

Invitae Corp  
Form 10-K  
March 16, 2017

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, 2016

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 (I.R.S. Employer

incorporation or organization) Identification No.)

1400 16<sup>th</sup> Street, San Francisco, California 94103

(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:

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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 No

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 (Do not check if a smaller reporting company) 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

As of June 30, 2016, the aggregate market value of common stock held by non-affiliates of the Registrant was approximately \$135.1 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 February 28, 2017 was 42,248,590.



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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 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 service 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 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 hereditary 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.

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 2016 with four key metrics:

- Lowering cost of goods sold per test (COGS);
- Increasing our content by expanding our test menu;
- Increasing our volumes; and
- Increasing our revenues and improving reimbursement.

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 hereditary 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 payers and believe that we can help payers and the healthcare system significantly reduce their current testing expenditures.

Since our inception we have focused on the immediate market for diagnosing patients with symptomatic disease. In the future, we plan on expanding our efforts in carrier and newborn testing markets and later into the health and wellness market. As our market share grows we expect that our business will develop in three stages over the longer term:

- 1) 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.



- 2) 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.
- 3) 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

We utilize 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 clinicians and their patients.

We launched our first commercial offering in November 2013 with an offering of more than 200 genes, growing the test menu over time to include more than 1,100 genes. Our volume has grown rapidly. In 2016 we delivered approximately 57,000 billable tests and received or “accessioned” more than 59,000 commercial samples. 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 2017 as we plan to introduce our medical exome, thus increasing our menu to more than 20,000 genes. Our revenues in 2016 were \$25.0 million and, at December 31, 2016, we had 332 employees. 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 \$44.6 million, \$42.8 million and \$22.1 million in 2016, 2015 and 2014, respectively.

Our products today

Our current products consist of assays totaling over 1,100 genes that can be used for multiple indications including hereditary cancer, neurological disorders, cardiovascular disorders, pediatric disorders and other hereditary conditions.

We offer comprehensive panels for hundreds of hereditary conditions in 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. We currently offer a free re-requisition of additional data within the same indication when ordered within 90 days of the original date of service.

As our genetic testing offering grows in scale, we have begun investing in informatics solutions and infrastructure that enable sharing of genetic information to improve healthcare and clinical outcomes. In January 2017, we acquired AltaVoice, formerly PatientCrossroads, a patient-centered data company with a global platform for collecting, curating, coordinating, and delivering safeguarded data from patients and clinicians. The acquisition, complemented by several other strategic partnerships, expands our genome network, designed to connect patients, clinicians, advocacy organizations, researchers, and therapeutic developers to accelerate the understanding, diagnosis, and treatment of hereditary disease. Both companies share common commitments: patients own their data; permission-based sharing of patient data can be valuable to improving patient outcomes; patients should decide what's best for them; and using technology to remove barriers to diagnosis and treatment.

AltaVoice has developed multiple patient-centered programs, including Patient Insights Networks, also known as PINs, which enable organizations to more efficiently build engaged, research-ready patient communities, recruit for trials, educate, and track patient outcomes. Since 2007, Alta Voice has developed programs for more than 400 diseases through its work with more than 100 advocacy groups, the National Institutes of Health (NIH), Patient-Centered Outcomes Research Institute (PCORI), as well as biotech and pharmaceutical companies. Invitae's ongoing testing business combined with AltaVoice's database of more than 75,000 patients brings together valuable capabilities, technology, and data to accelerate the use of genetic information for the diagnosis and



treatment of hereditary diseases.

We are aiming to build a more robust network for combining genetic information and clinical data into a seamless network to accelerate research, clinical trials and disease management. In the future, patients who participate in the combined network will be able to access aggregate and customized information based on their genotype and phenotype and participate in new research, clinical trials, treatment planning or other related purposes

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that may benefit the individual and/or their clinician. They can also decide to share information if they feel it will benefit them or will contribute more broadly to furthering knowledge about their conditions.

In addition, we have begun partnering with biopharmaceutical companies, including AstraZeneca, BioMarin, MyoKardia, Parion and others to support clinical trial recruitment and other research-related initiatives.

## 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; Baylor Genetics; Blueprint Genetics, Inc.; Centogene AC; Color Genomics, Inc.; Connective Tissue Gene Test LLC; Counsyl, Inc.; Courtagen Life Sciences, Inc.; Eurofins Scientific; GeneDx, a subsidiary of OPKO Health, Inc.; MNG Laboratories, LLC; Myriad Genetics, Inc.; Laboratory Corporation of America Holdings; PreventionGenetics, LLC; 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;
- quality;
- accessibility of results;
- turnaround time of testing results;
- 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
- utility 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, and 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, or AMA, published new Current Procedural Terminology, or 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 was established for 2016. Codes for which local gap filled rates were not established in 2015 were priced by the local MACs in 2016 insofar as an individual MAC determined 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.

The AMA also released several CPT codes effective January 2016 that may be appropriate to report certain of our tests. In a November 2015 final determination, CMS set the calendar year 2016 CLFS payment rate for these new codes by the gap-fill process. CMS and the local MACs went through the gap-fill process in 2016 and announced final gap-filled rates for 2017 on September 30, 2016. The calendar year 2017 national limitation amounts for certain codes are significantly less than the rates at which we have historically offered our tests.

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 the regulations implementing PAMA, laboratories that realize at least \$12,500 in Medicare CLFS revenues during the six month reporting period and that receive the majority of their Medicare revenue from payments made under the CLFS or the Physician Fee Schedule must report, beginning in 2017, 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 are 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.

As set forth under the regulations implementing PAMA, for tests furnished on or after January 1, 2018, 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, 2018. Any reductions to payment rates resulting from the new methodology are limited to 10% per test per year in each of the years 2018 through 2020 and to 15% per test per year in each of 2021 through 2023.

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 has created a new section of billing codes, Proprietary Laboratory Analyses, to facilitate implementation of this section of PAMA. At this time, it is unclear 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 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. We are licensed by the state of New York to perform tests for over 600 genes, including tests for cardiology, dermatology, hematology, hereditary cancer, immunology, metabolic disorders and newborn screening, neurology, ophthalmology, and pediatric genetics.

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

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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. Subsequently, on January 13, 2017, the FDA published a “discussion paper” in which the agency outlined a substantially revised “possible approach” to the oversight of LDTs. The discussion paper explicitly states that it is not a final version of the 2014 draft guidance and that it does not represent the agency’s “formal position”; rather, the discussion paper represents the latest iteration of the agency’s thinking on LDTs, which the agency posted to “spur further dialogue”. Notably, in the discussion paper, the agency expressed its willingness to consider “grandfathering” currently marketed LDTs from most or all FDA regulatory requirements. It is unclear at this time when, or if, the FDA will finalize its plans to end enforcement discretion, and even then, the new regulatory requirements are expected to be phased in over time. 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.

#### 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 protected health information used or disclosed by most healthcare providers and other covered entities and their respective 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. A subcontractor means any person to whom a business associate delegates a function, activity, or service, other than in the capacity of the business associate's workforce. As a general rule, a covered entity or business associate may not use or disclose protected health



information except as permitted under the privacy regulations. The privacy regulations also set forth certain rights that an individual has with respect to his or her protected health information maintained by a covered entity or business associate, including the right to access or amend certain records containing his or her protected health information, or to request restrictions on the use or disclosure of his or her protected health information.

Covered entities and business associates also must comply with the security regulations, which establish requirements for safeguarding the confidentiality, integrity, and availability of protected health information that is electronically transmitted or electronically stored. In addition, HITECH established, among other things, certain breach notification requirements with which covered entities and business associates must comply. In particular, a covered entity must notify any individual whose unsecured protected health information is breached according to the specifications set forth in the breach notification rule. A covered entity must also notify the Secretary of the U.S. Department of Health and Human Services and, under certain circumstances, the media.

The HIPAA privacy, security, and breach notification 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 or covertly, in cash or in kind, in order to induce or in return for the referral of an individual for the furnishing of or 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 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 payer, including commercial insurers.

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There are also federal laws related to healthcare fraud and false statements, among others, relating to healthcare matters. The healthcare fraud statute prohibits, among other things, knowingly and willfully executing a scheme to defraud any healthcare benefit program, including private payers. A violation of this statute is a felony and may result in fines, imprisonment, or exclusion from governmental payer 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 payer 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 payer 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 \$10,781 to \$21,563 for each false claim.

In addition, various states have enacted false claim laws analogous to the federal False Claims Act, and some of these state laws apply where a claim is submitted to any third party payer and not only a governmental payer 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 for items or services reimbursable by Medicare or a state healthcare program, unless an exception applies.

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

A federal law directed at "self referrals," commonly known as the "Stark Law," prohibits a physician from making referrals of Medicare patients for certain designated health services, including laboratory services, to an entity with which the physician, or an immediate family member, has a direct or indirect financial relationship, unless an exception applies. The prohibition also extends to payment for any services referred in violation of the Stark Law. A physician or entity that 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. 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 services furnished pursuant to a prohibited referral, 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 clinicians 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 enforced against entities that have a physical presence in the state.

#### 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. In recent 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 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).

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, three pending U.S. utility patent applications, three pending PCT applications, two pending U.S. provisional patent applications and nine pending non U.S. 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 clinicians. 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 30 countries and are currently pending in more than two countries. Applications for our logo (circle design) have been obtained in 28 countries and are currently pending in more than three countries, and one application is pending for INVITAE with the logo.

#### Environmental matters

Our operations require the use of hazardous materials (including biological materials) that 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 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, 2016, 2015 and 2014 the percentages of our revenue attributable to sources in the United States were 83%, 65% and 67% respectively; the percentages of our revenue attributable to sources in Canada were 10%, 25% and 19% respectively; and the percentages of our revenue attributable to countries excluding the United States and Canada were 7%, 10% and 14% respectively.

As of December 31, 2016 and 2015, we had net long lived assets in the United States of \$23.8 million and \$17.2 million, respectively, and net long lived assets in Chile of \$0 and \$1.5 million, respectively. As of December 31, 2016 and 2015, we did not have long lived assets outside of the United States and Chile.

As of December 31, 2016, substantially all of our revenue has been derived from sales of our assays. A single customer accounted for 11% of our revenue for the year ended December 31, 2016, a second single customer accounted for 13% of our revenue for the year ended December 31, 2015 and a third single customer accounted for 15% of our revenue for the year ended December 31, 2014.

#### 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. In February 2015 we completed an initial public offering of our common stock.

Our principal executive offices are located at 1400 16<sup>th</sup> Street, San Francisco, California 94103, 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

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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).

ITEM 1A. Risk Factors.

Risks related to our business and strategy

We expect to continue incurring significant losses, and we may not successfully execute our plan to achieve or sustain profitability.

We have incurred substantial losses since our inception. For the years ended December 31, 2016, 2015 and 2014, we had net losses of \$100.3 million, \$89.8 million and \$47.5 million, respectively. At December 31, 2016, we had an accumulated deficit of \$275.2 million. To date, we have generated limited revenue, and we expect to continue to incur significant losses. In addition, these losses may 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. Although we plan on achieving profitability by the end of 2018, we may not successfully execute our plan. 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 commercially launched our initial assay in late November 2013; accordingly, we have a relatively limited operating history upon which you can evaluate our business and prospects. 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 and maintain coverage and reimbursement by healthcare payers, provide rapid test turnaround times with accurate results at low prices, 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.

If third-party payers, including managed care organizations, private health insurers and government health plans do not provide adequate reimbursement for our tests or we are unable to comply with their requirements for reimbursement, 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 reimbursement for our tests from third-party payers. Reimbursement by a payer may depend on a number of factors, including a payer's determination that a test is appropriate, medically necessary, and cost-effective.

Since each payer 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 payer 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 many of the large commercial third-party payers in the United States, and in April 2016, the Centers for Medicare and Medicaid Services began providing reimbursement for our multi-gene tests for hereditary breast cancer-related disorders. We believe that establishing adequate reimbursement from Medicare is an important factor in gaining adoption from healthcare providers. Our claims for reimbursement from commercial payers 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.

In cases where we have established reimbursement rates with third-party payers, we face additional challenges in complying with their procedural requirements for reimbursement. These requirements may vary from payer to payer, and it may be time-consuming and require additional resources to meet these requirements. We may also experience delays in or denials of coverage if we do not adequately comply with these requirements. In addition, we have experienced, and may continue to experience, temporary delays in reimbursement when we transition to being an in-network provider with a payer.

We expect to continue to focus our resources on increasing adoption of, and expanding coverage and reimbursement for, our current tests and any future tests we may develop. If we fail to expand 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 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. We believe our existing cash and cash equivalents as of December 31, 2016, revenue from the sale of our tests and the net proceeds of a term loan, which was funded in March 2017, will be sufficient to meet our anticipated cash requirements for the 12-month period following the filing date of this report. We intend to generate sufficient cash from operations to fund our future operating needs, but there can be no assurance we will be able to do so. We may need additional funding to finance our operations prior to achieving profitability. 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. Our obligations under our new loan agreement are subject to covenants, including quarterly covenants to achieve certain revenue levels as well as additional covenants, including limits on our ability to dispose of assets, undergo a change in control, merge with or acquire other entities, incur debt, incur liens, pay dividends or other distributions to holders of our capital stock, repurchase stock and make investments, in each case subject to certain exceptions. The incurrence of additional indebtedness or the issuance of certain equity securities could result in increased fixed payment obligations and could also 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 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 continue to invest heavily in order to significantly scale our infrastructure, including our testing capacity and information systems, expand our commercial operations, customer service, billing and systems processes and enhance our internal quality assurance program. We need to continue 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. In addition, we need to continue to expand our sales force with qualified and experienced personnel. 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 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.

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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 Ambry Genetics, Inc., Athena Diagnostics, Baylor Genetics, Blueprint Genetics, Inc., Centogene AC, Color Genomics, Inc., Connective Tissue Gene Test LLC, Counsyl, Inc., Courtagen Life Sciences, Inc., Eurofins Scientific, GeneDx, a subsidiary of OPKO Health, Inc., MNG Laboratories, LLC, Myriad Genetics, Inc., or Myriad, and PreventionGenetics, LLC;

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 including Illumina, Inc., who is also one of our suppliers.

Hospitals, academic medical centers and eventually physician practice groups and individual clinicians 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:

- breadth and depth of content;
- reliability;
- accessibility of results;
- turnaround time of testing results;
- 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.

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 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. Increased competition and cost-saving initiatives on the part of governmental entities and other third-party payers 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.

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 are moving into a production facility in the first quarter of 2017, which could also affect our business operations and our ability to perform our tests. We may not be able to maintain the quality of or expected turnaround times for our tests, or satisfy customer demand as it grows. We will need to continue expanding our sales force to facilitate our growth and we may have difficulties locating, recruiting, training and retaining sales personnel. 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. 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.

Our success will depend in part on our ability to generate sales using our internal sales team and through alternative marketing strategies.

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 our 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 clinicians outside of oncology may not be successful, or may be difficult to do successfully without significant additional selling and marketing efforts and expense. In fact, we have significantly increased the size of our sales force in the first quarter of 2017. Our future sales will also 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 distributors to assist with sales, logistics, education, and customer support. 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.

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. In January 2017, we acquired AltaVoice (formerly PatientCrossroads), a privately-owned, patient-centered data company. With respect to AltaVoice and any acquisitions we may make 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 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 future 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. 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. In addition, our Loan Agreement limits our ability to merge with or acquire other entities, incur debt, incur liens, pay dividends or other distributions to holders of our capital stock and make investments, in each case subject to certain exceptions.

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.

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If we are not able to continue 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 continuing to drive 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 continued 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 further demand for our tests, we will need to continue to make clinicians 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 our current customer base. In addition, clinicians 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 clinicians 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. 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 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.

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 clinicians 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 clinicians 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.

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.

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, payers, 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 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 payers 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. In addition, in October 2015, the

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European Court of Justice invalidated a safe harbor agreement between the United States and European Union member states, which addressed how many U.S. companies handle personal information of their European customers. In October 2015, the Court of Justice of the European Union declared the Safe Harbor invalid. In February 2016, the European Commission announced an agreement with the U. S. Department of Commerce to replace the invalidated Safe Harbor agreement on transatlantic data flows with a new E.U.-U.S. "Privacy Shield." In July 2016, the European Commission approved the Privacy Shield. Laws governing data privacy and security are constantly evolving. In addition, it is possible that 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 can provide no assurance that we are or will remain in compliance with diverse privacy and security requirements in all of the jurisdictions in which we do business. Failure to comply with privacy and security requirements could result in civil or criminal penalties, which could have a material adverse effect on our business.

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., Roche Holdings Ltd., and Thermo Fisher Scientific Inc. 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 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 production facility in San Francisco, California, which we transitioned into in the first quarter of 2017. 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.

The loss of any member or change in structure 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 employees. In addition, we do not have a long-term retention agreement in place with our president and chief executive officer. We also recently announced that our former chief executive officer and chairman of the board was appointed executive chairman and our former president and chief operating officer was appointed president and chief executive officer. We may experience difficulties as our organization adapts to this new leadership structure.

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.

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, 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 clinicians, billing payers, 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.

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 distribution arrangements in several countries, and our business strategy contemplates significant international expansion. 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 payer reimbursement regimes, government payers, 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.

#### 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. Subsequently, on January 13, 2017, the FDA published a "discussion paper" in which it outlined a substantially revised "possible approach" to the oversight of LDTs. The discussion paper explicitly states that it is not a final version of the 2014 draft guidance and that it does not represent the FDA's "formal position"; rather, the discussion paper represents the latest iteration of the FDA's thinking on LDTs, which the FDA posted to "spur further dialogue". Notably, in the discussion paper, the FDA expressed its willingness to consider "grandfathering" currently marketed LDTs from most or all FDA regulatory requirements. 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 FDA will finalize its plan to end enforcement discretion, and even then, the new regulatory requirements are expected to be phased-in over time. 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.

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 payers, for our tests. We have current CLIA certification to conduct our tests at our laboratory in San Francisco. To renew this certification, 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 out-of-state laboratory licenses to conduct testing on specimens from Florida, Maryland, New York, Pennsylvania and Rhode Island. In addition to having a laboratory license in New York, our clinical reference laboratories are approved on test-specific bases by the New York State Department of Health, or NYDOH. 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. CAP asserts that its program is "designed to go well beyond regulatory compliance" and 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.

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 and expand vicarious liability, 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 payer, 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 clinicians 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 payers; and
- 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.

Healthcare policy changes, including 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 applied to sales of taxable medical devices from January 1, 2013 through December 31, 2015. The medical device tax has been suspended for 2016 and 2017, but is scheduled to return beginning in 2018. 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 that are in development.

- establishes an Independent Payment Advisory Board, or IPAB, to reduce the per capita rate of growth in Medicare spending if expenditures exceed certain targets. At this point, the triggers for IPAB proposals have not been met; it is unclear when such triggers may be made met in the future and when any IPAB-proposed reductions to payments could take effect.

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, effective January 1, 2015, the AMA released several new codes to report genomic sequencing procedures. 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, gap-filled payment rates were established for some, but not all, of the above-described codes. For those codes for which local gap-filled rate(s) were established in 2015, a national limitation amount for Medicare was established for 2016. Codes for which local gap-filled rates were not established in 2015 were 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.

The AMA also released several CPT codes effective January 1, 2016 that may be appropriate to report certain of our tests. In a November 2015 final determination, CMS set the calendar year 2016 CLFS payment rate for these new codes by the gap-fill process. CMS and the local MACs went through the gap-fill process in 2016 and announced final gap-filled rates for 2017 on September 30, 2016. The calendar year 2017 national limitation amounts for certain codes are significantly less than the rates at which we have historically offered our tests.

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 the final rule that implements PAMA, which was promulgated by CMS in June 2016, clinical laboratories must report to CMS private payer rates beginning in 2017 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.

We do not believe that our tests meet the definition of advanced diagnostic laboratory tests, but in the event that we seek designation for one or more of our tests as an advanced diagnostic laboratory test and the tests are determined by CMS to meet these criteria or new criteria developed by CMS, we would be required to report private payer data for

those tests annually. Otherwise, we will be required to report private payer rates for our tests on an every three years basis. Laboratories that fail to timely report the required payment information may be subject to substantial civil money penalties.

As set forth in the PAMA final rule, for tests furnished on or after January 1, 2018, 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, similar to prior law. Initial payment rates for new advanced diagnostic laboratory tests will be based on the actual list charge for the laboratory test. In April 2016, we announced that CMS had begun providing payments for our multi-gene tests for hereditary breast cancer-related disorders at an interim payment per test of \$622.53. On October 3, 2016, we announced that CMS had set final pricing for our multi-gene tests for hereditary breast cancer-related disorders at \$925.00 per test.

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 CPT® Editorial Panel approved a proposal to create a new section of billing codes to facilitate implementation of this section of PAMA, but it is unclear how this new section of billing codes will be adopted by CMS, and it is unclear how these codes would apply to our tests.

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 payers 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.

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

We are 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.

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## Risks related to our intellectual property

Litigation or other proceedings or third-party claims of intellectual property infringement or misappropriation may 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. As we continue to commercialize our tests in their current or an updated form, launch different and expanded tests, and enter new markets, 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. Our activities may be subject to claims that we infringe or otherwise violate patents or other intellectual property rights owned or controlled 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. Any adverse ruling or perception of an adverse ruling in defending ourselves could have a material adverse impact on our business and stock price. In the event of a successful claim of infringement against us by a third party, we may have to (1) pay substantial damages, possibly 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/or (4) redesign any infringing tests or other activities, which may be impossible or require substantial time and monetary expenditure, 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.

Although we view current U.S. Supreme Court precedent to be aligned with our belief that naturally occurring DNA sequences and detection of natural correlations between observed facts (such as patient genetic data) and an understanding of that fact's implications (such as a patient's risk of disease associated with certain genetic variations) 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 current law. 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 and detection of natural correlations between observed facts and an understanding of that fact's implications should not be patentable, which could result in third parties newly claiming that our business practices infringe patents drawn from categories of patents which we currently view to be invalid as directed to unpatentable subject matter.

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 those 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 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.

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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.

#### Risks related to being a public company

We 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 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 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 substantially increase our legal, accounting and financial compliance costs, require that we hire additional personnel and make some activities more time-consuming and costly. It may also be more expensive for us to obtain director and officer liability insurance.

If we are unable to 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.

We are required to maintain internal control over financial reporting and to report any material weaknesses in such internal controls. Section 404 of the Sarbanes-Oxley Act requires that we evaluate and determine the effectiveness of our internal control over financial reporting and 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 have only recently compiled the system and process documentation necessary to perform the evaluation needed to comply with Section 404 of the Sarbanes-Oxley Act. We will need to maintain and enhance these processes and controls as we grow and we may require additional personnel and resources to do so.

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.

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 until December 31, 2020, 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 payers; and

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.

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

At December 31, 2016, directors, executive officers, 5% or greater stockholders and their affiliates beneficially owned, in the aggregate, 63% of our outstanding capital stock. As a result, these stockholders will be able to exercise significant influence over all matters submitted to our stockholders 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.

At December 31, 2016, our total gross deferred tax assets were \$92.9 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, our loan agreement prohibits us from paying 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;
- 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.

Our production facility and headquarters is located in San Francisco, California, where we currently lease and occupy 103,213 square feet of laboratory and office space. The lease for this facility expires in July 2026 and we may renew the lease for an additional ten years. We began to take occupancy of this facility in the fourth quarter of 2016 and we expect to complete the move to the new facility in the first quarter of 2017.

Previously, our corporate headquarters and laboratory operations were located at another location in San Francisco, California, where we currently lease 7,795 square feet of laboratory and office space. The lease for our former headquarters expires in August 2017, with a five year extension at our option. Additionally, in a nearby building in San Francisco, we sublease 24,536 square feet of office space under an agreement that expires in April 2017.

We also lease additional facilities in Palo Alto and Oakland, California.

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 are 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, and the resolution of any such claims could be material.

ITEM 4. Mine Safety Disclosure.

Not applicable.

Executive Officers of the Registrant

The names of our executive officers and other corporate officers, and their ages as of March 1, 2017, are as follows:

Name	Age	Position
Executive officers		
Randal W. Scott, Ph.D.	59	Executive Chairman and Director President, Chief Executive Officer, Chief Operating Officer, Director and
Sean E. George, Ph.D.	43	Co-Founder
Lee Bendekgey	59	Chief Financial Officer and Secretary
Robert L. Nussbaum, M.D.	67	Chief Medical Officer

Other corporate officers

Thomas R. Brida	46	General Counsel
Patricia E. Dumond	52	Chief Accounting Officer
Katherine Stueland	41	Chief Commercial Officer

Randal W. Scott, Ph.D. has served as our Chairman since August 2012 and as a director since 2010. From August 2012 through January 2017, Dr. Scott served as our Chief Executive Officer. From 2000 through August

2012, Dr. Scott held a number of positions at Genomic Health, Inc., a publicly held genomic information company which he co-founded in 2000, most recently serving as the Chief Executive Officer of a wholly-owned subsidiary of Genomic Health, and as a director. Dr. Scott also served as Executive Chairman of the Board of Genomic Health from January 2009 until March 2012 and as 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.

Sean E. George, Ph.D. is one of our co-founders and is our Chief Executive Officer, a position he also held from January 2010 through August 2012. Dr. George has served as our President and Chief Operating Officer since August 2012. He has also served as a director since January 2010. 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.

Lee Bendekgey has served as our Chief Financial Officer since November 2013. Mr. Bendekgey also served as our General Counsel from November 2013 through January 2017. Prior to joining our company, he was the General Counsel of DNAnexus, Inc., a cloud-based genome informatics and data management company, 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. Mr. Bendekgey also 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.

Robert L. Nussbaum, M.D. has served as our Chief Medical Officer since August 2015. From April 2006 to August 2015, he was chief of the Division of Genomic Medicine at UCSF Health where he also held leadership roles in the Cancer Genetics and Prevention Program beginning in January 2009 and the Program in Cardiovascular Genetics beginning in July 2007. From April 2006 to August 2015, he served as a member of the UCSF Institute for Human Genetics. Prior to joining UCSF Health, Dr. Nussbaum was chief of the Genetic Disease Research Branch of the National Human Genome Research Institute, one of the National Institutes of Health, from 1994 to 2006. He is a member of the Institute of Medicine and a fellow at the American Academy of Arts and Sciences. Dr. Nussbaum is a board-certified internist and medical geneticist who holds a Bachelor of Science in Applied Mathematics from Harvard College and an M.D. from Harvard Medical School in the Harvard-MIT joint program in Health Sciences and Technology. He completed his residency in internal medicine at Barnes-Jewish Hospital and a fellowship in medical genetics at the Baylor College of Medicine.

Thomas R. Brida has served as our General Counsel since January 2017. Mr. Brida also served as our Deputy General Counsel from January 2016 to January 2017. Prior to joining Invitae, he was Associate General Counsel at Bio-Rad Laboratories, a life science research and clinical diagnostics manufacturer, from January 2004 to January 2016. He holds a B.A. from Stanford University and a J.D. from U.C. Berkeley School of Law.

Patricia E. Dumond has served as our Chief Accounting Officer since September 2013. From 2003 to August 2013, she held various financial positions at Genomic Health, Inc., most recently as Senior Director, Finance. She holds a B.S. in finance with a minor in accounting from California State University - Sacramento.

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Katherine A. Stueland has served as our Chief Commercial Officer since October 2016. From January 2014 to October 2016, she served as our head of communications and investor relations. Prior to joining Invitae, Ms. Stueland was a Principal at Vivo Communications, a healthcare communications company, from 2012 to 2014. Previously, she served as Vice President, Communications and Investor Relations at Dendreon Corporation, a biotechnology company. Ms. Stueland holds a B.S in English Literature from Miami University in Ohio.

## 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. The following table sets forth for the periods indicated the high and low sales prices per share of our common stock on the New York Stock Exchange:

	High	Low
<b>Year Ended December 31, 2015</b>		
First quarter (from February 12, 2015)	\$22.35	\$16.30
Second quarter	\$17.43	\$10.50
Third quarter	\$15.48	\$6.58
Fourth quarter	\$10.10	\$6.46
<b>Year Ended December 31, 2016</b>		
First quarter	\$11.25	\$5.66
Second quarter	\$11.85	\$7.14
Third quarter	\$9.84	\$7.22
Fourth quarter	\$9.50	\$5.76

On February 28, 2017, the closing price of our common stock as reported on the New York Stock Exchange was \$10.31 per share.

As of February 28, 2017, there were 32 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. In addition, the terms of our Loan Agreement prohibit the payment of dividends.

## Stock performance graph

The following information shall not be deemed to be soliciting material or to be filed with the SEC, or subject to Regulations 14A or 14C under the Securities Exchange Act of 1934 (“Exchange Act”) or to the liabilities of Section 18 of the Exchange Act nor shall such information be incorporated by reference into any future filing under the Securities Act or the Exchange Act, except to the extent that we specifically incorporate it by reference into such filing.

Comparison of Historical Cumulative Total Return Among Invitae Corporation, the S&P 500 Index and the S&P 500 Healthcare Index(\*).

(\*)The above graph shows the cumulative total stockholder return of an investment of \$100 in cash from February 12, 2015 (the date our common stock commenced trading on the New York Stock Exchange) through December 31, 2016 for: (i) our common stock; (ii) the S&P 500 Index; and (iii) the S&P 500 Healthcare Index. All values assume reinvestment of the full amount of all dividends. The comparisons in the table are required by the SEC and are not intended to be forecasts or indicative of future stockholder returns.

	2/12/2015	12/31/2015	12/31/2016
Invitae Corporation	\$ 100.00	\$ 48.15	\$ 46.57
S&P 500	\$ 100.00	\$ 97.87	\$ 107.20
S&P 500 Healthcare Index	\$ 100.00	\$ 102.41	\$ 97.94

#### 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 \$105.7 million in net proceeds after deducting underwriting discounts and commissions of \$8.2 million and offering expenses of approximately \$2.9 million payable by us. We registered the shares under the Securities Act of 1933 on a Registration Statement on Form S-1 (Registration No. 333-201433), which was declared effective on February 11, 2015, and on a Registration Statement on Form S-1 (Registration No. 333-202040), which was declared effective on February 11, 2015. The net proceeds from the offering described above have been used and will be used to support our operations including funding research and development, selling and marketing activities, capital expenditures and corporate and administrative expenses. 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).

## 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, 2016 and 2015 and the selected consolidated statements of operations data for each of the years ended December 31, 2016, 2015, and 2014 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, 2014, 2013 and 2012 and the selected consolidated statement of operations data for the years ended December 31, 2013 and 2012 have been derived from our audited consolidated financial statements not included in this report. Historical results are not necessarily indicative of results to be expected in any future period.

	Year Ended December 31,				
	2016	2015	2014	2013	2012
	(In thousands except share and per share data)				
<b>Consolidated Statements of Operations Data</b>					
Revenue	\$25,048	\$8,378	\$1,604	\$148	\$—
<b>Costs and operating expenses:</b>					
Cost of revenue (1)	27,878	16,523	5,624	667	—
Research and development (1)	44,630	42,806	22,063	16,039	5,557
Selling and marketing (1)	28,638	22,479	8,669	2,431	—
General and administrative (1)	24,085	16,047	12,600	5,764	3,004
Total costs and operating expenses	125,231	97,855	48,956	24,901	8,561
Loss from operations	(100,183 )	(89,477 )	(47,352 )	(24,753 )	(8,561 )
Other income (expense), net	348	(94 )	(79 )	(26 )	2
Interest expense	(421 )	(211 )	(61 )	(59 )	(43 )
Net loss	\$(100,256 )	\$(89,782 )	\$(47,492 )	\$(24,838 )	\$(8,602 )
Net loss attributable to common stockholders	\$(100,256 )	\$(89,782 )	\$(47,492 )	\$(24,989 )	\$(9,014 )
Net loss per share attributable to common					
stockholders, basic and diluted (2)	\$(3.02 )	\$(3.18 )	\$(56.14 )	\$(36.13 )	\$(14.18 )
<b>Shares used in computing net loss per common</b>					
share, basic and diluted	33,176,305	28,213,324	846,027	691,731	635,705

(1) Includes employee stock based compensation as follows:

	Year Ended December 31,				
	2016	2015	2014	2013	2012
	(In thousands)				
Cost of revenue	\$1,836	\$368	\$102	\$11	\$—
Research and development	4,525	1,545	382	165	46
Selling and marketing	1,677	688	216	42	—
General and administrative	2,661	876	271	42	19
Total stock based compensation	\$10,699	\$3,477	\$971	\$260	\$65

(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.

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	As of December 31,				
	2016	2015	2014	2013	2012
	(In thousands)				
<b>Consolidated Balance Sheet Data:</b>					
Cash and cash equivalents	\$66,825	\$73,238	\$107,027	\$43,070	\$21,801
Working capital	87,047	120,433	102,020	41,577	21,043
Total assets	130,651	156,676	128,778	53,103	25,973
Capital lease obligations	1,575	3,164	3,535	2,001	1,215
Debt	12,102	7,040	—	—	—
Convertible preferred stock	—	—	202,305	86,574	36,755
Accumulated deficit	(275,218)	(174,962)	(85,180)	(37,688)	(12,850)
Total stockholders' equity (deficit)	99,074	138,376	(83,576)	(37,280)	(12,759)

#### 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. We now have more than 1,100 genes in production and provide a variety of diagnostic tests that can be used in multiple indications. These additions to our test menu have resulted from a series of process improvements that have enabled us to continue to expand our test menu while maintaining our strategy of lowering the cost of genetic testing.

We have continued to experience rapid growth. For the years ended December 31, 2016 and 2015 our revenue was \$25.0 million and \$8.4 million, respectively and we incurred net losses of \$100.3 million and \$89.8 million, respectively. At December 31, 2016, we had an accumulated deficit of \$275.2 million. We increased our number of employees to 332 at December 31, 2016 from 280 on December 31, 2015. Our sales force grew to 51 at December 31, 2016 from 26 at December 31, 2015, and in January 2017, we hired an additional 10 sales personnel. We expect headcount will continue to increase in 2017, as we add staff to support anticipated growth.

Since our commercial launch through December 31, 2016, we have delivered approximately 79,800 billable tests. Sales of our tests have grown significantly. In 2015 we generated approximately 19,000 billable tests, in 2016 we generated approximately 57,000 billable tests. On a historical basis through December 31, 2016, approximately 23% of the billable tests we performed have been billable to institutions and patients, and the remainder have been billable to third-party payers. Many of the gene tests on our assays are tests for which private insurers reimburse. However, when we do not have reimbursement policies or contracts with private insurers, our claims for reimbursement 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 in achieving reimbursement, we may be paid at lower rates than if we were under contract with the third-party payer. 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 in our business. In 2015 we entered into a lease agreement for a new production facility and headquarters in San Francisco, California. This lease expires in July 2026 and at December 31, 2016, aggregate future minimum lease payments for the new facility are approximately \$69.7 million. We expect to incur capital expenditures for the new facility of at least \$12.0 million and we will receive a total lease incentive of \$5.2 million in the form of reimbursement from the landlord for a portion of the costs of leasehold improvements that we have made to the new facility.

As a result of these and other factors, we expect to incur operating losses for the near-term 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, achieve broad reimbursement coverage for our tests from third-party payers, increase the number of strategic 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

##### Number of billable tests

The growth in our genetic testing business is tied to the number of tests for which we bill third-party payers, 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.

##### Success obtaining and maintaining reimbursement

Our ability to increase the number of billable tests and our revenue will depend in part on our success achieving broad reimbursement coverage for our tests from third-party payers. Reimbursement may depend on a number of factors, including a payer's determination that a test is appropriate, medically necessary and cost-effective. Because each payer 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, clinicians 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 clinicians. We believe that establishing coverage from third-party payers, including the Centers for Medicare and Medicaid Services, or CMS, is an important factor in gaining adoption by ordering clinicians. We have received approval as a Medicare provider, which allows us to bill for our services to Medicare patients. In October, 2016, we announced that CMS had set final pricing for our multi-gene tests for hereditary breast cancer-related disorders at \$925.00 per test, an increase from the interim payment per test of \$622.53. In October, 2015, we entered into a National Master Business Agreement (the "Agreement") with Blue Cross and Blue Shield Association ("BCBSA"). The Agreement facilitates our ability to enter into supply agreements for our products and services with BCBSA affiliates, licensees and certain other entities. The Agreement does not provide for the sale of our products or services directly, nor is there any commitment by BCBSA to purchase products or services from us. As of December 31, 2016, we had secured payer contracts with several regional BCBSA plans, as well as with other third-party payers, providing coverage for patients in a total of ten states, as well as those covered by the Federal Employee Plan. In July 2016, we entered into an agreement to become part of Aetna's laboratory network, effective in August 2016. In October, 2016, we announced that we entered into national provider agreements for laboratory services with each of UnitedHealthcare Insurance Company and Humana, effective January 1, 2017 and December 1, 2016, respectively. The addition of these and other provider agreements, once effective, brings our current total covered lives in network to over 175 million.

In cases where we have established reimbursement rates with third-party payers, we face additional challenges in complying with their procedural requirements for reimbursement. These requirements may vary from payer to payer, and it may be time-consuming and require additional resources to meet these requirements. We may also experience delays in or denials of coverage if we do not adequately comply with these requirements. In addition, we have experienced, and may continue to experience, temporary delays in reimbursement when we transition to being an

in-network provider with a payer.

We expect to continue to focus our resources on increasing adoption of, and expanding coverage and reimbursement for, our current tests and any future tests we may develop. However, if we are not able to continue to obtain and maintain adequate reimbursement from third-party payers for our testing services and expand the base of clinicians ordering our tests, we may not be able to effectively increase the number of billable tests or our revenue.

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#### 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 assays and laboratory processes, modifying our platform-agnostic assays and laboratory processes to use materials and technologies that provide equal or greater quality at lower cost, improving how we manage our materials 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.

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

We plan to continue to invest significantly in our genetic testing and information management 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 our genetic interpretation and report sign-out procedures, to scale our customer service capabilities and to 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. We will also incur additional costs related to the build-out of our new production facility and headquarters. In addition, we expect to incur ongoing expenses as a result of operating as a public company. The expenses we incur may vary significantly by quarter, 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. While we recognized \$3.6 million of test revenue on an accrual basis in the year ended December 31, 2016, and while we anticipate the number of payers for whom we recognize revenue upon delivery of test results will increase in the future, we do not expect to recognize significant amounts of revenue on an accrual basis for some time. Until we achieve and maintain a predictable pattern of collection at a consistent payment amount from a large number of payers, we will continue to recognize the substantial majority of our revenue when cash is received. Because the timing and amount of cash payments received from payers is difficult to predict, we expect that our revenue will fluctuate significantly in any given quarter.

For the years ended December 31, 2016, 2015 and 2014, amounts billed for tests delivered totaled \$62.6 million, \$24.3 million, and \$6.6 million, respectively. In the year ended December 31, 2016, we recognized revenue of \$21.7 million related to amounts billed for tests delivered during 2016, \$0.2 million related to collaboration revenue earned in 2016, \$2.9 million related to amounts billed for tests delivered during 2015 and \$0.2 million related to amounts billed for tests delivered in 2014. Of the total revenue recognized for the years ended December 31, 2016 of \$25.0 million, \$21.3 million was recognized for test revenue upon cash receipt, \$3.6 million was recognized for test revenue on an accrual basis and \$0.1 million was recognized for collaboration revenue on an accrual basis. 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 collection history. Notwithstanding our efforts to obtain payment for these tests, payers 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 payers and claims denials. In addition, private payers often ask us to refrain from submitting claims for a period of up to 60 days after contract execution, which can cause

the timing of payments to vary significantly during the months after contract signing, which may in turn cause our revenues to vary significantly from quarter to quarter.

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 affect our 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. For most of our customers, we do not have sufficient history of collection and are not yet able to determine a predictable pattern of collection, and therefore 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 payers 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 clinicians 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 a 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. These costs are principally for process development associated with our efforts to expand the number of genes we can evaluate in our tests, with our efforts to lower the cost of performing our test. In addition, we incur process development costs to further develop the software we use to operate our laboratory, analyze the data it generates, process customer orders, deliver reports and automate our business processes. 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 in 2017 will be approximately equal to those incurred in 2016, as we continue our efforts to develop additional tests and reduce testing costs.

##### 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 expenses will increase significantly in 2017, compared to 2016, primarily driven by the cost of hiring additional sales account executives 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 in 2017, compared to 2016, as we continue to scale our operations.

## Other income (expense), net

Other income (expense), net, primarily consists of interest income and the net exchange gain/loss on foreign currency transactions related to the operations of our subsidiary in Chile. We closed our Chilean facility in 2016.

## Interest expense

Interest expense is attributable to our financing obligations under capital lease agreements and our Loan and Security Agreement.

## 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 assays. 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 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 payer's payment pattern. We review the number of tests paid against the number of tests billed over a period of at least several months and the payer'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. For most payers, we have not been able to demonstrate a predictable pattern of collectability, and therefore recognize revenue when payment is received. For payers who have demonstrated a consistent pattern of payment of tests billed at appropriate amounts, we recognize revenue upon delivery of test results.

## Stock-based compensation

Stock-based compensation expense is measured at the date of grant and is based on the estimated fair value of the award. Compensation cost is recognized as expense on a straight-line basis over the vesting period for options and restricted stock unit, or RSU, awards and on an accelerated basis for performance based restricted stock unit, or PRSU, awards. We recognize stock-based compensation expense associated with PRSU grants when we determine the

achievement of performance conditions is probable. In determining the fair value of stock options and Employee Stock Purchase Plan, or ESPP, purchases, we estimate the grant date fair value, and the resulting stock-based compensation expense, using the Black-Scholes option-pricing model. We estimate the grant date fair value of RSU and PRSU awards based on the grant date share price.

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.

For the years ended December 31, 2016, 2015 and 2014 we recorded stock-based compensation expense of \$10.7 million, \$3.5 million and \$1.0 million, respectively. At December 31, 2016, our unrecognized stock-based compensation expense related to unvested stock options, net of estimated forfeitures, was \$13.0 million, which we expect to recognize over a weighted-average period of 2.8 years. Unrecognized compensation expense related to RSUs and PRSUs at December 31, 2016 was \$6.7 million, which we expect to recognize on a straight-line basis over a weighted-average period of 2.0 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 until our initial public offering in February 2015 and did not have any trading history for our common stock, the expected volatility was estimated based 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'-length transactions; the valuation of publicly traded companies in our industry, as well as recently completed

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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 was 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, the fair value of each share of underlying common stock is the closing price of our common stock as reported on the date of grant.

## Results of Operations

### Comparison of the Years Ended December 31, 2016 and 2015

	Year Ended		Dollar Change	% Change	
	December 31, 2016	2015			
Revenue	\$25,048	\$8,378	\$16,670	199	%
Operating expenses:					
Cost of revenue	27,878	16,523	11,355	69	%
Research and development	44,630	42,806	1,824	4	%
Selling and marketing	28,638	22,479	6,159	27	%
General and administrative	24,085	16,047	8,038	50	%
Total operating expenses	125,231	97,855	27,376	28	%
Loss from operations	(100,183)	(89,477)	(10,706)	12	%
Other income (expense), net	348	(94 )	442	(470 )	%
Interest expense	(421 )	(211 )	(210 )	100	%
Net loss	\$(100,256)	\$(89,782)	\$(10,474)	12	%

### Revenue

The increase in revenue of \$16.7 million for the year ended December 31, 2016 compared to the same period in 2015 was due to increased test volume, which resulted in increased cash collections, as well as the commencement of payments from CMS for tests provided to Medicare patients. Approximately \$21.7 million of revenue in the year ended December 31, 2016 was from tests delivered in 2016. We recorded \$3.6 million of revenue in the year ended December 31, 2016 on an accrual basis.

### Cost of revenue

The increase in the cost of revenue of \$11.4 million for the year ended December 31, 2016 compared to the same period in 2015 was primarily due to costs associated with increased test volume. For the year ended December 31,

2016 the number of billed test results delivered increased to approximately 57,000 from approximately 19,000 for the same period in 2015. However, the effect of increased test volumes on cost of revenue was partially offset by efficiencies that resulted in lower costs per test. Reagent and laboratory materials costs increased by \$3.3 million and costs of other materials associated with fulfilling orders increased by \$2.6 million. Personnel costs increased by \$2.8 million reflecting stock-based compensation costs that increased by \$1.0 million as well as increased headcount and increased time spent processing revenue-generating tests. Allocated technology and facilities-related expenses increased by \$2.0 million and costs associated with equipment and equipment maintenance increased by \$0.8 million.

#### Research and development

The increase in research and development expenses of \$1.8 million for the year ended December 31, 2016 compared to the same period in 2015 was primarily driven by costs related to the continued development of our

assay platforms. Personnel costs increased by \$7.0 million reflecting additional headcount and increased stock-based compensation costs of \$3.4 million. Reference materials costs increased by \$0.3 million, also reflecting increased headcount, and data storage costs increased by \$0.2 million. These cost increases were partially offset by the effects of reduced validation sequencing activities and increased test volumes in 2016. Costs of reagents and laboratory materials decreased by \$2.5 million, as validation sequencing activity was greater in 2015 than in 2016, due principally to the expansion of our test menu introduced in October 2015. Increased test volumes resulted in a greater allocation of resources, by \$1.8 million, to cost of revenue in 2016. In addition, equipment costs decreased by \$0.5 million, costs associated with software and software licenses decreased by \$0.3 million, and consulting costs decreased by \$0.3 million.

#### Selling and marketing

The increase in selling and marketing expenses of \$6.2 million for the year ended December 31, 2016 compared to the same period in 2015 was due primarily to increased personnel costs of \$6.1 million, primarily reflecting increased headcount, increased sales commissions of \$1.5 million, increased stock-based compensation costs of \$1.0 million and increased severance costs of \$0.5 million primarily associated with the program to streamline our organization. In addition, costs associated with software and software licenses increased by \$0.9 million, allocations of technology and facilities-related expenses increased by \$0.7 million and travel costs increased by \$0.5 million. These increases were partially offset by a reduction of \$1.2 million in market collaboration costs due to the termination of certain collaboration projects and reductions in other consulting costs of \$0.8 million.

#### General and administrative

The increase in general and administrative expenses of \$8.0 million for the year ended December 31, 2016 compared to the same period in 2015 was primarily due to increased facilities costs of \$5.0 million reflecting facilities leases executed in the first quarter of 2015 and in subsequent periods. In February 2016, we began recognizing rent expense for our new production facility and headquarters in San Francisco. Rent expense relating to this facility was \$5.8 million for the year ended December 31, 2016 and we recorded this cost as general and administrative expense. Personnel costs increased by \$2.9 million principally reflecting increased headcount but also including increased stock-based compensation costs of \$1.8 million. Losses realized on the impairment and disposal of facility assets in 2016 were \$1.0 million and were for write-offs of leasehold improvements relating to facility lease terminations and for equipment disposals related to the shutdown of our Chilean operations. Billings and collection costs increased by \$1.0 million, reflecting increased billing-related cash collections, and consulting costs increased by \$0.5 million, principally due to internal systems development efforts.

These increases were partially offset by increased allocations of technology and facilities-related expenses to other functional groups of \$1.1 million. In addition, legal costs were lower by \$0.8 million in 2016, principally due to facility lease-related activities in 2015 that were not repeated in 2016. Consulting costs were lower by \$0.4 million reflecting reduced headcount growth and related recruiting costs as well as increased utilization of internal resources for recruiting functions.

#### Other income (expense), net

The net increase in other income (expense) of \$0.4 million for the year ended December 31, 2016 compared to the same period in 2015 was principally due to increases in interest income, foreign currency exchange gains and other income items.

#### Interest expense

The increase in interest expense of \$0.2 million for the year ended December 31, 2016, compared to the same period in 2015, was principally due to interest expense relating to term loans under the Loan and Security Agreement (the

Loan Agreement) executed in July 2015. See Note 5, “Commitments and contingencies” in the Notes to Consolidated Financial Statements included elsewhere in this report. We began borrowing activity pursuant to the Loan Agreement in July 2015 and in 2016 the amount borrowed under the Loan Agreement rose from \$7.5 million to \$15.0 million.



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Comparison of the Years Ended December 31, 2015 and 2014

Year  
Ended

December  
31,          Dollar