Invitae Corp
Form 10-K
March 06, 2018

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, 2017

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the transition period from to

Commission File No. 001 36847

Invitae Corporation

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

Delaware	27 1701898
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

1400 16th 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:

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, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer", "smaller reporting company" and "emerging growth 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
		Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

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, 2017, the aggregate market value of common stock held by non affiliates of the Registrant was approximately $252.0 million, based on the closing price of the common stock as reported on The New York Stock Exchange for that date.

The number of shares of the registrant's Common Stock outstanding as of March 2, 2018 was 53,705,786.

DOCUMENTS INCORPORATED BY REFERENCE

Items 10 (as to directors and Section 16(a) Beneficial Ownership Reporting Compliance), 11, 12, 13 and 14 of Part III incorporate by reference information from the registrant's proxy statement to be filed with the Securities and Exchange Commission in connection with the solicitation of proxies for the registrant's 2018 Annual Meeting of Stockholders.

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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 expected benefits, including cost-savings and synergies, from our acquisitions;
- 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 hiring;
- 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 attract and 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 and the growth of our business;
- our financial performance;
- our expectations regarding our future revenue, cost of revenue, operating expenses and capital expenditures, and our future capital requirements; and
- the impact of tax laws on our business.

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

Combining genetic testing services that support patient care throughout life’s journey – from family planning, to proactive health screening, to inherited disease diagnosis – with a unique, rapidly expanding network of patients, healthcare providers, biopharma and advocacy partners, Invitae is capturing the broad potential of genetics and helping to expand its use across the healthcare continuum. Through the custom design and application of automation, robotics and bioinformatics software solutions tailored to the complexity of sample processing and complex variant interpretation, Invitae can apply its world-class clinical expertise to medical interpretation at scale, simplifying the process of obtaining and utilizing affordable, high-quality genetic information to inform critical healthcare decisions. By pioneering new ways of sharing and understanding genetic information, Invitae is transforming the field of genetics from one-dimensional testing to complex information management.

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.

Mission

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 a majority of the world’s genetic information into a comprehensive network that enables sharing of data among network participants to improve healthcare and clinical outcomes.

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.

Vision

We are focused on making comprehensive, high-quality genetic information more accessible than ever before by lowering the cost of genetic testing, by creating a network of partners to increase the utility of genetic information across the healthcare continuum, and ultimately managing that information on behalf of our customers.

As our market share grows, we expect that our business will grow in three stages:

1) Genetic testing: making genetic testing more affordable and more accessible with fast turnaround time. 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 customers.
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 customer.

We seek to differentiate our service in the market by establishing an exceptional customer experience. To that end, we believe that elevating the needs of the customer over those of our other stakeholders is essential to our success. Thus, in our decision-making processes, we will strive to prioritize, in order:

- The needs of our customers;
- Motivating our employees to serve our customers; and
- Our long-term stockholder value.

We believe that focusing on customers as our top priority rather than short-term financial goals is the best way to build and operate an organization for maximum long-term value creation.

We launched our first commercial offering in November 2013 with an offering of approximately 200 genes, growing the test menu over time to include more than 20,000 genes. In 2017, we accessioned approximately 150,000 samples and generated revenue of approximately $68.2 million reflecting more than a 150% and 170% increase over 2016 volume and revenue, respectively. In 2017, we achieved a full-year gross profit of $18.1 million, compared to a full-year gross loss of $2.8 million in 2016. In support of our efforts to reduce cost per test, expand our test menu, and develop a scalable laboratory infrastructure, we incurred research and development expenses of $46.5 million, $44.6 million and $42.8 million in 2017, 2016, and 2015, respectively.

Our rapid growth in diagnostic testing has accelerated the transition of our business from a traditional sample-by-sample, indication-by-indication, test-by-test market to what we believe will become the most extensive, accurate and accessible network focused on utilization of genetics in personal healthcare. Invitae’s value proposition for customers is simple: Genetic information is more valuable when shared.

Our products today

We are aiming to combine genetic information and clinical data into a seamless genome network to accelerate research, clinical trials and disease management.

We began by building out our initial offering in competitive and technically challenging clinical areas, including comprehensive panels for hundreds of hereditary conditions in cancer, cardiology, neurology, pediatric and rare diseases. In 2017, we expanded our platform of clinical testing services to include assays totaling over 20,000 genes, including our medical exome, and began offering tests that could be used for proactive health and wellness screening. We also established a leading position in family health genetic information services through the strategic acquisition of reproductive health testing capabilities. In August 2017, we acquired Good Start Genetics, Inc., a molecular diagnostics company focused on preimplantation and carrier screening for inherited disorders. Good Start was the first to bring next-generation sequencing to reproductive health with a suite of offerings including carrier screening and preimplantation embryo testing, which provides women, their partners and their clinicians with insightful and actionable information to promote successful pregnancies and help build healthy families. In November 2017, we completed our acquisition of CombiMatrix Corporation, a company which specializes in prenatal diagnosis, miscarriage analysis and pediatric developmental disorders. CombiMatrix’s services include advanced technologies,

such as single nucleotide polymorphism chromosomal microarray analysis, next generation sequencing, and long-standing expertise handling a variety of technically challenging sample types.

With an established footprint, growing market share and breadth of service covering genetic testing needs across all stages of life, we are focusing our efforts on partnering with patients, family members, healthcare professionals, payers, industry professionals, researchers and clinical trial sponsors to advance the development of our genome network.

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 through 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.

This acquisition was subsequently complemented by the acquisition of Ommdom, Inc. in June 2017, the provider of a highly efficient, end-to-end platform for collecting and managing genetic family histories, CancerGene Connect.

CancerGene Connect was developed by clinicians for clinicians to streamline the collection, analysis, and management of patient family history information. The platform uses a cloud-based, mobile friendly patient interface to gather family history information prior to a clinician appointment. Once completed, powerful analysis tools using the latest research on hereditary risk analyze a patient’s predisposition to disease and provide actionable analysis to inform therapeutic decisions, such as genetic testing or treatment approaches. In addition, the platform provides clinicians with the ability to look beyond the individual to understand trends across all their patients.

In addition to investing in informatics solutions and infrastructure to support network development, we have begun partnering with biopharmaceutical companies, including Alnylam Pharmaceuticals, Inc., Ariad Pharmaceuticals, Inc. (a subsidiary of Takeda Pharmaceutical Company Limited), AstraZeneca and Merck & Co., Inc., BioMarin Pharmaceutical Inc., Blueprint Medicines Corporation, Jazz Pharmaceuticals plc, MyoKardia, Inc., Parion Sciences, Inc. and others to support clinical trial recruitment and other research-related initiatives. Our biopharmaceutical industry partnerships are complemented by partnerships with leading health systems, executive health programs and leading research institutions, including the Geisinger Health System, the Mayo Clinic, Memorial Sloan Kettering Cancer Center, MedCan, NorthShore University HealthSystem, and Stanford Health Care, among others.

Our goal is to build a network through which individuals can access, aggregate and customize information based on their genotype and phenotype and participate in new research, clinical trials, treatment planning or other related purposes that may benefit the individual and/or their clinician. Individuals can also decide to share information if they feel it will benefit them or will contribute more broadly to furthering knowledge about their conditions.

Performance statement

We believe the value of the network we are building can best be expressed as the total number of individuals multiplied by the amount of information per individual multiplied by the number of connections available through the network. Through December 31, 2017, Invitae's ongoing testing business has served more than 220,000 individuals, can generate more than 20,000 potential data points per person and connects over 200,000 individuals through patient insight networks and commercial partners.

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, a subsidiary of Konica Minolta Inc.; Athena Diagnostics, a subsidiary of Quest Diagnostics Incorporated; Baylor Genetics; Blueprint Genetics, Inc.; Centogene AC; Color Genomics, Inc.; Connective Tissue Gene Test LLC; Cooper Surgical; Counsyl, Inc.; Eurofins Scientific; GeneDx, a subsidiary of OPKO Health, Inc.; MNG Laboratories, LLC; Myriad Genetics, Inc.; Laboratory Corporation of America Holdings; Natera, Inc.; PreventionGenetics, LLC; Quest Diagnostics Incorporated; and Progenity, Inc. 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;
- customer 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, 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, the Centers for Medicare and Medicaid Services, or 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 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 were 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 uses 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 went into effect starting January 1, 2018. 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 laboratories in California and Massachusetts are required to hold certain federal certificates to conduct our business. Under CLIA, we are required to hold certificates 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 certifications under CLIA to perform testing at our laboratory locations in San Francisco, California, Irvine, California and Cambridge, Massachusetts. To renew our CLIA certifications, 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 laboratories. 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 laboratories are out of compliance with CLIA requirements, we may be subject to sanctions such as suspension, limitation or revocation of our CLIA certificates, 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 certifications 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 in-state licenses to conduct testing in California and Massachusetts. California laws establish standards for day to day operations of our laboratories in San Francisco and Irvine, and Massachusetts laws establish standards applicable to our laboratory in Cambridge. California and Massachusetts laws, respectively, mandate proficiency testing, which involves testing of specimens that have been specifically prepared for the laboratories. If our clinical reference laboratories are out of compliance with California standards, the California Department of Health Services, or DHS, may suspend, restrict or revoke our licenses to operate our clinical reference laboratories, assess substantial civil money penalties, or impose specific corrective action plans.

Similarly, if our Cambridge laboratory does not meet Massachusetts standards, the Massachusetts Department of Public Health, or DPH, may suspend, modify, or revoke our license to operate such laboratory, assess fines, or issue an order requiring certain corrective action. Any such actions could materially affect our business. We maintain current licenses in good standing with DHS and DPH. However, we cannot provide assurance that DHS and/or DPH 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 laboratories hold the required out of state laboratory licenses for Florida, Maryland, New York, Pennsylvania Rhode Island, and our Cambridge laboratory maintains an our-of-state laboratory license from California.

In addition to having laboratory licenses in New York, our clinical reference laboratories in California and in Massachusetts are 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.

Other states may adopt similar licensure requirements in the future, which may require us to modify, delay or stop our operations in such jurisdictions. Complying with licensure requirements in new jurisdictions may be expensive, time consuming, and subject us to significant and unanticipated delays. If we identify any other state with such requirements, or if we are contacted by any other state advising us of such requirements, we intend to follow instructions from the state regulators as to how we should comply with such requirements.

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

U.S. Food and Drug Administration, or FDA

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

Historically, the FDA has exercised enforcement discretion with respect to most LDTs and has not required laboratories that furnish LDTs to comply with the agency's requirements for medical devices (e.g., establishment registration, device listing, quality systems regulations, premarket clearance or premarket approval, and post market controls). In recent years, however, the FDA has stated it intends to end its policy of general enforcement discretion and regulate certain LDTs as medical devices. To this end, on October 3, 2014, the FDA issued two draft guidance documents, entitled "Framework for Regulatory Oversight of Laboratory Developed Tests (LDTs)" and "FDA Notification and Medical Device Reporting for Laboratory Developed Tests (LDTs)", respectively, that set forth a proposed risk based regulatory framework that would apply varying levels of FDA oversight to LDTs. The FDA has indicated that it does not intend to modify its policy of enforcement discretion until the draft guidance documents are finalized. 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.

Notwithstanding the FDA's current position with respect to oversight of our tests, we may voluntarily decide to pursue FDA pre market review for our current tests and/or tests we may offer in the future if we determine that doing so would be appropriate from a strategic perspective – e.g., if CMS indicated that it no longer intended to cover tests offered as LDTs. In November 2017, CMS published a draft national coverage determination, or NCD, for next generation sequencing, or NGS, tests for patients with advanced cancer, under which CMS proposed to provide full coverage for FDA-approved tests performed in patients that fall within the test's FDA-approved labeling, but proposed significant limits on coverage for NGS-based tests offered as LDTs. It is unclear whether CMS will finalize the NCD as proposed. While we do not believe the draft NCD was intended to apply to our tests, it could arguably be interpreted to apply to such tests. If CMS issues a final NCD that applies to our tests and is substantively similar to the draft NCD, our current and future tests may effectively be non-covered under Medicare unless and until we obtain FDA clearance or approval (as applicable).

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. Many states also have laws or regulations that specifically apply to the use or disclosure of genetic information and that are more stringent than the standards under HIPAA.

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 and State Consumer Protection Laws

The Federal Trade Commission, or FTC, is an independent U.S. law enforcement agency charged with protecting consumers and enhancing competition across broad sectors of the economy. The FTC's primary legal authority comes from Section 5 of the FTC Act, which prohibits unfair or deceptive practice in the marketplace. The FTC has increasingly used this broad authority to police data privacy and security, using its powers to investigate and bring lawsuits. Where appropriate, the FTC can seek a variety of remedies, including the implementation of comprehensive privacy and security programs, biennial assessments by independent experts, monetary redress to consumers, and provision of robust notice and choice mechanisms to consumers. In addition to its enforcement mechanisms, the FTC uses a variety of tools to protect consumers' privacy and personal information, including enforcement actions to stop violations of law, conducting studies and issuing reports, hosting public workshops, developing educational materials, and testifying before the U.S. Congress on issues that affect consumer privacy.

The vast majority of cases brought by the FTC fall under the "deceptive" prong of Section 5. These cases often involve a failure on the part of a company to adhere to its own privacy and data protection principles set forth in its policies. To avoid Section 5 violations, the FTC encourages companies to build privacy protections and safeguards into relevant portions of the business, and consider privacy and data protection as the company grows and evolves. In addition, privacy notices should clearly and accurately disclose the type(s) of information the company collects, how the company uses and shares the information, and the security measures used by the company to protect the information.

In recent years, the FTC's enforcement under Section 5 has included alleged violations of the "unfairness" prong. Many of these cases have alleged that companies were unfair to consumers because they failed to take reasonable and necessary measures to protect consumer data. The FTC has not provided bright line rules defining what constitutes "reasonable and necessary measures" for implementing a cybersecurity program, but it has provided guidance, tips and advice for companies. The FTC has also published past complaints and consent orders, which it urges companies use as examples to help avoid an FTC enforcement action, even if a data breach or loss occurs.

In addition to the FTC Act, most U.S. states have unfair and deceptive acts and practices statues, or UDAP statutes, that substantially mirror the FTC Act and have been applied in the privacy and data security context. These vary in substance and strength from state to state. Many have broad prohibitions against unfair and deceptive acts and practices, while New York's UDAP statute, for instance, is limited to only deceptive acts and practice. These statutes generally allow for private rights of action and are enforced by the states' Attorneys General. In addition, almost every U.S. state has a data breach notification law that requires entities to report certain security incidents to affected consumers and state regulators.

International Privacy and Data Protection Laws

There are a growing number of jurisdictions all over the world that have privacy and data protection laws. These laws are typically triggered by a company's establishment or physical location in the jurisdiction, data processing activities that take place in the jurisdiction, and/or the processing of personal information about residents of citizens of that jurisdiction. Certain international privacy and data protection laws, such as those in the European Union, can be more restrictive and prescriptive than those in the U.S., while other jurisdictions can have laws less restrictive or prescriptive than those in the U.S. Enforcement of these laws vary from jurisdiction to jurisdiction, with a variety of civil or criminal penalties.

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 knowingly and willfully offering, paying, soliciting or receiving remuneration, directly or indirectly, overtly or covertly, in cash or in kind, to induce or in return for the referral of an individual for the furnishing of or arranging for the furnishing of any item or service for which payment may be made in whole or in part by a federal healthcare program, or the 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. Many courts have held that the Anti Kickback Statute may be violated if any one purpose of the remuneration is to induce or reward 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. The Anti Kickback Statute is broad and may technically prohibit many innocuous or beneficial arrangements within the healthcare industry. The Anti-Kickback Statute includes several statutory exceptions, and the U.S. Department of Health and Human Services has issued a series of regulatory "safe harbors." These exceptions and safe harbor regulations set forth certain requirements for various types of arrangements, which, if met, will protect the arrangement from potential liability under the Anti Kickback Statute. Although full compliance with the statutory exceptions or regulatory safe harbors ensures against liability 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 violations of the Anti Kickback Statute 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.

There are also federal laws related to healthcare fraud and false statements, among others, that apply 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, among other things, 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 presenting or causing to be presented 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 for

each false claim. For penalties assessed after January 29, 2018, whose associated violations occurred after November 2, 2015, the penalties range from $11,181 to $22,363 for each false claim. The minimum and maximum per claim penalty amounts are subject to annual increases for inflation.

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. There are several exceptions to the prohibition on beneficiary inducement.

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 ten 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 referring a patient to an entity for certain Medicare-covered designated health services, including laboratory services, if the physician, or an immediate family member, has a financial relationship with the entity, unless an exception applies. The Stark Law also prohibits an entity from billing for services furnished pursuant to a prohibited referral. 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 apply to services covered by other third-party payers. The Stark Law also prohibits state receipt of Federal Medicaid matching funds for services furnished pursuant to a prohibited referral. This provision of the Stark Law has not been implemented by regulations, but 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.

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 do we rely on any such in licensed patent 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 customers. In this regard, we have issued U.S. patents, pending U.S. utility patent applications, a pending PCT application, and 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 customers 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 customers. As a consequence, we have invested significant resources in protection of our trademarks.

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 Illumina, Inc., Integrated DNA Technologies Incorporated, Qiagen N.V., Roche Holdings Ltd. and Twist Bioscience Corporation 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, 2017, 2016 and 2015 the percentages of our revenue attributable to sources in the United States were 92%, 83% and 65% respectively; the percentages of our revenue attributable to sources in Canada were 5%, 10% and 25% respectively; and the percentages of our revenue attributable to countries excluding the United States and Canada were 3%, 7%and 10% respectively.

As of December 31, 2017 and 2016, our long lived assets of $30.3 million and $23.8 million, respectively, were located in the United States.

As of December 31, 2017, substantially all our revenue has been derived from test reports generated from our assays. A single customer accounted for 13% of our revenue for the year ended December 31, 2017 and 11% of our revenue for the year ended December 31, 2016, and a second single customer accounted for 13% of our revenue for the year ended December 31, 2015.

Employees

We had 594 employees as of December 31, 2017.

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 16th Street, San Francisco, California 94103, and our telephone number is (415) 374 7782. Our website address is www.invitae.com. The information contained on, or that can be accessed through, our website is not part of this annual report on Form 10 K.

We make available free of charge on our website our annual reports on Form 10 K, quarterly reports on Form 10 Q, current reports on Form 8 K and amendments to those reports, as soon as reasonably practicable after we electronically file or furnish such materials to the Securities and Exchange Commission, or SEC. You may obtain a free copy of these reports in the Investor Relations section of our website, www.invitae.com. 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.

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, 2017, 2016 and 2015, our net losses were $123.4 million, $100.3 million and $89.8 million, respectively. At December 31, 2017, our accumulated deficit was $398.6 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 and expanding our testing capabilities. Our prior losses and expected future losses have had and will continue to have an

adverse effect on our stockholders' equity, working capital and stock price. 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.

We have acquired and may continue to 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 have pursued and may continue to 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. In June 2017, we acquired Ommdom, Inc., a privately-held company that develops and operates hereditary risk assessment and management software, including CancerGene Connect, a cancer genetic counseling platform. In August 2017, we acquired Good Start Genetics, a privately-held company focused on preimplantation and carrier screening for inherited disorders. In November 2017, we acquired CombiMatrix Corporation, a publicly-traded company which specializes in prenatal diagnosis, miscarriage analysis and pediatric developmental disorders.

With respect to AltaVoice, Ommdom, Good Start, CombiMatrix, 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. Furthermore, the loss of customers, payers, partners or suppliers following the completion of any acquisitions by us could harm our business. For example, we have experienced a reduction in Good Start's sales as a result of the termination of a contract by a third-party laboratory that had performed expanded carrier screening for Good Start. Changes in services, sources of revenue, and branding or rebranding initiatives may involve substantial costs and may not be favorably received by customers, resulting in an adverse impact on our financial results, financial condition and stock price. Integration of an acquired company or business also may require management's time and resources that otherwise would be available for ongoing development of our existing business. For example, we have diverted resources from other projects in order to develop an expanded carrier screening test as a result of the termination of the third-party laboratory contract with Good Start, and we may experience difficulties or delays in launching this test. We may also need to divert cash from other uses in order to fund these integration activities. Ultimately, we may not realize the anticipated benefits of any acquisition, technology license, strategic alliance, joint venture or investment, or these benefits may take longer to realize than we expected.

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. In August 2017, in a private placement to certain accredited investors, we offered and sold common stock and Series A convertible preferred stock for gross proceeds of approximately $73.5 million. The Series A preferred stock is a non-voting common stock equivalent and conversion of the Series A preferred stock is prohibited if the holder exceeds a specified threshold of voting security ownership. The Series A preferred stock is convertible into common stock on a one-for-one basis, subject to adjustment for events such as stock splits, combinations and the like. 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. In addition, our stockholders may experience substantial dilution as a result of additional securities we may issue for acquisitions. Open market sales of substantial amounts of our common stock issued to stockholders of companies we acquire could also depress our share price. Alternatively, it may be necessary for us to raise additional funds for our acquisition 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 Amended 2017 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.

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 the Centers for Medicare and Medicaid Services provides reimbursement for our multi-gene tests for hereditary breast cancer-related disorders as well as colon cancer. We believe that establishing adequate reimbursement from Medicare is an important factor in gaining adoption from healthcare providers. Our claims for reimbursement from third-party 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 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, 2017, revenue from the sale of our tests, and term loans available to us pursuant to the Amended 2017 Loan Agreement, will be sufficient to meet our anticipated cash requirements for our currently-planned operations for the 12-month period following the filing date of this report. We may need additional funding to finance operations prior to achieving profitability, or should we make additional acquisitions. 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 Amended 2017 Loan Agreement are subject to covenants, including quarterly covenants to achieve certain volume and 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 software developers, geneticists, biostatisticians, certified laboratory scientists and other scientific and technical personnel to process and interpret our genetic tests. In addition, we may in the future need 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.

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., a subsidiary of Konica Minolta Inc., Athena Diagnostics, a subsidiary of Quest Diagnostics Incorporated, Baylor Genetics, Blueprint Genetics, Inc., Centogene AC, Color Genomics, Inc., Connective Tissue Gene Test LLC, Cooper Surgical, Counsyl, Inc., Eurofins Scientific, GeneDx, a subsidiary of OPKO Health, Inc., MNG Laboratories, LLC, Myriad Genetics, Inc., or Myriad, Natera, Inc., PreventionGenetics, LLC and Progenity, Inc.;
- a few large, established general testing companies with large market share and significant channel power, such as Laboratory Corporation of America Holdings and Quest Diagnostics Incorporated;
- a large number of clinical laboratories in an academic or healthcare provider setting that perform clinical genetic testing on behalf of their affiliated institutions and often sell and market more broadly; and
- a large number of new entrants into the market for genetic information ranging from informatics and analysis pipeline developers to focused, integrated providers of genetic tools and services for health and wellness 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 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 may not be able to maintain the quality of or expected turnaround times for our tests, or satisfy customer demand as it grows. We may 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. We significantly increased the size of our sales force in 2017, especially late in 2017 with the integration of the sales forces from our acquired companies and the hiring of new sales personnel. 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 adversely impact our business.

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, technicians and software developers. 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, technicians and software developers, 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.

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, such as failure to detect genomic variants with high accuracy, or mistakes, such as failure to identify, or incompletely or incorrectly identifying, gene variants or their significance, could have a significant adverse impact on our business.

In August 2017, a client reported a discrepancy between an Invitae test report and a test report issued by another laboratory for the presence of a single rare variant in the MSH2 gene known as the Boland inversion. This gene is associated with Lynch syndrome, which is a familial cancer syndrome that significantly increases the risk of colorectal and other cancers. Our assay had reliably detected the Boland inversion event since its first validation. However, during the implementation of an update to the assay, we omitted the components designed specifically to identify the Boland inversion event. As soon as we learned of the error, we quickly rectified it and implemented three new quality checks designed to ensure this type of error does not happen again. We notified all potential patients impacted by this incident and reanalyzed our previous test results to ensure their accuracy. Less than 10 patients were affected by this incident.

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 regarding 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 a 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 such 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, 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 collect and store sensitive data, including 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, Patient Insights Network, or PIN, and CancerGene Connect platform. In addition to storing and transmitting sensitive personal information that is subject to myriad legal protections, 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. Any technical problems that may arise in connection with our data and systems, including those that are hosted by third-party providers, could result in interruptions in our business and operations. These types of problems may be caused by a variety of factors, including infrastructure changes, human or software errors, viruses, security attacks, fraud, spikes in customer usage and denial of service issues. From time to time, large third-party web hosting providers have experienced outages or other problems that have resulted in their systems being offline and inaccessible. Such outages could materially impact our business and operations.

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 what we believe to be reasonable and appropriate measures to protect sensitive information from unauthorized access or disclosure, our information technology and infrastructure 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, altered, 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 but not limited to the Health Insurance Portability and Accountability Act of 1996, or HIPAA, the Health Information Technology for Economic and Clinical Heath Act, or HITECH, state data security and data breach notification laws, and related 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, PIN and CancerGene Connect platform are currently accessible through our online portal and/or 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.

In addition to security risks, we also face privacy risks. While we have policies that govern our privacy practices and procedures that aim to keep our practices consistent with such policies, such procedures are not

invulnerable to human error. Should we inadvertently break the privacy promises we make to patients or consumers, we could receive a complaint from an affected individual or interested privacy regulator, such as the FTC or a state Attorney General. This risk is heightened given the sensitivity of the data we collect.

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. Penalties for unfair or deceptive acts or practices under the FTC Act or state UDAP statutes may also vary significantly.

There has been unprecedented activity in the development of data protection regulation around the world. As a result, 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. For example, the European Union’s forthcoming General Data Protection Regulation, or GDPR, takes effect in May 2018. While the text of the GDPR has been published, the European authorities have only begun to issue guidance and interpretations of the text, leaving companies in and outside of Europe to interpret the majority of the GDPR on their own. With this new EU law and many others all over the world, 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 Illumina, Inc., Integrated DNA Technologies Incorporated, Qiagen N.V., Roche Holdings Ltd., and Twist Bioscience Corporation 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 adverse affected.

If our laboratories in California and Massachusetts become inoperable due to disasters 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 facilities in San Francisco, California, Irvine, California and Cambridge, Massachusetts. Our laboratories 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 laboratories 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 laboratories are 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. In early 2017, we 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. In March 2018, our executive chairman ceased to be an employee, but continues to serve as chairman of the board. We may experience difficulties as our organization continues to adapt 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, our Patient Insights Networks, or PINs, 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, including financial reporting.

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 and financial 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.

Any technical problems that may arise in connection with our data and systems, including those that are hosted by third-party providers, could result in interruptions in our business and operations. These types of problems may be caused by a variety of factors, including infrastructure changes, human or software errors, viruses, security attacks, fraud, spikes in customer usage and denial of service issues. From time to time, large third-party web hosting providers have experienced outages or other problems that have resulted in their systems being offline and inaccessible. Such outages could materially impact our business and operations.

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

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

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

- multiple, conflicting and changing laws and regulations such as privacy regulations, tax laws, export and import restrictions, employment laws, regulatory requirements, and other governmental approvals, permits and licenses;
- failure by us or our distributors to obtain regulatory approvals for the use of our tests in various countries;
- complexities and difficulties in obtaining protection and enforcing our intellectual property;
- difficulties in staffing and managing foreign operations;

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

- logistics and regulations associated with shipping samples, including infrastructure conditions and transportation delays;
- limits on our ability to penetrate international markets if we do not to conduct our tests locally;
- 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 international 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 samples 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.

Changes in U.S. tax laws could adversely impact us.

On December 22, 2017, President Trump signed The Tax Cuts and Jobs Act (the "Tax Act") into law. The Tax Act contains significant changes to U.S. federal corporate income taxation, including reduction of the corporate tax rate from 35% to 21% for U.S. taxable income, resulting in a one-time remeasurement of deferred taxes to reflect their value at a lower tax rate of 21%, limitation of the deduction for net operating losses to 80% of current year taxable income and elimination of net operating loss carrybacks, deemed repatriation, resulting in one-time taxation of offshore earnings at reduced rates, elimination of U.S. tax on foreign earnings (subject to certain exceptions), and immediate deductions for certain new investments instead of deductions for depreciation expense over time. Although the Tax Act is generally effective January 1, 2018, GAAP requires recognition of the tax effects of new legislation during the reporting period that includes the enactment date, which was December 22, 2017. As a result of the lower corporate tax rate enacted as part of the Tax Act, we recorded a provisional estimate to reduce deferred tax assets by $48.8 million. The reduction in deferred tax assets was offset by a corresponding reduction in our valuation allowance resulting in no net impact to tax expense. We have determined that the adjustment to the deferred tax assets and valuation allowance recorded in connection with the remeasurement of certain deferred tax assets and liabilities is a reasonable estimate at December 31, 2017. Any subsequent adjustment to these amounts will be adjusted accordingly in the quarter of 2018 when the analysis is complete. Any such adjustment could adversely affect our tax positions, tax rate, or results of operations.

Impairment in the value of our goodwill or other intangible assets could have a material adverse effect on our operating results and financial condition.

We record goodwill and intangible assets at fair value upon the acquisition of a business. Goodwill represents the excess of amounts paid for acquiring businesses over the fair value of the net assets acquired. Goodwill and indefinite-lived intangible assets are evaluated for impairment annually, or more frequently if conditions warrant, by comparing the carrying value of a reporting unit to its estimated fair value. Intangible assets with definite lives are reviewed for impairment when events or circumstances indicate that their carrying value may not be recoverable. Declines in operating results, divestitures, sustained market declines and other factors that impact the fair value of a reporting unit could result in an impairment of goodwill or intangible assets and, in turn, a charge to net income. Any such charges could have a material adverse effect on our results of operations or financial condition.

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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. In March 2017, a draft bill titled "The Diagnostics Accuracy and Innovation Act" was released for discussion. The draft bill proposes a risk-based approach to regulate LDTs and creates a new in vitro clinical test category of regulated products, which includes LDTs, and a regulatory structure under the FDA. As proposed, the draft bill grandfathers many existing tests and phases in FDA oversight over a period of years (e.g., companies would have two years from the date the FDA promulgates final implementing regulations before such regulations became effective). We cannot predict if this draft bill will be enacted in its current (or any other) form and cannot quantify the effect of this draft bill on our business.

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 individualized enforcement action, or more generally, as outlined in final guidance or 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 certifications to conduct our tests at our laboratories in San Francisco and Irvine, California and Cambridge, Massachusetts. To renew these certifications, we are subject to survey and inspection every two years. Moreover, CLIA inspectors may make random inspections of our clinical reference laboratories.

We are also required to maintain licenses to conduct testing in California. California laws establish standards for day-to-day operation of our clinical reference laboratories in San Francisco and Irvine, including the training and skills required of personnel and quality control. We also maintain a Massachusetts clinical laboratory license to conduct testing at our laboratory in Cambridge, Massachusetts. We also maintain out-of-state laboratory licenses to conduct testing on specimens from Florida, Maryland, New York, Pennsylvania and Rhode Island, as well as California with respect to our laboratory in Cambridge.

In addition to having laboratory licenses 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 samples 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. We have CAP accreditations for our San Francisco and Cambridge laboratories. 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;
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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, to induce or in return for the referral of an individual, for the furnishing of or arrangement for the furnishing of any item or service for which payment may be made in whole or in part by a federal healthcare program, or the purchasing, leasing, ordering, arranging for, or recommend purchasing, leasing or ordering, any good, facility, item or service for which payment may be made, in whole or in part, under a federal healthcare program;

- the federal physician self-referral law, known as the Stark Law, which prohibits a physician from making a referral to an entity 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 unless an exception applies, and prohibits an entity from billing for designated health services furnished pursuant to a prohibited referral;
- 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 health care benefit 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 through 2019, but is scheduled to return beginning in 2020. 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.

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 were 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 priced our multi-gene tests for hereditary breast cancer-related disorders at $925.00 per test. The 2017 CLFS National Limitation Amount, or NLA, for this test was set at $931.47.

In November 2017, CMS posted a “final” file that summarized the 2018 CLFS payment rates calculated under the PAMA final rule. This file indicates that the median of private payer rates reported to Medicare for the code used to report our multi-gene test for hereditary breast cancer-related disorders was $136.47. The PAMA final rule caps the annual reduction in the calendar year 2018, 2019, and 2020 CLFS payment rates for any test to 10% of the previous year’s rates, so the proposed CLFS payment rate for this test will be substantially higher than the median for at least the next three years (i.e., $838.33 in 2018, $754.50 in 2019, and $679.05 in 2020). The PAMA final rule also caps the annual percentage reduction in 2021, 2022 and 2023 rates to 15% of the previous year’s rate, further phasing-in any reduction required calculated using data reported during 2020. Nevertheless, we expect to experience 10% decreases in Medicare reimbursement per test per year for at least the next three years.

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 these codes would apply to our tests.

In November 2017, CMS published a draft national coverage determination, or NCD, for next generation sequencing, or NGS, tests for patients with advanced cancer, under which CMS proposed to provide full coverage for FDA-approved tests performed in patients that fall within the test's FDA-approved labeling, but proposed significant limits on coverage for NGS-based tests offered as LDTs. It is unclear whether CMS will finalize the NCD as proposed. While we do not believe the draft NCD was intended to apply to our tests, it could arguably be interpreted to apply to such tests. If CMS issues a final NCD that applies to our tests and is substantively similar to the draft NCD, our current and future tests may effectively be non-covered under Medicare unless and until we obtain FDA clearance or approval (as applicable).

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. Notably, Congress enacted legislation in 2017 that eliminates the Affordable Care Act's "individual mandate" beginning in 2019, which may significantly impact the number of covered lives participating in exchange plans. 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.

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.

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. We will remain an emerging growth company until December 31, 2020, although if our revenue exceeds $1.07 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;
- general economic and market conditions; and
- issuances of significant amounts of our common stock.

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, change their price targets, 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, 2017, directors, executive officers, 5% or greater stockholders and their affiliates beneficially owned, in the aggregate, 49% 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, 2017, our total gross deferred tax assets were $106.2 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 completed acquisitions, or other 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, the recently enacted Tax Act limits the deduction for NOLs to 80% of current year taxable income and eliminates NOL carrybacks. Also, 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 completed the move to the new facility in the first quarter of 2017.

Our subsidiary Good Start Genetics leases 42,517 square feet of laboratory and office space in Cambridge, Massachusetts and Framingham, Massachusetts, and our subsidiary CombiMatrix leases 12,164 square feet of laboratory and office space in Irvine, California. 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 5, 2018, are as follows:

Name	Age	Position
Executive officers		
Randal W. Scott, Ph.D.	60	Executive Chairman and Director
Sean E. George, Ph.D.	44	President, Chief Executive Officer, Director and Co-Founder
Lee Bendekgey	60	Chief Operating Officer and Secretary
Shelly D. Guyer	57	Chief Financial Officer
Robert L. Nussbaum, M.D.	68	Chief Medical Officer
Other corporate officers		
Thomas R. Brida	47	General Counsel
Patricia E. Dumond	53	Chief Accounting Officer
Katherine A. Stueland	42	Chief Commercial Officer

Randal W. Scott, Ph.D. has served as our Executive Chairman since January 9, 2017 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 has been our President and Chief Executive Officer since January 2017, a position he also held from January 2010 through August 2012. Dr. George also served as our President since August 2012 and he has served as our Chief Operating Officer from August 2012 until January 2017. 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 Operating Officer since June 2017. Mr. Bendekgey also served as our Chief Financial Officer from November 2013 to June 2017 and 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.

Shelly D. Guyer has served as our Chief Financial Officer since June 2017. Ms. Guyer served as Chief Financial Officer of Veracyte, Inc., a genomic diagnostics company, from April 2013 to December 2016 and served as Veracyte's Secretary from April 2013 to March 2014. Previously, she served as Chief Financial Officer and Executive Vice President of Finance and Administration of iRhythm Technologies, Inc., a digital healthcare company, from April 2008 to December 2012. From March 2006 to August 2007, Ms. Guyer served as Vice President of Business Development and Investor Relations of Nuvelo Inc., a biopharmaceutical company. Prior to joining Nuvelo, Ms. Guyer worked at J.P. Morgan Securities and its predecessor companies for over 17 years, serving in a variety of roles including in healthcare investment banking. Ms. Guyer holds an A.B. in Politics from Princeton University and an M.B.A. from the Haas School of Business at the University of California Berkeley.

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.

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 January 2013 to December 2013. 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.

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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
Year Ended December 31, 2016		
First quarter	$11.25	$5.66
Second quarter	$11.85	$7.14
Third quarter	$9.84	$7.22
Fourth quarter	$9.50	$5.76
Year Ended December 31, 2017		
First quarter	$11.30	$7.95
Second quarter	$11.88	$8.17
Third quarter	$10.44	$8.73
Fourth quarter	$10.10	$7.50

On March 2, 2018, the closing price of our common stock as reported on the New York Stock Exchange was $6.84 per share.

As of March 2, 2018, there were 72 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, 2017 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	12/31/2017
Invitae Corporation	$ 100.00	$ 48.15	$ 46.57	$ 53.26
S&P 500	$ 100.00	$ 97.87	$ 107.20	$ 128.02
S&P 500 Healthcare Index	$ 100.00	$ 102.41	$ 97.94	$ 117.53

Sales of Unregistered Securities

On August 3, 2017, we completed a private placement of 5,188,235 shares of common stock at a price of $8.50 per share and 3,458,823 shares of Series A Convertible Preferred Stock, $0.0001 par value per share, or the Series A Preferred Stock, at a price of $8.50 per share, to certain accredited investors. The Series A Preferred Stock, which is a common stock equivalent but non-voting and with a blocker on conversion if the holder would exceed a specified threshold of voting security ownership, is convertible into common stock on a one-for-one basis, subject to adjustment for events such as stock splits, combinations and the like. Gross proceeds to us from the private placement were approximately $73.5 million, before deducting fees and certain expenses payable by us. The sale of the shares of common stock and Series A Convertible Preferred Stock was made pursuant to the terms of a Securities Purchase Agreement dated as of July 31, 2017. The shares issued in the private placement were sold in reliance on the exemption from registration provided by Section 4(a)(2) of the Securities Act of 1933 and Regulation D promulgated thereunder. We relied on this exemption from registration based in part on representations made by the investors. Cowen and Company, LLC and Leerink Partners LLC acted as joint placement agents in connection with the private placement and received fees of approximately $4.4 million. The net proceeds to us from the private placement, after deducting the placement agent fees and other expenses payable by us, were approximately $68.9 million.

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, 2017 and 2016 and the selected consolidated statements of operations data for each of the years ended December 31, 2017, 2016, and 2015 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, 2015, 2014 and 2013 and the selected consolidated statement of operations data for the years ended December 31, 2014 and 2013 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,				
	2017	2016	2015	2014	2013
	(In thousands except share and per share data)				
Consolidated Statements of Operations Data					
Test revenue	$65,169	$24,840	$8,378	$1,604	$148
Other revenue	3,052	208	—	—	—
Total revenue	68,221	25,048	8,378	1,604	148
Costs and operating expenses:					
Cost of test revenue (1)	50,142	27,878	16,523	5,624	667
Research and development (1)	46,469	44,630	42,806	22,063	16,039
Selling and marketing (1)	53,417	28,638	22,479	8,669	2,431
General and administrative (1)	39,472	24,085	16,047	12,600	5,764
Total costs and operating expenses	189,500	125,231	97,855	48,956	24,901
Loss from operations	(121,279)	(100,183)	(89,477)	(47,352)	(24,753)
Other income (expense), net	(303)	348	(94)	(79)	(26)
Interest expense	(3,654)	(421)	(211)		