Invitae Corp
Form 10-K
March 10, 2016

Use these links to rapidly review the document

Table of Contents

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 10-K

(Mark One)

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

For the fiscal year ended December 31, 2015

o **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	**27-1701898**
(State or other jurisdiction of incorporation or organization)	(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:	**Name of each exchange on which registered:**
Common Stock, par value $0.0001 per share	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 o No ý

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

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 ý No o

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 ý No o

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. ý

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 o	Accelerated filer ý	Non-accelerated filer o (Do not check if a smaller reporting company)	Smaller reporting company o

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

As of June 30, 2015, the aggregate market value of common stock held by non-affiliates of the Registrant was approximately $180.7 million, based on the closing price of the common stock as reported on The New York Stock Exchange for that date.

The number of shares of the registrant's Common Stock outstanding as of March 2, 2016 was 31,976,501.

Table of Contents

TABLE OF CONTENTS

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 and attract potential partners;
- 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 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;
- 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 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

Table of Contents

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 pricing 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 the Online Mendelian Inheritance in Man®, an online catalog of human genes and genetic disorders, 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 not only to 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 high quality, low cost service. We also plan on expanding into the health and wellness market, including carrier testing and newborn screening. 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.

Table of Contents

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 high quality genetic testing at a price that makes sense for broad healthcare adoption and reimbursement. We also are providing turnaround time of less than three weeks for the substantial majority of our tests, which in most cases is as good or better than other laboratories offering genetic testing. As such, we believe we are well positioned to address this challenge given our investment in infrastructure that will allow us to perform these complex tests in high volume at low cost while maintaining high quality and service levels. 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 clinicians and their patients while reducing the time required by our genetic specialists for interpretation and report sign-out.

We believe that the keys to our future success will be to steadily reduce the costs we incur in providing test results, which enables us to increase the amount of genetic content we offer in the form of an expanded test menu for the same or lower prices, thereby increasing demand and revenues. Therefore, we measured our success in 2015 with four key metrics:

lowering cost of goods sold (COGS);

increasing our content by expanding our test menu;

increasing our volumes; and

increasing our revenues and improving reimbursement.

We launched our first commercial offering in November 2013 with an offering of more than 200 genes. In October 2015, we expanded our test menu with more than 600 genes in production, offering tests for more than 120 disorders in cardiovascular, hereditary cancer, neurology, pediatrics and other rare diseases. We have a transparent pricing structure, charging one price per indication regardless the number of genes. For third party payers that are out of contract, we charge $1,500 per sample; for payers and institutions that are in contract with us, the contracted price is as low as $950 per indication depending on administrative criteria; and for patients who pay upfront and set up an account with us, we charge $475. We introduced this multi-tiered pricing structure in June 2015.

Our volume has grown rapidly. In 2015 we delivered approximately 19,000 billable tests, representing over 400% year-over-year annual growth, compared to the approximately 3,600 tests we delivered in 2014. We also received or "accessioned" more than 20,000 commercial samples in 2015, which is an important leading indicator for future volume. Substantiating a hypothesis that is fundamental to the success of our business model, we saw significant increases in our volume when we expanded our test menu, including meaningful growth in the non-cancer test portion of our market. We expect that will continue to be the case in 2016 as we plan to increase our menu to approximately 1,000 genes in production in the middle of the year and approximately 3,000 genes in production by the end of the year.

Importantly, with the growth in volume and content, we have succeeded in driving down our COGS in a meaningful way. At the beginning of 2015, our COGS were approximately $1,200 per

Table of Contents

sample accessioned, and we brought down those costs to less than $700 per sample accessioned in the fourth quarter.

In support of our efforts to reduce COGS, expand our test menu, and develop a scalable laboratory infrastructure, we incurred research and development expenses of $42.8 million, $22.1 million and $16.0 million in 2015, 2014 and 2013, respectively.

The expansion of our test menu in 2015, and the resulting growth in testing volume, translated into rapid growth in revenue. In 2015 our revenue was $8.4 million, as compared to revenue of $1.6 million in 2014 representing over 400% year-over-year annual growth.

We are headquartered in San Francisco, California, where we have offices and a CLIA-certified, CAP-accredited laboratory. We also have offices in Cambridge, Massachusetts; Oakland, California; and Palo Alto, California. We have a multi- disciplinary team of approximately 280 people as of December 31, 2015, 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.

The global opportunity for genetic testing

We believe that genes are fundamental particles 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 medicine. We also believe that eventually many individuals in a modern healthcare system will have their genomes 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 5-10% of all cancers have a hereditary basis;
- approximately 0.4% of the population has a cardiac genetic condition that may lead to early onset cardiovascular disease;
- approximately 0.5-5.0% of the population has a factor V Leiden variant that increases the genetic risk for blood clots;
- approximately 2% of new births result in a complication involving a genetic condition;
- approximately 0.3% of the population will have an epileptic seizure during their lifetime;
- 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; and
- approximately 2-5% of the population has a gene mutation that puts them at risk for a medically actionable condition.

Furthermore, everyone is carrying mutations that can cause severe illness in a child if the child's other parent provides a mutation in the same gene.

The global genetic testing market is growing rapidly. According to UnitedHealth Group, the U.S. genetic testing and molecular diagnostics market in 2010 was estimated to be approximately $5 billion,

Table of Contents

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.

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, payers generally restrict reimbursement of genetic testing to limited patient populations that meet specific criteria. In a survey by UnitedHealth, approximately 78% of clinicians 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 genetic testing result, which limits clinical applicability of genetic testing for patients who are in need of pressing follow-up treatment.

Our solution for genetic testing

We are focused on making comprehensive, high quality genetic testing more affordable and more accessible than ever before, pursuing a large and rapidly growing market. 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. We have learned that this value proposition resonates with clinicians and believe that we can help payers and the healthcare system significantly reduce their current testing expenditures.

Our products today

We launched our first commercial offering in late November 2013, an assay of 216 genes, and began selling and marketing our multi-gene panels with a focused effort on hereditary cancers, including breast, colon and pancreatic cancer. We subsequently expanded our test menu in October 2015, putting more than 600 genes in production and offering test panels for more than 120 disorders in cardiovascular, hereditary cancer, neurology, pediatrics and other rare diseases,

Unlike most diagnostic laboratories, we openly share our pricing structure with clinicians, patients and payers, and we charge one price per indication regardless the number of genes. For third party payers that are out of contract, we charge $1,500 per sample; for payers and institutions that are in contract with us, the contracted price is as low as $950 per indication depending on their administrative requirements; and for patients who pay upfront and set up an account with us, we charge $475. We introduced this multi-tiered pricing structure in June 2015. 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.

Table of Contents

Importantly, we are providing turnaround time of less than three weeks for the substantial majority of our tests.

Today, our goal is to provide clinicians with the information they need to get the right diagnosis for their patients. We have a simple and powerful offering that is best characterized by:

Breadth. We offer comprehensive panels for more than 120 conditions in hereditary cancer, cardiology, neuromuscular, pediatric and rare diseases. We offer full gene sequencing and deletion/duplication analysis as a standard for all of our tests at no additional charge.

Quality. Collaborations with leading academic centers confirm analytical and clinical concordance with established standards. In addition, our team of genetic and medical experts have developed a proprietary score-based system enabling objective, reproducible reporting across a wide range of disease areas.

Affordability. We want to make genetic testing affordable and accessible. Our entire test menu is available starting at $475 per indication. By offering affordable testing, we are part of a movement to decrease healthcare costs while improving quality of care.

Substantiating a hypothesis that is fundamental to the success of our business model, we saw significant increases in our volume when we released additional content, including meaningful growth in orders of non-cancer tests. We expect that will continue to be the case in 2016 as we plan to increase our menu to approximately 1,000 genes in production in mid-2016 and approximately 3,000 genes in production by the end of the year.

In the cancer markets, we have expanded beyond our initial hereditary breast and ovarian cancer and now offer more comprehensive, high quality testing with more than 40 test panels, comprised of more than 70 carefully curated genes. Importantly, through our offering, we are able to detect structural genetic variations, including various inversions, segmental duplications, insertions, deletions and promoter region variants that are important for clinical grade inherited genetic testing without needing to increase the price of our tests.

We have been increasing our non-cancer volume, as well. We now provide a comprehensive cardiology test menu with more than 30 test panels, representing more than 190 carefully curated genes. The expanded offering includes large combination panels for multiple conditions, including arrhythmias, cardiomyopathies, aortopathies, familial hypercholesterolemia, pulmonary hypertension, and congenital heart disease.

We have also expanded our neuromuscular test panels, comprising nearly 100 carefully curated genes for 15 major diagnostic indications including Duchenne/Becker muscular dystrophy, dystonia, Charcot-Marie-Tooth disease, and hereditary spastic paraplegia. We also have expanded our pediatric and rare disorder test menu with more than 40 test panels, comprised of more than 140 carefully curated genes, for disorders including the RASopathies and primary ciliary dyskinesia.

One of our goals is to significantly expand our neuromuscular, rare disease and pediatric offerings in early 2016, so we can further help the large number of people who suffer from these rare conditions. With our unique offering of a comprehensive test menu with high quality and affordable prices, we believe that the many hundreds of rare disease advocacy organizations, representing many hundreds of thousands of patients, will now have a partner in providing access to comprehensive, high quality, truly affordable genetic testing services. We have demonstrated that in our model, new content leads to more volume, which has the possibility of having a positive impact for our patients, providers and payers alike.

We plan to streamline our marketing efforts in 2016 as well as expand our sales efforts with additional sales representatives. We plan to have approximately 30 sales representatives by mid-2016. Since our initial commercialization, we have marketed additional panels involved in multiple different genetic disorders, including cardiology, hematology, neurology and pediatric panels.

Table of Contents

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 efforts to lower prices and expand our test menu while maintaining high quality will allow us to accelerate market adoption of our genetic tests.

Currently, we primarily target medical geneticists and genetic counselors, 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.

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.

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.

Table of Contents

Securing reimbursement

By focusing on comprehensive, high quality and affordable genetic testing, we designed our service offering to provide benefits to payers. 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. In these cases, the clinical utility of our service is generally well established and accepted in medical practice, including in relevant clinical guidelines.

We receive payment for our services from three categories of payers: patients, institutions and third-party payers. Given the relatively low cost of our tests, a small but consistent percentage of patients whose clinicians 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 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 payers are responsible for paying for the largest percentage of tests we deliver. These third-party payers consist of private health insurers and the Centers for Medicare and Medicaid Services, or CMS. We believe that establishing coverage from CMS will be an important factor in gaining adoption by healthcare providers. We have been accepted as a Medicare provider and have recently submitted the data package that we believe is required to complete Medicare's MolDx technical assessment, which is the final step in obtaining payment from CMS for qualified testing services provided to Medicare patients under CMS criteria. We believe that completing this technical assessment and establishing coverage from CMS will be an important factor in gaining adoption by private healthcare providers.

Further, as of December 31, 2015, we had entered into reimbursement contracts with Blue Shield of California, Capital Health Plan, Ohio State University Health Plan, SelectHealth, Three Rivers Provider Network, Tufts Health Plan, and UC Davis Health System. We have also entered into an agreement with Blue Cross and Blue Shield Association which facilitates our ability to enter into agreements to provide our tests to affiliates of the Association. 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 payers in whose plans the test patients are members.

Third-party payers, including both 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 payer 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.

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.

One of our most important collaborations was with the Stanford University School of Medicine and Massachusetts General Hospital. Multi-gene panels for hereditary breast and ovarian cancer risk assessment are gaining acceptance, not only as additions to but also as replacements for traditional BRCA1 and BRACA2 testing. To help determine which tests are appropriate for any given patient, it is important to understand the analytic and clinical performance of these tests by comparison with traditional testing. This study was designed to assess concordance between our panel test to traditional BRCA1 and BRCA2 tests in more than 1,000 patients.

The data from the prospective study demonstrated 100% analytic sensitivity and specificity for the Invitae panel compared to traditional genetic test results for both sequence alterations and deletions/duplications. Variant classifications were 99.8% concordant. A total of 1,105 individuals were tested using Invitae's 29-gene hereditary cancer panel. Sequence alterations and copy number deletions/duplications were determined by next generation sequencing using our custom biochemical and bioinformatics methodologies. For these 1,105 individuals, high-quality reference and confirmatory data were available for direct comparison. Variants were classified using a framework, called Sherloc, based on the American College of Medical Genetics and Genomics 2015 guidelines using only publicly available and not proprietary data resources. Classifications were compared for 975 individuals for whom traditional BRCA1 and BRACA2 test results from Myriad Genetics were available. Data from this collaboration were published in the Journal of Molecular Diagnostics in July 2015.

In another collaboration, we worked with researchers at Massachusetts General Hospital, Harvard Medical School, Stanford University, and Beth Israel Deaconess Medical Center to determine the clinical actionability of multi-gene testing for hereditary breast and ovarian cancer, also known as HBOC, risk. Genetic testing for HBOC is evolving rapidly, owing to the recent introduction of multi-gene panels. Compared with testing for BRCA1 and BRACA2 alone, these tests identify a greater number of individuals with genetic mutations. This study addresses how often and in which ways the identification of non-BRCA1 and non-BRACA2 mutations would alter clinical management under current practice guidelines.

In this study, more than 1,000 patients were prospectively enrolled. All patients met clinical criteria for HBOC evaluation and all were tested for BRCA1 and BRACA2 and at least 23 other cancer risk genes. For the 63 patients found to have non-BRCA1 and non-BRACA2mutations, detailed clinical records and family histories were reviewed. We determined whether the positive test result would warrant consideration of a change in management in comparison with management recommendations based on personal and family history alone. These analyses were based on the most recent update to the National Comprehensive Cancer Network guidelines for HBOC and other applicable current guidelines.

In a clinically representative cohort, we found that multi-gene panel testing for HBOC yields clinically actionable findings across a broad spectrum of cancer risk genes. Compared with the results of BRCA1 and BRACA2 testing alone, these findings are likely to change risk assessment and management for substantially more patients and their family members under current practice

Table of Contents

guidelines. The results of this research, published in *JAMA Oncology* in August 2015, show that positive panel test results warrant consideration of a change in management for the patient more often than is true for BRCA1 and BRCA2 testing alone.

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

Expanding genetic testing content while driving down COGS

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 clinicians 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 2015, we reduced our COGS from approximately $1,200 at the beginning of the year to under $700 per sample accessioned at the end of the year. This came both as a result of volume growth and from our continued investment in production infrastructure to scale effectively, reducing costs in sample processing and medical interpretation while meeting what we believe to be the highest standards of quality. We plan to continue driving down COGS in 2016 to below $500 by the end of the year. Given our ambitious content goals for the year, we do not expect this to be a linear path, but given our lineup of improvements to our production process, we expect to exit 2016 at this level or below.

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 clinicians and their patients 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 clinicians to establish a system where this genetic information is linked at the point of care for appropriate use as needs arise.

As the amount of information available for each patient expands, we envision a genome management program to provide clinicians and their patients with access to that additional information to answer healthcare questions as they arise. We expect to make additional genetic content accessible to clinicians 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.

Table of Contents

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.

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, payers, industry professionals, researchers and clinical trial sponsors.

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 Clinvitae, a web property that allows clinicians 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 clinicians to share more information about their variants and connect with other patients or clinicians who might be able to contribute additional information that could affect their health and wellness. 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.

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,

Table of Contents

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.

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 Ambry Genetics, Inc.; Athena Diagnostics; Counsyl; GeneDx, a subsidiary of OPKO Health, Inc.; Myriad Genetics, Inc.; Laboratory Corporation of America Holdings; and Quest Diagnostics Incorporated 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:

breadth and depth of content;

reliability;

accessibility of results;

turnaround time of testing results;

Table of Contents

price and quality of tests;

coverage and reimbursement arrangements with third-party payers;

convenience of testing;

brand recognition of test provider;

additional value-added services and informatics tools;

client service; and

quality of website content.

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 payers. 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.

Regulation

Reimbursement

In September 2014, the American Medical Association published new CPT codes for genomic sequencing procedures that are 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 2015 payment rate for these codes by the gap-fill process. Under the gap-fill process, local Medicare Administrative Contractors, or MACs, establish rates for those codes that each MAC believes meet the criteria for Medicare coverage and considering laboratory charges and discounts to charges, resources, amounts paid by other payers for the tests, and amounts paid by the MAC for similar tests. In 2015, gapfilled payment rates were established for some, but not all, of the above-referenced codes. For those codes for which local gap-filled rates were established in 2015, a national limitation amount for Medicare has been established for 2016. Codes for which local gap-filled rates were not established in 2015 will be priced by the local MACs in 2016 insofar as an individual MAC determines that such codes should be covered. Where available, 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) has or will set adequate reimbursement rates for these 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 payer payment rates and volumes for their tests. 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 payer 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 payer payment rates for the tests. Laboratories that fail to report the required payment information may be subject to substantial civil money penalties. CMS has not yet issued a final rule implementing the reporting and rate-setting requirements under PAMA.

Table of Contents

As set forth under PAMA, for tests furnished on or after January 1, 2017, Medicare payments for clinical diagnostic laboratory tests will be paid based upon these reported private payer 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 are set to be effective starting January 1, 2017, however, given the delay in release of rulemaking to implement PAMA, it is possible that implementation will be delayed beyond 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. It is unclear whether CMS will proceed with contractor consolidation under this authorization.

PAMA also authorized the adoption of new, temporary billing codes and/or unique test identifiers for FDA-cleared or approved tests as well as advanced diagnostic laboratory tests. The American Medical Association's Current Procedural Terminology (CPT®) Editorial Panel has approved a proposal to create a new section of billing codes to facilitate implementation of this section of PAMA. At this time, it is unclear whether or when the new section of billing codes will be implemented nor is it clear how these codes would apply to our tests.

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 current certification under CLIA to perform testing at our laboratory location in San Francisco. To renew our CLIA certification, 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 licensure

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

Table of Contents

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 and/or receive specimens from laboratories in those states. Our laboratory holds the required out-of-state laboratory licenses for Florida, Maryland, New York, Pennsylvania and Rhode Island.

In addition to having a laboratory license in New York, our clinical reference laboratory in California is also required to obtain approval on a test-specific basis by the New York State Department of Health, or NYDOH, before specific testing is performed on samples from New York. Because our genomic sequencing panels are not approved by New York, we are currently prohibited from performing genomic sequencing panels on 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.

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.

Table of Contents

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.

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 requirements for protecting the privacy and security of