical companies may seek to identify individuals with a particular genetic profile and medical history to participate in clinical trials of new treatments. Patients may be interested in accessing marketing information on healthcare products appropriate for their healthcare needs.

The first application of our network strategy is our Invitae Family History Tool, which is available as a free web or iPad application. This application enables users to quickly and easily build, modify, share and save relevant family genetic and health history information. All data is stored in a HIPAA-compliant cloud computing environment. A second part of our network strategy is Clinitae, a web property that allows physicians or patients to look up individual genes and variants in order to find out additional genetic information. In the future, we plan to add functionality to allow patients and physicians to share more information about their variants and connect with other patients or physicians who might be able to contribute additional information that could affect their health and wellness.

We do not believe that the genome network will contribute to our financial results for several years. The success of any network offering will depend on our ability to achieve scale in our genetic testing and genome management businesses. The success of the genome network will also require that we deliver infrastructure to enable the market for the permission-based sharing of genomic data in a way that is consistent with our core principles regarding patients' ownership and control of their data.

***Our strategy***

Our strategy for long-term growth is focused on five key drivers of our business, which we believe cumulate to create a flywheel effect:

**Lower the cost and price of genetic information.** Our goal is to provide clients with a broad menu of genetic content at a reasonable price and rapid turn-around time in order to grow volume and further achieve economies of scale. As we do so and experience further cost savings, we expect that those cost savings will allow us to deliver more comprehensive information at decreasing prices per gene.

**Expand our genetic testing content.** As we reduce our costs, we intend to continue to expand our test menus by steadily releasing additional genetic content for the same or lower prices per test, ultimately leading to affordable whole genome services. The breadth and flexibility of our offering is intended to contribute to an improved user experience.



Table of Contents

**Create a unique user experience.** A state-of-the-art interactive platform will enhance our service offering, leverage the uniquely empowering characteristics of online sharing of genetic information and, we believe, enable a superior economic offering to clients. We intend to continue to expend substantial efforts developing, acquiring and implementing technology-driven enhancements to our web properties and transaction-processing systems. We believe that an enhanced user experience and the resulting benefits to our brand and reputation will help draw clients to us.

**Drive traffic.** We intend to increase our brand equity and visibility through excellent service and a variety of marketing and promotional techniques, including scientific publication and presentation, sales, marketing, public relations, social media and web technology vehicles. We expect that increased traffic to our website and eventual increases in the volume of tests ordered will help us to attract partners and increase our revenue.

**Attract partners.** As we release additional genetic content and attract more clients, we believe our business becomes particularly attractive to potential partners that can help the patients in our network further benefit from their genetic information or that provide us access to new clients who may wish to join our network. The cumulative effect of the increased volume brought by all of these strategic components will allow us to lower the cost of our service.

We seek to differentiate our service in the market by establishing an exceptional client experience. To that end, we believe that elevating the needs of the client over those of our other stakeholders is essential to our success. Thus, in our decision-making processes, we will strive to prioritize, in order: (1) the needs of our clients; (2) motivating our employees to serve our clients; and (3) our long-term stockholder value. We believe that focusing on clients as our top priority rather than short-term financial goals is the best way to build and operate an organization for maximum long-term value creation.

***Competition***

Our competitors include companies that offer molecular genetic testing services, including specialty and reference laboratories that offer traditional single and multi-gene tests. Principal competitors include companies such as Myriad Genetics, Ambry Genetics, GeneDx, a subsidiary of Bio-Reference Laboratories, Laboratory Corporation of America and Quest Diagnostics, as well as other commercial and academic labs. In addition to the companies that currently offer traditional genetic testing services and research centers, other established and emerging healthcare, information technology and service companies may commercialize competitive products including informatics, analysis, integrated genetic tools and services for health and wellness.

We believe the principal competitive factors in our market are:

price and quality of tests;

turnaround time of testing results;

coverage and reimbursement arrangements with third-party payors;

breadth and depth of content;

convenience of testing;

brand recognition of test provider;

additional value-added services and informatics tools;

accessibility of results;

client service;

Table of Contents

quality of website content; and

reliability.

We believe that we compare favorably with our competitors on the basis of these factors. However, many of our competitors and potential competitors have longer operating histories, larger customer bases, greater brand recognition and market penetration, substantially greater financial, technological and research and development resources and selling and marketing capabilities, more experience dealing with third-party payors. As a result, they may be able to respond more quickly to changes in customer requirements, devote greater resources to the development, promotion and sale of their tests than we do, or sell their tests at prices designed to win significant levels of market share. We may not be able to compete effectively against these organizations.

**Near-term plan of operation**

From the date of this Report through June 30, 2015, we plan to primarily focus on increasing adoption of, and reimbursement for, our assay of 216 genes, expanding our commercial operations and advancing our assay of over 500 genes from clinical validation into commercial availability in 2015, working on future generations of our assays to support continued expansion of our genetic content, and continuing to automate our laboratory and medical interpretation processes. We anticipate that we will invest heavily in our business through June 30, 2015 in connection with the implementation of our strategy.

Specifically, we expect our research and development expenses will increase as we invest in developing additional assays, software analysis pipelines, report optimization systems for interpreting and reporting test results, and digital tools for use by clinicians and their patients. We also expect our selling and marketing expenses will increase as we hire additional sales, marketing and customer service personnel, further develop our web infrastructure and undertake additional marketing efforts through appearances at conferences and tradeshow in order to promote Invitae and to educate clinicians about our assay. Additionally, we expect that our general and administrative expenses will increase as we incur additional expenses necessary to comply with our obligations as a publicly-traded company and expand our billing and client services functions to support anticipated increased demand for our tests. We believe that the estimated net proceeds from our initial public offering, together with our existing cash and cash equivalents, will be sufficient to meet our anticipated cash requirements for at least the next 12 months, and as such, we do not expect it will be necessary to raise additional capital during that period.

We believe that we will require additional laboratory capacity in 2016 in order to meet the currently-anticipated demand for our assays, and we expect to incur approximately \$7.5 million in capital expenditures through June 30, 2015 to outfit our new laboratory and acquire laboratory equipment and computer systems necessary for the anticipated growth of our business. We anticipate that we will also lease additional office space in locations where we believe there is a pool of talent with the skills we need in order to continue to expand our business. We also plan to continue hiring employees to support the anticipated growth in our business, including in production, selling and marketing, research and development, and general and administrative functions. From December 31, 2014 through June 30, 2015, we expect to increase our headcount by approximately 30 to 40 full-time employees per quarter.

Our expectations with respect to our near-term operating plan and ability to effectively execute on this plan are subject to a number of factors and risks, and many of which are outside of our control. If one or more of these events were to occur, it may be necessary for us to shift our priorities and our plans, abandon or delay one or more of our planned activities, or otherwise adjust our proposed near- and long-term business plans. Please see "Item 1A. Risk Factors" for a discussion of some of these risks and events, and their potential effects on our business.

Table of Contents

**Regulation**

***Reimbursement***

In September 2014, the American Medical Association published new CPT codes for genomic sequencing procedures that will be effective for dates of service on or after January 1, 2015. These include genomic sequencing procedure codes for panels, including hereditary colon cancer syndromes, targeted genomic sequence analysis panels for solid organ neoplasms, targeted genomic sequence analysis panels for hematolymphoid neoplasm or disorders, whole exome analyses, and whole genome analyses. In a final determination under the Medicare Clinical Laboratory Fee Schedule, or CLFS, published in November 2014, CMS set the payment rate for these codes by the gap-fill process. Under the gap-fill process, local Medicare Administrative Contractors, or MACs, would establish rates in 2015 considering laboratory charges and discounts to charges, resources, amounts paid by other payors for the tests, and amounts paid by the MAC for similar tests. Based upon the local gap-filled rates established in 2015, a national limitation amount for Medicare will be established for 2016. The national limitation amount serves as a cap on the Medicare and Medicaid payment rates for a test procedure. If we are required to report our tests under these codes, there can be no guarantees that Medicare (or its contractors) will set adequate reimbursement rates for these new codes.

In April 2014, Congress passed the Protecting Access to Medicare Act of 2014, or PAMA, which included substantial changes to the way in which clinical laboratory services will be paid under Medicare. Under PAMA, laboratories that receive the majority of their Medicare revenue from payments made under the CLFS or the Physician Fee Schedule would report, beginning in 2016, and then every three years thereafter (or annually for "advanced diagnostic laboratory tests"), private payor payment rates and volumes for their tests. An advanced diagnostic laboratory test is a clinical diagnostic laboratory test covered under Medicare that is offered and furnished only by a single laboratory and not sold for use by a laboratory other than the original developing laboratory (or a successor owner) and meets one of the following criteria: (1) the test is an analysis of multiple biomarkers of DNA, RNA, or proteins combined with a unique algorithm to yield a single patient-specific result; (2) the test is cleared or approved by the Food and Drug Administration; or (3) the test meets other similar criteria established by the Secretary of Health and Human Services (no criteria have been established by the Secretary as of December 2014). We do not believe that our tests meet the current definition of advanced diagnostic laboratory tests, and therefore believe we will be required to report private payor rates for our tests on an every three years basis. CMS will use the rates and volumes reported by laboratories to develop Medicare payment rates for the tests equal to the volume-weighted median of the private payor payment rates for the tests. Laboratories that fail to report the required payment information may be subject to substantial civil money penalties.

For tests furnished on or after January 1, 2017, Medicare payments for clinical diagnostic laboratory tests will be paid based upon these reported private payor rates. For clinical diagnostic laboratory tests that are assigned a new or substantially revised code, initial payment rates for clinical diagnostic laboratory tests that are not advanced diagnostic laboratory tests will be assigned by the cross-walk or gap-fill methodology, as under prior law. Initial payment rates for new advanced diagnostic laboratory tests will be based on the actual list charge for the laboratory test.

The payment rates calculated under PAMA will be effective starting January 1, 2017. Any reductions to payment rates resulting from the new methodology are limited to 10% per test per year in each of the years 2017 through 2019 and to 15% per test per year in each of 2020 through 2022.

PAMA codified Medicare coverage rules for laboratory tests by requiring any local coverage determination to be made following the local coverage determination process. PAMA also authorizes CMS to consolidate coverage policies for clinical laboratory tests among one to four laboratory-specific MACs. These same contractors may also be designated to process claims if CMS determines that such a model is appropriate.

Table of Contents

***Clinical Laboratory Improvement Amendments of 1988, or CLIA***

Our clinical reference laboratory in California is required to hold certain federal certificates to conduct our business. Under CLIA, we are required to hold a certificate applicable to the type of laboratory examinations we perform and to comply with standards covering personnel, facilities administration, inspections, quality control, quality assurance and proficiency testing.

We have a current certificate under CLIA to perform testing at our laboratory location in San Francisco. To renew our CLIA certificate, we are subject to survey and inspection every two years to assess compliance with program standards. Moreover, CLIA inspectors may make random inspections of our clinical reference laboratory in California. The regulatory and compliance standards applicable to the testing we perform may change over time, and any such changes could have a material effect on our business.

If our clinical reference 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 directed 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 diagnostic services provided to Medicare and Medicaid beneficiaries. If we were to be found out of compliance with CLIA requirements and subjected to sanction, our business could be harmed.

***State laboratory testing***

We are required to maintain a license to conduct testing in California. California laws establish standards for day-to-day operations of our laboratory in San Francisco. California laws mandate proficiency testing, which involves testing of specimens that have been specifically prepared for the laboratory. If our clinical reference laboratory is out of compliance with California standards, the California Department of Health Services, or DHS, may suspend, restrict or revoke our license to operate our clinical reference laboratory, assess substantial civil money penalties, or impose specific corrective action plans. Any such actions could materially affect our business. We maintain a current license in good standing with DHS. However, we cannot provide assurance that DHS will at all times in the future find us to be in compliance with all such laws.

Several states require the licensure of out-of-state laboratories that accept specimens from those states. For example, New York requires a laboratory to hold a permit which is issued after an on-site inspection and approval of testing methodology, and has various requirements over and above CLIA and CAP, including those for personnel qualifications, proficiency testing, physical facility, equipment, and quality control standards. Our laboratory holds the required licenses for Florida, Maryland, Pennsylvania and Rhode Island.

Our clinical reference laboratory in California is required to be licensed on a test-specific basis by New York State as an out of state laboratory and our products, as LDTs, must be approved by the New York State Department of Health, or NYDOH, before they are performed on samples from New York. Once approved, we would also be subject to periodic inspection by the NYDOH and required to demonstrate ongoing compliance with NYDOH regulations and standards. Because our laboratory is not licensed by New York, we are currently prohibited from testing samples from New York.

Other states may adopt similar licensure requirements in the future, which may require us to modify, delay or stop our operations in such jurisdictions. Complying with licensure requirements in new jurisdictions may be expensive, time-consuming, and subject us to significant and unanticipated delays. 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.

Table of Contents

We may also be subject to regulation in foreign jurisdictions as we seek to expand international utilization of our tests or such jurisdictions adopt new licensure requirements, which may require review of our tests in order to offer them or may have other limitations such as restrictions on the transport of human blood necessary for us to perform our tests that may limit our ability to make our tests available outside of the United States.

*U.S. Food and Drug Administration, or FDA*

We provide our tests as laboratory-developed tests, or LDTs. CMS and certain state agencies regulate the performance of LDTs (as authorized by CLIA and state law, respectively).

Historically, the FDA, has exercised enforcement discretion with respect to most LDTs and has not required laboratories that furnish LDTs to comply with the agency's requirements for medical devices (e.g., establishment registration, device listing, quality systems regulations, premarket clearance or premarket approval, and post-market controls). In recent years, however, the FDA has stated it intends to end its policy of general enforcement discretion and regulate certain LDTs as medical devices. To this end, on October 3, 2014, the FDA issued two draft guidance documents, entitled "Framework for Regulatory Oversight of Laboratory Developed Tests (LDTs)" and "FDA Notification and Medical Device Reporting for Laboratory Developed Tests (LDTs)", respectively, that set forth a proposed risk-based regulatory framework that would apply varying levels of FDA oversight to LDTs. The FDA has indicated that it does not intend to modify its policy of enforcement discretion until the draft guidance documents are finalized. It is unclear at this time when, or if, the draft guidance documents will be finalized, and even then, the new regulatory requirements are proposed to be phased-in consistent with the schedule set forth in the guidance (in as little as 12 months after the draft guidance is finalized for certain high-priority LDTs). Nevertheless, the FDA may decide to regulate certain LDTs on a case-by-case basis at any time.

Legislative proposals addressing the FDA's oversight of LDTs have been introduced in previous Congresses, and we expect that new legislative proposals will be introduced from time-to-time. The likelihood that Congress will pass such legislation and the extent to which such legislation may affect the FDA's plans to regulate certain LDTs as medical devices is difficult to predict at this time.

If the FDA ultimately regulates certain LDTs as medical devices, whether via final guidance, final regulation, or as instructed by Congress, our tests may be subject to certain additional regulatory requirements. Complying with the FDA's requirements for medical devices can be expensive, time-consuming, and subject us to significant or unanticipated delays. Insofar as we may be required to obtain premarket clearance or approval to perform or continue performing an LDT, we cannot assure you that we will be able to obtain such authorization. Even if we obtain regulatory clearance or approval where required, such authorization may not be for the intended uses that we believe are commercially attractive or are critical to the commercial success of our tests. As a result, the application of the FDA's medical device requirements to our tests could materially and adversely affect our business, financial condition, and results of operations.

Failure to comply with applicable FDA regulatory requirements may trigger a range of enforcement actions by the FDA including warning letters, civil monetary penalties, injunctions, criminal prosecution, recall or seizure, operating restrictions, partial suspension or total shutdown of operations, and denial of or challenges to applications for clearance or approval, as well as significant adverse publicity.

In addition, in November 2013, the FDA issued final guidance regarding the distribution of products labeled for research use only. Certain of the reagents and other products we use in our tests are labeled as research use only products. Certain of our suppliers may cease selling research use only products to us and any failure to obtain an acceptable substitute could significantly and adversely affect our business, financial condition and results of operations.

Table of Contents

***HIPAA and HITECH***

Under the administrative simplification provisions of the Health Insurance Portability and Accountability Act of 1996, or HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, the U.S. Department of Health and Human Services issued regulations that establish uniform standards governing the conduct of certain electronic healthcare transactions and protecting the privacy and security of protected health information used or disclosed by most healthcare providers and other covered entities and their business associates, including the business associates' subcontractors. Four principal regulations with which we are required to comply have been issued in final form under HIPAA and HITECH: privacy regulations, security regulations, the breach notification rule, and standards for electronic transactions, which establish standards for common healthcare transactions.

The privacy regulations cover the use and disclosure of protected health information by covered entities as well as business associates, which are defined to include subcontractors that create, receive, maintain, or transmit protected health information on behalf of a business associate. They also set forth certain rights that an individual has with respect to his or her protected health information maintained by a covered entity, including the right to access or amend certain records containing protected health information, or to request restrictions on the use or disclosure of protected health information. The security regulations establish requirements for safeguarding the confidentiality, integrity, and availability of protected health information that is electronically transmitted or electronically stored. HITECH, among other things, established certain health information security breach notification requirements. A covered entity must notify any individual whose protected health information is breached according to the specifications set forth in the breach notification rule. The HIPAA privacy and security regulations establish a uniform federal "floor" and do not supersede state laws that are more stringent or provide individuals with greater rights with respect to the privacy or security of, and access to, their records containing protected health information or insofar as such state laws apply to personal information that is broader in scope than protected health information as defined under HIPAA. Massachusetts, for example, has a state law that protects the privacy and security of personal information of Massachusetts residents.

There are significant civil and criminal fines and other penalties that may be imposed for violating HIPAA. A covered entity or business associate is also liable for civil money penalties for a violation that is based on an act or omission of any of its agents, including a downstream business associate, as determined according to the federal common law of agency. Additionally, to the extent that we submit electronic healthcare claims and payment transactions that do not comply with the electronic data transmission standards established under HIPAA and HITECH, payments to us may be delayed or denied.

***Federal, state and foreign fraud and abuse laws***

In the United States, there are various fraud and abuse laws with which we must comply and we are potentially subject to regulation by various federal, state and local authorities, including CMS, other divisions of the U.S. Department of Health and Human Services (e.g., the Office of Inspector General), the U.S. Department of Justice, and individual U.S. Attorney offices within the Department of Justice, and state and local governments. We also may be subject to foreign fraud and abuse laws.

In the United States, the federal Anti-Kickback Statute prohibits, among other things, knowingly and willfully offering, paying, soliciting or receiving remuneration, directly or indirectly, overtly, covertly, in cash or in kind to induce or in return for the furnishing, arranging for the furnishing of, purchasing, leasing, ordering or arranging for or recommending purchasing, leasing or ordering of any good, facility, service or item for which payment may be made in whole or in part by a federal healthcare program. Courts have stated that a financial arrangement may violate the Anti-Kickback

Table of Contents

Statute if any one purpose of the arrangement is to encourage patient referrals or other federal healthcare program business, regardless of whether there are other legitimate purposes for the arrangement. The definition of "remuneration" has been broadly interpreted to include anything of value, including gifts, discounts, credit arrangements, payments of cash, consulting fees, waivers of co-payments, ownership interests, and providing anything at less than its fair market value. Although the Anti-Kickback Statute contains several exceptions, it is broad and may technically prohibit many innocuous or beneficial arrangements within the healthcare industry. Further, the U.S. Department of Health and Human Services issued a series of regulatory "safe harbors." These safe harbor regulations set forth certain provisions, which, if met, will assure healthcare providers and other parties that they will not be prosecuted under the federal Anti-Kickback Statute. Although full compliance with the statutory exceptions or regulatory safe harbors ensures against prosecution under the federal Anti-Kickback Statute, the failure of a transaction or arrangement to fit within a specific statutory exception or regulatory safe harbor does not necessarily mean that the transaction or arrangement is illegal or that prosecution under the federal Anti-Kickback Statute will be pursued. Penalties for federal anti-kickback violations are severe, and include imprisonment, criminal fines, civil money penalties, and exclusion from participation in federal healthcare programs. Many states also have anti-kickback statutes, some of which may apply to items or services reimbursed by any third-party payor, including commercial insurers.

There are also federal laws related to healthcare fraud and false statements, among others, relating to healthcare matters. The healthcare fraud statute prohibits knowingly and willfully executing a scheme to defraud any healthcare benefit program, including private payors. A violation of this statute is a felony and may result in fines, imprisonment, or exclusion from governmental payor programs such as the Medicare and Medicaid programs. The false statements statute prohibits knowingly and willfully falsifying, concealing or covering up a material fact, or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items, or services. A violation of this statute is a felony and may result in fines, imprisonment, or exclusion from governmental payor programs.

Another development affecting the healthcare industry is the increased enforcement of the federal False Claims Act and, in particular, actions brought pursuant to the False Claims Act's "whistleblower" or "qui tam" provisions. The False Claims Act imposes liability on any person or entity that, among other things, knowingly presents, or causes to be presented, a false or fraudulent claim for payment by a federal governmental payor 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 defrauded the federal government by submitting a false claim to the federal government and permit such individuals to share in any amounts paid by the entity to the government in fines or settlement. 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 ranging from \$5,500 to \$11,000 for each false claim.

In addition, various states have enacted false claim laws analogous to the federal False Claims Act, although many of these state laws apply where a claim is submitted to any third-party payor and not merely a governmental payor program.

Additionally, the civil monetary penalties statute imposes penalties against any person or entity that, among other things, is determined to have presented or caused to be presented a claim to a federal health program that the person knows or should know is for an item or service that was not provided as claimed or for a claim that is false or fraudulent. This law also prohibits the offering or transfer of remuneration to a Medicare or state healthcare program beneficiary if the person knows or should know it is likely to influence the beneficiary's selection of a particular provider, practitioner, or supplier of services reimbursable by Medicare or a state healthcare program, unless an exception applies.



Table of Contents

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 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.

***Physician referral prohibitions***

Under a federal law directed at "self-referral," commonly known as the "Stark Law," there are prohibitions, with certain exceptions, on referrals for certain designated health services, including laboratory services, that are covered by the Medicare program by physicians who personally, or through an immediate family member, have a financial relationship with the entity to which the referrals for designated health services are made. The prohibition also extends to payment for any testing referred in violation of the Stark Law. A person who engages in a scheme to circumvent the Stark Law's referral prohibition may be fined up to \$100,000 for each such arrangement or scheme. In addition, any person who presents or causes to be presented a claim to the Medicare program in violation of the Stark Law is subject to civil monetary penalties of up to \$15,000 per service, an assessment of up to three times the amount claimed and possible exclusion from participation in federal healthcare programs. In addition, any person who presents or causes to be presented a claim to the Medicare program in violation of the Stark Law is subject to civil monetary penalties of up to \$15,000 per service, an assessment of up to three times the amount claimed, and possible exclusion from participation in federal or state health care programs. Bills submitted in violation of the Stark Law may not be paid by Medicare, and any person collecting any amounts with respect to any such prohibited bill is obligated to refund such amounts. Many states have comparable laws that are not limited to Medicare referrals. The Stark Law also prohibits state receipt of Federal Medicaid matching funds for prohibited referrals, but this provision of the Stark Law has not been implemented by regulations. In addition, some courts have held that the submission of claims to Medicaid that would be prohibited as self-referrals under the Stark Law for Medicare could implicate the False Claims Act.

***Corporate practice of medicine***

Numerous states have enacted laws prohibiting business corporations, such as us, from practicing medicine and employing or engaging physicians to practice medicine, generally referred to as the prohibition against the corporate practice of medicine. These laws are designed to prevent interference in the medical decision-making process by anyone who is not a licensed physician. For example, California's Medical Board has indicated that determining what diagnostic tests are appropriate for a particular condition and taking responsibility for the ultimate overall care of the patient, including providing treatment options available to the patient, would constitute the unlicensed practice of medicine if performed by an unlicensed person. Violation of these corporate practice of medicine laws may result in civil or criminal fines, as well as sanctions imposed against us and/or the professional through licensure proceedings. Typically such laws are only applicable to entities that have a physical presence in the state.

Table of Contents

**Intellectual property**

We rely on a combination of intellectual property rights, including trade secrets, copyrights, trademarks, customary contractual protections and, to a lesser extent, patents, to protect our core technology and intellectual property. With respect to patents, we believe that the practice of patenting individual genes, along with patenting tools and methods specific to individual genes, has impeded the progress of the genetic testing industry beyond single gene tests and is antithetical to our core principle that patients should own and control their own genomic information. Over the past three years the U.S. Supreme Court has issued a series of unanimous (9-0) decisions setting forth limits on the patentability of natural phenomena, natural laws, abstract ideas and their applications *i.e. Mayo Collaborative v. Prometheus Laboratories (2012)*, or *Mayo*, *Association for Molecular Pathology v. Myriad Genetics (2013)*, or *Myriad*, and *Alice Corporation v. CLS Bank (2014)*, or *Alice*. As discussed below, we believe the *Mayo*, *Myriad* and *Alice* decisions bring clarity to the limits to which patents may cover specific genes, mutations of such genes, or gene-specific technology for determining a patient's genomic information.

**Patents**

Recent U.S. Supreme Court cases have clarified that naturally occurring DNA sequences are natural phenomena which should not be patentable. On June 13, 2013, the U.S. Supreme Court decided *Myriad*, a case challenging the validity of patent claims held by Myriad relating to the cancer genes BRCA1 and BRCA2. The *Myriad* Court held that genomic DNAs that have been isolated from, or have the same sequence as, naturally occurring samples, such as the DNA constituting the BRCA1 and BRCA2 genes or fragments thereof, are not eligible for patent protection. Instead, the *Myriad* Court held that only those complementary DNAs (cDNAs) which have a sequence that differs from a naturally occurring fragment of genomic DNA may be patent eligible. Because it will be applied by other courts to all gene patents, the holding in *Myriad* also invalidates patent claims to other genes and gene variants. Prior to *Myriad*, on August 16, 2012, the U.S. Court of Appeals for the Federal Circuit had held that certain patent claims of Myriad directed to methods of comparing or analyzing BRCA1 and BRCA2 sequences to determine whether or not a person has a variant or mutation are unpatentable abstract processes, and Myriad did not appeal such ruling.

We do not currently have any patents or patent applications directed to the sequences of specific genes or variants of such genes, nor have we in-licensed such patents rights of any third party. We believe that correlations between specific gene variants and a person's susceptibility to certain conditions or diseases are natural laws that are not patentable under the U.S. Supreme Court's decision in *Mayo*. The *Mayo* case involved patent claims directed to optimizing, on a patient-specific basis, the dosage of a certain drug by measuring its metabolites in a patient. The *Mayo* Court determined that patent claims directed at detection of natural correlations, such as the correlation between drug metabolite levels in a patient and that drug's optimal dosage for such patient, are not eligible for patent protection. The *Mayo* Court held that claims based on this type of comparison between an observed fact and an understanding of that fact's implications represent attempts to patent a natural law and, moreover, when the processes for making the comparison are not themselves sufficiently inventive, claims to such processes are similarly patent-ineligible. On June 19, 2014, the U.S. Supreme Court decided *Alice*, where it amplified its *Mayo* and *Myriad* decisions and clarified the analytical framework for distinguishing between patents that claim laws of nature, natural phenomena and abstract ideas and those that claim patent-eligible applications of such concepts. According to the *Alice* Court, the analysis depends on whether a patent claim directed to a law of nature, a natural phenomenon or an abstract idea contains additional elements, an "inventive concept," that "is 'sufficient to ensure that the patent in practice amounts to significantly more than a patent upon the [ineligible concept] itself'" (citing *Mayo*).

Table of Contents

We believe that *Mayo*, *Myriad* and *Alice* not only render as unpatentable genes, gene fragments and the detection of a person's sequence for a gene, but also have the same effect on generic applications of conventional technology to specific gene sequences. For example, we believe that generic claims to primers or probes directed to specific gene sequences and uses of such primers and probes in determining a person's genetic information are not patentable. We do not currently have any patents or patent applications directed to such subject matter nor have we in-licensed such patents rights of any third party.

Unlike patents directed to specific genes, we do rely upon, in part, patent protection to protect technology that is not gene-specific and that provides us with a potential competitive advantage as we focus on making comprehensive genetic information less expensive and more broadly available to our clients. In this regard, we have one issued U.S. patent, two pending U.S. utility patent application, one PCT application and three pending U.S. provisional patent applications directed to various aspects of our laboratory, analytic and business practices. We intend to pursue further patent protection where appropriate.

***Trade secrets***

In addition to seeking patent protection for some of our laboratory, analytic and business practices, we also rely on trade secrets, including unpatented know-how, technology and other proprietary information, to maintain and develop our competitive position. We have developed proprietary procedures for both the laboratory processing of patient samples and the analysis of the resulting data to generate clinical reports. For example, we have automated aspects of our processes for curating information about known variants, identifying variants in an individual's sequence information, associating those variants with known information about their potential effects on disease, and presenting that information for review by personnel responsible for its interpretation and for the delivery of test reports to physicians. We try to protect these trade secrets, in part, by taking reasonable steps to keep them confidential. This includes entering into nondisclosure and confidentiality agreements with parties who have access to them, such as our employees and certain third parties. We also enter into 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 may not enter into such agreements with all relevant parties, and these parties may not abide by the terms of their agreements. Despite measures taken to protect our intellectual property, unauthorized parties might copy or independently develop and commercially exploit aspects of our technology or obtain and use information that we regard as proprietary.

***Trademarks***

We work hard to achieve a high level of quality in our operations and to provide our clients with a superior experience when interacting with us. As a consequence, our brand is very important to us, as it is a symbol of our reputation and representative of the goodwill we seek to generate with our clients. As a consequence, we have invested significant resources in protection of our trademarks. To date, we have filed for trademark protection for INVITAE as well as our logo (circle design) and INVITAE with the logo. Registrations for INVITAE have been obtained in 21 countries and are currently pending in more than 19 countries. Applications for our logo (circle design) have been obtained in three countries and are currently pending in more than 29 countries, and one application is pending for INVITAE with the logo.

**Environmental matters**

Our operations require the use of hazardous materials (including biological materials) which subject 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

Table of Contents

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.

**Raw materials and suppliers**

We rely on a limited number of suppliers, or, in some cases, sole suppliers, including Agilent Technologies, Inc., Illumina, Inc., Integrated DNA Technologies Incorporated, Qiagen N.V. and Roche Holdings Ltd. for certain laboratory reagents, as well as sequencers and other equipment and materials which we use in our laboratory operations. We rely on Illumina as the sole supplier of next generation sequencers and associated reagents and as the sole provider of maintenance and repair services for these sequencers. Our laboratory operations could be interrupted if we encounter delays or difficulties in securing these reagents, sequencers or other equipment or materials, and if we cannot obtain an acceptable substitute. Any such interruption could significantly affect our business, financial condition, results of operations and reputation. We believe that there are only a few other manufacturers that are currently capable of supplying and servicing the equipment necessary for our laboratory operations, including sequencers and various associated reagents. The use of equipment or materials provided by these replacement suppliers would require us to alter our laboratory operations. Transitioning to a new supplier would be time consuming and expensive, may result in interruptions in our laboratory operations, could affect the performance specifications of our laboratory operations or could require that we revalidate our tests. We cannot assure you that we would be able to secure alternative equipment, reagents and other materials, or bring such equipment, reagents and materials on line and revalidate them without experiencing interruptions in our workflow. If we encounter delays or difficulties in securing, reconfiguring or revalidating the equipment and reagents we require for our tests, our business and reputation could be adversely affected.

**Customer and geographic concentrations**

For the years ended December 31, 2014 and 2013, the percentages of our revenue attributable to sources in the United States were 67 and 42, respectively; the percentages of our revenue attributable to sources in Canada were 19 and one, respectively; the percentages of our revenue attributable to sources in Israel were 7 and 44, respectively; and the percentages of our revenue attributable to countries excluding the United States, Canada and Israel were 7 and 13, respectively.

As of December 31, 2014 and 2013, we had net long-lived assets in the United States of \$13.9 million and \$5.9 million, respectively, and net long-lived assets in Chile of \$1.8 million and \$2.2 million, respectively. As of December 31, 2014 and 2013, we did not have long-lived assets outside of the United States and Chile.

As of December 31, 2014, all of our revenue has been derived from sales of our assay of 216 genes. United Healthcare accounted for 15% of our revenue for the year ended December 31, 2014. Teva Pharmaceuticals Industries Ltd. accounted for 44% of our revenue for the year ended December 31, 2013.

**Our culture and employees**

Growing and retaining a strong team is critical to our long-term success. Our multidisciplinary team includes bioinformaticians, clinical and medical geneticists, commercial and managed care experts, genetic counselors, scientists, software engineers, web developers, graphic designers and lab automation specialists, as well as staff in our administrative and corporate teams. We pride ourselves on the quality and integrity of the people we hire, and we strive to foster a motivating and unique culture in which we hope they will thrive.

## Edgar Filing: Invitae Corp - Form 10-K

### Table of Contents

Our people have widely varied skills and capabilities, and our success hinges on our ability to apply all of those skills and capabilities in concert to achieve our mission. We relish individuality, and we strive to make sure that in efforts to create a cohesive working environment, we preserve diversity of views and approaches.

Our mission and relentless focus on our clients' needs drive attitudes and behaviors across the company. To support our values, we implement the following strategies:

**Attracting and Retaining Exceptional Employees.** We believe that versatile and experienced employees, management and directors provide significant advantages in the rapidly evolving market in which we compete. Since inception, we have devoted and will continue to devote substantial efforts to building a talented employee base and to attracting an experienced management team with a track record in fast-growing organizations. We provide significant autonomy, much more than would typically be given, to the individual and to leaders within the organization but hold each employee accountable through a steady-state peer review feedback systems in which every employee is evaluated by peers on a weekly basis. This system provides us with a large amount of performance data on a consistent basis as a starting point for developing and mentoring our employees.

**Commitment to Experimentation and Data-Informed Decisions.** We strive to make decisions informed by data, and look for counterintuitive information that might go against the conventional wisdom in the industry to give us a business advantage. We experiment with different commercial and technology hypotheses across our business and make decisions based on supporting data. We intend to research and develop not only new technology processes but business strategy as well.

**Transparency.** We strive to be transparent with our clients, employees and shareholders. We believe the best execution happens where information is broadly shared. We view a state of heightened transparency within companies and with the public as a growing trend that will only accelerate in the future.

As of December 31, 2014, we had 161 employees, the significant majority of which are based in San Francisco or Palo Alto, California. Of these employees, 77 were in research and development, 12 were in commercial laboratory operations, 44 were in sales and marketing and 28 were in general and administrative. None of our employees are represented by a labor union, and we consider our employee relations to be good.

### **General Information**

We were incorporated in the State of Delaware on January 13, 2010 under the name Locus Development, Inc. and changed our name to Invitae Corporation in 2012. Our principal executive offices are located at 458 Brannan Street, San Francisco, California 94107, and our telephone number is (415) 374-7782. Our website address is [www.invitae.com](http://www.invitae.com). The information contained on, or that can be accessed through, our website is not part of this annual report on Form 10-K.

We make available free of charge on our website our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and amendments to those reports, as soon as reasonably practicable after we electronically file or furnish such materials to the Securities and Exchange Commission, or SEC. You may obtain a free copy of these reports in the Investor Relations section of our website, [www.invitae.com](http://www.invitae.com). All reports that we file with the SEC may be read and copied at the SEC's Public Reference Room at 100 F Street, N.E., Washington, DC, 20549. Information about the operation of the Public Reference Room can be obtained by calling the SEC at 1-800-SEC-0330. All reports that we file are also available at [www.sec.gov](http://www.sec.gov).

Table of Contents

**ITEM 1A. Risk Factors.**

**Risks related to our business and strategy**

***We are an early-stage company with a history of losses, we expect to incur significant losses for the foreseeable future, and we may not be able to achieve or sustain profitability.***

We have incurred substantial losses since our inception. For the years ended December 31, 2014, 2013 and 2012, we had a net loss of \$47.5 million, \$24.8 million and \$8.6 million, respectively. As of December 31, 2014, we had an accumulated deficit of \$85.2 million. To date, we have generated limited revenue, and we may never achieve revenue sufficient to offset our expenses. In addition, we expect to continue to incur significant losses for the foreseeable future, and we expect these losses to increase as we focus on scaling our business and operations. Our prior losses and expected future losses have had and will continue to have an adverse effect on our stockholders' equity and working capital. Our failure to achieve and sustain profitability in the future would negatively affect our business, financial condition, results of operations and cash flows, and could cause the market price of our common stock to decline.

We began operations in January 2010, and we have only a limited operating history upon which you can evaluate our business and prospects. We commercially launched our assay of 216 genes in late November 2013. Our limited commercial history makes it difficult to evaluate our current business and makes predictions about our future results, prospects or viability subject to significant uncertainty. Our prospects must be considered in light of the risks and difficulties frequently encountered by companies in their early stage of development, particularly companies in new and rapidly evolving markets such as ours. These risks include an evolving and unpredictable business model and the management of growth. To address these risks, we must, among other things, increase our customer base, implement and successfully execute our business and marketing strategy, continue to expand, automate and upgrade our laboratory, technology and data systems, obtain coverage and reimbursement by healthcare payors such as Medicare and private health insurers, provide rapid test turnaround times with accurate results at a low price, provide superior customer service, respond to competitive developments and attract, retain and motivate qualified personnel. We cannot assure you that we will be successful in addressing these risks, and the failure to do so could have a material adverse effect on our business, prospects, financial condition and results of operations.

***We will need to scale our infrastructure in advance of demand for our tests, and our failure to generate sufficient demand for our tests would have a negative impact on our business and our ability to attain profitability.***

Our success will depend in large part on our ability to extend our market position, to provide customers with high quality test reports quickly and at a lower price than our competitors, and to achieve sufficient test volume to realize economies of scale. In order to execute our business model, we intend to invest heavily in order to significantly scale our infrastructure, including our testing capacity and information systems, expand our customer service, billing and systems processes and enhance our internal quality assurance program. We will also need to hire and retain sufficient numbers of skilled personnel, including geneticists, biostatisticians, certified laboratory scientists and other scientific and technical personnel to process and interpret our genetic tests. We expect that much of this growth will be in advance of demand for our tests. Our current and future expense levels are to a large extent fixed and are largely based on our investment plans and our estimates of future revenue. Because the timing and amount of revenue from our tests is difficult to forecast, when revenue does not meet our expectations we may not be able to adjust our spending promptly or reduce our spending to levels commensurate with our revenue. Even if we are able to successfully scale our infrastructure and operations, we cannot assure you that demand for our tests will increase at levels consistent with the growth of our infrastructure. If we fail to generate demand commensurate with this growth or if we fail

Table of Contents

to scale our infrastructure sufficiently in advance of demand to successfully meet such demand, our business, prospects, financial condition and results of operations could be adversely affected.

***If we are not able to generate substantial demand of our tests, our commercial success will be negatively affected.***

Our business model assumes that we will be able to generate significant test volume, and we may not succeed in driving clinical adoption of our test to achieve sufficient volumes. Inasmuch as detailed genetic data from broad-based testing panels such as our tests have only recently become available at relatively affordable prices, the pace and degree of clinical acceptance of the utility of such testing is uncertain. Specifically, it is uncertain how much genetic data will be accepted as necessary or useful, as well as how detailed that data should be, particularly since medical practitioners may have become accustomed to genetic testing that is specific to one or a few genes. Given the substantial amount of additional information available from a broad-based testing panel such as ours, there may be distrust as to the reliability of such information when compared with more limited and focused genetic tests. To generate demand for our tests, we will need to continue to make physicians aware of the benefits of our tests, including the price, the breadth of our testing options, and the benefits of having additional genetic data available from which to make treatment decisions. Because broad-based testing panels are relatively new, it may be more difficult or take more time for us to expand clinical adoption of our assay beyond a relatively small number of early adopters. In addition, physicians in other areas of medicine may not adopt genetic testing for hereditary disease as readily as it has been adopted in hereditary cancer and our efforts to sell our tests to physicians outside of oncology may not be successful. A lack of or delay in clinical acceptance of broad-based panels such as our tests would negatively impact sales and market acceptance of our tests and limit our revenue growth and potential profitability. In addition, as we make physicians aware of our plans to release new assays with more genes, physicians may decide not to order our current assay, opting instead to wait until the new assay is available. Genetic testing is expensive and many potential customers may be sensitive to pricing. In addition, potential customers may not adopt our tests if adequate reimbursement is not available, or if we are not able to maintain low prices in the future relative to our competitors. If we are not able to generate demand for our tests at sufficient volume, or if it takes significantly more time to generate this demand than we anticipate, our business, prospects, financial condition and results of operations could be materially harmed.

***If third-party payors, including managed care organizations, private health insurers and government health plans do not provide coverage and adequate reimbursement for our tests, our commercial success could be negatively affected.***

Our ability to increase the number of billable tests and our revenue will depend on our success achieving broad reimbursement for our tests from third-party payors. Physicians may not order our tests unless third-party payors, such as managed care organizations, private health insurers and government healthcare programs, such as Medicare and Medicaid, cover and provide adequate reimbursement for a substantial portion of the price of our tests. Reimbursement by a payor may depend on a number of factors, including a payor's determination that a test is appropriate, medically necessary, and cost-effective.

Since each payor makes its own decision as to whether to establish a policy or enter into a contract to cover our tests, as well as the amount it will reimburse for a test, seeking these approvals is a time-consuming and costly process. In addition, the determination by a payor to cover and the amount it will reimburse for our tests will likely be made on an indication by indication basis. To date, we have obtained policy-level reimbursement approval or contractual reimbursement for some indications for our test from a small number of commercial third-party payors, and have not obtained coverage from Medicare or any state Medicaid program. Further, we believe that establishing adequate

Table of Contents

reimbursement from Medicare is an important factor in gaining adoption from healthcare providers. Our claims for reimbursement from commercial payors may be denied upon submission, and we must appeal the claims. The appeals process is time consuming and expensive, and may not result in payment. In cases where there is not a contracted rate for reimbursement, there is typically a greater co-insurance or co-payment requirement from the patient which may result in further delay or decreased likelihood of collection.

We expect to continue to focus substantial resources on increasing adoption of, and coverage and reimbursement for, our current tests and any future tests we may develop. We believe it may take several years to achieve coverage and adequate contracted reimbursement with a majority of third-party payors. However, we cannot predict whether, under what circumstances, or at what payment levels payors will reimburse for our tests. If we fail to establish and maintain broad adoption of, and coverage and reimbursement for, our tests, our ability to generate revenue could be harmed and our future prospects and our business could suffer.

***Our success will depend on our ability to use rapidly changing genetic data to interpret test results accurately and consistently, and our failure to do so would have an adverse effect on our operating results and business, harm our reputation and could result in substantial liabilities that exceed our resources.***

Our success depends on our ability to provide reliable, high-quality tests that incorporate rapidly evolving information about the role of genes and gene variants in disease and clinically relevant outcomes associated with those variants. Errors, including if our tests fail to detect genomic variants with high accuracy, or mistakes, including if we fail to or incompletely or incorrectly identify the significance of gene variants, could have a significant adverse impact on our business. Hundreds of genes can be implicated in some disorders, and overlapping networks of genes and symptoms can be implicated in multiple conditions. As a result, a substantial amount of judgment is required in order to interpret testing results for an individual patient and to develop an appropriate patient report. We classify variants in accordance with published guidelines as benign, likely benign, variants of uncertain significance, likely pathogenic or pathogenic, and these guidelines are subject to change. In addition, it is our practice to offer support to physicians and geneticists ordering our tests around which genes or panels to order as well as interpretation of genetic variants. We also rely on clinicians to interpret what we report and to incorporate specific information about an individual patient into the physician's treatment decision.

The marketing, sale and use of our genetic tests could subject us to liability for errors in, misunderstandings of, or inappropriate reliance on, information we provide to physicians or geneticists, and lead to claims against us if someone were to allege that our test failed to perform as it was designed, if we failed to correctly interpret the test results, or if the ordering physician were to misinterpret test results or improperly rely on them when making a clinical decision. 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 liability insurance, including for errors and omissions, we cannot assure you that our insurance would fully protect us from the financial impact of defending against these types of claims or any judgments, fines or settlement costs arising out of any such claims. Any liability claim, including an errors and omissions liability claim, brought against us, with or without merit, could increase our insurance rates or prevent us from securing insurance coverage in the future. Additionally, any liability lawsuit could cause injury to our reputation or cause us to suspend sales of our tests. The occurrence of any of these events could have an adverse effect on our business, reputation and results of operations.



Table of Contents

*We face intense competition, which is likely to intensify further as existing competitors devote additional resources to, and new participants enter, the market. If we cannot compete successfully, we may be unable to increase our revenue or achieve and sustain profitability.*

With the development of next generation sequencing, the clinical genetics market is becoming increasingly competitive, and we expect this competition to intensify in the future. We face competition from a variety of sources, including:

dozens of relatively specialized competitors focused on inherited clinical genetics and gene sequencing, such as Myriad Genetics, Inc., or Myriad, Ambry Genetics, Inc. and GeneDx, Inc., a subsidiary of Bio-Reference Laboratories, Inc.;

a few large, established general testing companies with large market share and significant channel power, such as Laboratory Corporation of America Holdings and Quest Diagnostics Incorporated;

a large number of clinical laboratories in an academic or healthcare provider setting that perform clinical genetic testing on behalf of their affiliated institutions and often sell and market more broadly; and

a large number of new entrants into the market for genetic information ranging from informatics and analysis pipeline developers to focused, integrated providers of genetic tools and services for health and wellness.

Hospitals, academic medical centers and eventually physician practice groups and individual physicians may also seek to perform at their own facilities the type of genetic testing we would otherwise perform for them. In this regard, continued development of equipment, reagents, and other materials as well as databases and interpretation services may enable broader direct participation in genetic testing and analysis.

Participants in closely related markets such as prenatal testing and clinical trial or companion diagnostic testing could converge on offerings that are competitive with the type of tests we perform. Instances where potential competitors are aligned with key suppliers or are themselves suppliers could provide such potential competitors with significant advantages.

In addition, the biotechnology and genetic testing fields are intensely competitive both in terms of service and price, and continue to undergo significant consolidation, permitting larger clinical laboratory service providers to increase cost efficiencies and service levels, resulting in more intense competition.

We believe the principal competitive factors in our market are:

price and quality of tests;

test turnaround time of testing results;

coverage and reimbursement arrangements with third-party payors;

breadth and depth of content;

convenience of testing;

brand recognition of test provider;

Edgar Filing: Invitae Corp - Form 10-K

additional value-added services and informatics tools;

accessibility of results;

client service;

Table of Contents

quality of website content; and

reliability.

Many of our competitors and potential competitors have longer operating histories, larger customer bases, greater brand recognition and market penetration, higher margins on their tests, substantially greater financial, technological and research and development resources and selling and marketing capabilities, and more experience dealing with third-party payors. As a result, they may be able to respond more quickly to changes in customer requirements, devote greater resources to the development, promotion and sale of their tests than we do, or sell their tests at prices designed to win significant levels of market share. We may not be able to compete effectively against these organizations. Increased competition and cost-saving initiatives on the part of governmental entities and other third-party payors are likely to result in pricing pressures, which could harm our sales, profitability or ability to gain market share. In addition, competitors may be acquired by, receive investments from or enter into other commercial relationships with larger, well-established and well-financed companies as use of next generation sequencing for clinical diagnosis and preventative care increases. Certain of our competitors may be able to secure key inputs from vendors on more favorable terms, devote greater resources to marketing and promotional campaigns, adopt more aggressive pricing policies and devote substantially more resources to website and systems development than we can. In addition, companies or governments that control access to genetic testing through umbrella contracts or regional preferences could promote our competitors or prevent us from performing certain services. If we are unable to compete successfully against current and future competitors, we may be unable to increase market acceptance and sales of our tests, which could prevent us from increasing our revenue or achieving profitability and could cause our stock price to decline.

***Our industry is subject to rapidly changing technology and new and increasing amounts of scientific data related to genes and genetic variants and their role in disease. Our failure to develop tests to keep pace with these changes could make us obsolete.***

In recent years, there have been numerous advances in methods used to analyze very large amounts of genomic information and the role of genetics and gene variants in disease and treatment therapies. Our industry has and will continue to be characterized by rapid technological change, increasingly larger amounts of data, frequent new testing service introductions and evolving industry standards, all of which could make our tests obsolete. Our future success will also depend on our ability to keep pace with the evolving needs of our customers on a timely and cost-effective basis and to pursue new market opportunities that develop as a result of technological and scientific advances. Our tests could become obsolete unless we continually update our offerings to reflect new scientific knowledge about genes and genetic variations and their role in diseases and treatment therapies.

***We have limited experience in marketing and selling our tests, and our success will depend in part on our ability to generate sales using a relatively small internal sales team and through alternative marketing strategies.***

We have limited experience marketing and selling our tests, which we began selling in late 2013. We may not be able to market or sell our current tests and any future tests we may develop effectively enough to drive demand sufficient to support our planned growth. We currently sell our tests in the United States through a relatively small internal sales force and outside the United States with the assistance of distributors. Historically, our sales efforts have been focused primarily on hereditary cancer and our efforts to sell our tests to physicians outside of oncology may not be successful, or may be difficult to do successfully without significant additional selling and marketing efforts and expense. As part of our strategy to reduce the cost of genetic testing, we will need to maintain our selling and marketing expenses at levels that are lower than many of our competitors through the use of focused

Table of Contents

sales efforts. Our future sales will depend in large part on our ability to develop and substantially expand awareness of our company and our tests through alternative strategies including through education of key opinion leaders, through social media-related and online outreach, education and marketing efforts, and through focused channel partner strategies designed to drive demand for our tests. We have limited experience implementing these types of alternative marketing efforts. We may not be able to drive sufficient levels of revenue using these sales and marketing methods and strategies necessary to support our planned growth, and our failure to do so could limit our revenue and potential profitability.

Outside the United States we use and intend to continue to use distributors to assist with sales, logistics, education, and customer support. Identifying, qualifying, and engaging distributors with local industry experience and knowledge will be necessary to effectively market and sell our tests outside the United States. We may not be successful in finding, attracting and retaining additional distributors, or we may not be able to enter into additional distribution arrangements on favorable terms. Sales practices utilized by our distributors that are locally acceptable may not comply with sales practices standards required under U.S. laws that apply to us, which could create additional compliance risk. If our sales and marketing efforts are not successful outside the United States, we may not achieve significant market acceptance for our tests outside the United States, which could materially and adversely impact our business operations.

***We rely on a limited number of suppliers or, in some cases, sole suppliers, for some of our laboratory instruments and materials, and we may not be able to find replacements or immediately transition to alternative suppliers.***

We rely on a limited number of suppliers, or, in some cases, sole suppliers, including Agilent Technologies, Inc., Illumina, Inc., Integrated DNA Technologies Incorporated, Qiagen N.V., and Roche Holdings Ltd. for certain laboratory substances used in the chemical reactions incorporated into our processes, which we refer to as reagents, as well as sequencers and other equipment and materials which we use in our laboratory operations. We do not have any short- or long-term agreements with our suppliers, and our suppliers could cease supplying these materials and equipment at any time, or fail to provide us with sufficient quantities of materials or materials that meet our specifications. Our laboratory operations could be interrupted if we encounter delays or difficulties in securing these reagents, sequencers or other equipment or materials, and if we cannot obtain an acceptable substitute. Any such interruption could significantly affect our business, financial condition, results of operations and reputation. We rely on Illumina as the sole supplier of next generation sequencers and associated reagents and as the sole provider of maintenance and repair services for these sequencers. Any disruption in Illumina's operations could impact our supply chain and laboratory operations as well as our ability to conduct our tests, and it could take a substantial amount of time to integrate replacement equipment into our laboratory operations.

We believe that there are only a few other manufacturers that are currently capable of supplying and servicing the equipment necessary for our laboratory operations, including sequencers and various associated reagents. The use of equipment or materials provided by these replacement suppliers would require us to alter our laboratory operations. Transitioning to a new supplier would be time consuming and expensive, may result in interruptions in our laboratory operations, could affect the performance specifications of our laboratory operations or could require that we revalidate our tests. We cannot assure you that we will be able to secure alternative equipment, reagents and other materials, and bring such equipment, reagents and materials on line and revalidate them without experiencing interruptions in our workflow. In the case of an alternative supplier for Illumina, we cannot assure you that replacement sequencers and associated reagents will be available or will meet our quality control and performance requirements for our laboratory operations. If we encounter delays or difficulties in

Table of Contents

securing, reconfiguring or revalidating the equipment and reagents we require for our tests, our business, financial condition, results of operations and reputation could be adversely affected.

***If our laboratory in San Francisco becomes inoperable due to an earthquake or for any other reason, we will be unable to perform our tests and our business will be harmed.***

We perform all of our tests at our laboratory in San Francisco, California. Our laboratory and the equipment we use to perform our tests would be costly to replace and could require substantial lead time to replace and qualify for use. Our laboratory may be harmed or rendered inoperable by natural or man-made disasters, including earthquakes, flooding, fire 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 or the backlog that could develop if our laboratory is inoperable for even a short period of time may result in the loss of customers or harm our reputation. Although we maintain insurance for damage to our property and the disruption of our business, this insurance may not be sufficient to cover all of our potential losses and may not continue to be available to us on acceptable terms, if at all.

We currently have a second laboratory established in Santiago, Chile, however this laboratory has not been used for the performance of our tests in significant volume. The use of such laboratory as a back-up facility for our laboratory operations in San Francisco would require substantial lead time, including to obtain CLIA certification, as well as to secure the necessary equipment, labor and other resources. In addition, a number of third-party payors, including Medicare, do not reimburse for tests performed outside of the United States.

***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, personally identifiable information, intellectual property and proprietary business information owned or controlled by ourselves or our customers, payors, and other parties. 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. We also communicate sensitive patient data through our Invitae Family History Tool. 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 a number of risks relative to protecting this critical information, including loss of access risk, inappropriate disclosure, inappropriate modification, and the risk of our being unable to adequately monitor and modify our controls over our critical information.

The secure processing, storage, maintenance and transmission of this critical information are vital to our operations and business strategy, and we devote significant resources to protecting such information. Although we take measures to protect sensitive information from unauthorized access or disclosure, our information technology and infrastructure, and that of our third-party billing and collections provider, may be vulnerable to attacks by hackers or viruses or breached due to employee error, malfeasance, or other disruptions. Any such breach or interruption could compromise our networks and the information stored there could be accessed by unauthorized parties, publicly disclosed, lost, or stolen. Any such access, disclosure or other loss of information could result in legal claims or proceedings, liability under federal or state laws that protect the privacy of personal information, such as the Health Insurance Portability and Accountability Act of 1996, or HIPAA, the Health Information Technology for Economic and Clinical Health Act, or HITECH, and regulatory penalties. Although we have implemented security measures and a formal, dedicated enterprise security program to prevent unauthorized access to patient data, our Invitae Family History Tool is currently

Table of Contents

accessible through our online portal and through our mobile applications, and there is no guarantee we can protect our online portal or our mobile applications from breach. Unauthorized access, loss or dissemination could also disrupt our operations (including our ability to conduct our analyses, provide test results, bill payors or patients, process claims and appeals, provide customer assistance, conduct research and development activities, collect, process, and prepare company financial information, provide information about our tests and other patient and physician 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.

Penalties for failure to comply with a requirement of HIPAA and HITECH vary significantly, and include civil monetary penalties of up to \$1.5 million per calendar year for each provision of HIPAA that is violated. A person who knowingly obtains or discloses individually identifiable health information in violation of HIPAA may face a criminal penalty of up to \$50,000 and up to one-year imprisonment. The criminal penalties increase if the wrongful conduct involves false pretenses or the intent to sell, transfer, or use identifiable health information for commercial advantage, personal gain, or malicious harm.

In addition, the interpretation and application of consumer, health-related, and data protection laws in the United States, 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. In addition, these privacy regulations may differ from country to country, and may vary based on whether testing is performed in the United States or in the local country. 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.

***We may not be able to manage our future growth effectively, which could make it difficult to execute our business strategy.***

Our expected future growth could create a strain on our organizational, administrative and operational infrastructure, including laboratory operations, quality control, customer service, marketing and sales, and management. We may not be able to maintain the quality of or expected turnaround times for our tests, or satisfy customer demand as it grows. Our ability to manage our growth properly will require us to continue to improve our operational, financial and management controls, as well as our reporting systems and procedures. We plan to implement new enterprise software systems in a number of areas affecting a broad range of business processes and functional areas. The time and resources required to implement these new systems is uncertain, and failure to complete these activities in a timely and efficient manner could adversely affect our operations. In addition, we plan to hire a chief medical officer, as well as add additional geneticists, biostatisticians, certified laboratory scientists and other scientific and technical personnel. If we are unable to manage our growth effectively, it may be difficult for us to execute our business strategy and our business could be harmed. Future growth in our business could also make it difficult for us to maintain our corporate culture.

***The loss of any member of our senior management team could adversely affect our business.***

Our success depends in large part upon the skills, experience and performance of members of our executive management team and others in key leadership positions. The efforts of these persons will be critical to us as we continue to develop our technologies and test processes and focus on scaling our business. If we were to lose one or more key executives, we may experience difficulties in competing effectively, developing our technologies and implementing our business strategy. All of our executives and employees are at-will, which means that either we or the executive or employee may terminate their employment at any time. We do not carry key man insurance for any of our executives or

Table of Contents

employees. In addition, we do not have a long-term retention agreement or long-term equity incentives in place with our chief executive officer.

***We rely on highly skilled personnel in a broad array of disciplines and, if we are unable to hire, retain or motivate these individuals, or maintain our corporate culture, we may not be able to maintain the quality of our services or grow effectively.***

Our performance, including our research and development programs and laboratory operations, largely depend on our continuing ability to identify, hire, develop, motivate, and retain highly skilled personnel for all areas of our organization, including scientists, biostatisticians and technicians. Competition in our industry for qualified employees is intense, and we may not be able to attract or retain qualified personnel in the future, including scientists, biostatisticians and technicians, due to the competition for qualified personnel among life science businesses as well as universities and public and private research institutions, particularly in the San Francisco Bay Area. In addition, our compensation arrangements, such as our equity award programs, may not always be successful in attracting new employees and retaining and motivating our existing employees. If we are not able to attract and retain the necessary personnel to accomplish our business objectives, we may experience constraints that could adversely affect our ability to scale our business, support our research and development efforts and our clinical laboratory. We believe that our corporate culture fosters innovation, creativity and teamwork. However, as our organization grows, we may find it increasingly difficult to maintain the beneficial aspects of our corporate culture. This could negatively impact our ability to retain and attract employees and our future success.

***Development of new tests is a complex process, and we may be unable to commercialize new tests on a timely basis, or at all.***

We cannot assure you that we will be able to develop and commercialize new tests on a timely basis. Before we can commercialize any new tests, we will need to expend significant funds in order to:

conduct research and development;

further develop and scale our laboratory processes; and

further develop and scale our infrastructure to be able to analyze increasingly larger and more diverse amounts of data.

Our testing service development process involves risk, and development efforts may fail for many reasons, including:

failure of any test to perform as expected;

lack of validation or reference data; or

failure to demonstrate utility of a test.

As we develop tests, we will have to make significant investments in development, marketing and selling resources. In addition, competitors may develop and commercialize competing tests faster than we are able to do so.

***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.***

We currently have a laboratory in Chile and distribution arrangements in several countries, and our business strategy contemplates significant international expansion. We plan to enter into additional distribution relationships to conduct physician outreach activities and to develop and expand payor

## Edgar Filing: Invitae Corp - Form 10-K

### Table of Contents

relationships outside of the United States. Doing business internationally involves a number of risks, including:

multiple, conflicting and changing laws and regulations such as privacy regulations, tax laws, export and import restrictions, employment laws, regulatory requirements, and other governmental approvals, permits and licenses;

failure by us or our distributors to obtain regulatory approvals for the use of our tests in various countries;

complexities and difficulties in obtaining protection and enforcing our intellectual property;

difficulties in staffing and managing foreign operations;

complexities associated with managing multiple payor reimbursement regimes, government payors, or patient self-pay systems;

logistics and regulations associated with shipping blood samples, including infrastructure conditions and transportation delays;

limits on our ability to penetrate international markets if we do not to conduct our tests locally;

financial risks, such as longer payment cycles, difficulty collecting accounts receivable, the impact of local and regional financial conditions on demand and payment for our tests, and exposure to foreign currency exchange rate fluctuations;

natural disasters, political and economic instability, including wars, terrorism, and political unrest, outbreak of disease, boycotts, curtailment of trade and other business restrictions; and

regulatory and compliance risks that relate to maintaining accurate information and control over activities that may fall within the purview of the U.S. Foreign Corrupt Practices Act, or FCPA, its books and records provisions, or its anti-bribery provisions.

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

In addition, applicable export or import laws and regulations such as prohibitions on the export of blood imposed by countries outside of the United States, or international privacy or data restrictions that are different or more stringent than those of the United States, may require that we build additional laboratories or engage in joint ventures or other business partnerships in order to offer our tests internationally in the future. Any such restrictions would impair our ability to offer our tests in such countries and could have an adverse effect on our business, financial condition and results of operations.

***Our inability to raise additional capital on acceptable terms in the future may limit our ability to develop and commercialize new tests and expand our operations.***

We expect capital expenditures and operating expenses to increase over the next several years as we expand our infrastructure, commercial operations and research and development activities. The proceeds from our initial public offering will not be sufficient to fully fund our business and growth strategy. We may seek to raise additional capital through equity offerings, debt financings, collaborations or licensing arrangements. Additional funding may not be available to us on acceptable terms, or at all. If we raise funds by issuing equity securities, dilution to our stockholders would result. Any equity securities issued also may provide for rights, preferences or privileges senior to those of holders of our common stock. The terms of debt securities issued or borrowings, if available, could impose significant restrictions on our operations. The



incurrence of additional indebtedness or the issuance of certain equity securities could result in increased fixed payment obligations and could also

Table of Contents

result in restrictive covenants, such as limitations on our ability to incur additional debt or issue additional equity, limitations on our ability to acquire or license intellectual property rights, and other operating restrictions that could adversely affect our ability to conduct our business. In addition, the issuance of additional equity securities by us, or the possibility of such issuance, may cause the market price of our common stock to decline. In the event that we enter into collaborations or licensing arrangements to raise capital, we may be required to accept unfavorable terms. These agreements may require that we relinquish or license to a third party on unfavorable terms our rights to tests we otherwise would seek to develop or commercialize ourselves, or reserve certain opportunities for future potential arrangements when we might be able to achieve more favorable terms. If we are not able to secure additional funding when needed, we may have to delay, reduce the scope of or eliminate one or more research and development programs or selling and marketing initiatives. In addition, we may have to work with a partner on one or more aspects of our tests or market development programs, which could lower the economic value of those tests or programs to our company.

***We may acquire businesses or assets, form joint ventures or make investments in other companies or technologies that could harm our operating results, dilute our stockholders' ownership, or cause us to incur debt or significant expense.***

As part of our business strategy, we may pursue acquisitions of complementary businesses or assets, as well as technology licensing arrangements. We also may pursue strategic alliances that leverage our core technology and industry experience to expand our offerings or distribution, or make investments in other companies. As an organization, we have limited experience with respect to acquisitions as well as the formation of strategic alliances and joint ventures. If we make any acquisitions in the future, 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 could harm our operating results. Integration of an acquired company or business 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, joint venture or investment.

To finance any acquisitions or investments, we may choose to raise additional funds. If we raise funds by issuing equity securities, dilution to our 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 funds by issuing debt securities, these debt securities would have rights, preferences and privileges senior to those of holders of our common stock. The terms of debt securities issued or borrowings could impose significant restrictions on our operations. If we raise funds through collaborations and licensing arrangements, we might be required to relinquish significant rights to our technologies or products, or grant licenses on terms that are not favorable to us. Once we become a public company, if the price of our common stock is low or volatile, we may not be able to acquire other companies for stock. Alternatively, it may be necessary for us to raise additional funds for these activities through public or private financings. Additional funds may not be available on terms that are favorable to us, or at all.

***We depend on our information technology systems, and any failure of these systems could harm our business.***

We depend on information technology and telecommunications systems for significant elements of our operations, including our laboratory information management system, our bioinformatics analytical software systems, our database of information relating to genetic variations and their role in disease process and drug metabolism, our clinical report optimization systems, our customer-facing web-based software, our customer reporting, and our family history and risk assessment tools. We have installed,

Table of Contents

and expect to expand, a number of enterprise software systems that affect a broad range of business processes and functional areas, including for example, systems handling human resources, financial controls and reporting, customer relationship management, regulatory compliance, and other infrastructure operations. In addition, we intend to extend the capabilities of both our preventative and detective security controls by augmenting the monitoring and alerting functions, the network design, and the automatic countermeasure operations of our technical systems. These information technology and telecommunications systems support a variety of functions, including laboratory operations, test validation, sample tracking, quality control, customer service support, billing and reimbursement, research and development activities, scientific and medical curation, and general administrative activities. In addition, our third-party billing and collections provider depends upon technology and telecommunications systems provided by outside vendors.

Information technology and telecommunications systems are vulnerable to damage from a variety of sources, including telecommunications or network failures, malicious human acts and natural disasters. Moreover, despite network security and back-up measures, some of our servers are potentially vulnerable to physical or electronic break-ins, computer viruses, and similar disruptive problems. Despite the precautionary measures we have taken to prevent unanticipated problems that could affect our information technology and telecommunications systems, failures or significant downtime of our information technology or telecommunications systems or those used by our third-party service providers could prevent us from conducting tests, preparing and providing reports to physicians, billing payors, processing reimbursement appeals, handling physician or patient inquiries, conducting research and development activities, and managing the administrative aspects of our business. Any disruption or loss of information technology or telecommunications systems on which critical aspects of our operations depend could have an adverse effect on our business.

***Ethical, legal and social concerns related to the use of genetic information could reduce demand for our tests.***

Genetic testing has raised ethical, legal, and social issues regarding privacy and the appropriate uses of the resulting information. Governmental authorities could, for social or other purposes, limit or regulate the use of genetic information or genetic testing or prohibit testing for genetic predisposition to certain conditions, particularly for those that have no known cure. Similarly, these concerns may lead patients to refuse to use, or clinicians to be reluctant to order, genomic tests even if permissible. These and other ethical, legal and social concerns may limit market acceptance of our tests or reduce the potential markets for our tests, either of which could have an adverse effect on our business, financial condition, or results of operations.

***Our employees may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements, which could cause significant liability for us and harm our reputation.***

We are exposed to the risk of employee fraud or other misconduct, including intentional failures to comply with government regulations or similar regulations of comparable foreign regulatory authorities, to provide accurate information to the FDA or comparable foreign regulatory authorities, to comply with federal and state healthcare fraud and abuse laws and regulations and similar laws and regulations established and enforced by comparable foreign regulatory authorities, and to report financial information or data accurately or disclose unauthorized activities to us. We have a code of conduct and ethics for our directors, officers and employees, but it is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business and results of operations, including the imposition of significant fines or other sanctions.

Table of Contents

**Risks related to government regulation**

*If the FDA regulates our tests as medical devices, we could incur substantial costs and our business, financial condition, and results of operations could be adversely affected.*

We provide our tests as laboratory-developed tests, or LDTs. The Centers for Medicare and Medicaid Services, or CMS, and certain state agencies regulate the performance of LDTs (as authorized by the Clinical Laboratory Improvement Amendments of 1988, or CLIA, and state law, respectively).

Historically, the U.S. Food and Drug Administration, or FDA, has exercised enforcement discretion with respect to most LDTs and has not required laboratories that furnish LDTs to comply with the agency's requirements for medical devices (e.g., establishment registration, device listing, quality systems regulations, premarket clearance or premarket approval, and post-market controls). In recent years, however, the FDA has stated it intends to end its policy of general enforcement discretion and regulate certain LDTs as medical devices. To this end, on October 3, 2014, the FDA issued two draft guidance documents, entitled "Framework for Regulatory Oversight of Laboratory Developed Tests (LDTs)" and "FDA Notification and Medical Device Reporting for Laboratory Developed Tests (LDTs)", respectively, that set forth a proposed risk-based regulatory framework that would apply varying levels of FDA oversight to LDTs. The FDA has indicated that it does not intend to modify its policy of enforcement discretion until the draft guidance documents are finalized. It is unclear at this time when, or if, the draft guidance documents will be finalized, and even then, the new regulatory requirements are proposed to be phased-in consistent with the schedule set forth in the guidance (in as little as 12 months after the draft guidance is finalized for certain high-priority LDTs). Nevertheless, the FDA may decide to regulate certain LDTs on a case-by-case basis at any time.

Legislative proposals addressing the FDA's oversight of LDTs have been introduced in previous Congresses, and we expect that new legislative proposals will be introduced from time-to-time. The likelihood that Congress will pass such legislation and the extent to which such legislation may affect the FDA's plans to regulate certain LDTs as medical devices is difficult to predict at this time.

If the FDA ultimately regulates certain LDTs as medical devices, whether via final guidance, final regulation, or as instructed by Congress, our tests may be subject to certain additional regulatory requirements. Complying with the FDA's requirements for medical devices can be expensive, time-consuming, and subject us to significant or unanticipated delays. Insofar as we may be required to obtain premarket clearance or approval to perform or continue performing an LDT, we cannot assure you that we will be able to obtain such authorization. Even if we obtain regulatory clearance or approval where required, such authorization may not be for the intended uses that we believe are commercially attractive or are critical to the commercial success of our tests. As a result, the application of the FDA's medical device requirements to our tests could materially and adversely affect our business, financial condition, and results of operations.

Failure to comply with applicable FDA regulatory requirements may trigger a range of enforcement actions by the FDA including warning letters, civil monetary penalties, injunctions, criminal prosecution, recall or seizure, operating restrictions, partial suspension or total shutdown of operations, and denial of or challenges to applications for clearance or approval, as well as significant adverse publicity.

In addition, in November 2013, the FDA issued final guidance regarding the distribution of products labeled for research use only. Certain of the reagents and other products we use in our tests are labeled as research use only products. Certain of our suppliers may cease selling research use only products to us and any failure to obtain an acceptable substitute could significantly and adversely affect our business, financial condition and results of operations.

Table of Contents

*If we fail to comply with federal, state and foreign laboratory licensing requirements, we could lose the ability to perform our tests or experience disruptions to our business.*

We are subject to CLIA, a federal law that regulates clinical laboratories that perform testing on specimens derived from humans for the purpose of providing information for the diagnosis, prevention, or treatment of disease. CLIA regulations establish specific standards with respect to personnel qualifications, facility administration, proficiency testing, quality control, quality assurance, and inspections. CLIA certification is also required in order for us to be eligible to bill state and federal healthcare programs, as well as many private third-party payors, for our tests. We have a current CLIA certificate to conduct our tests at our laboratory in San Francisco. To renew this certificate, we are subject to survey and inspection every two years. Moreover, CLIA inspectors may make random inspections of our clinical reference laboratory.

We are also required to maintain a license to conduct testing in California. California laws establish standards for day-to-day operation of our clinical reference laboratory in San Francisco, including the training and skills required of personnel and quality control. We also maintain licenses to conduct testing in Florida, Maryland, Pennsylvania and Rhode Island. Our clinical reference laboratories are required to be licensed on a test-specific basis by New York State as an out of state laboratory and our products, as LDTs, must be approved by the New York State Department of Health, or NYDOH, before they are performed on specimens from New York. Once approved, we would also be subject to periodic inspection by the NYDOH and required to demonstrate ongoing compliance with NYDOH regulations and standards. Because our laboratories are not licensed by New York, we are currently prohibited from testing samples from New York. Other states may adopt similar licensure requirements in the future, which may require us to modify, delay or stop our operations in such jurisdictions. We may also be subject to regulation in foreign jurisdictions as we seek to expand international utilization of our tests or such jurisdictions adopt new licensure requirements, which may require review of our tests in order to offer them or may have other limitations such as restrictions on the transport of human blood necessary for us to perform our tests that may limit our ability to make our tests available outside of the United States. Complying with licensure requirements in new jurisdictions may be expensive, time-consuming, and subject us to significant and unanticipated delays.

Failure to comply with applicable clinical laboratory licensure requirements may result in a range of enforcement actions, including license suspension, limitation, or revocation, directed plan of action, onsite monitoring, civil monetary penalties, criminal sanctions, and cancellation of the laboratory's approval to receive Medicare and Medicaid payment for its services, as well as significant adverse publicity. Any sanction imposed under CLIA, its implementing regulations, or state or foreign laws or regulations governing clinical laboratory licensure, or our failure to renew our CLIA certificate, a state or foreign license, or accreditation, could have a material adverse effect on our business, financial condition and results of operations. Even if we were able to bring our laboratory back into compliance, we could incur significant expenses and potentially lose revenue in doing so.

The College of American Pathologists, or CAP, maintains a clinical laboratory accreditation program. Designed to go well beyond regulatory compliance, CAP asserts that the program helps laboratories achieve the highest standards of excellence to positively impact patient care. While not required to operate a CLIA-certified laboratory, many private insurers require CAP accreditation as a condition to contracting with clinical laboratories to cover their tests. In addition, some countries outside the United States require CAP accreditation as a condition to permitting clinical laboratories to test samples taken from their citizens. In November 2014, we obtained CAP accreditation for our San Francisco laboratory. Failure to maintain CAP accreditation could have a material adverse effect on the sales of our tests and the results of our operations.

## Edgar Filing: Invitae Corp - Form 10-K

### Table of Contents

***Complying with numerous statutes and regulations pertaining to our business is an expensive and time-consuming process, and any failure to comply could result in substantial penalties.***

Our operations are subject to other extensive federal, state, local and foreign laws and regulations, all of which are subject to change. These laws and regulations currently include, among others:

HIPAA, which established comprehensive federal standards with respect to the privacy and security of protected health information and requirements for the use of certain standardized electronic transactions;

amendments to HIPAA under HITECH, which strengthen and expand HIPAA privacy and security compliance requirements, increase penalties for violators, extend enforcement authority to state attorneys general, and impose requirements for breach notification;

the federal Anti-Kickback Statute, which prohibits knowingly and willfully offering, paying, soliciting, or receiving remuneration, directly or indirectly, overtly or covertly, in cash or in kind, in return for or to induce such person to refer an individual, or to purchase, lease, order, arrange for, or recommend purchasing, leasing or ordering, any good, facility, item or service that is reimbursable, in whole or in part, under a federal healthcare program;

the federal Stark physician self-referral law, which prohibits a physician from making a referral for certain designated health services covered by the Medicare program, including laboratory and pathology services, if the physician or an immediate family member has a financial relationship with the entity providing the designated health services, and prohibits that entity from billing or presenting a claim for the designated health services furnished pursuant to the prohibited referral, unless an exception applies;

the federal false claims laws, which impose liability on any person or entity that, among other things, knowingly presents, or causes to be presented, a false or fraudulent claim for payment to the federal government;

the federal Civil Monetary Penalties Law, which prohibits, among other things, the offering or transfer of remuneration to a Medicare or state healthcare program beneficiary if the person knows or should know it is likely to influence the beneficiary's selection of a particular provider, practitioner, or supplier of services reimbursable by Medicare or a state healthcare program, unless an exception applies;

the HIPAA fraud and abuse provisions, which created new federal criminal statutes that prohibit, among other things, defrauding healthcare programs, willfully obstructing a criminal investigation of a healthcare offense and falsifying or concealing a material fact or making any materially false statements in connection with the payment for healthcare benefits, items or services;

other federal and state fraud and abuse laws, such as anti-kickback laws, prohibitions on self-referral, fee-splitting restrictions, insurance fraud laws, anti-markup laws, prohibitions on the provision of tests at no or discounted cost to induce physician or patient adoption, and false claims acts, which may extend to services reimbursable by any third-party payor, including private insurers;

the prohibition on reassignment of Medicare claims, which, subject to certain exceptions, precludes the reassignment of Medicare claims to any other party;

state laws that prohibit other specified practices, such as billing physicians for testing that they order; waiving coinsurance, copayments, deductibles, and other amounts owed by patients; billing a state Medicaid program at a price that is higher than

what is charged to one or more other payors; and

Table of Contents

similar foreign laws and regulations that apply to us in the countries in which we operate or may operate in the future.

We have adopted policies and procedures designed to comply with these laws and regulations. In the ordinary course of our business, we conduct internal reviews of our compliance with these laws. Our compliance is also subject to governmental review. The growth of our business and our expansion outside of the United States may increase the potential of violating these laws or our internal policies and procedures. The risk of our being found in violation of these or other laws and regulations is further increased by the fact that many have not been fully interpreted by the regulatory authorities or the courts, and their provisions are open to a variety of interpretations. Any action brought against us for violation of these or other 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. If our operations are found to be in violation of any of these laws and regulations, we may be subject to any applicable penalty associated with the violation, including administrative, civil and criminal penalties, damages, fines, individual imprisonment, exclusion from participation in Federal healthcare programs, refunding of payments received by us, and curtailment or cessation of our operations. Any of the foregoing consequences could seriously harm our business and our financial results.

***We could be adversely affected by violations of the FCPA and other worldwide anti-bribery laws.***

We are also subject to the FCPA, which prohibits companies and their intermediaries from making payments in violation of law to non-U.S. government officials for the purpose of obtaining or retaining business or securing any other improper advantage. Our reliance on independent distributors to sell our tests internationally demands a high degree of vigilance in maintaining our policy against participation in corrupt activity, because these distributors could be deemed to be our agents, and we could be held responsible for their actions. Other U.S. companies in the medical device and pharmaceutical fields have faced criminal penalties under the FCPA for allowing their agents to deviate from appropriate practices in doing business with these individuals. We are also subject to similar anti-bribery laws in the jurisdictions in which we operate, including the United Kingdom's Bribery Act of 2010, which also prohibits commercial bribery and makes it a crime for companies to fail to prevent bribery. These laws are complex and far-reaching in nature, and, as a result, we cannot assure you that we would not be required in the future to alter one or more of our practices to be in compliance with these laws or any changes in these laws or the interpretation thereof. Any violations of these laws, or allegations of such violations, could disrupt our operations, involve significant management distraction, involve significant costs and expenses, including legal fees, and could result in a material adverse effect on our business, prospects, financial condition, or results of operations. We could also incur severe penalties, including criminal and civil penalties, disgorgement, and other remedial measures.

***Healthcare policy changes, including recently enacted legislation reforming the U.S. healthcare system, may have a material adverse effect on our financial condition, results of operations and cash flows.***

In March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, collectively referred to as the Affordable Care Act, was enacted in the United States, which made a number of substantial changes in the way healthcare is financed by both governmental and private insurers. Among other things, the Affordable Care Act:

requires each medical device manufacturer to pay a sales tax equal to 2.3% of the price for which such manufacturer sells its medical devices, and began to apply to sales of taxable medical devices after December 31, 2012. It is unclear at this time when, or if, the provision of our LDTs will trigger the medical device tax if the FDA ends its policy of general enforcement discretion and regulates certain LDTs as medical devices. It is possible, however, that this tax will apply to some or all of our tests or tests which are in development.



Table of Contents

mandates a reduction in payments for clinical laboratory services paid under the Medicare Clinical Laboratory Fee Schedule of 1.75% for the years 2011 through 2015. In addition, a multi-factor productivity adjustment is made to the fee schedule payment amount.

establishes an Independent Payment Advisory Board to reduce the per capita rate of growth in Medicare spending. The Independent Payment Advisory Board has broad discretion to propose policies, which may have a negative impact on payment rates for our tests beginning in 2016.

The Medicare Physician Fee Schedule rates for diagnostic tests are updated annually under the current statutory formula. For the past several years, the application of the statutory formula would have resulted in substantial payment reductions to all items and services reimbursed under the Physician Fee Schedule if Congress had failed to intervene. In the past, Congress has passed interim legislation to prevent the decreases, with the most current legislation postponing the payment reductions through March 31, 2015. If Congress fails to pass legislation to prevent application of the sustainable growth rate payment reductions beginning April 1, 2015, or for any future deadline, the resulting decrease in payment could materially adversely impact our revenue for services reimbursed under the Medicare Physician Fee Schedule, *e.g.*, physician interpretation of molecular testing.

Many of the Current Procedure Terminology, or CPT, procedure codes that we use to bill our tests were revised by the American Medical Association, effective January 1, 2013. Moreover, the AMA recently released new codes to report genomic sequencing procedures, and in November 2014, CMS published a final determination that sets the price for these codes for purposes of calendar year 2015 via the gap-filling methodology, where Medicare contractors establish jurisdiction-specific payment amounts for these tests, from which national limits may be set under Medicare for 2016. We do not yet know how our tests may fit under these new codes, but if we are required to report our tests under these codes, we cannot assure you that Medicare or its contractors will set adequate reimbursement rates for these new codes.

In April 2014, Congress passed the Protecting Access to Medicare Act of 2014, or PAMA, which included substantial changes to the way in which clinical laboratory services will be paid under Medicare. Under PAMA, clinical laboratories must report to Medicare private payor rates beginning in 2016 and every three years thereafter for clinical diagnostic laboratory tests that are not advanced diagnostic laboratory tests and every year for advanced diagnostic laboratory tests. An advanced diagnostic laboratory test is a clinical diagnostic laboratory test covered under Medicare that is offered and furnished only by a single laboratory and not sold for use by a laboratory other than the original developing laboratory (or a successor owner) and meets one of the following criteria: (1) the test is an analysis of multiple biomarkers of DNA, RNA, or proteins combined with a unique algorithm to yield a single patient-specific result; (2) the test is cleared or approved by the FDA; or (3) the test meets other similar criteria established by the Secretary of Health and Human Services (no criteria have been established by the Secretary as of October 2014).

We do not believe that our tests meet the current definition of advanced diagnostic laboratory tests, but in the event that our tests are determined by CMS to meet these criteria or new criteria developed by CMS, we would be required to report private payor data for those tests annually. Otherwise, we will be required to report private payor rates for our tests on an every three years basis. Laboratories that fail to report the required payment information may be subject to substantial civil money penalties.

For tests furnished on or after January 1, 2017, Medicare payments for clinical diagnostic laboratory tests will be paid based upon these reported private payor rates. For clinical diagnostic laboratory tests that are assigned a new or substantially revised code, initial payment rates for clinical diagnostic laboratory tests that are not advanced diagnostic laboratory tests will be assigned by the cross-walk or gap-fill methodology, as under prior law. Initial payment rates for new advanced diagnostic laboratory tests will be based on the actual list charge for the laboratory test. The impact of

Table of Contents

the new payment system on rates for our tests, including any current or future clinical diagnostic laboratory tests or advanced diagnostic laboratory tests we develop, is not clear at this time.

We cannot predict whether future healthcare initiatives will be implemented at the federal or state level, or how any future legislation or regulation may affect us. For instance, the payment reductions imposed by the Affordable Care Act and the expansion of the federal and state governments' role in the U.S. healthcare industry as well as changes to the reimbursement amounts paid by payors for our tests and future tests or our medical procedure volumes may reduce our profits and have a materially adverse effect on our business, financial condition, results of operations, and cash flows. Moreover, Congress has proposed on several occasions to impose a 20% coinsurance on patients for clinical laboratory tests reimbursed under the clinical laboratory fee schedule, which would increase our billing and collecting costs and decrease our revenue.

***If we use hazardous materials in a manner that causes injury, we could be liable for resulting damages.***

Our activities currently require the use of hazardous chemicals and biological material. 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. The cost of compliance with these laws and regulations may become significant, and our failure to comply may result in substantial fines or other consequences, and either could negatively affect our operating results.

**Risks related to our intellectual property**

***Litigation or other proceedings or third-party claims of intellectual property infringement or misappropriation have and may continue to require us to spend significant time and money, and could in the future prevent us from selling our tests or impact our stock price.***

Our commercial success will depend in part on our avoiding infringement of patents and proprietary rights of third parties, including for example the intellectual property rights of competitors. Our activities may be subject to claims that we infringe or otherwise violate patents owned or controlled by third parties. Numerous U.S. and foreign patents and pending patent applications exist in the genetic testing market and are owned by third parties. We cannot assure you that our operations do not, or will not in the future, infringe existing or future patents. We may be unaware of patents that a third party, including for example a competitor in the genetic testing market, might assert are infringed by our business. There may also be patent applications that, if issued as patents, could be asserted against us. Third parties making claims against us for infringement or misappropriation of their intellectual property rights may seek and obtain injunctive or other equitable relief, which could effectively block our ability to perform our tests. Further, if a patent infringement suit were brought against us, we could be forced to stop or delay our development or sales of any tests or other activities that are the subject of such suit. Defense of these claims, regardless of merit, could cause us to incur substantial expenses and be a substantial diversion of our employee resources. In the event of a successful claim of infringement against us by a third party, we may have to (1) pay substantial damages, including treble damages and attorneys' fees if we are found to have willfully infringed patents; (2) obtain one or more licenses, which may not be available on commercially reasonable terms (if at all); (3) pay royalties; and (4) redesign any infringing tests or other activities, which may be impossible or require substantial time and monetary expenditure.

On November 26, 2013, in response to infringement allegations by Myriad we sued Myriad in the Northern District of California for declaratory judgment that certain of its U.S. patents are invalid and

Table of Contents

not infringed by our tests. This case was consolidated for pre-trial proceedings with actions for infringement by Myriad together with certain of its licensors, the Myriad Plaintiffs, against six other companies. See "Item 3 Legal proceedings." The Myriad Plaintiffs counterclaimed against us, alleging that our tests infringe those patents and alleging that we are willfully infringing those patents. On January 23, 2015, the Myriad Plaintiffs stipulated to the dismissal with prejudice of all of their claims and granted us a covenant not to sue for all of the patents they had asserted against us, and on January 26, 2015, the court issued an order dismissing the case with prejudice thereby ending the litigation.

As we continue to commercialize our tests in their current or an updated form, launch different and expanded tests, and enter new markets, other competitors might claim that our tests infringe or misappropriate their intellectual property rights as part of business strategies designed to impede our successful commercialization and entry into new markets. If such a suit were brought, regardless of merit, we could incur substantial costs and diversion of the attention of our management and technical personnel in defending ourselves against such claims. Any adverse ruling or perception of an adverse ruling in defending ourselves could have a material adverse impact on our cash position and stock price. Furthermore, parties making claims against us may seek and thereby potentially obtain injunctive or other relief, which could block our ability to commercialize our tests, and could result in the award of substantial damages against us. In the event of a successful claim of infringement or misappropriation against us, we may be required to pay damages and obtain one or more licenses from third parties, or be prohibited from commercializing certain tests, all of which could have a material adverse impact on our cash position and business and financial condition.

If licenses to third-party intellectual property rights are or become required for us to engage in our business, we may be unable to obtain them at a reasonable cost, if at all. Even if such licenses are available, we could incur substantial costs related to royalty payments for licenses obtained from third parties, which could negatively affect our gross margins. Moreover, we could encounter delays in the introduction of tests while we attempt to develop alternatives. Defense of any lawsuit or failure to obtain any of these licenses on favorable terms could prevent us from commercializing tests, which could materially affect our ability to grow and thus adversely affect our business and financial condition.

***Developments in patent law could have a negative impact on our business.***

We believe that naturally occurring DNA sequences should not be patentable, and we do not currently have any patents or patent applications directed to such sequences nor have we in-licensed such patents rights of any third party. In this regard, a few key cases involving diagnostic method claims and "gene patents" have recently been decided by the U.S. Supreme Court. On March 20, 2012, the U.S. Supreme Court issued a decision in *Mayo Collaborative v. Prometheus Laboratories*, or *Mayo*, a case involving patent claims directed to optimizing on a patient-specific basis the dosage of a certain drug by measuring its metabolites in a patient. In *Mayo*, the U.S. Supreme Court determined that patent claims directed at detection of natural correlations, such as the correlation between drug metabolite levels in a patient and that drug's optimal dosage for such patient, are not eligible for patent protection. The *Mayo* Court held that claims based on this type of comparison between an observed fact and an understanding of that fact's implications represent attempts to patent a natural law and, moreover, when the processes for making the comparison are not themselves sufficiently inventive, claims to such processes are similarly patent-ineligible. On June 13, 2013, the U.S. Supreme Court decided *Association for Molecular Pathology v. Myriad Genetics*, or *Myriad*, a case brought by multiple plaintiffs challenging the validity of certain patent claims held by Myriad relating to the breast cancer susceptibility genes BRCA1 and BRCA2. In *Myriad*, the U.S. Supreme Court held that genomic DNAs that have been isolated from, or have the same sequence as, naturally occurring samples, such as the DNA constituting the BRCA1 and BRCA2 genes or fragments thereof, are not eligible for patent protection. Instead, the

Table of Contents

*Myriad* Court held that only those complementary DNAs, or cDNAs, which have a sequence that differs from a naturally occurring fragment of genomic DNA may be patent eligible. Because it will be applied by other courts to all gene patents, the holding in *Myriad* also invalidates patent claims to other genes and gene variants. On June 19, 2014, the U.S. Supreme Court decided *Alice Corporation v. CLS Bank (2014)*, or *Alice*, where it amplified its *Mayo* and *Myriad* decisions and clarified the analytical framework for distinguishing between patents that claim laws of nature, natural phenomena and abstract ideas and those that claim patent-eligible applications of such concepts. According to the *Alice* Court, the analysis depends on whether a patent claim directed to a law of nature, a natural phenomenon or an abstract idea contains additional elements, an "inventive concept," that "is 'sufficient to ensure that the patent in practice amounts to significantly more than a patent upon the [ineligible concept] itself'" (citing *Mayo*).

Although we view the *Mayo*, *Myriad* and *Alice* cases as aligned with our belief that naturally occurring DNA sequences should not be patentable, it is possible that subsequent determinations by the U.S. Supreme Court or other federal courts could limit, alter or potentially overrule the holdings of such cases. Moreover, from time to time the U.S. Supreme Court, other federal courts, the United States Congress or the U.S. Patent and Trademark Office, or USPTO, may change the standards of patentability, and any such changes could run contrary to, or otherwise be inconsistent with, our belief that naturally occurring DNA sequences should not be patentable.

We cannot fully predict what impact the U.S. Supreme Court's decisions in *Mayo*, *Myriad* and *Alice* may have on the ability of various third parties, including competitors with substantial resources, to obtain or enforce patents relating to genes, genomic discoveries or genetic testing services currently or in the future. The *Mayo*, *Myriad* and *Alice* decisions are relatively new, and the precise contours of patent eligibility with respect to claims to laws of nature, natural phenomena or abstract ideas are not yet fully settled and may take many years to develop, including through further interpretation in the courts. There are many patents claiming testing methods based on similar or related correlations that issued before *Mayo*, and although some or many of these patents may be invalid under the standard set forth in *Mayo*, until successfully challenged, these patents may be entitled to a presumption of validity and enforceability in litigation, and certain third parties could allege that we infringe, or request that we obtain a license to, these patents. Whether based on patents issued prior to or after *Mayo*, we could have to defend ourselves against claims of patent infringement, or choose to license rights, if available, under patents claiming such methods. Moreover, although the U.S. Supreme Court has held in *Myriad* that isolated genomic DNA is not patent-eligible subject matter, certain third parties could allege that activities that we may undertake infringe other classes of gene-related patent claims, and we could have to defend ourselves against these claims by asserting non-infringement or invalidity positions, or pay to obtain a license to these claims. In any of the foregoing or in other situations involving third-party intellectual property rights, if we are unsuccessful in defending against claims of patent infringement, we could be forced to pay damages or be subjected to an injunction that would prevent us from utilizing the patented subject matter in question if we are unable to obtain a license on reasonable terms. Such outcomes could materially affect our ability to offer our tests and have a material adverse impact on our business. Even if we are able to obtain a license or successfully defend against claims of patent infringement, the cost and distraction associated with the defense or settlement of these claims could have a material adverse impact on our business.

With respect to our own patent protection, recent patent reform legislation could increase the uncertainties and costs surrounding the prosecution of any patent applications and the enforcement or defense of any patents that issue. On September 16, 2011, the Leahy-Smith America Invents Act, or the Leahy-Smith Act, was signed into law. The Leahy-Smith Act includes a number of significant changes to U.S. patent law. These include provisions that affect the way patent applications are prosecuted, redefine prior art, may affect patent litigation and switch the U.S. patent system from a "first-to-invent" system to a "first-to-file" system. Under a "first-to-file" system, assuming the other

Table of Contents

requirements for patentability are met, the first inventor to file a patent application generally will be entitled to the patent on an invention regardless of whether another inventor had made the invention earlier. The USPTO has developed new regulations and procedures to govern administration of the Leahy-Smith Act, and many of the substantive changes to patent law associated with the Leahy-Smith Act, including in particular the first-to-file provisions, became effective on March 16, 2013. Among other changes to the patent laws are features that limit where a patentee may file a patent infringement suit and that provide opportunities for third parties to challenge any issued patent in the USPTO. The Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of any patents that issue, all of which could harm our business and financial condition. In addition, further patent reform legislation may pass in the future that could lead to additional uncertainties and increased costs surrounding the prosecution, enforcement and defense of patent applications and any patents we may obtain.

***Our inability to effectively protect our proprietary technologies, including the confidentiality of our trade secrets, could harm our competitive position.***

We currently rely upon trade secret protection and copyright, as well as non-disclosure agreements and invention assignment agreements with our employees, consultants and third-parties, and to a limited extent patent protection, to protect our confidential and proprietary information. Although our competitors have utilized and are expected to continue utilizing similar methods and have aggregated and are expected to continue to aggregate similar databases of genetic testing information, our success will depend upon our ability to develop proprietary methods and databases and to defend any advantages afforded to us by such methods and databases relative to our competitors. If we do not protect our intellectual property adequately, competitors may be able to use our methods and databases and thereby erode any competitive advantages we may have.

We will be able to protect our proprietary rights from unauthorized use by third parties only to the extent that our proprietary technologies are covered by valid and enforceable patents or are effectively maintained as trade secrets. In this regard, we have applied, and we intend to continue applying, for patents covering such aspects of our technologies as we deem appropriate. However, we expect that potential patent coverage we may obtain will not be sufficient to prevent substantial competition. In this regard, we believe it is probable that others will independently develop similar or alternative technologies or design around technologies for which we may obtain patent protection. In addition, any patent applications we file may be challenged and may not result in issued patents or may be invalidated or narrowed in scope after they are issued. Questions as to inventorship or ownership may also arise. Any finding that our patents or applications are unenforceable could harm our ability to prevent others from practicing the related technology, and a finding that others have inventorship or ownership rights to our patents and applications could require us to obtain certain rights to practice related technologies, which may not be available on favorable terms, if at all. If we initiate lawsuits to protect or enforce our patents, or litigate against third party claims, which would be expensive, and, if we lose, we may lose some of our intellectual property rights. Furthermore, these lawsuits may divert the attention of our management and technical personnel.

We expect to rely primarily upon trade secrets and proprietary know-how protection for our confidential and proprietary information, and we have taken security measures to protect this information. These measures, however, may not provide adequate protection for our trade secrets, know-how, or other confidential information. Among other things, we seek to protect our trade secrets and confidential information by entering into confidentiality agreements with employees and consultants. There can be no assurance that any confidentiality agreements that we have with our employees and consultants will provide meaningful protection for our trade secrets and confidential information or will provide adequate remedies in the event of unauthorized use or disclosure of such

Table of Contents

information. Accordingly, there also can be no assurance that our trade secrets will not otherwise become known or be independently developed by competitors. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret can be difficult, expensive, and time-consuming, and the outcome is unpredictable. In addition, trade secrets may be independently developed by others in a manner that could prevent legal recourse by us. If any of our confidential or proprietary information, such as our trade secrets, were to be disclosed or misappropriated, or if any such information was independently developed by a competitor, our competitive position could be harmed.

***We may not be able to enforce our intellectual property rights throughout the world.***

The laws of some foreign countries do not protect proprietary rights to the same extent as the laws of the United States, and many companies have encountered significant challenges in establishing and enforcing their proprietary rights outside of the United States. These challenges can be caused by the absence of rules and methods for the establishment and enforcement of intellectual property rights outside of the United States. In addition, the legal systems of some countries, particularly developing countries, do not favor the enforcement of patents and other intellectual property protection, especially those relating to healthcare. This could make it difficult for us to stop the infringement of our patents, if obtained, or the misappropriation of our other intellectual property rights. For example, many foreign countries have compulsory licensing laws under which a patent owner must grant licenses to third parties. In addition, many countries limit the enforceability of patents against third parties, including government agencies or government contractors. In these countries, patents may provide limited or no benefit. Patent protection must ultimately be sought on a country-by-country basis, which is an expensive and time-consuming process with uncertain outcomes. Accordingly, we may choose not to seek patent protection in certain countries, and we will not have the benefit of patent protection in such countries. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business. Accordingly, our efforts to protect our intellectual property rights in such countries may be inadequate. In addition, changes in the law and legal decisions by courts in the United States and foreign countries may affect our ability to obtain adequate protection for our technology and the enforcement of intellectual property.

***Third parties may assert that our employees or consultants have wrongfully used or disclosed confidential information or misappropriated trade secrets.***

We employ individuals who were previously employed at universities or genetic testing, diagnostic or other healthcare companies, including our competitors or potential competitors. Although we try to ensure that our employees and consultants do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or our employees or consultants have inadvertently or otherwise used or disclosed intellectual property, including trade secrets or other proprietary information, of a former employer or other third parties. Further, we may be subject to ownership disputes in the future arising, for example, from conflicting obligations of consultants or others who are involved in developing our intellectual property. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

Table of Contents

**Risks related to being a public company**

***We will incur increased costs and demands on management as a result of compliance with laws and regulations applicable to public companies, which could harm our operating results.***

As a public company, we will incur significant legal, accounting and other expenses that we did not incur as a private company, including costs associated with public company reporting requirements. In addition, the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act, as well as rules implemented by the SEC and the New York Stock Exchange, or NYSE, impose a number of requirements on public companies, including with respect to corporate governance practices. The SEC and other regulators have continued to adopt new rules and regulations and make additional changes to existing regulations that require our compliance. In July 2010, the Dodd-Frank Wall Street Reform and Consumer Protection Act, or the Dodd-Frank Act, was enacted. There are significant corporate governance and executive-compensation-related provisions in the Dodd-Frank Act that require the SEC to adopt additional rules and regulations in these areas. Our management and other personnel will need to devote a substantial amount of time to these compliance and disclosure obligations. If these requirements divert the attention of our management and personnel from other aspects of our business concerns, they could have a material adverse effect on our business, financial condition and results of operations. Moreover, these rules and regulations applicable to public companies will substantially increase our legal, accounting and financial compliance costs, require that we hire additional personnel and make some activities more time-consuming and costly. We also expect that it will be more expensive for us to obtain director and officer liability insurance. We cannot predict or estimate the amount or timing of additional costs we may incur to comply with these requirements.

***If we are unable to implement and maintain effective internal control over financial reporting, investors may lose confidence in the accuracy and completeness of our reported financial information and the market price of our common stock may be negatively affected.***

As a public company, we will be required to maintain internal control over financial reporting and to report any material weaknesses in such internal control. Section 404 of the Sarbanes-Oxley Act requires that we evaluate and determine the effectiveness of our internal control over financial reporting and, beginning with our annual report for the year ending December 31, 2015, provide a management report on our internal control over financial reporting. If we have a material weakness in our internal control over financial reporting, we may not detect errors on a timely basis and our financial statements may be materially misstated. We are in the process of compiling the system and processing documentation necessary to perform the evaluation needed to comply with Section 404 of the Sarbanes-Oxley Act. We may not be able to complete our evaluation, testing and any required remediation in a timely fashion.

During the evaluation and testing process, if we identify one or more material weaknesses in our internal controls, our management will be unable to conclude that our internal control over financial reporting is effective. Moreover, when we are no longer an emerging growth company, our independent registered public accounting firm will be required to issue an attestation report on the effectiveness of our internal control over financial reporting. Even if our management concludes that our internal control over financial reporting is effective, our independent registered public accounting firm may conclude that there are material weaknesses with respect to our internal controls or the level at which our internal controls are documented, designed, implemented or reviewed.

If we are unable to conclude that our internal control over financial reporting is effective, or when we are no longer an emerging growth company, if our auditors were to express an adverse opinion on the effectiveness of our internal control over financial reporting because we had one or more material weaknesses, investors could lose confidence in the accuracy and completeness of our financial disclosures, which could cause the price of our common stock to decline. Internal control deficiencies could also result in the restatement of our financial results in the future.

## Edgar Filing: Invitae Corp - Form 10-K

### Table of Contents

*We are an emerging growth company and may elect to comply with reduced public company reporting requirements applicable to emerging growth companies, which could make our common stock less attractive to investors.*

We are an emerging growth company, as defined under the Securities Act of 1933, or the Securities Act. We will remain an emerging growth company for up to five years, although if our revenue exceeds \$1 billion in any fiscal year before that time, we would cease to be an emerging growth company as of the end of that fiscal year. In addition, if the market value of our common stock that is held by non-affiliates exceeds \$700 million as of the last business day of our second fiscal quarter of any fiscal year before the end of that five-year period, we would cease to be an emerging growth company as of December 31 of that year. As an emerging growth company, we may choose to take advantage of exemptions from various reporting requirements applicable to certain other public companies, including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act, reduced financial statement and financial-related disclosures, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, and exemptions from the requirement of holding a nonbinding advisory vote on executive compensation and obtaining stockholder approval of any golden parachute payments not previously approved by our stockholders. We cannot predict whether investors will find our common stock less attractive if we choose to rely on any of these exemptions. If investors find our common stock less attractive as a result of any choices to reduce future disclosure we may make, there may be a less active trading market for our common stock and our stock price may be more volatile.

### **Risks Related to Our Common Stock**

*Our stock price may be volatile, and you may not be able to sell shares of our common stock at or above the price you paid.*

Prior to our initial public offering in February 2015, there was no public market for our common stock, and an active and liquid public market for our stock may not develop or be sustained. In addition, the trading price of our common stock is likely to be highly volatile and could be subject to wide fluctuations in response to various factors, some of which are beyond our control. These factors include:

actual or anticipated fluctuations in our operating results;

competition from existing tests or new tests that may emerge;

announcements by us or our competitors of significant acquisitions, strategic partnerships, joint ventures, collaborations, or capital commitments;

failure to meet or exceed financial estimates and projections of the investment community or that we provide to the public;

issuance of new or updated research or reports by securities analysts or changed recommendations for our stock;

our focus on long term goals over short term results;

the timing of our investments in the growth of our business;

actual or anticipated changes in regulatory oversight of our business;

additions or departures of key management or other personnel;

disputes or other developments related to our intellectual property or other proprietary rights, including litigation;

changes in reimbursement by current or potential payors; and





Table of Contents

general economic and market conditions.

In addition, the stock market in general, and the market for stock of life sciences companies in particular, has experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of those companies. Broad market and industry factors may seriously affect the market price of our common stock, regardless of our actual operating performance. In addition, in the past, following periods of volatility in the overall market and the market price of a particular company's securities, securities class action litigation has often been instituted against these companies. This litigation, if instituted against us, could result in substantial costs and a diversion of our management's attention and resources.

***If securities or industry analysts issue an adverse opinion regarding our stock or do not publish research or reports about our company, our stock price and trading volume could decline.***

The trading market for our common stock will depend 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 company and such lack of research coverage may adversely affect the market price of our common stock. The price of our common stock could also decline if one or more equity research analysts downgrade our common stock or issue other unfavorable commentary or cease publishing reports about us or our business. If one or more equity research analysts cease coverage of our company, we could lose visibility in the market, which in turn could cause our stock price to decline.

***Future sales of shares by existing stockholders could cause our stock price to decline.***

If our existing stockholders sell, or indicate an intention to sell, substantial amounts of our common stock in the public market after the lock-up and other legal restrictions on resale resulting from our recent initial public offering, the trading price of our common stock could decline. On February 28, 2015, 31,813,353 shares of common stock were outstanding. Of these shares, 7,302,500 are freely tradable, without restriction, in the public market. Each of our directors and officers and substantially all of our other stockholders has entered into a lock-up agreement with the underwriters of our initial public offering that restricts their ability to sell or transfer their shares. The lock-up agreements will expire in August 2015. The underwriters, however, may, in their sole discretion, waive the contractual lock-up prior to the expiration of the lock-up agreements. After the lock-up agreements expire, based on shares outstanding as of February 28, 2015, up to an additional 24,510,853 shares of common stock will be eligible for sale in the public market, of which 7,384,156 shares are held by directors, executive officers and other affiliates and will be subject to volume limitations under Rule 144 under the Securities Act, and various vesting agreements. In addition, 2,012,565 shares of common stock that are subject to outstanding options as of February 28, 2015 will become eligible for sale in the public market to the extent permitted by the provisions of various vesting agreements, the lock-up agreements and Rules 144 and 701 under the Securities Act. We have filed a registration statement on Form S-8 under the Securities Act covering all of the shares of common stock subject to options outstanding and reserved for issuance under our stock plans. That registration statement became effective immediately upon filing, and shares covered by that registration statement are eligible for sale in the public markets, subject to Rule 144 limitations applicable to affiliates and any lock-up agreements described above. If these additional shares are sold, or if it is perceived that they will be sold, in the public market, the trading price of our common stock could decline.

***Insiders will exercise significant control over our company and will be able to influence corporate matters.***

As of February 28, 2015, directors, executive officers, 5% or greater stockholders and their affiliates beneficially owned, in the aggregate, 64% of our outstanding capital stock. As a result, these stockholders will be able to exercise significant influence over all matters submitted to our stockholders

Table of Contents

for approval, including the election of directors and approval of significant corporate transactions, such as a merger or sale of our company or its assets. This concentration of ownership may have the effect of delaying or preventing a third party from acquiring control of our company and could adversely affect the market price of our common stock.

***Our ability to use our net operating loss carryforwards and certain other tax attributes may be limited.***

As of December 31, 2014, our total gross deferred tax assets were \$29.9 million. Due to our lack of earnings history and uncertainties surrounding our ability to generate future taxable income, the net deferred tax assets have been fully offset by a valuation allowance. The deferred tax assets were primarily comprised of federal and state tax net operating losses and tax credit carryforwards. Furthermore, under Section 382 of the Internal Revenue Code of 1986, as amended, or the Internal Revenue Code, if a corporation undergoes an "ownership change," the corporation's ability to use its pre-change net operating loss carryforwards, or NOLs, and other pre-change tax attributes (such as research tax credits) to offset its future taxable income may be limited. In general, an "ownership change" occurs if there is a cumulative change in our ownership by "5% shareholders" that exceeds 50 percentage points over a rolling three-year period. Our existing NOLs and tax credit carryovers may be subject to limitations arising from previous ownership changes, and if we undergo one or more ownership changes in connection with future transactions in our stock, our ability to utilize NOLs and tax credit carryovers could be further limited by Section 382 of the Internal Revenue Code. As a result, if we earn net taxable income, our ability to use our pre-change net operating loss and tax credit carryforwards to offset U.S. federal taxable income may be subject to limitations, which could potentially result in increased future tax liability to us. The annual limitation may result in the expiration of certain net operating loss and tax credit carryforwards before their utilization. In addition, at the state level, there may be periods during which the use of NOLs is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed.

***We have never paid dividends on our capital stock and we do not anticipate paying dividends in the foreseeable future.***

We have never paid dividends on any of our capital stock and currently intend to retain any future earnings to fund the growth of our business. In addition, we may enter into credit agreements or other borrowing arrangements in the future that will restrict our ability to declare or pay cash dividends on our common stock. Any determination to pay dividends in the future will be 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. As a result, capital appreciation, if any, of our common stock will be the sole source of gain for the foreseeable future.

***Anti-takeover provisions in our charter documents and under Delaware law could discourage, delay or prevent a change in control and may affect the trading price of our common stock.***

Provisions in our restated certificate of incorporation and our amended and restated bylaws may have the effect of delaying or preventing a change of control or changes in our management. Our restated certificate of incorporation and amended and restated bylaws include provisions that:

authorize our board of directors to issue, without further action by the stockholders, up to 20,000,000 shares of undesignated preferred stock;

require that any action to be taken by our stockholders be effected at a duly called annual or special meeting and not by written consent;

specify that special meetings of our stockholders can be called only by our board of directors, our chairman of the board, or our chief executive officer;

## Edgar Filing: Invitae Corp - Form 10-K

### Table of Contents

establish an advance notice procedure for stockholder approvals to be brought before an annual meeting of our stockholders, including proposed nominations of persons for election to our board of directors;

establish that our board of directors is divided into three classes, Class I, Class II and Class III, with each class serving staggered terms;

provide that our directors may be removed only for cause;

provide that vacancies on our board of directors may, except as otherwise required by law, be filled only by a majority of directors then in office, even if less than a quorum; and

require a super-majority of votes to amend certain of the above-mentioned provisions as well as to amend our bylaws generally.

In addition, we are subject to the provisions of Section 203 of the Delaware General Corporation Law regulating corporate takeovers. Section 203 generally prohibits us from engaging in a business combination with an interested stockholder subject to certain exceptions.

*Our certificate of incorporation designates the Court of Chancery of the State of Delaware as the sole and exclusive forum for certain types of actions and proceedings that may be initiated by our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or other employees.*

Our certificate of incorporation provides that, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware shall be the sole and exclusive forum for:

any derivative action or proceeding brought on our behalf;

any action asserting a claim of breach of a fiduciary duty owed by any of our directors, officers, or other employees to us or our stockholders;

any action asserting a claim arising pursuant to any provision of the Delaware General Corporation Law; or

any action asserting a claim against us governed by the internal affairs doctrine.

Any person or entity purchasing or otherwise acquiring any interest in shares of our capital stock shall be deemed to have notice of and consented to the provisions of our certificate of incorporation described above. This choice of forum provision may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees, which may discourage such lawsuits against us and our directors, officers, and other employees. Alternatively, if a court were to find these provisions of our certificate of incorporation inapplicable to, or unenforceable in respect of, one or more of the specified types of actions or proceedings, we may incur additional costs associated with resolving such matters in other jurisdictions, which could adversely affect our business, financial condition or results of operations.

#### **ITEM 1B. Unresolved Staff Comments.**

None.

#### **ITEM 2. Properties.**

## Edgar Filing: Invitae Corp - Form 10-K

Our corporate headquarters and laboratory operations are located in San Francisco, California, where we lease and occupy 7,795 square feet of space. The lease for our headquarters expires in August 2017, with a five-year extension at our option. Additionally, we sublease 8,852 square feet of

Table of Contents

laboratory and office space in a nearby building under an agreement that expires in February 2017. We lease 12,286 square feet of office space at another location in San Francisco under an agreement that expires in April 2017. We also lease 8,348 square feet of office space in Palo Alto, California pursuant to an agreement that expires in March 2020. We also lease additional facilities in Oakland, California and Santiago, Chile.

We believe that our facilities are adequate for our current needs and that additional space will be available on commercially reasonable terms if required.

**ITEM 3. Legal Proceedings.**

We were not a party to any material legal proceedings on the date of this report. We may from time to time become involved in legal proceedings arising in the ordinary course of business.

On November 25, 2013, the University of Utah Research Foundation, the Trustees of the University of Pennsylvania, HSC Research and Development Limited Partnership, Endorecherche, Inc. and Myriad (referred to collectively as the Myriad Plaintiffs) filed a complaint in the U.S. District Court in the District of Utah (referred to as the Utah Action), alleging that certain of our genetic testing services infringe certain claims of U.S. Patent Nos. 7,753,441; 6,951,721; 7,250,497; 6,033,857; 6,051,379; 7,470,510; 7,622,258; and 7,838,237 (referred to collectively as the Myriad Patents). On November 26, 2013, we filed a complaint for declaratory judgment in the U.S. District Court in the Northern District of California (referred to as the California Action), asserting that the Myriad Patents are invalid and we do not infringe them, and the Myriad Plaintiffs counterclaimed alleging that we infringe the Myriad Patents. Although the Utah Action was dismissed, on February 19, 2014, the Judicial Panel on Multidistrict Litigation granted the Myriad Plaintiffs' motion to consolidate for pre-trial proceedings all actions concerning the Myriad Patents (referred to as the MDL Proceedings), with the MDL Proceedings taking place in the District of Utah. On January 23, 2015, the Myriad Plaintiffs stipulated to the dismissal with prejudice of all of their claims in the California Action and granted us a covenant not to sue for all of the patents they had asserted against us, and on January 26, 2015, the court issued an order dismissing the California Action with prejudice thereby ending our involvement in the MDL Proceedings.

**ITEM 4. Mine Safety Disclosure.**

Not applicable.

Table of Contents

**PART II**

**ITEM 5. Market For Registrant's Common Equity, Related Stockholder Matters And Issuer Purchases Of Equity Securities.**

Our common stock has been publicly traded on the New York Stock Exchange under the symbol "NVTA" since February 12, 2015. Prior to that time, there was no public market for our common stock. As a result, we have not set forth quarterly information with respect to the high and low prices for our common stock for the two most recent fiscal years.

On March 26, 2015, the closing price for our common stock as reported on the New York Stock Exchange was \$17.45 per share.

As of February 28, 2015, there were 112 stockholders of record of our common stock. The actual number of stockholders is greater than this number of record holders and includes stockholders who are beneficial owners but whose shares are held in street name by brokers and other nominees.

**Dividend policy**

We have never declared or paid any cash dividends on our capital stock. We currently intend to retain any future earnings and do not expect to pay any dividends in the foreseeable future. Any determination to pay dividends in the future will be 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.

**Stock performance graph**

The stock performance graph required by Section 201(e) of Regulation S-K has been omitted as our common stock was not publicly traded during any portion of the period described in Section 201(e).

**Use of proceeds**

On February 18, 2015, we completed an initial public offering, or IPO, of our common stock. In connection with the IPO, we issued and sold 7,302,500 shares of common stock at a price to the public of \$16.00 per share. As a result of the IPO, we received approximately \$116.8 million in gross proceeds, and \$105.8 million in net proceeds after deducting underwriting discounts and commissions of \$8.2 million and offering expenses of approximately \$2.8 million payable by us. None of the expenses associated with the IPO were paid to directors, officers, persons owning 10% or more of any class of our equity securities, or to their associates, or to our affiliates. J.P. Morgan Securities LLC acted as the sole book-running manager and Cowen and Company, LLC and Leerink Partners LLC acted as co-managers for the offering.

We registered the shares under the Securities Act of 1933 on a Registration Statement on Form S-1 (Registration No. 333-201433), which was filed with the SEC on January 9, 2015 and declared effective on February 11, 2015, and on a Registration Statement on Form S-1 (Registration No. 333-202040), which was filed on February 11, 2015 and was immediately effective.

The IPO closed on February 18, 2015. The offering terminated after all of the shares of common stock were sold.

There has been no material change in the planned use of proceeds from our IPO as described in our final prospectus filed with the SEC on February 12, 2015 pursuant to Rule 424(b).

Table of Contents

**Recent sales of unregistered securities**

During the year ended December 31, 2014, we sold an aggregate of 60 million shares of Series F convertible preferred stock at a per share price of \$2.00, for aggregate gross proceeds of \$120 million to a total of 38 accredited investors.(1)

During the year ended December 31, 2014, we issued 181,407 shares of common stock to our officers, directors and employees upon the exercise of options to purchase shares of common stock under our 2010 Stock Plan for aggregate consideration of approximately \$208,000 at per share exercise prices ranging from \$0.30 to \$2.82.(2)

We believe that each transaction was exempt from the registration requirements of the Securities Act in reliance on the following exemptions:

(1) These transactions were deemed to be exempt from registration under the Securities Act in reliance upon Section 4(2) of the Securities Act as transactions by an issuer not involving any public offering. The recipients of the securities in each of these transactions represented their intentions to acquire the securities for investment only and not with a view to or for sale in connection with any distribution thereof, and appropriate legends were placed upon the stock certificates issued in these transactions. All recipients had adequate information about us or had adequate access, through their relationships with us, to information about us.

(2) These transactions were deemed to be exempt from registration under the Securities Act in reliance upon Rule 701 promulgated under Section 3(b) of the Securities Act pursuant to benefit plans and contracts relating to compensation as provided under Rule 701. The recipients of the securities in each of these transactions represented their intentions to acquire the securities for investment only and not with a view to or for sale in connection with any distribution thereof, and appropriate legends were placed upon the stock certificates issued in these transactions. All recipients had adequate information about us or had adequate access, through their relationships with us, to information about us.



Table of Contents**ITEM 6. Selected Financial Data.**

The information set forth below should be read together with "Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations" and our financial statements and related notes included elsewhere in this report. The selected consolidated balance sheet data at December 31, 2014 and 2013 and the selected consolidated statements of operations data for each of the years ended December 31, 2014, 2013 and 2012 have been derived from our audited consolidated financial statements that are included elsewhere in this report. The selected consolidated balance sheet data at December 31, 2012 has been derived from our audited consolidated financial data not included in this report. Historical results are not necessarily indicative of results to be expected in any future period.

	Year Ended December 31,		
	2014	2013	2012
	(In thousands except share and per share data)		
<b>Consolidated Statements of Operations Data:</b>			
Revenue	\$ 1,604	\$ 148	\$
Costs and operating expenses:			
Cost of revenue(1)	5,624	667	
Research and development(1)	22,063	16,039	5,557
Selling and marketing(1)	8,669	2,431	
General and administrative(1)	12,600	5,764	3,004
Total costs and operating expenses(1)	48,956	24,901	8,561
Loss from operations	(47,352)	(24,753)	(8,561)
Other income (expense), net	(79)	(26)	2
Interest expense	(61)	(59)	(43)
Net loss	\$ (47,492)	\$ (24,838)	\$ (8,602)
Net loss attributable to common stockholders(2)	\$ (47,492)	\$ (24,989)	\$ (9,014)
Net loss per share attributable to common stockholders, basic and diluted(2)	\$ (56.14)	\$ (36.13)	\$ (14.18)
Shares used in computing net loss per common share, basic and diluted	846,027	691,731	635,705

(1)

Includes employee stock-based compensation as follows:

	Year Ended December 31,		
	2014	2013	2012
	(In thousands)		
Cost of revenue	\$ 102	\$ 11	\$
Research and development	382	165	46
Selling and marketing	216	42	
General and administrative	271	42	19
Total stock-based compensation	\$ 971	\$ 260	\$ 65

## Edgar Filing: Invitae Corp - Form 10-K

### Table of Contents

- (2) See Notes 2 and 10 to our audited consolidated financial statement included elsewhere in this report for an explanation of the calculations of our basic and diluted net loss per share attributable to common stockholders.

	As of December 31,		
	2014	2013	2012
	(In thousands)		
<b>Consolidated Balance Sheets Data:</b>			
Cash and cash equivalents	\$ 107,027	\$ 43,070	\$ 21,801
Working capital	102,020	41,577	21,043
Total assets	128,778	53,103	25,973
Capital lease obligations	3,535	2,001	1,215
Convertible preferred stock	202,305	86,574	36,755
Accumulated deficit	(85,180)	(37,688)	(12,850)
Total stockholders' deficit	(83,576)	(37,280)	(12,759)
		62	

---

Table of Contents

**ITEM 7. Management's Discussion And Analysis Of Financial Condition And Results Of Operations.**

*The following discussion of our financial condition and results of operations should be read in conjunction with our financial statements and the related notes included in Item 8 of this report. Historic results are not necessarily indicative of future results.*

**Business overview**

Our mission is to bring comprehensive genetic information into mainstream medical practice to improve the quality of healthcare for billions of people. Our goal is to aggregate most of the world's genetic tests into a single service with higher quality, faster turnaround time and lower price than many single gene tests today. By aggregating large numbers of currently available genetic tests into a single service, we can achieve great economies of scale that allow us to not only provide primary single gene or multi-gene tests but also to generate and store additional genetic information on behalf of the patient for future use. We refer to the service of managing genetic information over the course of disease or the lifetime of a patient as "genome management." In addition, as more individuals gain access to their genetic information, we believe that sharing genetic information will provide an economic opportunity for patients and us to participate in advancing the understanding and treatment of disease.

From our inception through December 31, 2014, we raised an aggregate of \$207.0 million in equity financing, established the infrastructure necessary to launch our service and were primarily focused on the research and development of our initial assay. We launched our first commercial offering in late November 2013, an assay of 216 genes comprising 85 different genetic disorders and 17 targeted panels, and began selling and marketing our panels with a focused effort on hereditary cancers, including breast, colon and pancreatic cancer. We charge \$1,500 per sample in most cases, which allows our clients to receive test results on any or all genes in a specific indication or multi-gene panel. We also currently offer a free re-requisition of additional data within the same indication when ordered within 90 days of the date of service. In addition, clients may obtain test results on genes that are in other indications or panels, or genes within the same indication or panel more than 90 days after the date of initial service, for an additional fee. Importantly, we are providing turnaround time of less than three weeks for the substantial majority of our tests. Since our initial launch, we have marketed additional panels based on the same assay of 216 genes.

We have experienced rapid growth in recent periods. For the years ended December 31, 2014, 2013, and 2012 our revenue was \$1.6 million, \$0.1 million and \$0, respectively. For the years ended December 31, 2014, 2013 and 2012 we incurred a net loss of \$47.5 million, \$24.8 million and \$8.6 million, respectively. As of December 31, 2014, we had an accumulated deficit of \$85.2 million. We also increased our number of employees to 161 at December 31, 2014 from 44 on January 1, 2013. Our sales force grew to nine people in the fourth quarter of 2014 from six people in the first quarter of 2014.

Since our commercial launch, we have delivered more than 3,800 billable tests as of December 31, 2014. Sales of our tests have grown significantly in 2014 from over 200 billable tests in the first quarter of 2014 to over 1,800 billable tests in the fourth quarter of 2014, which we believe is evidence that our value proposition is attractive to our clients. As the market for our billable tests develops, we expect that competitors will release offerings with broader content that is clinically relevant to particular patients. We thus expect our rate of growth in delivered billable tests to slow in periods leading up to commercial releases of our expanding platform, including the period in 2015 leading up to the first planned expansion of our current assay of 216 genes. We estimate that the U.S. market for hereditary cancer tests is greater than \$650 million per year and thus represents a key growth opportunity for us. From inception through December 31, 2014, approximately 26% of billable tests have been paid. On a historical basis through December 31, 2014, approximately 37% of the billable tests we performed have

Table of Contents

been billable to institutions and patients, and the remainder have been billable to third-party payors. Many of the gene tests on our assay are tests for which private insurers reimburse. However, because we do not have reimbursement policies or contracts with very many private insurers, our claims for reimbursement from them may be denied upon submission, and we must appeal the claims. The appeals process is time consuming and expensive, and may not result in payment. Even if we are successful achieving reimbursement, we may be paid at lower rates than if we were under contract with the third-party payor. When there is not a contracted rate for reimbursement, there is typically a greater co-insurance or co-payment requirement from the patient which may result in further delay or decreased likelihood of collection.

We intend to continue to invest aggressively in our business and to incur additional expenditures as a public company. As a result of these and other factors, we expect to incur operating losses for the foreseeable future and may need to raise additional capital in order to fund our operations. If we are unable to achieve our revenue growth objectives and successfully manage our costs, we may not be able to achieve profitability.

We believe that the keys to our future growth will be to steadily increase the amount of genetic content we offer, consistently improve the client experience, drive physician and patient utilization of our website for ordering and delivery of results, increase the number of partners working with us to add value for our clients and consistently drive down the price per gene for genetic analysis and interpretation.

**Factors affecting our performance**

*Ability to lower the costs associated with performing our tests*

Reducing the costs associated with performing our genetic tests is both a near-term focus and a strategic objective of ours. Over the long term we will need to reduce the cost of raw materials by improving the output efficiency of our assay and laboratory processes, modifying our platform-agnostic assay and laboratory processes to use materials and technologies that provide equal or greater quality at lower cost, improving how we manage our inventory and negotiating favorable terms for our materials purchases. We also intend to design and implement hardware and software tools that will reduce personnel cost for both laboratory and clinical operations by increasing personnel efficiency and thus lowering labor costs per test.

*Ability to expand our genetic content*

As we reduce our costs, we intend to continue to expand our test menus by steadily releasing additional genetic content for the same or lower prices per test, ultimately leading to affordable whole genome services. The breadth and flexibility of our offering will be a critical factor in our ability to address new markets for genetic testing services. Both of these will be critical to our ability to continue to grow the volume of billable tests we deliver.

*Number of billable tests*

The growth in our genetic testing business is tied to the number of tests for which we bill third-party payors, institutions or patients, which we refer to as billable tests. We bill for our services following delivery of the billable test report derived from testing samples and interpreting the results. We incur the expenses associated with a test in the period in which the test is processed regardless of when payment is received with respect to that test. We believe the number of billable tests in any period is an important indicator of the growth in our business.

Table of Contents

***Success obtaining reimbursement***

Our ability to increase the number of billable tests and our revenue will depend on our success achieving broad reimbursement coverage for our tests from third-party payors. Reimbursement may depend on a number of factors, including a payor's determination that a test is appropriate, medically necessary and cost-effective. Because each payor makes its own decision as to whether to establish a policy or enter into a contract to reimburse for our testing services, seeking these approvals is a time-consuming and costly process. In addition, physicians may decide not to order our tests if the cost of the test is not covered by insurance. Because we require an ordering physician to requisition a test, our revenue growth also depends on our ability to successfully promote the adoption of our testing services and expand our base of ordering physicians. We believe that establishing coverage from third-party payors, including the Center for Medicare and Medicaid Services, or CMS, is an important factor in gaining adoption by ordering physicians. We have received approval as a Medicare provider, which allows us to bill for our services to Medicare patients. Further we have entered into reimbursement contracts with Blue Shield of California and SelectHealth. If we are not able to obtain and maintain adequate reimbursement from third-party payors for our testing services and expand the base of physicians ordering our tests, we may not be able to effectively increase the number of billable tests or our revenue.

***Investment in our business and timing of expenses***

We plan to continue to invest significantly in our genetic testing, genome management and genome network business. We deploy state-of-the-art and costly technologies in our genetic testing services, and we intend to significantly scale our infrastructure, including our testing capacity and information systems. We also expect to incur software development costs as we seek to further automate our laboratory processes and genetic interpretation and report sign-out procedures, conduct ongoing research and development activities, scale our customer service capabilities and expand the functionality of our website. As part of our growth, we also plan to hire additional personnel, including software engineers, sales and marketing personnel, research and development personnel, medical specialists, biostatisticians and geneticists. In addition, we expect to incur additional expenses as a result of operating as a public company. The expenses we incur may vary significantly by quarter depending, for example, on when large equipment purchases are made or significant hiring takes place, and as we focus on building out different aspects of our business.

***How we recognize revenue***

Our historical revenue has been recognized when cash is received. We do not expect to recognize significant amounts of revenue on an accrual basis for some period of time. Until we achieve and maintain a predictable pattern of collection at a consistent payment amount from a large number of payors, we will continue to recognize the substantial majority of our revenue when cash is received. Additionally, as we commercialize new test offerings, we will need to achieve a predictable pattern of collection at a consistent payment amount for each payor for each new product offering prior to being able to recognize the related test revenue on an accrual basis. Because the timing and amount of cash payments received from payors is difficult to predict, we expect that our revenue will fluctuate significantly in any given quarter.

For the year ended December 31, 2014 and 2013, amounts billed for tests delivered totaled \$6.6 million and \$0.3 million, respectively. As of December 31, 2014, we had recognized revenue of \$1.5 million related to amounts billed for tests delivered during the year ended December 31, 2014 and \$0.1 million related to amounts billed for tests delivered during the year ended December 31, 2013. It is difficult to predict future revenue from previously delivered but unpaid tests. Accordingly, we cannot provide any assurance as to when, if ever, or to what extent any of these amounts will be collected. Because we are in the early stages of commercializing our tests, we have had limited payment and

Table of Contents

collection history. Notwithstanding our efforts to obtain payment for these tests, payors may deny our claims, in whole or in part, and we may never receive revenue from any previously delivered but unpaid tests. Revenue from these tests, if any, may not be equal to the billed amount due to a number of factors, including differences in reimbursement rates, the amounts of patient co-payments, the existence of secondary payors and claims denials.

We incur and recognize expenses for tests in the period in which the test is conducted and recognize revenue for tests in the period in which our revenue recognition criteria are met. Accordingly, any revenue that we receive in respect of previously delivered but unpaid tests will favorably impact our liquidity and results of operations in future periods.

**Financial overview**

*Revenue*

We generate revenue from the sale of our tests which provide the analysis and associated interpretation of the sequencing of parts of the genome. Clients are billed upon delivery of test results to the physician. As we do not have sufficient history of collection and are not yet able to determine a predictable pattern of collection, we currently recognize revenue when cash is received. Our ability to increase our revenue will depend on our ability to increase our market penetration, obtain contracted reimbursement coverage from third-party payors and increase the rate at which we are paid for tests performed.

*Cost of revenue*

Cost of revenue reflects the aggregate costs incurred in delivering test results to physicians and includes expenses for materials and supplies, personnel costs, equipment and infrastructure expenses associated with testing and allocated overhead including rent, equipment depreciation and utilities. Costs associated with performing our test are recorded as the patient's sample is processed regardless of whether and when revenue is recognized with respect to that test. As a result, our cost of revenue as percentage of revenue may vary significantly from period to period because we generally do not recognize revenue in the period in which costs are incurred. We expect cost of revenue to generally increase in line with the increase in the number of tests we perform. However, we expect that the cost per test will decrease over time due to the efficiencies we may gain as test volume increases and from automation and other cost reductions.

*Operating expenses*

Our operating expenses are classified into three categories: research and development, selling and marketing, and general and administrative. For each category, the largest component is personnel costs, which include salaries, employee benefit costs, bonuses, commissions, as applicable, and stock-based compensation expense.

*Research and development*

Research and development expenses represent costs incurred to develop our technology and future tests, including costs associated with our efforts to expand the number of genes we can evaluate in our tests. These costs consist of personnel costs, laboratory supplies and equipment expenses, consulting costs and allocated overhead including rent, information technology, equipment depreciation and utilities.

We expense all research and development costs in the periods in which they are incurred. We expect our research and development expenses will substantially increase in absolute dollars in future periods as we continue to invest in research and development activities related to developing additional tests. We expect that in the next 12 months the substantial increase in research and development

Table of Contents

expenses will be for the continued development and support of our assay of 216 genes and other new testing services and programs under development.

*Selling and marketing*

Selling and marketing expenses consist of personnel costs, client service expenses, direct marketing expenses, educational and promotional expenses, market research and analysis, and allocated overhead including rent, information technology, equipment depreciation and utilities. We expect our selling and marketing expenses to substantially increase over the next 12 months, primarily driven by the cost of hiring additional account executives and business development personnel associated with efforts to further penetrate the domestic market.

*General and administrative*

General and administrative expenses include executive, finance and accounting, legal and human resources functions. These expenses include personnel-related costs, audit and legal expenses, consulting costs, and allocated overhead including rent, information technology, equipment depreciation and utilities. We expect our general and administrative expenses will increase as we scale our operations. We also expect to incur additional general and administrative expenses as a result of our initial public offering and operating as a public company, including expenses related to compliance with the rules and regulations of the SEC and the New York Stock Exchange, additional insurance expenses, investor relations activities and other administration and professional services.

*Other income (expense), net*

Other income (expense), net primarily consists of the net exchange gain/loss on foreign currency transactions related to the operations of our subsidiary in Chile.

*Interest expense*

Interest expense is attributable to our financing obligation under our capital lease agreements in connection with the purchase of laboratory equipment.

*Critical accounting policies and estimates*

Management's discussion and analysis of our financial condition and results of operations is based on our consolidated financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles, or U.S. GAAP. The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements, as well as the reported revenue generated and expenses incurred during the reporting periods. Our estimates are based on our historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions and any such differences may be material. We believe that the accounting policies discussed below are critical to understanding our historical and future performance, as these policies relate to the more significant areas involving management's judgments and estimates.

*Revenue recognition*

We generate revenue from delivery of test reports generated from our assay of 216 genes. Revenue is recognized when persuasive evidence of an arrangement exists; delivery has occurred or services have been rendered; the fee is fixed or determinable; and collectability is reasonably assured. The assessment

Table of Contents

of the fixed or determinable nature of the fees charged for testing performed and the collectability of those fees require significant judgment by management. When evaluating these criteria, we consider whether we have sufficient history to reliably estimate a payor's payment pattern. We review the number of tests paid against the number of tests billed and the payor's outstanding balance for unpaid tests to determine whether payments are being made at a consistently high percentage of tests billed and at appropriate amounts given the amount billed. To date, we have not been able to demonstrate a predictable pattern of collectability, and therefore recognize revenue when payment is received following delivery of the report.

*Deferred tax assets*

We use the liability method of accounting for income taxes. Under this method, deferred tax assets and liabilities are determined based on the differences between the financial reporting and the tax bases of assets and liabilities and are measured using the enacted tax rates and laws that will be in effect when the differences are expected to reverse. We assess the likelihood that the resulting deferred tax assets will be realized. A valuation allowance is provided when it is more likely than not that some portion or all of a deferred tax asset will not be realized.

As of December 31, 2014, our total gross deferred tax assets were \$29.9 million. Due to our lack of earnings history and uncertainties surrounding our ability to generate future taxable income, the net deferred tax assets have been fully offset by a valuation allowance. The deferred tax assets were primarily comprised of federal and state tax net operating losses and tax credit carryforwards. Utilization of the net operating loss and tax credit carryforwards may be subject to an annual limitation due to historical or future ownership percentage change rules provided by the Internal Revenue Code of 1986, and similar state provisions. The annual limitation may result in the expiration of certain net operating loss and tax credit carryforwards before their utilization.

*Stock-based compensation*

Stock-based compensation expense is measured at the date of grant, based on the estimated fair value of the award and recognized as an expense over the employee's requisite service period on a straight-line basis. We estimate the grant date fair value, and the resulting stock-based compensation expense, using the Black-Scholes option-pricing model.

We account for stock-based compensation arrangements with non-employees using a fair value approach. The fair value of these options is measured using the Black-Scholes option-pricing model reflecting the same assumptions as applied to employee options in each of the reported periods, other than the expected life, which is assumed to be the remaining contractual life of the option. The compensation expenses of these arrangements are subject to remeasurement over the vesting terms as earned.

We recorded stock-based compensation expense of \$1.0 million, \$0.3 million and \$65,000 for the years ended December 31, 2014, 2013 and 2012. As of December 31, 2014, we had \$5.3 million of unrecognized stock-based compensation expense, net of estimated forfeitures, which we expect to recognize over a weighted-average period of 3.4 years.

The Black-Scholes option-pricing model requires the use of highly subjective assumptions which determine the fair value of stock-based awards. These assumptions include:

*Expected term* The expected term represents the period that stock-based awards are expected to be outstanding. We used the simplified method to determine the expected term, which is based on the mid-point between the vesting date and the end of the contractual term.

*Expected volatility* Since we were privately held up to our initial public offering in February 2015 and did not have any trading history for our common stock, the expected volatility was estimated based



Table of Contents

on the average volatility for comparable publicly traded life sciences, including molecular diagnostics, companies over a period equal to the expected term of the stock option grants. When selecting comparable publicly traded life sciences, including molecular diagnostics, companies on which we based our expected stock price volatility, we selected companies with comparable characteristics to us, including enterprise value, risk profiles, position within the industry, and with historical share price information sufficient to meet the expected life of the stock-based awards. The historical volatility data was computed using the daily closing prices for the selected companies' shares during the equivalent period of the calculated expected term of the stock-based awards. We will continue to apply this process until a sufficient amount of historical information regarding the volatility of our own stock price becomes available.

*Risk-free interest rate* The risk-free interest rate is based on the U.S. Treasury zero coupon issues in effect at the time of grant for periods corresponding with the expected term of an option.

*Dividend yield* We have never paid dividends on our common stock and have no plans to pay dividends on our common stock. Therefore, we used an expected dividend yield of zero.

In addition to the Black-Scholes assumptions, we estimate our forfeiture rate based on an analysis of our actual forfeitures and will continue to evaluate the adequacy of the forfeiture rate based on actual forfeiture experience, analysis of employee turnover behavior, and other factors. The impact from any forfeiture rate adjustment would be recognized in full in the period of adjustment and if the actual number of future forfeitures differs from our estimates, we might be required to record adjustments to stock-based compensation in future periods.

Historically, for all periods prior to our initial public offering, the fair values of the shares of common stock underlying our share-based awards were estimated on each grant date by our board of directors. In order to determine the fair value of our common stock underlying option grants, our board of directors considered, among other things, contemporaneous valuations of our common stock prepared by an independent third-party valuation firm in accordance with the guidance provided by the American Institute of Certified Public Accountants Practice Guide, *Valuation of Privately-Held-Company Equity Securities Issued as Compensation*. Given the absence of a public trading market for our common stock, our board of directors exercised reasonable judgment and considered a number of objective and subjective factors to determine the best estimate of the fair value of our common stock, including our stage of development; progress of our research and development efforts; our operating and financial performance, including our levels of available capital resources; the rights, preferences and privileges of our convertible preferred stock relative to those of our common stock; sales of our convertible preferred stock in arms<sup>1</sup>-length transactions; the valuation of publicly traded companies in our industry, as well as recently completed mergers and acquisitions of peer companies; equity market conditions affecting comparable public companies; and the lack of marketability of our common stock.

In determining a fair value for our common stock, we estimated the enterprise value of our business using the market approach or option pricing back-solve method. The estimated enterprise value is then allocated to the common stock using the Option Pricing Method, or OPM, and the Probability Weighted Expected Return Method, or PWERM, or the hybrid method. The hybrid method applied the PWERM utilizing the probability of two public offering exit scenarios with a low and high value, and the OPM was utilized in the remaining private scenario.

For valuations after the completion of our initial public offering, our board of directors determines the fair value of each share of underlying common stock based on the closing price of our common stock as reported on the date of grant.

Table of Contents**Results of Operations***Comparison of the Years Ended December 31, 2014 and 2013*

	Year Ended December 31,		Dollar Change	% Change
	2014	2013		
	(In thousands)			
Revenue	\$ 1,604	\$ 148	\$ 1,456	984%
Operating expenses:				
Cost of revenue	5,624	667	4,957	743%
Research and development	22,063	16,039	6,024	38%
Selling and marketing	8,669	2,431	6,238	257%
General and administrative	12,600	5,764	6,836	119%
Total operating expenses	48,956	24,901	24,055	97%
Loss from operations	(47,352)	(24,753)	(22,559)	91%
Other expense, net	(79)	(26)	(53)	204%
Interest expense	(61)	(59)	(2)	3%
Net loss	\$ (47,492)	\$ (24,838)	\$ (22,654)	91%

*Revenue*

Revenue increased \$1.5 million, or 984%, in the year ended December 31, 2014 compared to the same period in 2013. The increase is due to an increase in the adoption of our test, which resulted in an increase in cash collections during 2014. Revenue for the year ended December 31, 2013 resulted from an early access program we offered beginning in the first quarter of 2013.

*Cost of revenue*

Cost of revenue increased \$5.0 million, or 743%, in the year ended December 31, 2014 compared to the same period in 2013. This increase was primarily due to a \$3.2 million increase in costs of reagents, laboratory materials and test validation costs and a \$1.5 million increase in personnel costs related to the increase in headcount. The number of billed test results delivered increased to over 3,600 for the year ended December 31, 2014 from over 200 for the same period in 2013.

*Research and development*

Research and development expenses increased \$6.0 million, or 38%, for the year ended December 31, 2014 compared to the same period in 2013. The increase was primarily driven by a \$4.1 million increase in personnel costs related to the increase in headcount, a \$1.4 million increase in allocated facilities-related expenses due to the expansion of our operations into two additional locations and a \$0.5 million increase in costs of laboratory materials and laboratory equipment maintenance.

*Selling and marketing*

Selling and marketing expenses increased \$6.2 million, or 257%, for the year ended December 31, 2014 compared to the same period in 2013. The increase was due to a \$3.7 million increase in personnel costs and travel related expenses due to the increase in headcount, a \$1.0 million increase in conferences, marketing activities and trade show-related expenses, a \$0.8 million increase in consulting fees incurred in connection with various marketing and branding activities, and a \$0.6 million increase related to an increase in allocated technology and facilities related expenses as the result of our office expansion.

Table of Contents*General and administrative*

General and administrative expenses increased \$6.8 million, or 119%, for the year ended December 31, 2014 compared to the same period in 2013. The increase was due to a \$2.5 million increase in legal costs incurred primarily related to the Myriad litigation matter, a \$2.1 million increase in personnel costs resulting from an increase in headcount, a \$1.0 million increase in professional services to support our increasing infrastructure as we expanded our operations and prepared to become a public company and a \$1.0 million increase related to an increase in allocated technology and facilities related expenses as the result of our office expansion.

*Comparison of the Years Ended December 31, 2013 and 2012*

	Year Ended December 31,		Dollar Change	% Change
	2013	2012		
	(In thousands)			
Revenue	\$ 148	\$	\$ 148	*
Operating expenses:				
Cost of revenue	667		667	*
Research and development	16,039	5,557	10,482	189%
Selling and marketing	2,431		2,431	*
General and administrative	5,764	3,004	2,760	92%
Total operating expenses	24,901	8,561	16,340	191%
Loss from operations	(24,753)	(8,561)	(16,192)	189%
Other income (expense), net	(26)	2	(28)	*
Interest expense	(59)	(43)	(16)	37%
Net loss	\$ (24,838)	\$ (8,602)	\$ (16,236)	189%

---

\*  
Not meaningful

*Revenue*

Revenue was \$0.1 million in 2013 compared to \$0 in 2012 as we had an early access program, which started in the first quarter of 2013, and we launched our first commercial offering in late November 2013.

*Cost of revenue*

Cost of revenue was \$0.7 million in 2013 compared to \$0 in 2012. We incurred costs for over 200 billable test results that we delivered during the year ended December 31, 2013. We did not begin commercial operations until the first quarter of 2013 when we had an early access program and the first commercial launch of our assay of 216 genes was in late November 2013.

*Research and development*

Research and development expenses increased \$10.5 million, or 189%, in 2013 compared to 2012. The increase was primarily driven by a \$5.1 million increase in personnel related costs due to the increase in headcount, a \$3.0 million increase in laboratory materials, a \$1.1 million increase in allocated facility related costs as a result of our expansion into two offices starting in March 2013, a \$0.7 million increase in depreciation expense due to the increase in laboratory equipment, and a \$0.3 million increase in outside consulting costs incurred for temporary lab engineering consultants hired to assist with an increase in our research activities. Further, we conduct extensive validation assays to confirm

## Edgar Filing: Invitae Corp - Form 10-K

the analytical validity of our genetic testing platform and we sometimes conduct our own clinical studies to further demonstrate the utility of already known genetic tests in order to promote broader application and market adoption by the clinical community.

Table of Contents

*Selling and marketing*

Selling and marketing expenses were \$2.4 million for 2013 compared to \$0 for 2012. We did not begin commercial operations until we launched our early access program in the first quarter of 2013. The increase was due to a \$2.1 million increase in personnel costs and travel related expenses due to the increase in headcount, a \$0.2 million increase in consulting fees incurred to assist with our marketing and branding activities related to the launch of our first test and a \$0.1 million increase in allocated facilities related costs as the result of our expansion of operations into two locations in 2013.

*General and administrative*

General and administrative expenses increased \$2.8 million, or 92%, in 2013 compared to 2012. The increase was related to a \$1.3 million increase in legal and accounting professional services due to the growth in our operations, a \$0.8 million increase in allocated facilities related costs as the result of our expansion of operations into two locations in 2013, and a \$0.7 million increase in personnel-related expenses resulting from an increase in headcount.

**Liquidity and capital resources**

*Liquidity and capital expenditures*

We have incurred net losses since our inception. For the years ended December 31, 2014, 2013 and 2012, we had a net loss of \$47.5 million, \$24.8 million and \$8.6 million, respectively, and we expect to incur additional losses in the foreseeable future. As of December 31, 2014, we had an accumulated deficit of \$85.2 million. To date, we have generated only limited revenue, and we may never achieve revenue sufficient to offset our expenses.

Since inception, our operations have been financed primarily by net proceeds of \$202.3 million from sales of our convertible preferred stock through December 31, 2014. In addition, we have entered into various capital lease agreements for an aggregate financing amount of \$6.6 million from inception through December 31, 2014 to obtain laboratory equipment. The terms of the capital leases are typically three years with interest rates ranging from 3.5%-18.9%. The leases are secured by the underlying equipment. As of December 31, 2014 and 2013, we had \$107.0 million and \$43.1 million of cash and cash equivalents, respectively.

In our initial public offering, which we completed on February 12, 2015, we sold 7,302,500 shares of common stock at \$16.00 per share and received approximately \$105.8 million in net proceeds, after deducting underwriting discounts and commissions, and offering expenses payable by us. This includes the exercise in full by the underwriters of their option to purchase up to 952,500 shares of common stock at the same price to cover over-allotments.

Our primary uses of cash are to fund our operations as we continue to grow our business. Cash used to fund operating expenses is impacted by the timing of when we pay expenses, as reflected in the change in our outstanding accounts payable and accrued expenses.

We believe that our existing cash and cash equivalents as of December 31, 2014, along with the net proceeds from our initial public offering, will be sufficient to meet our anticipated cash requirements for at least the next 12 months. However, management may in the future elect to finance operations by selling equity or debt securities. If we raise funds by issuing equity securities, dilution to stockholders may result. Any equity securities issued may also provide for rights, preferences or privileges senior to those of holders of our common stock. If we raise funds by issuing debt securities, these debt securities would have rights, preferences and privileges senior to those of holders of our common stock. The terms of debt securities or borrowings could impose significant restrictions on our operations. If additional funding is required, there can be no assurance that additional funds will be available to us on acceptable terms on a timely basis, if at all, or that we will generate sufficient cash from operations

## Edgar Filing: Invitae Corp - Form 10-K

### Table of Contents

to adequately fund our operating needs or sustain profitability. If we are unable to raise additional capital or generate sufficient cash from operations to adequately fund our operations, we will need to curtail planned activities to reduce costs. Doing so will likely have an unfavorable effect on our ability to execute on our business plan.

The following table summarizes our cash flows for the years ended December 31, 2014, 2013 and 2012:

	<b>Years Ended December 31,</b>		
	<b>2014</b>	<b>2013</b>	<b>2012</b>
	<b>(in thousands)</b>		
Cash used in operating activities	\$ (42,440)	\$ (23,030)	\$ (9,154)
Cash used in investing activities	(6,716)	(4,580)	(826)
Cash provided by financing activities	113,113	48,879	28,802

#### ***Cash flows from operating activities***

For the year ended December 31, 2014, cash used in operating activities was \$42.4 million. The net cash outflow from operations primarily resulted from our net loss of \$47.5 million offset by non-cash charges of \$2.3 million for depreciation and amortization, and \$1.0 million for stock-based compensation. The change in net operating assets of \$1.7 million was primarily due to an increase in accounts payable and accrued liabilities of \$4.5 million due to the growth in our business, partially offset by an increase in prepaid expenses of \$1.9 million related to an increase in prepaid equipment maintenance fees and software license fees of \$0.5 million and an increase in inventory of \$1.4 million, and an increase in other assets of \$0.4 million primarily related to security deposits on our new office leases.

For the year ended December 31, 2013, cash used in operating activities of \$23.0 million primarily resulted from our net loss of \$24.8 million offset by \$0.9 million for depreciation and amortization and non-cash charges of \$0.3 million for stock-based compensation. The increase in net operating assets of \$0.6 million was primarily due to the \$1.0 million increase in payables to suppliers and partially offset by the increase in prepaid expenses of \$0.4 million mainly related to the increase in tenant incentive receivables due from the landlord of our new office.

For the year ended December 31, 2012, cash used in operating activities of \$9.2 million was primarily from our net loss of \$8.6 million offset by \$0.3 million for depreciation and amortization and non-cash charges of \$0.1 million for stock-based compensation. The change in the net operating assets of \$0.9 million was mainly due to the \$0.9 million increase in other assets related to the security deposit for our new Palo Alto office.

#### ***Cash flows from investing activities***

Cash used in investing activities is primarily related to the acquisition of property and equipment of \$6.7 million, \$4.5 million and \$0.8 million for the years ended December 31, 2014, 2013 and 2012, respectively. In addition, amounts held as restricted cash increased by \$30,000, \$60,000, and \$60,000 for the years ended December 31, 2014, 2013 and 2012, respectively.

#### ***Cash flows from financing activities***

Cash provided by financing activities for the year ended December 31, 2014 of \$113.1 million was primarily from \$115.7 million in net proceeds from the issuance of convertible preferred stock, partially offset by payments of \$1.4 million on our capital lease obligations and payments of \$1.5 million related to our initial public offering.

## Edgar Filing: Invitae Corp - Form 10-K

### Table of Contents

In 2013, we generated \$48.9 million from financing activities primarily resulting from \$49.8 million in net proceeds from issuance of convertible preferred stock. These cash inflows were partially offset by payments of \$1.0 million on our capital lease obligations.

In 2012, we generated \$28.8 million from financing activities primarily resulting from \$29.4 million in net proceeds from issuance of convertible preferred stock. These cash inflows were partially offset by payments of \$0.6 million on our capital lease obligations.

### **Contractual obligations**

The following table summarizes our contractual obligations, including interest, as of December 31, 2014 (in thousands):

Contractual obligations:	Payments due by period				Total
	Less than 1 year	1 to 3 years	3 to 5 years	More than 5 years	
Operating leases	\$ 2,635	\$ 3,999	\$ 1,562	\$ 199	\$ 8,395
Capital leases	1,573	2,092	70		3,735
<b>Total</b>	<b>\$ 4,208</b>	<b>\$ 6,091</b>	<b>\$ 1,632</b>	<b>\$ 199</b>	<b>\$ 12,130</b>

In March 2015, we leased additional space in San Francisco and Oakland, California. The leases expire in April and June 2017 and aggregate future minimum lease payments for these facilities are approximately \$2.4 million.

### **Off-balance sheet arrangements**

We have not entered into any off-balance sheet arrangements and do not have any holdings in variable interest entities..

### **Recent accounting pronouncements**

On May 28, 2014, the Financial Accounting Standards Board, or FASB, issued Accounting Standards Update, or ASU, 2014-09, *Revenue from Contracts with Customers* (ASU 2014-09), which requires an entity to recognize the amount of revenue to which it expects to be entitled for the transfer of promised goods or services to customers. ASU 2014-09 will replace most existing revenue recognition guidance in U.S. GAAP when it becomes effective. The new standard will become effective for us on January 1, 2017. Early application is not permitted. The standard permits the use of either the retrospective or cumulative effect transition method. We are evaluating the effect that ASU 2014-09 will have on our consolidated financial statements and related disclosures. We have not yet selected a transition method nor have we determined the effect of the standard on our ongoing financial reporting.

In August 2014, the FASB issued ASU No. 2014-15 (Subtopic 205-40) *Presentation of Financial Statements - Going Concern: Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern* ("ASU 2014-15") which provides guidance about management's responsibility to evaluate whether or not there is substantial doubt about our ability to continue as a going concern and to provide related footnote disclosure. ASU 2014-15 is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2016. Early application is permitted. The adoption of this standard is not expected to have an impact on our consolidated financial statements.

Table of Contents

**ITEM 7A. 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 capital lease obligations of \$3.5 million and \$2.0 million as of December 31, 2014 and December 31, 2013, respectively, which result from various capital lease agreements to obtain our lab equipment. We had cash and cash equivalents of \$107.0 million and \$43.1 million as of December 31, 2014 and December 31, 2013, respectively, 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.

We face foreign exchange risk as a result of entering into transactions denominated in currencies other than U.S. dollars (Chilean peso). Due to the uncertain timing of expected payments in foreign currencies, we do not utilize any forward exchange contracts. All foreign transactions settle on the applicable spot exchange basis at the time such payments are made. An adverse movement in foreign exchange rates could have a material effect on payments made to foreign suppliers and for license agreements. A hypothetical 10% change in foreign exchange rates during any of the periods presented would not have had a material impact on our financial statements.



Table of Contents

**ITEM 8. Financial Statements And Supplementary Data.**

**Invitae Corporation  
Index to Audited Consolidated Financial Statements**

	<b>Page</b>
<u>Report of independent registered public accounting firm</u>	<u>77</u>
<u>Consolidated balance sheets</u>	<u>78</u>
<u>Consolidated statements of operations and comprehensive loss</u>	<u>79</u>
<u>Consolidated statements of convertible preferred stock and stockholders' deficit</u>	<u>80</u>
<u>Consolidated statements of cash flows</u>	<u>81</u>
<u>Notes to consolidated financial statements</u>	<u>82</u>

Table of Contents

**Report of Independent Registered Public Accounting Firm**

The Board of Directors and Stockholders  
Invitae Corporation

We have audited the accompanying consolidated balance sheets of Invitae Corporation (the Company) as of December 31, 2014 and 2013, and the related consolidated statements of operations and comprehensive loss, convertible preferred stock and stockholders' deficit, and cash flows for each of the three years in the period ended December 31, 2014. 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 consolidated financial position of Invitae Corporation at December 31, 2014 and 2013, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2014, in conformity with U.S. generally accepted accounting principles.

/s/ Ernst & Young LLP

Redwood City, California  
March 27, 2015

Table of Contents**INVITAE CORPORATION****Consolidated Balance Sheets**

	<b>December 31,</b>	
	<b>2014</b>	<b>2013</b>
	<b>(In thousands, except share and per share amounts)</b>	
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 107,027	\$ 43,070
Prepaid expenses and other current assets	2,616	736
<b>Total current assets</b>	<b>109,643</b>	<b>43,806</b>
Property and equipment, net	15,672	8,164
Restricted cash	150	120
Other assets	3,313	1,013
<b>Total assets</b>	<b>\$ 128,778</b>	<b>\$ 53,103</b>
<b>Liabilities, convertible preferred stock, and stockholders' deficit</b>		
Current liabilities:		
Accounts payable	\$ 2,862	\$ 498
Accrued liabilities	3,237	886
Capital lease obligation, current portion	1,524	845
<b>Total current liabilities</b>	<b>7,623</b>	<b>2,229</b>
Capital lease obligation, net of current portion	2,011	1,156
Other long-term liabilities	401	393
Liabilities related to early exercise of stock options	14	31
<b>Total liabilities</b>	<b>10,049</b>	<b>3,809</b>
Commitments and contingencies (Note 5)		
Convertible preferred stock, \$0.0001 par value; 141,131,524 and 81,131,537 shares authorized, 141,131,524 and 81,131,524 shares issued and outstanding as of December 31, 2014 and December 31, 2013, respectively; aggregate liquidation value of \$207,002 and \$87,002 as of December 31, 2014 and December 31, 2013, respectively	202,305	86,574
Stockholders' deficit:		
Common stock, \$0.0001 par value; 160,131,524 and 98,131,537 shares authorized, 944,581 and 732,670 shares issued and outstanding as of December 31, 2014 and December 31, 2013, respectively		
Additional paid-in capital	1,604	408
Accumulated deficit	(85,180)	(37,688)
<b>Total stockholders' deficit</b>	<b>(83,576)</b>	<b>(37,280)</b>
<b>Total liabilities, convertible preferred stock, and stockholders' deficit</b>	<b>\$ 128,778</b>	<b>\$ 53,103</b>

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



Table of Contents

## INVITAE CORPORATION

## Consolidated Statements of Operations and Comprehensive Loss

	Year ended December 31,		
	2014	2013	2012
	(In thousands, except share and per share amounts)		
Revenue	\$ 1,604	\$ 148	\$
Costs and operating expenses:			
Cost of revenue	5,624	667	
Research and development	22,063	16,039	5,557
Selling and marketing	8,669	2,431	
General and administrative	12,600	5,764	3,004
Total costs and operating expenses	48,956	24,901	8,561
Loss from operations	(47,352)	(24,753)	(8,561)
Other income (expense), net	(79)	(26)	2
Interest expense	(61)	(59)	(43)
Net loss and comprehensive loss	\$ (47,492)	\$ (24,838)	\$ (8,602)
Net loss attributable to common stockholders	\$ (47,492)	\$ (24,989)	\$ (9,014)
Net loss per share attributable to common stockholders, basic and diluted	\$ (56.14)	\$ (36.13)	\$ (14.18)
Shares used in computing net loss per share attributable to common stockholders, basic and diluted	846,027	691,731	635,705

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

Table of Contents

## INVITAE CORPORATION

## Consolidated Statements of Convertible Preferred Stock and Stockholders' Deficit

	Convertible preferred stock		Common stock		Additional paid-in capital	Accumulated deficit	Total stockholders' deficit
	Shares	Amount	Shares	Amount			
(In thousands, except share and per share amounts)							
Balance as of January 1, 2012	15,874,997	\$ 7,362	613,647	\$	\$ 9	\$ (4,248)	\$ (4,239)
Issuance of Series C convertible preferred stock for cash and the conversion of convertible notes at \$0.95 per share, net of issuance costs of \$164	31,112,750	29,393					
Common stock issued on exercise of stock options			20,865		8		8
Vesting of common stock related to early exercise of options			26,606		9		9
Stock-based compensation expense					65		65
Net loss						(8,602)	(8,602)
Balance as of December 31, 2012	46,987,747	36,755	661,118		91	(12,850)	(12,759)
Issuance of Series D convertible preferred stock for cash at \$1.25 per share, net of issuance costs of \$67	8,000,000	9,933					
Issuance of Series E convertible preferred stock for cash at \$1.53 per share, net of issuance costs of \$114	26,143,777	39,886					
Common stock issued on exercise of stock options			31,666		39		39
Vesting of common stock related to early exercise of options			39,886		18		18
Stock-based compensation expense					260		260
Net loss						(24,838)	(24,838)
Balance as of December 31, 2013	81,131,524	86,574	732,670		408	(37,688)	(37,280)
Issuance of Series F convertible preferred stock for cash at \$2.00 per share, net of issuance costs of \$4,268	60,000,000	115,731					
Common stock issued on exercise of stock options			168,867		209		209
Vesting of common stock related to early exercise of options			43,044		16		16
Stock-based compensation expense					971		971
Net loss						(47,492)	(47,492)
Balance as of December 31, 2014	141,131,524	\$ 202,305	944,581	\$	\$ 1,604	\$ (85,180)	\$ (83,576)

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

Table of Contents

## INVITAE CORPORATION

## Consolidated Statements of Cash Flows

	Year ended December 31,		
	2014	2013	2012
	(In thousands)		
<b>Cash flows from operating activities</b>			
Net loss	\$ (47,492)	\$ (24,838)	\$ (8,602)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	2,315	928	277
Stock-based compensation	971	260	65
Loss on disposal of assets	37		
Changes in operating assets and liabilities:			
Prepaid expenses and other current assets	(1,880)	(363)	(303)
Other assets	(849)	(4)	(992)
Accounts payable	2,072	220	174
Accrued expenses and other liabilities	2,386	767	227
Net cash used in operating activities	(42,440)	(23,030)	(9,154)
<b>Cash flows from investing activities</b>			
Purchases of property and equipment	(6,686)	(4,520)	(766)
Change in restricted cash	(30)	(60)	(60)
Net cash used in investing activities	(6,716)	(4,580)	(826)
<b>Cash flows from financing activities</b>			
Capital lease principal payments	(1,376)	(1,007)	(609)
Proceeds from issuance of convertible notes			2,000
Proceeds from issuance of common stock upon exercise of stock options	209	67	18
Payments for deferred offering costs	(1,451)		
Proceeds from issuance of convertible preferred stock, net of issuance costs	115,731	49,819	27,393
Net cash provided by financing activities	113,113	48,879	28,802
<b>Net increase in cash and cash equivalents</b>	<b>63,957</b>	<b>21,269</b>	<b>18,822</b>
<b>Cash and cash equivalents at beginning of period</b>	<b>43,070</b>	<b>21,801</b>	<b>2,979</b>
<b>Cash and cash equivalents at end of period</b>	<b>\$ 107,027</b>	<b>\$ 43,070</b>	<b>\$ 21,801</b>
<b>Supplemental cash flow information:</b>			
Interest paid	\$ 61	\$ 56	\$ 29
<b>Supplemental cash flow information of non-cash investing and financing activities:</b>			
Equipment acquired through capital leases	\$ 2,850	\$ 1,793	\$ 1,539
Conversion of convertible notes and accrued interest into Series C convertible preferred stock	\$	\$	\$ 2,018
Purchases of property and equipment in accounts payable and accrued liabilities.	\$ 325	\$ 49	\$ 64
Deferred offering costs included in accounts payable and accrued liabilities	\$ 450	\$	\$

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





Table of Contents

**INVITAE CORPORATION**

**Notes to Consolidated Financial Statements**

**December 31, 2014**

**1. Organization and description of business**

Invitae Corporation (the "Company") was incorporated in the state of Delaware on January 13, 2010, as Locus Development, Inc. and changed its name to Invitae Corporation in 2012. The Company utilizes an integrated portfolio of laboratory processes, software tools and informatics capabilities to process DNA-containing samples, analyze information about patient-specific genetic variation and generate test reports for physicians and their patients. The Company has two laboratories: one in San Francisco, California and a second in Santiago, Chile. The Company's first product is an assay of 216 genes that can be used for multiple indications. The test includes multiple genes associated with hereditary cancer, neurological disorders, cardiovascular disorders and other hereditary conditions. The Company operates in one segment.

***Reverse Stock Split***

In January 2015, the Company's board of directors approved an amendment to the Company's amended and restated certificate of incorporation to effect a reverse split of the Company's issued and outstanding common stock at a 1-for-6 ratio, which was effected on February 9, 2015. The par value and authorized shares of common stock and convertible preferred stock were not adjusted as a result of the reverse split. All issued and outstanding common stock, options to purchase common stock and per share amounts contained in the financial statements have been retroactively adjusted to reflect the reverse stock split for all periods presented. The financial statements have also been retroactively adjusted to reflect a proportional adjustment to the conversion ratio for each series of preferred stock that will be effected in connection with the reverse stock split.

***Initial Public Offering***

On February 12, 2015, the Company completed an initial public offering ("IPO") through the sale of 7,302,500 shares of common stock at \$16.00 per share, which raised approximately \$105.8 million in proceeds, net of underwriting discounts and commissions and offering expenses, as detailed in Note 12 "Subsequent events."

**2. Summary of significant accounting policies**

***Principles of consolidation***

The Company's consolidated financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America ("U.S. GAAP"). The consolidated financial statements include the accounts of the Company and its wholly owned subsidiaries. All intercompany balances and transactions have been eliminated in consolidation.

***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 liabilities as of the date of the financial statements and the reported amounts of revenue and expenses during the reporting period. The Company believes judgment is involved in determining revenue recognition; the recoverability of long-lived assets; the fair value of the Company's common stock; stock-based compensation expense; and income tax uncertainties. The Company bases these

Table of Contents**INVITAE CORPORATION****Notes to Consolidated Financial Statements (Continued)****December 31, 2014****2. Summary of significant accounting policies (Continued)**

estimates on historical and anticipated results, trends, and various other assumptions that the Company believes are reasonable under the circumstances, including assumptions as to future events. Actual results could differ materially from those estimates and assumptions.

***Concentrations of credit risk and other risks and uncertainties***

Financial instruments that potentially subject the Company to a concentration of credit risk consist of cash and cash equivalents. The Company's cash and cash equivalents are held by financial institutions in the United States and Chile. Such deposits may exceed federally insured limits.

As of December 31, 2014, substantially all of the Company's revenue has been derived from sales of its assay of 216 genes. Significant customers are those which represent 10% or more of the Company's total revenue for each year presented on the statements of operations and comprehensive loss. For each significant customer, revenue as a percentage of total revenue are as follows:

Customers	December 31,	
	2014	2013
Customer A	*	44%
Customer B	15%	

\*  
Less than 10% of total revenue

***Cash equivalents***

The Company considers all highly liquid investments with original maturities of three months or less from the date of purchase to be cash equivalents. Cash equivalents consist primarily of amounts invested in money market accounts.

***Restricted cash***

Restricted cash consists of a money market account that serves as collateral for a credit card agreement at one of the Company's financial institutions.

***Property and equipment***

Property and equipment are stated at cost less accumulated depreciation and amortization. Depreciation is computed using the straight-line method over the estimated useful lives of the assets, generally between three and seven years. Leasehold improvements are amortized using the straight-line method over the shorter of the estimated useful life of the asset or the term of the lease. Amortization expense of assets acquired through capital leases is included in depreciation and amortization expense in the consolidated statements of operations and comprehensive loss. Maintenance and repairs are charged to expense as incurred, and improvements and betterments are capitalized. When assets are retired or otherwise disposed of, the cost and accumulated depreciation are removed from the balance sheet and any resulting gain or loss is reflected in the statements of operations and comprehensive loss in the period realized.

Table of Contents**INVITAE CORPORATION****Notes to Consolidated Financial Statements (Continued)****December 31, 2014****2. Summary of significant accounting policies (Continued)**

The useful lives of the property and equipment are as follows:

Furniture and fixtures	7 years
Automobiles	7 years
Laboratory equipment	5 years
Computer equipment	3 years
Software	3 years
Leasehold improvements	Shorter of lease term or estimated useful life
<i>Internal-use software</i>	

The Company capitalizes third-party costs incurred in the application development stage to design and implement the software used in its tests and Invitae Family History Tool mobile application. Costs incurred in the application development stage of the software and mobile application are capitalized and will be amortized over an estimated useful life of three years on a straight line basis.

During the years ended December 31, 2014 and 2013, the Company capitalized \$550,000 and \$250,000, respectively, of software development costs. The \$250,000 was recorded in property and equipment as construction-in-progress as of December 31, 2013, as it had not been completed and placed in service.

***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 are offset against IPO proceeds upon the closing of the offering. As of December 31, 2014, the Company capitalized \$1.9 million of deferred offering costs in other assets on the consolidated balance sheets.

***Long-lived assets***

The Company reviews long-lived assets for impairment whenever events or changes in circumstances indicate that the carrying amount of the assets may not be recoverable. An impairment loss is recognized when the total estimated future undiscounted cash flows expected to result from the use of the asset and its eventual disposition are less than its carrying amount. Impairment, if any, would be assessed using discounted cash flows or other appropriate measures of fair value. The Company has not recorded an impairment of any long-lived assets during any of the periods presented.

***Fair value of financial instruments***

Fair value accounting is applied for all financial assets and liabilities and non-financial assets and liabilities that are recognized or disclosed at fair value in the financial statements on a recurring basis (at least annually).

Table of Contents

**INVITAE CORPORATION**

**Notes to Consolidated Financial Statements (Continued)**

**December 31, 2014**

**2. Summary of significant accounting policies (Continued)**

***Revenue recognition***

Revenue is generated from the sale of tests that provide analysis and associated interpretation of the sequencing of parts of the genome. Revenue associated with subsequent re-requisition services was de minimis for all periods presented.

Revenue is recognized when persuasive evidence of an arrangement exists; delivery has occurred or services have been rendered; the fee is fixed or determinable; and collectability is reasonably assured. The criterion for whether the fee is fixed or determinable and whether collectability is reasonably assured are based on management's judgments. When evaluating collectability, in situations where contracted reimbursement coverage does not exist, the Company considers whether the Company has sufficient history to reliably estimate a payor's individual payment patterns. The Company reviews the number of tests paid against the number of tests billed and the payor's outstanding balance for unpaid tests to determine whether payments are being made at a consistently high percentage of tests billed and at appropriate amounts given the amount billed. The Company has not been able to demonstrate a predictable pattern of collectability, and therefore recognizes revenue when payment is received.

***Cost of revenue***

Cost of revenue reflects the aggregate costs incurred in delivering the genetic testing results to physicians and includes expenses for personnel costs including stock-based compensation, materials and supplies, equipment and infrastructure expenses associated with testing and allocated overhead including rent, equipment depreciation and utilities. Costs associated with performing the Company's test are recorded as the test is processed regardless of whether and when revenue is recognized with respect to that test.

***Research and development***

Research and development costs are charged to operations as incurred. Research and development costs include, but are not limited to, payroll and personnel-related expenses, stock-based compensation expense, reagents and laboratory supplies, consulting costs, and allocated overhead including rent, information technology, equipment depreciation and utilities.

***Income taxes***

The Company uses the asset and liability method of accounting for income taxes. Under this method, deferred tax assets and liabilities are determined based on the differences between the financial reporting and the tax bases of assets and liabilities and are measured using the enacted tax rates and laws that will be in effect when the differences are expected to reverse. A valuation allowance is provided when it is more likely than not that some portion or all of a deferred tax asset will not be realized.

***Stock-based compensation***

The Company measures its stock-based payment awards made to employees and directors based on the estimated fair values of the awards and recognizes the compensation expense over the requisite service period. The Company uses the Black-Scholes option-pricing model to estimate the fair value of

Table of Contents

**INVITAE CORPORATION**

**Notes to Consolidated Financial Statements (Continued)**

**December 31, 2014**

**2. Summary of significant accounting policies (Continued)**

its stock-based awards. Stock-based compensation expense is recognized using the straight-line method. Stock-based compensation expense is based on the value of the portion of stock-based payment awards that is ultimately expected to vest. As such, the Company's stock-based compensation is reduced for the estimated forfeitures at the date of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates.

The Company accounts for compensation expense related to stock options granted to non-employees based on the fair values estimated using the Black-Scholes model. Stock options granted to non-employees are remeasured at each reporting date until the award is vested.

***Foreign currency transactions***

The Company uses the U.S. dollar as its functional currency for its subsidiary in Chile. Foreign currency assets and liabilities are remeasured into U.S. dollars using the end of period exchange rates except for nonmonetary assets and liabilities, which are remeasured using historical exchange rates. Expenses are remeasured using an average exchange rate for the respective period. Gains or losses from foreign currency transactions are included in other income (expense), net, on the consolidated statements of operations and comprehensive loss. Foreign currency transaction gains and losses have not been significant to the consolidated financial statements for all periods presented.

***Comprehensive loss***

Comprehensive loss is composed of two components: net loss and other comprehensive loss. Other comprehensive loss refers to gains and losses that under U.S. GAAP are recorded as an element of stockholders' deficit, but are excluded from net loss. The Company did not record any transactions within other comprehensive loss in the periods presented and, therefore, net loss and comprehensive loss were the same for all periods presented.

***Net loss per share attributable to common stockholders***

Basic net loss per share attributable to common stockholders is calculated by dividing net loss attributable to common stockholders by the weighted-average number of common shares outstanding during the period, without consideration of common stock equivalents. Diluted net loss per share attributable to common stockholders is computed by dividing net loss attributable to common stockholders by the weighted-average number of common share equivalents outstanding for the period determined using the treasury stock method. Potentially dilutive securities consisting of convertible preferred stock and options to purchase common stock are considered to be common stock equivalents and were excluded from the calculation of diluted net loss per share attributable to common stockholders because their effect would be antidilutive for all periods presented. Common shares subject to repurchase are excluded from the weighted-average shares. For the years ended December 31, 2014, 2013 and 2012, 23,903, 54,407 and 58,367 shares subject to repurchase, respectively, are excluded from basic loss per share calculation.

Table of Contents**INVITAE CORPORATION****Notes to Consolidated Financial Statements (Continued)****December 31, 2014****2. Summary of significant accounting policies (Continued)*****Recent accounting pronouncements***

On May 28, 2014, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") 2014-09, *Revenue from Contracts with Customers* ("ASU 2014-09"), which requires an entity to recognize the amount of revenue to which it expects to be entitled for the transfer of promised goods or services to customers. ASU 2014-09 will replace most existing revenue recognition guidance in U.S. GAAP when it becomes effective. The new standard will become effective for the Company on January 1, 2017. Early application is not permitted. The standard permits the use of either the retrospective or cumulative effect transition method. The Company is evaluating the effect that ASU 2014-09 will have on its consolidated financial statements and related disclosures. The Company has not yet selected a transition method nor has it determined the effect of the standard on its ongoing financial reporting.

In August 2014, the FASB issued ASU No. 2014-15 (Subtopic 205-40) *Presentation of Financial Statements - Going Concern: Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern* ("ASU 2014-15") which provides guidance about management's responsibility to evaluate whether there is substantial doubt about the Company's ability to continue as a going concern and to provide related footnote disclosure. ASU 2014-15 is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2016. Early application is permitted. The adoption of this standard is not expected to have an impact on the Company's consolidated financial statements.

**3. Balance sheet components*****Property and equipment, net***

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

	<b>December 31,</b>	
	<b>2014</b>	<b>2013</b>
Leasehold improvements	\$ 1,914	\$ 1,527
Laboratory equipment	6,528	3,567
Equipment under capital lease	3,735	3,735
Computer equipment	1,156	120
Software	831	18
Furniture and fixtures	158	21
Automobiles		16
Construction-in-progress	4,853	410
<b>Total property and equipment, gross</b>	<b>19,175</b>	<b>9,414</b>
Accumulated depreciation and amortization	(3,503)	(1,250)
<b>Total property and equipment, net</b>	<b>\$ 15,672</b>	<b>\$ 8,164</b>

Included in the construction-in-progress balance as of December 31, 2014 was \$2.9 million of capital lease equipment that had not been placed in service. Depreciation and amortization expense was \$2.3 million, \$0.9 million and \$0.3 million for the years ended December 31, 2014, 2013 and 2012, respectively.

Table of Contents**INVITAE CORPORATION****Notes to Consolidated Financial Statements (Continued)****December 31, 2014****3. Balance sheet components (Continued)***Accrued liabilities*

Accrued liabilities consisted of the following (in thousands):

	<b>Year ended December 31,</b>	
	<b>2014</b>	<b>2013</b>
Accrued compensation and related expenses	\$ 1,439	\$ 279
Accrued professional services	1,030	201
Accrued costs for construction-in-progress	32	168
Other	736	238
<b>Total accrued liabilities</b>	<b>\$ 3,237</b>	<b>\$ 886</b>

**4. Fair value measurements**

Financial assets and liabilities are recorded at fair value. The carrying amounts of certain of the Company's financial instruments, including cash equivalents, and accounts payable, are valued at cost, which approximates fair value due to their short maturities. Fair value is defined as the price that would be received to sell an asset or paid to transfer a liability (an exit price) in an orderly transaction between market participants at the reporting date. The authoritative guidance establishes a three-level valuation hierarchy that prioritizes the inputs to valuation techniques used to measure fair value based upon whether such inputs are observable or unobservable. Observable inputs reflect market data obtained from independent sources, while unobservable inputs reflect market assumptions made by the reporting entity.

The three-level hierarchy for the inputs to valuation techniques is briefly summarized as follows:

Level 1 Observable inputs such as quoted prices (unadjusted) for identical instruments in active markets.

Level 2 Observable inputs such as quoted prices for similar instruments in active markets, quoted prices for identical or similar instruments in markets that are not active, or model-derived valuations whose significant inputs are observable.

Level 3 Unobservable inputs that reflect the reporting entity's own assumptions.

The Company's financial instruments consist only of Level 1 assets, which are highly liquid money market accounts. At December 31, 2014 and 2013, the Company had \$15.2 million and \$33.2 million, respectively, in money market accounts that are included in cash and cash equivalents and restricted cash on the consolidated balance sheets.

**5. Commitments and contingencies***Convertible Notes*

The Company entered into a Note Purchase Agreement dated May 22, 2012, as amended June 27, 2012 and July 26, 2012 with investors and issued notes in the aggregate principal amount of \$2.0 million. The convertible notes had a maturity date of November 1, 2012 and an annual interest

Table of Contents**INVITAE CORPORATION****Notes to Consolidated Financial Statements (Continued)****December 31, 2014****5. Commitments and contingencies (Continued)**

rate of 8.0%. In August 2012, the outstanding principal \$2.0 million and accrued interest of \$18,000 were converted into Series C convertible preferred stock at the price paid by other purchasers for the Series C convertible preferred stock.

***Operating leases***

The Company has entered into various non-cancelable operating lease agreements for office and laboratory facilities located in California with lease periods expiring between 2016 and 2020. In May 2013, the Company entered into a lease agreement for laboratory space in Santiago, Chile with a lease term of two years with an automatic two-year renewal option. Some of the lease agreements include scheduled rent increases over the terms of the leases. Rent increases, including the impact of rent holidays and leasehold improvement allowances from landlords, were recognized as deferred rent and are amortized on a straight-line basis over the term of the original lease. The Company has provided security deposits of \$1.4 million and \$1.0 million as of December 31, 2014 and 2013, respectively, as collateral for the leases which is included in other assets in the Company's balance sheets. Future minimum lease payments under non-cancellable operating leases as of December 31, 2014 are as follows (in thousands):

<b>Year ending December 31,</b>	<b>Amounts</b>
2015	\$ 2,635
2016	2,674
2017	1,325
2018	770
2019	792
Thereafter	199
<b>Total minimum lease payments</b>	<b>\$ 8,395</b>

Rent expense was \$1.4 million, \$0.8 million and \$0.2 million for the years ended December 31, 2014, 2013 and 2012, respectively.

***Capital leases***

The Company has entered into various capital lease agreements to obtain lab equipment. The original term of the capital leases is typically three years with interest rates ranging from 3.5% 18.9%. The leases are secured by the underlying equipment. The portion of the future payments designated as



Table of Contents**INVITAE CORPORATION****Notes to Consolidated Financial Statements (Continued)****December 31, 2014****5. Commitments and contingencies (Continued)**

principal repayment was classified as a capital lease obligation on the consolidated balance sheets. Future payments under the capital lease as of December 31, 2014 are as follows (in thousands):

<b>Year ending December 31,</b>	<b>Amounts</b>
2015	\$ 1,573
2016	1,217
2017	875
2018	70
<b>Total capital lease obligations</b>	<b>3,735</b>
Less: amount representing interest	(200)
<b>Present value of net minimum capital lease payments</b>	<b>3,535</b>
Less: current portion	(1,524)
<b>Total noncurrent capital lease obligations</b>	<b>\$ 2,011</b>

Interest expense related to capital leases was \$61,000, \$59,000 and \$25,000 for the years ended December 31, 2014, 2013 and 2012, respectively.

Property and equipment under capital leases was \$6.6 million and \$3.7 million as of December 31, 2014 and 2013, respectively, including \$2.9 million of capital lease equipment that had not been placed in service as of December 31, 2014. Accumulated depreciation and amortization, collectively, on these assets was \$1.4 million and \$0.6 million as of December 31, 2014 and 2013, respectively.

***Guarantees and indemnifications***

As permitted under Delaware law and in accordance with the Company's bylaws, the Company indemnifies its officers and directors for certain events or occurrences while the officer or director is or was serving in such capacity. The maximum amount of potential future indemnification is unlimited; however, the Company currently holds director and officer liability insurance. This insurance allows the transfer of the risk associated with the Company's exposure and may enable it to recover a portion of any future amounts paid. The Company believes the fair value of these indemnification agreements is minimal. Accordingly, the Company has not recorded any liabilities associated with these indemnification agreements as of December 31, 2014 or 2013.

***Contingencies***

On November 25, 2013, the University of Utah Research Foundation, the Trustees of the University of Pennsylvania, HSC Research and Development Limited Partnership, Endorecherche, Inc. and Myriad Genetics, Inc. (collectively, the Myriad Plaintiffs) filed a complaint in the District of Utah (the Utah Action), alleging that certain of the Company's genetic testing services infringe certain claims of various U.S. Patents (collectively, the Myriad Patents). On November 26, 2013, the Company filed a complaint for declaratory judgment in the Northern District of California (the California Action), asserting that the Myriad Patents are invalid and the Company does not infringe them, and the Myriad Plaintiffs counterclaimed alleging that the Company infringes the Myriad Patents. Although the Utah Action was dismissed, on February 19, 2014, the Judicial Panel on Multidistrict Litigation granted the Myriad Plaintiffs' motion to consolidate for pre-trial proceedings all actions concerning the Myriad

Table of Contents**INVITAE CORPORATION****Notes to Consolidated Financial Statements (Continued)****December 31, 2014****5. Commitments and contingencies (Continued)**

Patents (the MDL Proceedings), with the MDL Proceedings taking place in the District of Utah. On January 23, 2015, the Myriad Plaintiffs stipulated to the dismissal with prejudice of all of their claims and granted the Company a covenant not to sue for all of the patents they had asserted against the Company. On January 26, 2015, the court issued an order dismissing the California Action with prejudice, thereby ending the litigation.

The Company may become party to various other claims and complaints arising in the ordinary course of business. Management does not believe that any ultimate liability resulting from any of these claims will have a material adverse effect on its results of operations, financial condition, or liquidity. However, management cannot give any assurance regarding the ultimate outcome of these claims, and their resolution could be material to operating results for any particular period, depending upon the level of income for the period.

**6. Convertible preferred stock**

Convertible preferred stock as of December 31, 2014 and 2013 consists of the following (in thousands, except share and per share data):

	Shares authorized	Original issue price	Shares issued and outstanding	Aggregate liquidation amount	Proceeds, net of issuance costs
Series A	11,693,179	\$ 0.44	11,693,179	\$ 5,145	\$ 5,109
Series B	4,181,818	0.55	4,181,818	2,300	2,253
Series C	31,112,750	0.95	31,112,750	29,557	29,393
Series D	8,000,000	1.25	8,000,000	10,000	9,933
Series E	26,143,777	1.53	26,143,777	40,000	39,886
Series F	60,000,000	2.00	60,000,000	120,000	115,781
Balance at December 31, 2014	141,131,524		141,131,524	\$ 207,002	\$ 202,355

	Shares authorized	Original issue price	Shares issued and outstanding	Aggregate liquidation amount	Proceeds, net of issuance costs
Series A	11,693,179	\$ 0.44	11,693,179	\$ 5,145	\$ 5,109
Series B	4,181,818	0.55	4,181,818	2,300	2,253
Series C	31,112,750	0.95	31,112,750	29,557	29,393
Series D	8,000,000	1.25	8,000,000	10,000	9,933
Series E	26,143,790	1.53	26,143,777	40,000	39,886
Balance at December 31, 2013	81,131,537		81,131,524	\$ 87,002	\$ 86,574

Table of Contents

**INVITAE CORPORATION**

**Notes to Consolidated Financial Statements (Continued)**

**December 31, 2014**

**6. Convertible preferred stock (Continued)**

The rights, preferences and privileges of the convertible preferred stock are as follows:

***Dividends***

The holders of the outstanding shares of Series B, Series C, Series D, Series E, and Series F convertible preferred stock are entitled to receive, when and if declared by the Board of Directors, a non-cumulative cash dividend at the rate of \$0.044, \$0.076, \$0.10, \$0.1224, and \$0.16 per share per annum, respectively. Such dividends are payable in preference to any dividends on common stock declared by the Board of Directors. The holders of the outstanding shares of Series A convertible preferred stock are entitled to receive, when and if declared by the Board of Directors, the amount of any dividend paid on any other shares of capital stock (including shares of Series B, Series C, Series D, Series E and Series F convertible preferred stock). Such dividends are payable in preference to any dividends on common stock and pari passu with any dividends on Series B, Series C, Series D, Series E and Series F convertible preferred stock, except that an amount equal on average to \$0.0895 per share of Series A convertible preferred stock would, if a dividend is declared by the Board of Directors, be payable in preference to any dividends on Series B, Series C, Series D, Series E and Series F convertible preferred stock. No dividends have been declared to date.

***Conversion rights***

Each share of Series A, Series B, Series C, Series D, Series E, and Series F convertible preferred stock is, at the option of the holder, convertible into the number of fully paid and non-assessable shares of common stock as determined by dividing the original issue price applicable to such convertible preferred stock by the conversion price in effect at that time. The conversion price for each series of convertible preferred stock shall initially be the original issue price of such series of preferred stock and shall be adjusted in accordance with conversion provisions contained in the Company's Amended and Restated Certificate of Incorporation.

Each share of convertible preferred stock will be automatically converted into shares of common stock based on the then effective conversion price (i) upon the affirmative election of the holders of at least a majority of the outstanding shares of the convertible preferred stock or (ii) immediately upon the closing of a firmly underwritten public offering filed under the Securities Act of 1933, as amended, covering the offer and sale of common stock for the account of the Company at a price of at least \$12.00 per share (subject to adjustment in the event of any stock split) and in which the gross proceeds to the Company are at least \$30.0 million. In connection with the completion of the initial public offering on February 12, 2015, all shares of convertible preferred stock were converted into common stock on a 1-for-6 basis.

***Voting rights***

Each holder is entitled to the number of votes equal to the number of shares of common stock into which the shares of preferred stock could be converted.

**INVITAE CORPORATION**

**Notes to Consolidated Financial Statements (Continued)**

**December 31, 2014**

**6. Convertible preferred stock (Continued)**

***Liquidation rights***

Upon liquidation, dissolution, or winding up of the Company, the holders of the convertible preferred stock shall be entitled to receive, prior and in preference to any distribution of any of the assets or surplus funds of the Company to the holders of shares of common stock, an amount equal to the per share issue price of such series of preferred stock (\$0.44 per share for Series A convertible preferred stock, \$0.55 per share for Series B convertible preferred stock, \$0.95 per share for Series C convertible preferred stock, \$1.25 per share for Series D convertible preferred stock, \$1.53 per share for Series E convertible preferred stock, and \$2.00 per share for Series F convertible preferred stock), plus all declared and unpaid dividends on such shares and, in the instance of Series A convertible preferred stock, an additional amount equal on average to \$0.0895 per share (the "liquidation preference"). If available assets are insufficient to pay the full liquidation preference, the available assets will be distributed among the holders of the convertible preferred stock, on a pari passu and pro rata basis. After the payment of the liquidation preference, all remaining assets available for distribution will be distributed ratably among the holders of the common stock.

***Other***

The convertible preferred stock is recorded at fair value on the dates of issuance, net of issuance costs. The Company classifies the convertible preferred stock outside of stockholders' equity because the shares contain liquidation features that are not solely within its control. During the years ended December 31, 2014, 2013 and 2012, the Company did not adjust the carrying values of the convertible preferred stock to the deemed redemption values of such shares since a liquidation event was not probable.

**7. Stockholders' deficit**

***Common stock***

The holders of each share of common stock have one vote for each share of stock. The common stockholders are also entitled to receive dividends whenever funds and assets are legally available and when declared by the Board of Directors, subject to the prior rights of holders of all series of convertible preferred stock outstanding.

Table of Contents**INVITAE CORPORATION****Notes to Consolidated Financial Statements (Continued)****December 31, 2014****7. Stockholders' deficit (Continued)**

As of December 31, 2014 and 2013, the Company had reserved shares of common stock, on an as-if converted basis, for issuance as follows:

	As of December 31,	
	2014	2013
Conversion of Series A convertible preferred stock	1,948,860	1,948,860
Conversion of Series B convertible preferred stock	696,969	696,969
Conversion of Series C convertible preferred stock	5,185,453	5,185,453
Conversion of Series D convertible preferred stock	1,333,332	1,333,332
Conversion of Series E convertible preferred stock	4,357,286	4,357,286
Conversion of Series F convertible preferred stock	9,999,989	
Options issued and outstanding	1,923,332	1,173,019
Options available for grant under stock option plan	276,805	873,233
<b>Total</b>	<b>25,722,026</b>	<b>15,568,152</b>

**8. Stock incentive plan*****2010 Stock incentive plan***

In 2010, the Company adopted the 2010 Incentive Plan (the "2010 Plan"). The 2010 Plan provides for the granting of stock-based awards to employees, directors, and consultants under terms and provisions established by the Board of Directors. Under the terms of the 2010 Plan, options may be granted at an exercise price not less than fair market value. For employees holding more than 10% of the voting rights of all classes of stock, the exercise prices for incentive and nonstatutory stock options must be at least 110% of fair market of the common stock on the grant date, as determined by the Board of Directors. The terms of options granted under the 2010 Plan may not exceed ten years.

Options granted generally vest over a period of four years. Typically, the vesting schedule for options granted to newly hired employees provides that  $\frac{1}{4}$  of the grant vests upon the first anniversary of the employee's date of hire, with the remainder of the shares vesting monthly thereafter at a rate of  $\frac{1}{48}$  of the total shares subject to the option. All other options typically vest in equal monthly installments over the four-year vesting schedule.

Table of Contents

## INVITAE CORPORATION

## Notes to Consolidated Financial Statements (Continued)

December 31, 2014

**8. Stock incentive plan (Continued)**

Activity under the 2010 Plan is set forth below (in thousands, except share and per share amounts and years):

	Shares available for grant	Stock options outstanding	Weighted- average exercise price	Weighted-average remaining contractual life (years)	Aggregate intrinsic value
Balances at December 31, 2012	801,850	752,966	0.88	9.61	\$ 196
Additional options authorized	559,027				
Granted	(506,142)	506,142	2.37		
Cancelled	18,498	(18,498)	1.61		
Exercised		(67,591)	0.94		
Balances at December 31, 2013	873,233	1,173,019	\$ 1.40	9.00	\$ 2,155
Additional options authorized	333,333				
Repurchase of unvested early exercise shares	1,959				
Granted	(1,164,990)	1,164,990	6.21		
Cancelled	233,270	(233,270)	2.07		
Exercised		(181,407)	1.15		
Balances at December 31, 2014	276,805	1,923,332	\$ 4.37	8.90	\$ 15,946
Options exercisable at December 31, 2014		401,159	\$ 1.49	7.85	\$ 4,481
Options vested and expected to vest at December 31, 2014		1,870,101	\$ 4.33	8.88	\$ 15,582

The aggregate intrinsic value is calculated as the difference between the exercise price of the underlying stock options and the fair value of the Company's common stock for stock options that were in-the-money.

The weighted-average fair value of options to purchase common stock granted was \$4.68, \$1.83 and \$0.80 per share in the years ended December 31, 2014, 2013 and 2012, respectively.

The fair value of options to purchase common stock vested was \$494,000, \$204,000 and \$34,000 in the years ended December 31, 2014, 2013 and 2012.

The intrinsic value of options to purchase common stock exercised was \$644,000, \$60,000 and \$0 in the years ended December 31, 2014, 2013 and 2012, respectively.

**Early exercise of stock options**

The 2010 Plan allows for the granting of options that may be exercised before the options have vested. Shares issued as a result of early exercise that have not vested are subject to repurchase by the Company upon termination of the purchaser's employment or services, at the price paid by the purchaser, and are not deemed to be issued for accounting purposes until those related shares vest. The amounts received in exchange for these shares have been recorded as a liability on the accompanying balance sheets and will be reclassified into common stock and additional paid-in-capital as the shares vest. The Company's right to repurchase these shares generally lapses  $\frac{1}{4}$  after a one-year cliff then at a monthly rate of  $\frac{1}{48}$  thereafter.

Table of Contents

**INVITAE CORPORATION**

**Notes to Consolidated Financial Statements (Continued)**

**December 31, 2014**

**8. Stock incentive plan (Continued)**

At December 31, 2014 and 2013, there were 23,903 and 54,407 shares of common stock outstanding, respectively, subject to the Company's right of repurchase at prices ranging from \$0.30 to \$1.26 per share. At December 31, 2014 and 2013, the Company recorded \$14,000 and \$31,000, respectively, as liabilities associated with shares issued with repurchase rights.

***Stock-based compensation***

The Company uses the grant date fair value of its common stock to value both employee and non-employee options when granted. The Company revalues non-employee options each reporting period using the fair market value of the Company's common stock as of the last day of each reporting period.

In determining the fair value of the stock-based awards, the Company uses the Black-Scholes option-pricing model and assumptions discussed below. Each of these inputs is subjective and its determination generally requires significant judgment.

*Expected term* The expected term represents the period that the Company's stock-based awards are expected to be outstanding and is determined using the simplified method (based on the midpoint between the vesting date and the end of the contractual term).

*Expected volatility* Because the Company was privately held and did not have any trading history for its common stock, the expected volatility was estimated based on the average volatility for comparable publicly traded biopharmaceutical companies over a period equal to the expected term of the stock option grants. When selecting comparable publicly traded companies in a similar industry on which it has based its expected stock price volatility, the Company selected companies with comparable characteristics to it, including enterprise value, risk profiles, position within the industry, and with historical share price information sufficient to meet the expected life of the stock-based awards. The historical volatility data was computed using the daily closing prices for the selected companies' common stock during the equivalent period of the calculated expected term of the stock-based awards. The Company will continue to apply this process until a sufficient amount of historical information regarding the volatility of its own stock price becomes available.

*Risk-free interest rate* The risk-free interest rate is based on the U.S. Treasury zero coupon issues in effect at the time of grant for periods corresponding with the expected term of the option.

*Dividend yield* The Company has never paid dividends on its common stock and has no plans to pay dividends on its common stock. Therefore, the Company used an expected dividend yield of zero.

Table of Contents**INVITAE CORPORATION****Notes to Consolidated Financial Statements (Continued)****December 31, 2014****8. Stock incentive plan (Continued)**

The fair value of share-based payments for option granted to employees and directors was estimated on the date of grant using the Black-Scholes option-pricing valuation model based on the following assumptions:

	Year ended December 31,		
	2014	2013	2012
Expected term (in years)	6.03	6.03	6.02
Expected volatility	83.8 - 86.6%	88.5 - 94.5%	88.6 - 89.1%
Risk-free interest rate	1.53 - 1.91%	0.99 - 1.97%	0.82 - 1.28%

## Dividend yield

Stock-based compensation related to stock options granted to non-employees is recognized as the stock options are earned. The fair value of the stock options granted is calculated at each reporting date using the Black-Scholes option pricing model with the following assumptions: expected life is equal to the remaining contractual term of the award as of the measurement date ranging from 9.37 years to 9.40 years as of December 31, 2014, 9.25 years to 9.60 years as of December 31, 2013, and 8.19 years to 10.00 years as of December 31, 2012, respectively; risk free rate is based on the U.S. Treasury Constant Maturity rate with a term similar to the expected life of the option at the measurement date; expected dividend yield of 0%; and volatility of 83.8% as of December 31, 2014, 88.5% as of December 31, 2013 and 88.5% to 89.0% as of December 31, 2012, respectively.

The following table summarizes stock-based compensation expense related to stock options for the years ended December 31, 2014 and 2013 included in the statements of operations and comprehensive loss as follows (in thousands):

	Year ended December 31,		
	2014	2013	2012
Cost of revenue	\$ 102	\$ 11	\$
Research and development	382	165	46
Selling and marketing	216	42	
General and administrative	271	42	19
<b>Total stock-based compensation expense</b>	<b>\$ 971</b>	<b>\$ 260</b>	<b>\$ 65</b>

As of December 31, 2014, unrecognized compensation expense related to unvested options, net of estimated forfeitures, was \$5.3 million, which the Company expects to recognize on a straight-line basis over a weighted-average period of 3.4 years.



Table of Contents

## INVITAE CORPORATION

## Notes to Consolidated Financial Statements (Continued)

December 31, 2014

**9. Income taxes**

The Company did not record a provision or benefit for income taxes during the years ended December 31, 2014, 2013 and 2012. The components of loss before income taxes by U.S. and foreign jurisdictions are as follows (in thousands):

	Year ended December 31,		
	2014	2013	2012
United States	\$ 46,328	\$ 23,522	\$ 8,602
Foreign	1,164	1,316	
<b>Total</b>	<b>\$ 47,492</b>	<b>\$ 24,838</b>	<b>\$ 8,602</b>

The following table presents a reconciliation of the tax expense computed at the statutory federal rate and the Company's tax expense for the periods presented:

	Year ended December 31,		
	2014	2013	2012
U.S. federal taxes at statutory rate	34.0%	34.0%	34.0%
State taxes (net of federal benefit)	0.7	0.9	5.8
Non-deductible expenses	(0.7)	(0.4)	(0.6)
Foreign tax differential	(0.8)	(1.8)	
Change in valuation allowance	(33.2)	(32.7)	(39.2)
<b>Total</b>	<b>0.0%</b>	<b>0.0%</b>	<b>0.0%</b>

The tax effects of temporary differences and carryforwards that give rise to significant portions of the deferred tax assets are as follows (in thousands):

	As of December 31,	
	2014	2013
Deferred tax assets:		
Net operating loss carryforwards	\$ 28,022	\$ 13,624
Tax credits	13	31
Accruals and other	1,914	115
<b>Gross deferred tax assets</b>	<b>29,949</b>	<b>13,770</b>
Valuation allowance	(29,498)	(13,413)
<b>Net deferred tax assets</b>	<b>451</b>	<b>357</b>
Deferred tax liabilities:		
Property and equipment	\$ (451)	\$ (357)
<b>Total deferred tax liabilities</b>	<b>(451)</b>	<b>(357)</b>
<b>Net deferred tax assets</b>	<b>\$</b>	<b>\$</b>



Table of Contents**INVITAE CORPORATION****Notes to Consolidated Financial Statements (Continued)****December 31, 2014****9. Income taxes (Continued)**

The Company has established a full valuation allowance against its deferred tax assets due to the uncertainty surrounding realization of such assets. The valuation allowance increased by \$16.1 million and \$8.4 million during the years ended December 31, 2014 and 2013, respectively.

As of December 31, 2014, the Company had net operating loss carryforwards of approximately \$77.4 million and \$41.3 million available to reduce future taxable income, if any, for Federal and California state income tax purposes, respectively. None of these amounts represents federal and state tax deductions from stock based compensation which will be recorded as an adjustment to additional paid-in capital when they reduce taxes payable. The U.S. federal and California state net operating loss carryforwards will begin to expire in 2030.

As of December 31, 2014, the Company had net operating loss carryforwards for foreign income tax purposes of \$2.4 million which have no expiration date.

As of December 31, 2014, the Company had research and development credit carryforwards of approximately \$2.2 million and \$2.0 million available to reduce its future tax liability, if any, for Federal and California state income tax purposes, respectively. The Federal credit carryforwards begin to expire in 2030. California credit carryforwards have no expiration date. As of December 31, 2014, the Company has other tax credits of \$18,000 that have no expiration period for the majority of the credits.

Utilization of the net operating loss carryforwards and credits may be subject to an annual limitation due to the ownership change limitations provided by the Internal Revenue Code of 1986 and similar state provisions. The annual limitation may result in the expiration of net operating losses and credits before utilization. No Section 382 study has been completed as of December 31, 2014.

As of December 31, 2014, the Company had unrecognized tax benefits of \$5.7 million, none of which would currently affect the Company's effective tax rate if recognized due to the Company's deferred tax assets being fully offset by a valuation allowance. The Company has not accrued interest and penalties related to the unrecognized tax benefits reflected in the financial statements for the years ended December 31, 2014, 2013 and 2012. Unrecognized tax benefits are not expected to change in the next 12 months.

A reconciliation of the beginning and ending amount of unrecognized tax benefits is as follows (in thousands):

	Year ended December 31,		
	2014	2013	2012
Unrecognized tax benefits, beginning of period	\$ 2,100	\$ 618	\$ 152
Gross increases current period tax positions	1,874	1,482	466
Gross increases prior period tax positions	1,687		
Unrecognized tax benefits, end of period	\$ 5,661	\$ 2,100	\$ 618

The Company's policy is to include penalties and interest expense related to income taxes as a component of tax expense. There was no interest expense or penalties related to unrecognized tax benefits recorded through December 31, 2014.

Table of Contents**INVITAE CORPORATION****Notes to Consolidated Financial Statements (Continued)****December 31, 2014****9. Income taxes (Continued)**

The Company's major tax jurisdictions are the United States and California. All of the Company's tax years will remain open for examination by the Federal and state tax authorities for three and four years, respectively, from the date of utilization of the net operating loss or research and development credit. The Company does not have any tax audits pending.

**10. Net loss per share attributable to common stockholders**

The following table presents the calculation of basic and diluted net loss per share attributable to common stockholders for the years ended December 31, 2014, 2013 and 2012 (in thousands, except share and per share amounts):

	Year ended December 31,		
	2014	2013	2012
Net loss	\$ (47,492)	\$ (24,838)	\$ (8,602)
Less: dividends on convertible preferred stock		(151)	(412)
Net loss attributable to common stockholders	\$ (47,492)	\$ (24,989)	\$ (9,014)
Shares used in computing net loss per share attributable to common stockholders, basic and diluted	846,027	691,731	635,705
Net loss per share attributable to common stockholders, basic and diluted	\$ (56.14)	\$ (36.13)	\$ (14.18)

The following outstanding shares of common stock equivalents have been excluded from diluted net loss per share attributable to common stockholders for the years ended December 31, 2014, 2013 and 2012 because their inclusion would be anti-dilutive:

	Year ended December 31,		
	2014	2013	2012
Shares of common stock subject to outstanding options	1,923,332	1,173,019	752,966
Shares of common stock subject to conversion from preferred stock	23,521,889	13,521,900	7,831,282
Shares of common stock subject to unvested early exercise of outstanding options subject to repurchase	23,903	54,407	58,367
Total shares of common stock equivalents	25,469,124	14,749,326	8,642,615

Table of Contents

## INVITAE CORPORATION

## Notes to Consolidated Financial Statements (Continued)

December 31, 2014

**11. Geographic information**

Revenue by country is determined based on the billing address of the customer. The following presents revenue by country for December 31, 2014 and 2013 (in thousands):

	December 31,	
	2014	2013
United States	\$ 1,067	\$ 62
Israel	109	65
Canada	310	2
Rest of world	118	19
Revenue	\$ 1,604	\$ 148

Long-lived assets (net) by location are summarized as follows (in thousands):

	December 31,	
	2014	2013
United States	\$ 13,858	\$ 5,934
Chile	1,814	2,230
Total long-lived assets, net	\$ 15,672	\$ 8,164

**12. Subsequent events***Initial public offering*

On February 12, 2015, the Company sold 7,302,500 shares of common stock at \$16.00 per share for aggregate net proceeds of \$105.8 million after underwriting discounts and commissions and offering expenses related to the IPO. This includes the exercise in full by the underwriters of their option to purchase up to 952,500 additional shares of common stock at the same price to cover over-allotments. Upon the closing of the IPO, all shares of convertible preferred stock then outstanding converted into 23,521,889 shares of common stock.

*2015 Stock Incentive Plan*

In January 2015, the Company adopted the 2015 Stock Incentive Plan, or the 2015 Plan, which became effective upon the closing of the IPO. The 2015 Plan had 4,370,452 shares of common stock available for future issuance at the time of its effectiveness, which included 120,452 shares under the 2010 Plan which were transferred to the 2015 Plan upon effectiveness of the 2015 Plan. The 2015 Plan provides for automatic annual increases in shares available for grant, beginning on January 1, 2016 through January 1, 2025. In addition, shares subject to awards under the 2010 Plan that are forfeited or terminated will be added to the 2015 Plan. The 2015 Plan provides for the grant of incentive stock options, nonstatutory stock options, restricted stock awards, stock units, stock appreciation rights and other forms of equity compensation, all of which may be granted to employees, including officers, non-employee directors and consultants. Additionally, the 2015 Plan provides for the grant of cash-based awards.



Table of Contents

## INVITAE CORPORATION

## Notes to Consolidated Financial Statements (Continued)

December 31, 2014

**12. Subsequent events (Continued)*****2015 Employee Stock Purchase Plan***

In January 2015, the Company adopted the 2015 Employee Stock Purchase Plan (the "ESPP"), which became effective upon the closing of the IPO. A total of 325,000 shares of common stock are reserved for issuance under the ESPP. Eligible employees may purchase common stock at 85% of the lesser of the fair market value of common stock on the purchase date or last trading day preceding the offering date. The ESPP provides for automatic annual increases in shares available for grant, beginning on January 1, 2016 through January 1, 2025. The Company has not determined the date on which the initial purchase period will commence under the ESPP.

***New Leases***

In March 2015, the Company leased additional space in San Francisco and Oakland, California. The leases expire in April and June 2017 and aggregate future minimum lease payments for these facilities are approximately \$2.4 million.

**13. Selected Quarterly Data (Unaudited)**

The following table contains quarterly financial information for 2014 and 2013. The Company believes that the following information reflects all normal recurring adjustments necessary for a fair statement of the information for the periods presented. The operating results for any quarter are not necessarily indicative of results for any future period.

(In thousands, except per share amounts)	Three months ended							
	Dec 31, 2014	Sept 30, 2014	June 30, 2014	Mar 31, 2014	Dec 31, 2013	Sept 30, 2013	June 30, 2013	Mar 31, 2013
Revenue	\$ 875	\$ 310	\$ 301	\$ 118	\$ 88	\$ 54	\$ 6	\$
Loss from operations	\$ (15,283)	\$ (12,534)	\$ (10,516)	\$ (9,019)	\$ (8,115)	\$ (7,003)	\$ (5,412)	\$ (4,223)
Net loss	\$ (15,305)	\$ (12,615)	\$ (10,539)	\$ (9,033)	\$ (8,131)	\$ (7,044)	\$ (5,427)	\$ (4,236)
Net loss attributable to common stockholders	\$ (15,305)	\$ (12,615)	\$ (10,539)	\$ (9,033)	\$ (8,131)	\$ (7,044)	\$ (5,477)	\$ (4,337)
Net loss per share attributable to common stockholders, basic and diluted	\$ (16.56)	\$ (14.24)	\$ (12.81)	\$ (12.06)	\$ (11.18)	\$ (10.17)	\$ (8.04)	\$ (6.51)

102

Table of Contents

**ITEM 9. Changes In And Disagreements With Accountants On Accounting And Financial Disclosure.**

Not applicable.

**ITEM 9A. Controls And Procedures.**

**Evaluation of disclosure controls and procedures**

We maintain "disclosure controls and procedures," as such term is defined in Rule 13a-15(e) under the Securities Exchange Act of 1934, or Exchange Act, that are designed to ensure that information required to be disclosed by us in reports that we file or submit under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in Securities and Exchange Commission rules and forms, and that such information is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate, to allow timely decisions regarding required disclosure. In designing and evaluating our disclosure controls and procedures, management recognized that disclosure controls and procedures, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the disclosure controls and procedures are met. Our disclosure controls and procedures have been designed to meet reasonable assurance standards. Additionally, in designing disclosure controls and procedures, our management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible disclosure controls and procedures. The design of any disclosure controls and procedures also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions.

Based on their evaluation as of the end of the period covered by this Annual Report on Form 10-K, our Chief Executive Officer (our principal executive officer) and Chief Financial Officer (our principal financial officer) have concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

**Management's annual report on internal control over financial reporting**

This annual report does not include a report of management's assessment regarding internal control over financial reporting or an attestation report of our registered public accounting firm due to a transition period established by rules of the Securities and Exchange Commission for newly public companies.

**ITEM 9B. Other Information.**

None.



Table of Contents**PART III****ITEM 10. Directors, Executive Officers And Corporate Governance.****Executive officers and directors**

The following table sets forth, as of March 1, 2015, certain information regarding our executive officers and directors:

Name	Age	Position
Randal W. Scott, Ph.D.	57	Chairman, Chief Executive Officer and Director President, Chief Operating Officer, Director and
Sean E. George, Ph.D.	41	Co-Founder
Lisa Alderson	44	Chief Commercial Officer
Lee Bendekgey	57	Chief Financial Officer, General Counsel and Secretary
Eric Aguiar, M.D.(1)(2)(3)	53	Director
Geoffrey S. Crouse(1)(2)(3)	44	Director

- (1) Member of our Compensation Committee
- (2) Member of our Audit Committee
- (3) Member of our Nominating and Corporate Governance Committee

**Executive officers**

*Randal W. Scott, Ph.D.* has served as our Chairman and Chief Executive Officer since August 2012 and as a director since 2010. From 2000 through August 2012, Dr. Scott held a number of positions at Genomic Health, Inc., a public-held genomic information company which he co-founded in 2000, most recently as the Chief Executive Officer of a wholly-owned subsidiary of Genomic Health, and as a director. Prior to that, Dr. Scott served as Executive Chairman of the Board of Genomic Health, from January 2009 until March 2012 and Chairman of the Board and Chief Executive Officer from August 2000 until December 2008. Dr. Scott was a founder of Incyte Corporation, which at the time was a genomic information company, and served in various roles from 1991 through 2000, including Chairman of the Board, President and Chief Scientific Officer. Dr. Scott holds a B.S. in Chemistry from Emporia State University and a Ph.D. in Biochemistry from the University of Kansas. We believe that Dr. Scott is qualified to serve on our board due to his years of experience in the life sciences industry and his extensive executive leadership and management experience at public companies.

*Sean E. George, Ph.D.* is one of our co-founders and has served as our President and Chief Operating Officer since August 2012. He has also served as a director since January 2010. He initially served as our Chief Executive Officer from January 2010 to August 2012. Prior to co-founding Invitae, Dr. George served as Chief Operating Officer from 2007 to November 2009 at Navigenics, Inc., a personalized medicine company. Previously, he served as Senior Vice President of Marketing and Senior Vice President, Life Science Business at Affymetrix, Inc., a provider of life science and molecular diagnostic products, as well as Vice President, Labeling and Detection Business at Invitrogen Corporation, a provider of tools to the life sciences industry, during his tenure there from 2002 to 2007. Dr. George holds a B.S. in Microbiology and Molecular Genetics from the University of California Los Angeles, an M.S. in Molecular and Cellular Biology from the University of California Santa Barbara, and a Ph.D. in Molecular Genetics from the University of California Santa Cruz. We believe that Dr. George is qualified to serve on our board of directors due to his extensive experience in the life science industry, his broad leadership experience with life science companies and his educational background.

Table of Contents

*Lisa Alderson* has served as our Chief Commercial Officer since September 2012. Ms. Alderson is also a founding partner of Tech Care Now, an information technology and service company, and has served on its board since January 2011. She previously was the Executive Vice President of Plum District, an e-commerce company, from July 2011 to May 2012. From January 2010 to January 2011, Ms. Alderson was a consultant, advisor and angel investor. Prior to that, she served as Chief Executive Officer and President of CrossLoop, Inc., a marketplace for technical services, from April 2007 to January 2010, and as President of Cinema Circle, Inc., a subscription-based home entertainment company, from 2004 to 2006. Previously, she was part of the start-up team at Genomic Health, Inc., from 2000 to 2002, and a Manager of Strategic Planning at The Walt Disney Company from 1997 to 1999. Ms. Alderson holds a B.A. in Journalism and International Studies from Colorado State University and an M.B.A. from Harvard Business School.

*Lee Bendekgey* has served as our Chief Financial Officer and General Counsel since November 2013. Mr. Bendekgey is the former General Counsel of DNAnexus, Inc., a cloud-based genome informatics and data management company, where he served from September 2011 to October 2013. From March 2009 until September 2011, Mr. Bendekgey pursued personal interests. Prior to that, he was Chief Financial Officer and General Counsel for Nuvelo, Inc., a biopharmaceutical company, from July 2004 to March 2009; and he served as General Counsel and Chief Financial Officer for Incyte Corporation from 1998 to July 2004. Mr. Bendekgey holds a B.A. in French and Political Science from Kalamazoo College and a J.D. from Stanford Law School.

***Non-employee directors***

*Eric Aguiar, M.D.* has been a member of our board of directors since September 2010. He has been a partner in the venture capital firm Thomas, McNerney & Partners since 2007. Prior to joining that firm, he was a Managing Director of HealthCare Ventures, a healthcare focused venture capital firm, from 2001 to 2007. Dr. Aguiar was Chief Executive Officer and a director of Genovo, Inc., a biopharmaceutical company focused on gene delivery and gene regulation, from 1998 to 2000. Dr. Aguiar previously served as a director of Amarin Pharmaceuticals, a publicly-held biopharmaceutical company, as well as on the boards of numerous private companies including companies in the life sciences industry. He is a member of the Board of Overseers of the Tufts School of Medicine and a member of the Council on Foreign Relations. He received an M.D. with honors from Harvard Medical School and a B.A. in Arts and Sciences from Cornell University. Dr. Aguiar was also a Luce Fellow and is a Chartered Financial Analyst. We believe that Dr. Aguiar is qualified to serve on our board of directors due to his extensive experience with in the life science field, his experience on various boards, and his management and financial experience with life sciences companies.

*Geoffrey S. Crouse* has served on our board of directors since March 2012. Since September 2012 he has served as Chief Executive Officer of Cord Blood Registry, a company focusing on storing stem cells from umbilical cords. He previously served as Chief Operating Officer at Immucor, Inc., a publicly traded in vitro diagnostics company, from August 2009 to April 2011. From April 2011 through September 2012, Mr. Crouse was a consultant. Prior to Immucor, he served as Vice President of the life sciences business at Millipore Corporation, a publicly traded provider of technologies, tools and services for the life science industry, from 2006 to 2009. Prior to joining Millipore, he worked at Roche, a pharmaceuticals and diagnostics company, where he held various roles from 2003 to 2006. Mr. Crouse holds a B.A. in English and Japanese from Boston College and an M.B.A. and Masters of Public Health from the University of California Berkeley. We believe that Mr. Crouse is qualified to serve on our board of directors due to his extensive experience in the life sciences industry and his management and financial experience with life sciences companies.

Table of Contents

**Board composition**

Our amended and restated bylaws, provide that our board shall consist of such number of directors as the board of directors may from time to time determine. Our board of directors consists of four directors. The authorized number of directors may be changed by resolution of our board of directors. Vacancies on our board can be filled by resolution of our board of directors. Our board of directors will be divided into three classes, each serving staggered, three-year terms:

Our Class I director will be Geoffrey S. Crouse and his term will expire at our 2016 annual meeting of stockholders;

Our Class II director will be Randal W. Scott and his term will expire at our 2017 annual meeting of stockholders; and

Our Class III directors will be Eric Aguiar and Sean E. George and their terms will expire at our 2018 annual meeting of stockholders.

As a result, only one class of directors will be elected at each annual meeting of stockholders, with the other classes continuing for the remainder of their respective terms.

**Code of business conduct and ethics**

We believe our corporate governance initiatives comply with the Sarbanes-Oxley Act and the rules and regulations of the SEC adopted thereunder. In addition, we believe our corporate governance initiatives comply with the rules of the New York Stock Exchange, or NYSE. Our board of directors will continue to evaluate our corporate governance principles and policies.

Our board of directors has adopted a code of business conduct and ethics that applies to each of our directors, officers and employees. The code addresses various topics, including:

compliance with laws, rules and regulations;

confidentiality;

conflicts of interest;

corporate opportunities;

competition and fair dealing;

payments or gifts from others;

health and safety;

insider trading;

protection and proper use of company assets;

record keeping; and

giving and accepting gifts.

Our board of directors has adopted a code of ethics for senior financial officers applicable to our Chief Executive Officer and Chief Financial Officer as well as other key management employees addressing ethical issues. The code of business conduct and the code of ethics are each posted on our website [www.invitae.com](http://www.invitae.com). The code of business conduct and the code of ethics can only be amended by the approval of a majority of our board of directors. Any waiver to the code of business conduct for an executive officer or director or any waiver of the code of ethics may only be granted by our board of directors or our nominating and corporate governance committee and must be timely disclosed as required by applicable law. We have implemented whistleblower procedures that establish formal

Table of Contents

protocols for receiving and handling complaints from employees. Any concerns regarding accounting or auditing matters reported under these procedures will be communicated promptly to our audit committee. Stockholders may request a free copy of our code of business conduct and code of ethics by contacting Invitae Corporation, Attention: Chief Financial Officer, 458 Brannan Street, San Francisco, California 94107.

To date, there have been no waivers under our code of business conduct or code of ethics. We intend to disclose future amendments to certain provisions of our code of business conduct or code of ethics or waivers of such codes granted to executive officers and directors on our website at <http://www.invitae.com> within four business days following the date of such amendment or waiver.

**Director independence**

Our board of directors determined that Eric Aguiar and Geoffrey S. Crouse are "independent directors" as defined under the rules of the NYSE. There are no family relationships among any of our directors or executive officers. The NYSE permits a phase-in period of up to one year for an issuer listing its securities on the NYSE in connection with its initial public offering in order meet the requirement that a majority of the board of directors be comprised of independent directors. We intend to take advantage of this phase-in period.

**Board leadership structure**

Our board of directors is currently chaired by Randal W. Scott. Our board believes that having a combined chairman of the board and chief executive officer is the most effective leadership structure for our company at this time. The board believes that Dr. Scott is the director best situated to identify strategic opportunities and focus the activities of the board due to his full-time commitment to our business and his industry-specific experience. The board also believes that the combined role of chairman and chief executive officer promotes effective execution of strategic imperatives and facilitates information flow between management and the board.

**Role of the board in risk oversight**

Our board of directors is responsible for overseeing the overall risk management process at the company. The responsibility for managing risk rests with executive management while the committees of our board of directors and our board of directors as a whole participate in the oversight process. Our board of directors' risk oversight process builds upon management's risk assessment and mitigation processes, which include reviews of long-term strategic and operational planning, executive development and evaluation, regulatory and legal compliance, and financial reporting and internal controls.

**Board committees**

We have established an audit committee, compensation committee and nominating and corporate governance committee, each of which operate under a charter that has been approved by our board. Copies of each charter are posted on the corporate governance section of our website at [www.invitae.com](http://www.invitae.com). We believe that the composition of these committees meets the criteria for independence under, and the functioning of these committees complies with the applicable requirements of, the Sarbanes-Oxley Act, and the current rules and regulations of the SEC and the NYSE. We intend to comply with future requirements as they become applicable to us. Each committee has the composition and responsibilities described below.

*Audit committee*

Dr. Aguiar and Mr. Crouse serve on our audit committee. Dr. Aguiar is the chairperson of this committee. Our audit committee assists our board of directors in fulfilling its legal and fiduciary

Table of Contents

obligations in matters involving our accounting, auditing, financial reporting, internal control and legal compliance functions, and is directly responsible for the approval of the services performed by our independent registered public accounting firm and reviewing of their reports regarding our accounting practices and systems of internal accounting control. Our audit committee also oversees the audit efforts of our independent registered public accounting firm and takes actions as it deems necessary to satisfy itself that such firm is independent of management. Our audit committee is also responsible for monitoring the integrity of our consolidated financial statements and our compliance with legal and regulatory requirements as they relate to financial statements or accounting matters. Our board of directors has determined that each of Dr. Aguiar and Mr. Crouse is an audit committee financial expert, as defined by the rules promulgated by the SEC, and each of the members of our audit committee has the requisite financial sophistication as defined under the applicable rules and regulations of NYSE. Under NYSE rules, our audit committee must have three members. However, the NYSE permits a phase-in period of up to one year for an issuer registering securities in an initial public offering to meet this requirement. We intend to take advantage of such phase-in period.

***Compensation committee***

Dr. Aguiar and Mr. Crouse serve on our compensation committee. Mr. Crouse is the chairperson of this committee. Our compensation committee assists our board of directors in meeting its responsibilities with regard to oversight and determination of executive compensation and assesses whether our compensation structure establishes appropriate incentives for officers and employees. Our compensation committee reviews and makes recommendations to our board of directors with respect to our major compensation plans, policies and programs. In addition, our compensation committee reviews and makes recommendations for approval by the independent members of our board of directors regarding the compensation for our executive officers, establishes and modifies the terms and conditions of employment of our executive officers and administers our stock option plans.

***Nominating and corporate governance committee***

Dr. Aguiar and Mr. Crouse serve on our nominating and corporate governance committee. Dr. Aguiar is the chairperson 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. In addition, our nominating and corporate governance committee is responsible for overseeing our corporate governance guidelines, and reporting and making recommendations to the board of directors concerning corporate governance matters.

**Director compensation**

Employee directors do not receive any compensation for service as a member of our board of directors. While we reimburse our non-employee directors for their reasonable out-of-pocket costs and travel expenses in connection with their attendance at board and committee meetings, we do not have a standard compensation policy for our non-employee directors, other than Mr. Crouse, who currently is paid \$20,000 annually and eligible to receive an annual option grant to purchase 2,500 shares of common stock. However, we intend to review and consider future proposals regarding non-employee director compensation now that we have completed our initial public offering.

## Edgar Filing: Invitae Corp - Form 10-K

### Table of Contents

The following table shows certain information with respect to the compensation of our non-employee directors who served during the fiscal year ended December 31, 2014:

Name	Fees earned or paid in cash	Option awards(3)	Total
Eric Aguiar, M.D.(1)			
Geoffrey S. Crouse	\$ 20,000	\$ 10,842(2)	\$ 30,842

(1) Dr. Aguiar serves is not currently compensated by us for his services.

(2) On October 24, 2014, we granted Mr. Crouse an option to acquire 2,500 shares of our common stock, vesting in equal monthly installments over one year, commencing on February 27, 2014. The option has an exercise price of \$8.70 per share. The amount in this column represents the aggregate fair value of the option award computed as of the grant date in accordance with Financial Accounting Standards Board Accounting Standards Codification No. 718, Compensation-Stock Compensation, or FASB ASC Topic 718, rather than amounts paid to or realized by Mr. Crouse. See the notes to our consolidated financial statements for a discussion of assumptions made in determining the grant date fair value and compensation expense of our stock options.

(3) Other than as described in (2) above, no options to purchase our common stock were outstanding as of December 31, 2014.

### **Compensation committee interlocks and insider participation**

None of the members of our compensation committee is or has in the past served as one of our officers or employees. 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.

### **Director nomination policy**

The nominating and corporate governance committee is responsible for identifying, evaluating, recruiting and recommending qualified candidates to our board for nomination or election. Our board nominates directors for election at each annual meeting of stockholders, and elects new directors to fill vacancies if they occur.

Our board strives to find directors who are experienced and dedicated individuals with diverse backgrounds, perspectives and skills. Our governance guidelines contain membership criteria that call for candidates to be selected for their character, judgment, diversity of experience, business acumen and ability to act on behalf of all stockholders. In addition, we expect each director to be committed to enhancing stockholder value and to have sufficient time to effectively carry out his or her duties as a director. Our nominating and corporate governance committee also seeks to ensure that a majority of our directors are independent under the NYSE rules and that one or more of our directors is an "audit committee financial expert" under SEC rules.

Prior to our annual meeting of stockholders, our nominating and corporate governance committee identifies director nominees first by evaluating the current directors whose terms will expire at the annual meeting and who are willing to continue in service. The candidates are evaluated based on the criteria described above, the candidate's prior service as a director, and the needs of the board of directors for any particular talents and experience. If a director no longer wishes to continue in service, if the nominating and corporate governance committee decides not to re-nominate a director, or if a vacancy is created on the board of directors because of a resignation or an increase in the size of the board or other event, then the committee will consider whether to replace the director or to decrease

## Edgar Filing: Invitae Corp - Form 10-K

### Table of Contents

the size of the board. If the decision is to replace a director, the nominating and corporate governance committee will consider various candidates for board membership, including those suggested by committee members, by other board members, a director search firm engaged by the committee or our stockholders. Prospective nominees are evaluated by the nominating and corporate governance committee based on the membership criteria described above and set forth in our governance guidelines.

A stockholder who wishes to recommend a prospective nominee to the board for consideration by the nominating and corporate governance committee should notify our Corporate Secretary in writing at our principal executive office. Such notice must be delivered to our offices by the deadline relating to stockholder proposals to be considered for inclusion in our proxy materials, as set forth in our bylaws.

Each notice delivered by a stockholder who wishes to recommend a prospective nominee to the Board for consideration by the nominating and corporate governance committee generally must include the following information about the prospective nominee:

the name, age, business address and residence address of the person;

the principal occupation of the person;

the number of shares of our capital stock owned by the person;

a description of all compensation and other relationships during the past three years between the stockholder and the person;

any other information relating to the person required to be disclosed pursuant to Section 14 of the Securities Exchange Act of 1934, or Exchange Act; and

the person's written consent to serve as a director if elected.

The nominating and corporate governance committee may require any prospective nominee recommended by a stockholder to furnish such other information as the committee reasonably may require to determine the person's eligibility to serve as an independent director or that could be material to a stockholder's understanding of the person's independence or lack thereof.

### **Limitation on liability and indemnification matters**

Our amended and restated certificate of incorporation contains provisions that limit the personal liability of our directors for monetary damages to the fullest extent permitted by the General Corporation Law of the State of Delaware, or the DGCL. Consequently, our directors will not be personally liable to us or our stockholders for monetary damages for any breach of fiduciary duties as directors, except liability for:

any breach of the director's duty of loyalty to us or our stockholders;

any act or omission not in good faith or that involves intentional misconduct or a knowing violation of law;

unlawful payments of dividends or unlawful stock repurchases or redemptions as provided in Section 174 of the DGCL; or any transaction from which the director derived an improper personal benefit.

Our amended and restated certificate of incorporation and amended and restated bylaws provide that we are required to indemnify our directors, in each case to the fullest extent permitted by the DGCL. Our bylaws also provide that we shall advance expenses incurred by a director in advance of the final disposition of any action or proceeding, and permit us to secure insurance on behalf of any officer, director, employee or other agent for any liability arising out of his or her actions in that





Table of Contents

capacity regardless of whether we would otherwise be permitted to indemnify him or her under the provisions of the DGCL. We have entered into agreements to indemnify our directors and expect to continue to enter into agreements to indemnify our directors. With certain exceptions, these agreements provide for indemnification for related expenses including, among other things, attorneys' fees, judgments, fines and settlement amounts incurred by any of our directors in any action or proceeding. We believe that these certificate of incorporation and bylaw provisions and indemnification agreements are necessary to attract and retain qualified persons as directors. We also maintain directors' and officers' liability insurance.

The limitation of liability and indemnification provisions in our certificate of incorporation and bylaws may discourage stockholders from bringing a lawsuit against our directors for breach of their fiduciary duty of care. They may also reduce the likelihood of derivative litigation against our directors and officers, even though an action, if successful, might benefit us and other stockholders. Further, a stockholder's investment may be adversely affected to the extent that we pay the costs of settlement and damage awards against directors and officers. At present, there is no pending litigation or proceeding involving any of our directors, officers or employees for which indemnification is sought, and we are not aware of any threatened litigation that may result in claims for indemnification.

**Section 16(a) beneficial ownership reporting compliance**

Section 16(a) of the Securities Exchange Act of 1934 requires our executive officers and directors, and persons who own more than 10% of a registered class of our equity securities to file reports of ownership on Forms 3, 4 and 5 with the SEC. Officers, directors and greater than 10% stockholders are required to furnish us with copies of all Forms 3, 4 and 5 they file. Because our initial public offering occurred after December 31, 2014, we were not subject to Section 16(a) for the period covered by this report.

Table of Contents**ITEM 11. Executive Compensation.****2014 summary compensation table**

The following table presents information concerning the total compensation of our named executive officers, for services rendered to us in all capacities during the fiscal year ended December 31, 2014. Our named executive officers consist of our Chief Executive Officer and the two other highest paid executive officers who were serving at fiscal year-end:

<b>Name and principal position</b>	<b>Fiscal year</b>	<b>Salary (\$)</b>	<b>Option awards (\$)(1)</b>	<b>Total (\$)</b>
Randal W. Scott, Ph.D.	2014	203,703		203,703
<i>Chairman and Chief Executive Officer</i>	2013	200,000		200,000
Sean E. George, Ph.D.	2014	281,857	454,355(2)	736,212
<i>President and Chief Operating Officer</i>	2013	280,000		280,000
Lisa Alderson	2014	286,646	251,405(3)	538,051
<i>Chief Commercial Officer</i>	2013	239,583(4)		239,583

- (1) The amounts in this column represent the aggregate fair value of the option awards computed as of the grant dates in accordance with FASB ASC Topic 718, rather than amounts paid to or realized by the individual. See the notes to our consolidated financial statements for a discussion of assumptions made in determining the grant date fair value and compensation expense of our stock options.
- (2) On each of February 28, 2014 and October 15, 2014, we granted Dr. George an option to purchase 50,000 shares of our common stock at an exercise price of \$3.42 and \$8.70 per share, respectively. The options vest as to 25% of the shares on the one-year anniversary of the grant date and 1/48th of the shares vest each month thereafter over the remaining three years.
- (3) On February 28, 2014 and October 15, 2014, we granted Ms. Alderson an option to purchase 33,333 shares and 25,000 shares, respectively, of our common stock at an exercise price of \$3.42 and \$8.70 per share, respectively. The options vest as to 25% of the shares on the one-year anniversary of the grant date and 1/48th of the shares vest each month thereafter over the remaining three years.
- (4) Ms. Alderson was employed on a part-time basis until October 1, 2013. Her annualized salary was \$287,500.

## Edgar Filing: Invitae Corp - Form 10-K

### Table of Contents

#### 2014 outstanding equity awards at fiscal year-end

The following table presents information regarding outstanding equity awards held by our named executive officers as of December 31, 2014:

Name	Grant date	Option awards				Stock awards	
		Number of securities underlying unexercised options (exercisable) (#)	Number of securities underlying unexercised options (#)	Option exercise price (\$/share)	Option expiration date	Number of shares or units that have not vested (#)	Market value of shares or units that have not vested (\$)
Randal W. Scott, Ph.D.							
Sean E. George, Ph.D.	11-16-12	19,444	13,889(1)	1.26	11-16-22		
	2-28-14	0	50,000	3.42	2-28-24(2)		
	10-15-14	0	50,000	8.70	10-15-24(2)		
Lisa Alderson	11-16-12	24,305	17,361(1)	1.26	11-16-22		
	11-16-12					6,944(1)(3)	111,104(4)
	2-28-14	0	33,333	3.42	2-28-24(2)		
	10-15-14	0	25,000	8.70	10-15-24(2)		

- (1) The awards vest over a four-year period at the rate of 25% of the total award on the one-year anniversary of the vesting start date of August 31, 2012 and 1/48th of the total award on a monthly basis thereafter over the subsequent three-year period.
- (2) The option vests as to 25% of the shares on the one-year anniversary of the grant date and 1/48th of the shares vest each month thereafter over the remaining three years.
- (3) Represents shares acquired upon the early exercise of a time-based stock option, which shares are subject to a right of repurchase at the original exercise price paid for the shares if the executive terminates employment before the shares have vested.
- (4) As there was no public market value for our common stock as of December 31, 2014, we have set the fair market value at the initial public offering price.

#### Employment arrangements

In July 2010, we entered into an executive employment agreement with Sean E. George, Ph.D., our President and Chief Operating Officer. This agreement was subsequently terminated in November 2014. Pursuant to the executive employment agreement, Dr. George was provided the right to purchase 166,666 shares of our common stock at \$0.0006 per share, subject to a restricted stock purchase agreement dated July 15, 2010. The restricted shares have now fully vested. The restricted stock purchase agreement imposes restrictions on the transfer, grants us a right of first refusal and subjects the shares to a 180-day lock-up period after the effective date of our initial public offering. The right of first refusal terminated upon the completion of our initial public offering. Under his executive employment agreement prior to its termination, in the event of a "change of control" (such as a merger or reorganization which results in our stockholders immediately prior to such transaction holding less than 50% of the voting power of the surviving entity, or the sale or transfer of all or substantially all of our assets), the vesting for any unvested equity awards held by Dr. George would have accelerated and become immediately exercisable. Subject to his execution of a general release of all claims against us, the executive employment agreement provided prior to its termination that if Dr. George's employment with us was terminated by us without "cause" or not in connection with his death or disability, or if following a "change of control" he resigned for "good reason" (such as a material reduction in base salary or responsibilities, or a material change in the geographic location of his primary work facility), then Dr. George would have been entitled to receive the following: (1) a cash payment equal to 12 months of his then-existing base salary, payable in monthly installments; and (2) if he elected to continue health insurance coverage under COBRA for himself or his eligible dependents, we would have reimbursed him for the applicable premiums until the earlier of a 12-month period or until he or his eligible dependents became covered under similar plans or became ineligible for coverage. If such a termination occurred outside of a "change of control" context, Dr. George also would have received accelerated vesting of any unvested equity awards in an amount equal to the number of

shares that would have vested had he remained employed for an additional 12 months.

Table of Contents**ITEM 12. Security Ownership Of Certain Beneficial Owners And Management And Related Stockholder Matters.****Equity compensation plan information**

The following table summarizes the number of outstanding options granted to our employees, consultants and directors, as well as the number of shares of common stock remaining available for future issuance under our equity compensation plans as of December 31, 2014.

	Number of Securities to be issued upon exercise of Outstanding Options (a)	Weighted Average Exercise Price of Outstanding Options and Rights (b)	Reserved for Future Issuance Under Equity Compensation Plans (Excluding Securities Reflected in Column(a))
Equity compensation plans approved by security holders	1,921,517	\$ 4.37	276,667
Equity compensation plans not approved by security holders			
<b>Total</b>	<b>1,921,517</b>	<b>\$ 4.37</b>	<b>276,667</b>

The information above relates to our 2010 Stock Incentive Plan, which was terminated in connection with our initial public offering in February 2015 and was replaced by our 2015 Stock Incentive Plan.

**Security ownership of certain beneficial owners and management**

The following table sets forth information regarding the number of shares of common stock beneficially owned on February 28, 2015, by:

each person who is known by us to beneficially own 5% or more of our common stock;

each of our named executive officers and directors; and

all of our executive officers and directors as a group.

We have determined beneficial ownership in accordance with SEC rules. Except as indicated by the footnotes below, we believe, based on the information furnished to us, that the persons and entities named in the table below have sole voting and investment power with respect to all shares of common stock that they beneficially own, subject to applicable community property laws.

Applicable percentage ownership is based on 31,813,353 shares of common stock outstanding at February 28, 2015. In computing the number of shares of common stock beneficially owned by a person and the percentage ownership of that person, we deemed to be outstanding all shares of common stock subject to options held by that person or entity that are exercisable within 60 days of February 28, 2015. We did not deem these shares outstanding, however, for the purpose of computing the percentage ownership of any other person.

## Edgar Filing: Invitae Corp - Form 10-K

### Table of Contents

Except as otherwise set forth in footnotes to the table below, the address of each of the persons listed below is c/o Invitae Corporation, 458 Brannan Street, San Francisco, California 94107.

Name and address of beneficial owner	Number of shares beneficially owned	Percentage of shares beneficially owned
<b>Executive Officers and Directors:</b>		
Randal W. Scott, Ph.D.	3,439,559	10.8%
Sean E. George, Ph.D.(1)	204,669	*
Lisa Alderson(2)	60,950	*
Eric Aguiar, M.D.(3)	3,732,460	11.7%
Geoffrey S. Crouse(4)	21,759	*
All current executive officers and directors as a group (6 persons)(5)	7,482,452	23.4%
<b>5% Stockholders:</b>		
Baker Brothers Life Sciences, L.P. and affiliates(6)	6,554,967	20.6%
BlackRock, Inc.(7)	4,166,662	13.1%
Thomas, McNerney & Partners II, L.P. and affiliates(3)	3,732,460	11.7%
Genomic Health, Inc.(8)	2,207,793	6.9%

\*

Represents beneficial ownership of less than 1%.

(1)

Includes options to purchase 36,110 shares of common stock exercisable within 60 days of February 28, 2015.

(2)

Includes options to purchase 36,110 shares of common stock exercisable within 60 days of February 28, 2015.

(3)

Consists of 3,682,968 shares held by Thomas, McNerney & Partners II, L.P. ("Thomas McNerney"): 13,256 shares held by TMP Associates II, L.P. ("TMP Associates"); and 36,236 shares held by TMP Nominee II, LLC ("TMP Nominee"). Thomas, McNerney & Partners II, LLC ("TMP LLC") is the general partner of each of Thomas McNerney and TMP Associates. Eric Aguiar is a manager of TMP LLC and has shared voting and investment control over the shares held by each of Thomas McNerney and TMP Associates and indirectly shares investment control over the shares held by TMP Nominee. Dr. Aguiar disclaims beneficial ownership of such shares, except to the extent of any pecuniary interest therein. The mailing address of Thomas McNerney and its affiliates is 60 South Sixth Street, Suite 3620, Minneapolis, MN 55402.

(4)

Includes options to purchase 2,500 shares of common stock exercisable within 60 days of February 28, 2015.

(5)

Includes options to purchase an aggregate of 98,296 shares of common stock exercisable within 60 days of February 28, 2015.

(6)

Based solely on a Schedule 13G filed on February 12, 2015. Consists of 5,816,409 shares held by Baker Brothers Life Sciences, L.P. ("Baker Brothers"); 665,187 shares held by 667, L.P. ("667"); and 73,371 shares held by 14159, L.P. ("14159"). Baker Bros Advisors LP ("Baker Advisors") is the investment advisor of 667, Baker Brothers and 14159, and has sole voting and dispositive power with respect to these shares. Julian C. Baker and Felix J. Baker are managing members of Baker Advisors. Baker Advisors, Julian C. Baker and Felix J. Baker disclaim beneficial ownership of the securities held by the funds except to the extent of their pecuniary interest therein. The mailing address of

## Edgar Filing: Invitae Corp - Form 10-K

### Table of Contents

Baker Brothers and its affiliates is 667 Madison Avenue, 21st Floor, New York, NY 10065.

(7)

BlackRock, Inc. is the ultimate parent holding company of certain advisory subsidiaries that have the power to vote or dispose of the shares. Of the 4,166,662 shares listed above, 2,365,865 are for the benefit of BlackRock Global Allocation Fund, Inc., 482,772 are for the benefit of BlackRock Global Allocation V.I. Fund of BlackRock Variable Series Funds, Inc., 10,802 are for the benefit of BlackRock Global Allocation Portfolio of BlackRock Series Fund, Inc., 41,249 are for the benefit of BlackRock Global Allocation Fund (Australia), 27,973 are for the benefit of MassMutual Select BlackRock Global Allocation Fund, 139,878 are for the benefit of JNL/BlackRock Global Allocation Fund of JNL Series Trust, 933,904 are for the benefit of BlackRock Global Funds Global Allocation Fund, 61,576 are for the benefit of BlackRock Global Funds Global Dynamic Equity Fund, 31,073 are for the benefit of AZL BlackRock Global Allocation Fund, a Series of Allianz Variable Insurance Products Trust, and 71,570 are for the benefit of BlackRock Global Allocation Collective Fund (collectively, the "BlackRock Funds"). On behalf of BlackRock Investment Management, LLC and BlackRock Institutional Trust Company, N.A., the Investment Manager, Adviser, Sub-Adviser and/or Trustee (as applicable) of the BlackRock Funds, Dennis Stattman, as a Managing Director of BlackRock Investment Management, LLC and BlackRock Institutional Trust Company, N.A., has voting and investment power over the shares held by the BlackRock Funds. Dennis Stattman expressly disclaims beneficial ownership of all shares held by the BlackRock Funds. The address of the BlackRock Funds, BlackRock Investment Management, LLC, BlackRock Institutional Trust Company, N.A. and Dennis Stattman is c/o BlackRock Investment Management, LLC, 1 University Square Drive, Princeton, NJ 08540.

(8)

The address of Genomic Health is 301 Penobscot Drive, Redwood City, CA 94036.



Table of Contents**ITEM 13. Certain Relationships And Related Transactions, And Director Independence.**

In addition to the cash and equity compensation arrangements of our directors and named executive officers discussed above under the sections entitled "Director Compensation" and "Executive Compensation", respectively, the following is a description of transactions since January 1, 2014 to which we have been a party in which the amount involved exceeded or will exceed \$120,000 and in which any of our directors, executive officers, beneficial holders of more than 5% of our capital stock, or entities affiliated with or immediate family members of any of the foregoing, had or will have a direct or indirect material interest.

**Sales of convertible preferred stock**

The following table summarizes purchases of our convertible preferred stock since January 1, 2014 by certain of our directors, executive officers and holders of more than 5% of our capital stock and their affiliated entities. Each outstanding share of preferred stock automatically converted into one-sixth of one share of our common stock immediately prior to the completion of our initial public offering.

Purchaser	Shares of Series F preferred stock(2)	Aggregate purchase price
<b>Executive Officers and Directors:</b>		
Randal W. Scott, Ph.D.	1,000,000	\$ 2,000,000
<b>5% Stockholders:</b>		
Baker Brothers Life Sciences, L.P.(1)	12,500,000	\$ 25,000,000
BlackRock, Inc.(1)	25,000,000	\$ 50,000,000
Thomas, McNerney & Partners II, L.P.(1)	2,500,000	\$ 5,000,000
Genomic Health, Inc.	1,000,000	\$ 2,000,000

(1) Includes securities purchased by affiliates of the purchaser listed in the table. See "Item 12 Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters" for additional information.

(2) Issued in August and October 2014 at \$2.00 per share.

**Investors' rights agreement**

In August 2014, we entered into a fifth amended and restated investors' rights agreement with certain holders of our outstanding convertible preferred stock, including Genomic Health, Inc., an entity with which our director Randal W. Scott was affiliated when it made its initial investment in our convertible preferred stock in 2011, and Thomas, McNerney & Partners II, L.P. and affiliates, entities with which our director Eric Aguiar is affiliated, as well as Baker Brothers Life Sciences, L.P. and its affiliates, BlackRock, Inc. and its affiliates, and funds advised by Wellington Management Company LLP. This agreement provides that certain holders of common stock issued upon conversion of our preferred stock have the right to demand that we file a registration statement or request that their shares of common stock be covered by a registration statement that we are otherwise filing. In addition to the registration rights, the investors' rights agreement provided for certain information rights, board observer rights and rights of first offer if we propose to offer or sell any new equity securities. The provisions of the investors' rights agreement, other than those relating to registration rights, terminated upon completion of our initial public offering.

Table of Contents

**Right of first refusal and co-sale agreement**

In August 2014, we entered into a fifth amended and restated right of first refusal and co-sale agreement with certain holders of our preferred stock, including Genomic Health, Inc., an entity with which our director Randal W. Scott was affiliated when it made its initial investment in our convertible preferred stock in 2011, and Thomas, McNemey & Partners II, L.P. and affiliates, entities with which our director Eric Aguiar is affiliated, as well as Baker Brothers Life Sciences, L.P. and its affiliates, BlackRock, Inc. and its affiliates, and funds advised by Wellington Management Company LLP. This agreement provided certain holders of preferred stock a right of purchase and of co-sale in respect of sales of shares of capital stock and for a market stand-off following an initial public offering. These rights of purchase and co-sale terminated immediately prior to the completion of our initial public offering.

**Voting agreement**

In August 2014, we entered into a fifth amended and restated voting agreement with certain holders of our preferred stock, including Genomic Health, Inc., an entity with which our director Randal W. Scott was affiliated when it made its initial investment in our convertible preferred stock in 2011, and Thomas, McNemey & Partners II, L.P. and affiliates, entities with which our director Eric Aguiar is affiliated, as well as Baker Brothers Life Sciences, L.P. and its affiliates, BlackRock, Inc. and its affiliates, and funds advised by Wellington Management Company LLP. This agreement contained provisions regarding voting and size of our board of directors, board composition and removal rights, and drag-along sale rights. The voting agreement terminated upon the completion of our initial public offering.

**Management rights**

In connection with our sale of convertible preferred stock to our investors, we are party to management rights letters with certain purchasers of our convertible preferred stock, including Thomas, McNemey & Partners II, L.P. and its affiliates, BlackRock, Inc. and its affiliates, and OrbiMed Private Investments V, L.P., pursuant to which such entities were granted certain management rights, including the right to consult with and advise our management on significant business issues, attend board of directors meetings and receive board materials in certain cases, review our financial data and operating plans, examine our books and records and inspect our facilities. These management rights terminated upon the completion of our initial public offering.

**Stock options granted to executive officers and directors**

We have granted stock options to our executive officers and directors, as more fully described in "Item 10. Directors, Executive Officers and Corporate Governance."

**Indemnification agreements**

We have entered into indemnification agreements with our directors and executive officers. These agreements require us to indemnify these individuals to the fullest extent permitted under Delaware law against liabilities that may arise by reason of their service to us, and to advance expenses incurred as a result of any proceeding against them as to which they could be indemnified.

**Related party transaction policy**

We have adopted a written policy that our executive officers, directors, holders of more than 5% of any class of our voting securities, and any member of the immediate family of and any entity affiliated with any of the foregoing persons, are not permitted to enter into a related party transaction with us without the prior consent of our audit committee, or other independent members of our board

Table of Contents

of directors in the event it is inappropriate for our audit committee to review such transaction due to a conflict of interest. Any request for us to enter into a transaction with an executive officer, director, principal stockholder, or any of their immediate family members or affiliates, in which the amount involved exceeds \$120,000 must first be presented to our audit committee for review, consideration and approval. 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, but not limited to, 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. All of the transactions described above were entered into prior to the adoption of such policy.

Although we did not have a written policy for the review and approval of transactions with related persons prior to the closing of our initial public offering, our board of directors has historically reviewed and approved any transaction where a director or officer had a financial interest, including all of the transactions described above. Prior to approving such a transaction, the material facts as to a director's or officer's relationship or interest as to the agreement or transaction were disclosed to our board of directors. Our board of directors would take this information into account when evaluating the transaction and in determining whether such a transaction was fair to us and in the best interests of all of our stockholders. In addition, for each related party transaction described above, the disinterested directors in the context of each such transaction approved the applicable agreement and transaction.

**ITEM 14. Principal Accountant Fees And Services.**

The audit committee has appointed Ernst & Young LLP as our independent registered public accounting firm for the fiscal year ending December 31, 2015. Ernst & Young LLP audited our financial statements in 2014.

The following table sets forth the fees billed by Ernst & Young LLP for audit and other services rendered in 2014:

	<b>Year Ended December 31, 2014</b>	
	<b>(In thousands)</b>	
Audit Fees(1)	\$	1,110
Audit-related Fees		
Tax Fees		
All Other Fees		
<b>Total</b>	<b>\$</b>	<b>1,110</b>

- (1) Audit fees include fees and out-of-pocket expenses, whether or not yet invoiced, for professional services provided in connection with the audit of our annual financial statements and review of our quarterly financial statements, and also include fees for our IPO, review of our registration statements, and services provided in connection with other SEC filings.

**Pre-approval policies and procedures**

In connection with our IPO, the audit committee established a policy to pre-approve all audit and permissible non-audit services provided by our independent registered public accounting firm. All of the services provided in 2014 were pre-approved to the extent required. During the approval process, the audit committee considers the impact of the types of services and the related fees on the independence of the independent registered public accounting firm. The services and fees must be deemed compatible with the maintenance of that firm's independence, including compliance with rules and regulations of the SEC. Throughout the year, the audit committee will review any revisions to the estimates of audit and non-audit fees initially approved.

Table of Contents

**PART IV**

**ITEM 15. Exhibits And Financial Statement Schedules.**

(a) Documents filed as part of this report

1. Financial Statements:

Reference is made to the Index to Financial Statements of Invitae Corporation included in Item 8 of Part II hereof.

2. Financial Statement Schedules

All schedules have been omitted because they are not required, not applicable, or the required information is included in the financial statements or notes thereto.

3. Exhibits

See Item 15(b) below. Each management contract or compensating plan or arrangement required to be filed has been identified.

(b) Exhibits

<b>Exhibit Number</b>	<b>Description</b>
3.1	Restated Certificate of Incorporation of the Registrant (incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K filed February 23, 2015).
3.2	Amended and Restated Bylaws of the Registrant (incorporated by reference to Exhibit 3.2 to the Registrant's Current Report on Form 8-K filed February 23, 2015).
4.1	Form of Common Stock Certificate (incorporated by reference to Exhibit 4.1 to the Registrant's Registration Statement on Form S-1 (File No. 333-201433), as amended, declared effective on February 11, 2015).
4.2	Fifth Amended and Restated Investors' Rights Agreement, dated August 26, 2014, among Invitae Corporation and certain investors (incorporated by reference to Exhibit 4.2 to the Registrant's Registration Statement on Form S-1 (File No. 333-201433), as amended, declared effective on February 11, 2015).
4.3	Omnibus Approval and Amendment with Respect to: Series F Preferred Stock Purchase Agreement; Fifth Amended and Restated Investors' Rights Agreement; and Fifth Amended and Restated Voting Agreement, dated October 9, 2014, among Invitae Corporation and certain investors (incorporated by reference to Exhibit 4.3 to the Registrant's Registration Statement on Form S-1 (File No. 333-201433), as amended, declared effective on February 11, 2015).
10.1	Form of Indemnification Agreement between the Registrant and its officers and directors (incorporated by reference to Exhibit 10.1 to the Registrant's Registration Statement on Form S-1 (File No. 333-201433), as amended, declared effective on February 11, 2015).
10.2 <sup>#</sup>	2010 Stock Plan and forms of agreements thereunder (incorporated by reference to Exhibits 10.2, 10.3 and 10.4 to the Registrant's Registration Statement on Form S-1 (File No. 333-201433), as amended, declared effective on February 11, 2015).
10.3 <sup>#</sup>	2015 Stock Incentive Plan and forms of agreements thereunder (incorporated by reference to Exhibits 10.5, 10.6 and 10.7 to the Registrant's Registration Statement on Form S-1 (File No. 333-201433), as amended, declared effective on February 11, 2015).



## Edgar Filing: Invitae Corp - Form 10-K

### Table of Contents

<b>Exhibit Number</b>	<b>Description</b>
10.4#	Employee Stock Purchase Plan (incorporated by reference to Exhibit 10.8 to the Registrant's Registration Statement on Form S-1 (File No. 333-201433), as amended, declared effective on February 11, 2015).
10.5#	Executive Employment Agreement, dated July 30, 2010, by and between Invitae Corporation (f/k/a Locus Development, Inc.) and Sean E. George (incorporated by reference to Exhibit 10.9 to the Registrant's Registration Statement on Form S-1 (File No. 333-201433), as amended, declared effective on February 11, 2015).
10.6#	Restricted Stock Purchase Agreement, dated July 15, 2010, by and between Invitae Corporation (f/k/a Locus Development, Inc.) and Sean E. George (incorporated by reference to Exhibit 10.11 to the Registrant's Registration Statement on Form S-1 (File No. 333-201433), as amended, declared effective on February 11, 2015).
10.7	Lease (Standard Form), dated September 1, 2011, by and between Invitae Corporation (f/k/a Locus Development, Inc.) and Martin E. Harband, Trustee of the Harband Family Trust, as amended (incorporated by reference to Exhibit 10.12 to the Registrant's Registration Statement on Form S-1 (File No. 333-201433), as amended, declared effective on February 11, 2015).
10.8	Sublease, dated December 6, 2013, by and between Invitae Corporation and Sutter West Bay Hospitals (incorporated by reference to Exhibit 10.13 to the Registrant's Registration Statement on Form S-1 (File No. 333-201433), as amended, declared effective on February 11, 2015).
10.9	Lease, dated October 31, 2012, by and between Invitae Corporation and 278 University Investors, LLC (incorporated by reference to Exhibit 10.14 to the Registrant's Registration Statement on Form S-1 (File No. 333-201433), as amended, declared effective on February 11, 2015).
10.10	Sublease, dated November 21, 2014, by and between Invitae Corporation and InMobi Inc (incorporated by reference to Exhibit 10.15 to the Registrant's Registration Statement on Form S-1 (File No. 333-201433), as amended, declared effective on February 11, 2015).
21.1	List of Subsidiaries (incorporated by reference to Exhibit 21.1 to the Registrant's Registration Statement on Form S-1 (File No. 333-201433), as amended, declared effective on February 11, 2015).
23.1*	Consent of independent registered public accounting firm.
24.1*	Power of Attorney (contained on the signature page to this Form 10-K).
31.1*	Principal Executive Officer's Certifications Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2*	Principal Financial Officer's Certifications Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1*+	Certification Pursuant to 18 U.S.C. § 1350 (Section 906 of Sarbanes-Oxley Act of 2002).
32.2*+	Certification Pursuant to 18 U.S.C. § 1350 (Section 906 of Sarbanes-Oxley Act of 2002).

---

# Indicates management contract or compensatory plan or arrangement.

\* Filed herewith.

## Edgar Filing: Invitae Corp - Form 10-K

### Table of Contents

+

In accordance with Item 601(b)(32)(ii) of Regulation S-K and SEC Release No. 34-47986, the certifications furnished in Exhibits 32.1 and 32.2 hereto are deemed to accompany this Form 10-K and will not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934 (the "Exchange Act") or deemed to be incorporated by reference into any filing under the Exchange Act or the Securities Act of 1933 except to the extent that the registrant specifically incorporates it by reference.

Copies of the above exhibits not contained herein are available to any stockholder, upon payment of a reasonable per page fee, upon written request to: Chief Financial Officer, Invitae Corporation, 458 Brannan Street, San Francisco, California 94107.

(c)

Financial Statement Schedules

Reference is made to Item 15(a) 2 above.

