

Edgar Filing: Invitae Corp - Form 10-K

Invitae Corp

Form 10-K

February 28, 2019

false--12-31FY434652018-12-3110-K000150113476811562YestruettrueAccelerated Filer477800000Invitae CorpfalsefalseNoYesNVTA00P3Y1.000.020800000.00010.000140000000040000000053597000754810005359700075481000001501134 2018-01-01 2018-12-31 0001501134 nvta:CombiMatrixCorporationMember 2018-01-01 2018-12-31 0001501134 nvta:GoodStartGeneticsIncMember 2018-01-01 2018-12-31 0001501134 nvta:OmmdomIncMember 2018-01-01 2018-12-31 0001501134 nvta:AltaVoiceMember 2018-01-01 2018-12-31 0001501134 2018-06-29 0001501134 2019-02-22 0001501134 2017-12-31 0001501134 2018-12-31 0001501134 2016-01-01 2016-12-31 0001501134 2017-01-01 2017-12-31 0001501134 nvta:CollaborationAndGenomeNetworkMember 2018-01-01 2018-12-31 0001501134 nvta:CollaborationAndGenomeNetworkMember 2016-01-01 2016-12-31 0001501134 nvta:CollaborationAndGenomeNetworkMember 2017-01-01 2017-12-31 0001501134 nvta:DiagnosticTestsMember 2018-01-01 2018-12-31 0001501134 nvta:DiagnosticTestsMember 2016-01-01 2016-12-31 0001501134 nvta:DiagnosticTestsMember 2017-01-01 2017-12-31 0001501134 us-gaap:AdditionalPaidInCapitalMember 2017-01-01 2017-12-31 0001501134 us-gaap:CommonStockMember 2015-12-31 0001501134 2015-12-31 0001501134 us-gaap:PreferredStockMember 2018-12-31 0001501134 us-gaap:AdditionalPaidInCapitalMember 2018-01-01 2018-12-31 0001501134 us-gaap:RetainedEarningsMember 2018-01-01 2018-12-31 0001501134 us-gaap:CommonStockMember 2017-01-01 2017-12-31 0001501134 us-gaap:CommonStockMember 2017-12-31 0001501134 us-gaap:CommonStockMember 2018-12-31 0001501134 us-gaap:CommonStockMember 2018-01-01 2018-12-31 0001501134 us-gaap:RetainedEarningsMember 2017-12-31 0001501134 2016-12-31 0001501134 us-gaap:AdditionalPaidInCapitalMember 2015-12-31 0001501134 us-gaap:CommonStockMember 2016-01-01 2016-12-31 0001501134 us-gaap:PreferredStockMember 2015-12-31 0001501134 us-gaap:RetainedEarningsMember 2018-01-01 0001501134 us-gaap:AccumulatedOtherComprehensiveIncomeMember 2018-12-31 0001501134 us-gaap:CommonStockMember 2016-12-31 0001501134 us-gaap:AdditionalPaidInCapitalMember 2016-12-31 0001501134 us-gaap:AdditionalPaidInCapitalMember 2016-01-01 2016-12-31 0001501134 us-gaap:AdditionalPaidInCapitalMember 2017-12-31 0001501134 us-gaap:PreferredStockMember 2017-01-01 2017-12-31 0001501134 us-gaap:RetainedEarningsMember 2015-12-31 0001501134 us-gaap:AccumulatedOtherComprehensiveIncomeMember 2018-01-01 2018-12-31 0001501134 us-gaap:AccumulatedOtherComprehensiveIncomeMember 2017-12-31 0001501134 us-gaap:RetainedEarningsMember 2016-01-01 2016-12-31 0001501134 us-gaap:PreferredStockMember 2016-12-31 0001501134 us-gaap:AccumulatedOtherComprehensiveIncomeMember 2015-12-31 0001501134 us-gaap:PreferredStockMember 2017-12-31 0001501134 us-gaap:RetainedEarningsMember 2017-01-01 2017-12-31 0001501134 us-gaap:AccumulatedOtherComprehensiveIncomeMember 2016-01-01 2016-12-31 0001501134 us-gaap:AdditionalPaidInCapitalMember 2018-12-31 0001501134 us-gaap:RetainedEarningsMember 2018-12-31 0001501134 us-gaap:RetainedEarningsMember 2016-12-31 0001501134 2018-01-01 0001501134 us-gaap:AccumulatedOtherComprehensiveIncomeMember 2017-01-01 2017-12-31 0001501134 us-gaap:GeneralAndAdministrativeExpenseMember us-gaap:LeaseholdImprovementsMember 2016-01-01 2016-12-31 0001501134 nvta:CustomerMember us-gaap:AccountsReceivableMember us-gaap:CustomerConcentrationRiskMember 2018-01-01 2018-12-31 0001501134 srt:MaximumMember 2018-01-01 2018-12-31 0001501134 nvta:CustomerMember srt:MaximumMember us-gaap:SalesRevenueNetMember us-gaap:CustomerConcentrationRiskMember 2018-01-01 2018-12-31 0001501134 nvta:CustomerMember us-gaap:AccountsReceivableMember us-gaap:CustomerConcentrationRiskMember 2017-01-01 2017-12-31 0001501134 srt:MaximumMember us-gaap:CustomerRelationshipsMember 2018-01-01 2018-12-31 0001501134 nvta:CustomerMember us-gaap:SalesRevenueNetMember us-gaap:CustomerConcentrationRiskMember 2017-01-01 2017-12-31 0001501134 nvta:CustomerMember us-gaap:SalesRevenueNetMember us-gaap:CustomerConcentrationRiskMember 2016-01-01 2016-12-31 0001501134 nvta:CustomerMember us-gaap:SalesRevenueNetMember us-gaap:CustomerConcentrationRiskMember 2018-01-01 2018-12-31 0001501134 us-gaap:FurnitureAndFixturesMember 2018-01-01 2018-12-31 0001501134 us-gaap:EquipmentMember 2018-01-01 2018-12-31 0001501134 us-gaap:SoftwareAndSoftwareDevelopmentCostsMember 2018-01-01 2018-12-31 0001501134 us-gaap:AutomobilesMember 2018-01-01 2018-12-31 0001501134 us-gaap:ComputerEquipmentMember 2018-01-01 2018-12-31 0001501134 srt:MinimumMember 2018-01-01

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nvta:AltaVoiceMember

nvta:NewContingentMilestoneBasedOnAchievingRevenueTargetDuringTwoThousandSeventeenAndTwoThousandEighteenM

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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**  
Washington, D.C. 20549  
**Form 10 K**

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

For the fiscal year ended December 31, 2018

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

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

**Invitae Corporation**

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

Delaware 27 1701898

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

1400 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 x No o



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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 every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) 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 (§229.405 of this chapter) 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.

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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.

Large accelerated filer  Accelerated filer   
Non-accelerated filer  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 Act). Yes  No

As of June 29, 2018, the aggregate market value of common stock held by non-affiliates of the Registrant was approximately \$477.8 million, based on the closing price of the common stock as reported on The New York Stock Exchange for that date.

The number of shares of the registrant’s Common Stock outstanding as of February 22, 2019 was 76,811,562.

**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 2019 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” similar expressions, are forward looking statements. Forward looking statements include, but are not limited to, statements about:

- our views regarding the future of genetic testing and its role in mainstream medical practice;
- our mission and strategy for our business, products and technology, including our ability to expand our content and develop new content 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;
- our competitive strengths;
- 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, including potential acquisitions;
- our financial performance;
  - the impact of accounting pronouncements and our critical accounting policies, judgments, estimates and assumptions on our financial results;
- 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.

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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 companies and organizations in this report.

### **Overview**

Combining genetic testing services that support patient care throughout life’s journey – from inherited disease diagnosis, to family planning, to proactive health screening – 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.

### **Mission and strategy**

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.

Our strategy for long-term growth centers on five key drivers of our business, which we believe work in conjunction to create a flywheel effect extending our leadership position in the new market we are building:

**Expanding our content offering.** We intend to continue steadily adding additional content to the Invitae platform, ultimately leading to affordable access to the personal molecular information relevant

in enabling personalized medicine. The breadth and depth of our offering is a core and central contribution to an improved user experience.

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

**Driving volume.** We intend to increase our brand equity and visibility through excellent service and a variety of marketing and promotional techniques, including scientific publications and presentations, sales, marketing, public relations, social media and web technology vehicles. We believe that rapidly increasing the volume of customers using our platform helps us to attract partners.

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

**Lowering the cost and price of genetic information.** Our goal is to provide customers with a broad menu of genetic content at a reasonable price and rapid turn-around time in order to grow volume and further achieve economies of scale. As we do so and benefit from further cost savings, we expect that those cost savings will allow us to deliver still more comprehensive information at decreasing prices and further improve the customer experience, allowing us to reap the cumulative benefits from all of the efforts outlined above.

We seek to differentiate our service in the market by establishing an exceptional experience for our customers. 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 are certain 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.

#### ***Business overview***

We are focused on making comprehensive, high-quality genetic information more accessible 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 by 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 allows us to serve a large number of customers. 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 to help diagnose disease, inform family planning, and serve healthy individuals. In 2018, we accessioned approximately 303,000 samples and generated revenue of \$147.7 million reflecting an

approximate 102% and 117% increase over 2017 volume and revenue, respectively. In 2018, we achieved a full-year gross profit of \$67.6 million, compared to a full-year gross profit of \$18.1 million in 2017. In support of our efforts to reduce the cost per test, expand our test menu, and develop a scalable laboratory infrastructure, we incurred research and development expenses of \$63.5 million, \$46.5 million and \$44.6 million in 2018, 2017, and 2016, respectively.

**Genome network:** sharing genetic information on a global scale to advance science and medicine. We 2) 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. 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.

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, BioMarin Pharmaceutical Inc., Blueprint Medicines Corporation, Jazz Pharmaceuticals plc, Merck & Co., Inc., 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.

**Genome management:** building a secure and trusted genome management infrastructure. By 3)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.

### **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 AG; Color Genomics, Inc.; Connective Tissue Gene Test LLC; Cooper Surgical, Inc.; Eurofins Scientific; GeneDx, a subsidiary of OPKO Health, Inc.; Laboratory Corporation of America Holdings; MNG Laboratories, LLC; Myriad Genetics, Inc.; Natera, Inc.; Perkin Elmer, Inc.; PreventionGenetics, LLC; Progenity, Inc.; Quest Diagnostics Incorporated; and Sema4 Genomics; as well as other commercial and academic labs. In addition, there are 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. which is also one of our suppliers. 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;
- 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.

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.

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## **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 are 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 are 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. Where applicable, 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 (following a second round of private payer rate reporting in 2020 to establish rates for 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.

In March 2018, CMS published a final national coverage determination, or NCD, for next generation sequencing, or NGS, tests for patients with advanced cancer. The final NCD establishes full coverage for FDA-approved or FDA-cleared NGS-based companion diagnostic assays when offered for their FDA-approved or FDA-cleared use(s), ordered by the patient's treating physician for Medicare beneficiaries with advanced cancer (recurrent, relapsed, refractory, metastatic, or advanced stage III or IV cancer) who have not have previously been tested with the same test for the same primary diagnosis of cancer or are seeking repeat testing for a new primary cancer diagnosis, and have decided to seek further cancer treatment. The final NCD also gives MACs the authority to establish local coverage for NGS-based assays that are not FDA-approved or FDA-cleared companion diagnostics when offered to patients meeting the above-referenced criteria. It is unclear, however, whether MACs retain the authority to establish local coverage for NGS-based tests provided for patients with cancer that do not meet the above-referenced criteria - e.g., patients with earlier stage cancers or patients with a personal history of cancer - or if such tests are nationally non-covered under the NCD. If CMS interprets the final NCD to exclude coverage for patients with earlier stage cancers or patients with a personal history of cancer, MACs will no longer have discretion to cover our current tests when offered to such patients, notwithstanding historical Medicare coverage for such tests. An interpretation of the NCD that results in Medicare non-coverage for our current and future assays would have significant negative impact on our business, financial condition, and results of operations.

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

Our clinical reference laboratories in California 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. In 2018, we closed our laboratory in Cambridge, Massachusetts and transferred operations from that facility to our laboratory in San Francisco, California.

We have current certifications under CLIA to perform testing at our laboratory locations in San Francisco and Irvine, California. 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. California laws establish standards for day to day operations of our laboratories in San Francisco and Irvine. Such laws 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. Any such actions could materially affect our business. We maintain current licenses in good standing with DHS. However, we cannot provide assurance that DHS will at all times in the future find us to be in compliance with all such laws.

Several states require the licensure of out of state laboratories that accept specimens from those states and/or receive specimens from laboratories in those states. Our laboratories hold the required out of state laboratory licenses for Maryland, New York, Pennsylvania, and Rhode Island.

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

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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 or saliva 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 describes the evolution 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.

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 of 2009, 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 covered entities, including health care providers 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 persons or entities that perform certain functions for or on behalf of a covered entity that involve the creation, receipt, maintenance, or transmittal of protected health information. Business associates are defined to include a subcontractor 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 of a breach of unsecured protected health information.

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 penalties that may be imposed on a covered entity or business associate for violating HIPAA. A covered entity or business associate may also be 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 acts or practices 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, such as but not limited to 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 pursuing 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 statutes, 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, 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 individuals located in 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.

The European Union’s General Data Protection Regulation, or GDPR, took effect in May 2018. The GDPR applies to any business, regardless of its location, that provides goods or services to residents in the European Union. The GDPR imposes strict requirements on controllers and processors of personal data, including special protections for “sensitive information” which includes health and genetic information of data subjects residing in the European Union. The GDPR also grants individuals various rights in relation to their personal data including the right to access, rectification, objection to processing and deletion, and provides an individual with an express right to seek legal remedies if the individual believes his or her rights have been violated. Failure to comply with the requirements of the GDPR and the related national data protection laws of the member states of the European Union, which may deviate slightly from the GDPR, may result in significant fines.

#### ***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.

A recently enacted law, the Eliminating Kickbacks in Recovery Act of 2018 (“EKRA”), prohibits payments for referrals to recovery homes, clinical treatment facilities, and laboratories. EKRA’s reach extends beyond federal health care programs, to include private insurance (i.e., it is an “all payer” statute). For purposes of EKRA, the term “laboratory” is defined broadly and without reference to any connection to substance use disorder treatment. EKRA is a criminal statute and violations can result in fines of up to \$200,000, up to 10 years in prison, or both, per violation. The law includes a limited number of exceptions, some of which closely align with corresponding Anti-Kickback Statute exceptions and safe harbors and others that materially differ.

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. 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**

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. patent applications and corresponding non-U.S. patents and patent applications directed to various aspects of our laboratory, analytic and business practices. We intend to pursue further patent protection where appropriate.



### ***Trade secrets***

In addition to seeking patent protection for some of our laboratory, analytic and business practices, we also rely on trade secrets, including unpatented know how, technology and other proprietary information, to maintain and develop our competitive position. We have developed proprietary procedures for both the laboratory processing of patient samples and the analysis of the resulting data to generate clinical reports. For example, we have automated aspects of our processes for curating information about known variants, identifying variants in an individual's sequence information, associating those variants with known information about their potential effects on disease, and presenting that information for review by personnel responsible for its interpretation and for the delivery of test reports to 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 concentration**

We receive payment for our tests from partners, patients, institutional customers and third-party payers. As of December 31, 2018, substantially all our revenue has been derived from test reports generated from our assays. A single payer accounted for 22%, 13%, and 11% of our revenue for the years ended December 31, 2018, 2017, and 2016, respectively.

## **Employees**

We had 788 employees as of December 31, 2018.

## **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](http://www.invitae.com). The information contained on, or that can be accessed through, our website is not part of this annual report on Form 10 K.

We make available free of charge on our website our annual reports on Form 10 K, quarterly reports on Form 10 Q, current reports on Form 8 K and amendments to those reports, as soon as reasonably practicable after we electronically file or furnish such materials to the Securities and Exchange Commission, or SEC. You may obtain a free copy of these reports in the Investor Relations section of our website, [www.invitae.com](http://www.invitae.com). All reports that we file are also available at [www.sec.gov](http://www.sec.gov).

## **ITEM 1A. Risk Factors.**

### **Risks related to our business and strategy**

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

We have incurred substantial losses since our inception. For the years ended December 31, 2018, 2017 and 2016, our net losses were \$129.4 million, \$123.4 million and \$100.3 million, respectively. At December 31, 2018, our accumulated deficit was \$516.7 million. While our revenue has increased over time, 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, which may increase our operating expenses. In addition, as a result of the integration of acquired businesses, we may be subject to unforeseen or additional expenditures, costs or liabilities. 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; identify, acquire and successfully integrate companies, assets or technologies in areas that are complementary to our business strategy; successfully enter into other strategic collaborations or relationships; obtain access to capital on acceptable terms and effectively utilize that capital; identify, hire and successfully integrate additional employees; continue to expand, automate and upgrade our laboratory, technology and data systems; obtain, maintain and expand 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 2017, we established a leading position in family health genetic information services through the strategic acquisition of reproductive health testing capabilities, which included our acquisition of Good Start Genetics, Inc., or Good Start, a molecular diagnostics company focused on preimplantation and carrier screening for inherited disorders, and CombiMatrix Corporation, a company specializing in prenatal diagnosis, miscarriage analysis and pediatric developmental disorders. In 2017 we also 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, and Ommdom, Inc. and its product, CancerGene Connect, an end-to-end platform for collecting and managing genetic family histories to deliver personalized genetic risk information.

With respect to our acquired businesses 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 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 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. 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 raise additional funds. If we raise funds by issuing equity securities, dilution to our stockholders could result. Any equity securities issued also may provide for rights, preferences or privileges senior to those of holders of our common stock. If we raise funds by issuing debt securities, these debt securities would have rights, preferences and privileges senior to those of holders of our common stock. The terms of debt securities issued or borrowings could impose significant restrictions on our operations. If we raise funds through collaborations and licensing arrangements, we might be required to relinquish significant rights to our technologies or products, or grant licenses on terms that are not favorable to us. If the price of our common stock is low or volatile, we may not be able to acquire other companies for stock. 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, we may 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 2018 Note Purchase 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, cost-effective

and has received prior authorization.

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 most of the large commercial third-party payers in the United States, and the Centers for Medicare and Medicaid Services, or CMS, 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

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a contracted rate for reimbursement, there is typically a greater coinsurance or copayment 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 often vary from payer to payer, and we have needed additional time and resources to comply with them. We have also experienced, and may continue to experience, delays in or denials of coverage if we do not adequately comply with these requirements. Our third-party payers have also requested, and in the future may request, audits of the amounts paid to us. We could be adversely affected if we are required to repay these or other payers for alleged overpayments due to lack of compliance with their reimbursement policies. 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, research and development activities and pursue acquisitions. We believe our existing cash and cash equivalents as of December 31, 2018, revenue from sales of our tests and available debt under our 2018 Note Purchase 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 2018 Note Purchase Agreement are subject to covenants, including quarterly covenants to achieve certain revenue levels as well as additional covenants, including limits on our ability to dispose of assets, undergo a change in control, merge with or acquire other entities, incur debt, incur liens, pay dividends or other distributions to holders of our capital stock, repurchase stock and make investments, in each case subject to certain exceptions. Our obligations under our 2018 Note Purchase Agreement are secured by a security interest on substantially all of our and certain of our subsidiaries' assets.

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, selling and marketing initiatives, or potential

acquisitions. 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 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 AG, Color Genomics, Inc., Connective Tissue Gene Test LLC, Cooper Surgical, Inc., Eurofins Scientific, GeneDx, a subsidiary of OPKO Health, Inc., MNG Laboratories, LLC, Myriad Genetics, Inc., Natera, Inc., Perkin Elmer, Inc., PreventionGenetics, LLC, Progenity, Inc. and Sema4 Genomics;

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., which 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;

quality;

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, selling and marketing capabilities, lobbying efforts, 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, sell their tests at prices designed to win significant levels of market share, or obtain reimbursement from more third-party payers and at higher prices than we do. 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

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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. In addition, some of our competitors have obtained approval or clearance for certain of their tests from the U.S. Food and Drug Administration, or FDA. If payers decide to reimburse only for tests that are FDA-approved or FDA-cleared, or if they are more likely to reimburse for such tests, we may not be able to compete effectively unless we obtain similar approval or clearance for our tests. 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 will likely 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. As we grow, any failure of our controls or interruption of our production facilities or systems will have a larger impact on our business and financial operations. 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.

***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, credit card 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 Health 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 Unfair and Deceptive Acts and Practices, or 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. The European Union's General Data Protection Regulation, or GDPR, took effect in May 2018. The GDPR applies to any business, regardless of its location, that provides goods or services to residents in the European Union. The GDPR imposes strict requirements on controllers and processors of personal data, including special protections for "sensitive information" which includes health and genetic information of data subjects residing in the European Union. The GDPR also grants individuals various rights in relation to their personal data including the right to access, rectification, objection to processing and deletion, and provides an individual with an express right to seek legal remedies if the individual believes his or her rights have been violated. Failure to comply with the requirements of the GDPR and the related national data protection laws of the member states of the European Union, which may deviate slightly from the GDPR, may result in significant fines.

Additionally, the implementation of GDPR has led other jurisdictions to either amend or propose legislation to amend their existing data privacy and cybersecurity laws to resemble the requirements of GDPR. For example, on June 28, 2018, California adopted the California Consumer Privacy Act of 2018, or CCPA and amended the law in September 2018 to exempt all protected health information (PHI) collected by certain parties subject to HIPAA. The effective date of the CCPA is January 1, 2020; however, legislators have stated that they intend to propose amendments to the CCPA before it goes into effect. The CCPA gives California residents expanded rights to access and delete their personal information, opt out of certain personal information sharing, and receive detailed information about how their personal information is used. The CCPA provides for civil penalties for violations, as well as a private right of action for data breaches that is expected to increase data breach litigation.

It is possible the GDPR, CCPA and other data protection 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 state to state, and may vary based on whether testing is performed in the United States or in the local country. Complying with these various laws and regulations 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 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 software developers, geneticists, biostatisticians, certified laboratory scientists and other

scientific and technical personnel to process and interpret our genetic tests. In addition, we expect the need to continue to expand our sales force with qualified and experienced personnel. Competition in our industry for qualified employees is intense, and we may not be able to attract or retain qualified personnel in the future due to the competition for qualified personnel among life science and technology 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.

***We 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 depends 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 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.

***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. Also, we plan to introduce patient-initiated testing in 2019, in which we will facilitate the ordering of our genetic tests through an online network of physicians. Since we have limited experience directly marketing to patients, we may not be successful in increasing demand for our tests through this new channel. Patient-initiated testing may also be perceived negatively by our existing customer base of clinicians and genetic counselors, in which case our core business could be harmed.



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.

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. In addition, our entry into the reproductive health testing market exposes us to increased liability. 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 and our business adversely affected unless we continually update our offerings to reflect new scientific knowledge about genes and genetic variations and their role in diseases and treatment therapies.

***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 primarily through our internal sales force. Historically, our sales efforts have been focused primarily on hereditary cancer and more recently, on reproductive health. 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, 2018, and early 2019. 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 also plan to increase our consumer advertising in connection with our introduction of patient-initiated testing in 2019, which could be costly. We have limited experience implementing these types of 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 a limited number of 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.

***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.

***We rely on a limited number of suppliers or, in some cases, sole suppliers, for some of our laboratory instruments, materials and services, 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 short- or long-term agreements with most of 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 also rely on a subsidiary of Illumina, Verinata Health, Inc., to perform non-invasive prenatal screening, or NIPS, testing on our behalf. In the event of any disruption or termination of these services by Verinata, it may be difficult to find a replacement NIPS offering, which could harm our business, financial condition, results of operation 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 will be able to secure alternative equipment, reagents and other materials, and bring such equipment, reagents and materials on line and revalidate them without experiencing interruptions in our workflow. In the case of an alternative supplier for Illumina, we cannot assure you that replacement sequencers and associated reagents will be available or will meet our quality control and performance requirements for our laboratory operations. If we encounter delays or difficulties in securing, reconfiguring or revalidating the equipment and reagents we require for our tests, our business, financial condition, results of operations and reputation could be adversely affected.

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***If our laboratories in California 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 and Irvine, California. 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. This risk is especially high for us since we perform the substantial majority of our tests at our San Francisco laboratory, which is located in an active seismic region, and we do not have a redundant facility to perform the same tests in the event our San Francisco laboratory is inoperable. 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.

***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.

***Changes in financial accounting standards may cause adverse and unexpected revenue fluctuations and affect our reported results of operations.***

We prepare our financial statements in accordance with U.S. GAAP. These principles are subject to interpretation by the SEC and various bodies formed to interpret and create appropriate accounting principles. Changes in these accounting standards or practices may have a significant effect on our results

of operations. For example, in May 2014, the Financial Accounting Standards Boards, or FASB, issued Accounting Standards Update 2014-09, "Revenue from Contracts from Customers (Topic 606)," which superseded most existing revenue recognition guidance. We implemented Topic 606 effective January 1, 2018. Please see Note 2, "Summary of significant accounting policies" in the Notes to Consolidated Financial Statements for more information.

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From inception through December 2017, we recognized revenue principally when cash was received. Under Topic 606 we now generally recognize revenue on an accrual basis. Accrual amounts are recognized based on estimates of the consideration that we expect to receive and such estimates will be updated and subsequently recorded until fully settled. Adjustments to these estimates may cause fluctuations in our revenue, and may have a material adverse effect on our revenue and our results of operations.

***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 Invitae Family History Tool, PIN, and CancerGene Connect platform. 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 and results of operations.

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 a limited number of 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 was 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. In the fourth quarter of 2018, we completed our analysis to determine the effect of the Tax Act and no material adjustments were recognized as of December 31, 2018.

**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. 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 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 December 2018, a draft bill titled the “Verifying Accurate Leading-edge IVCT Development Act of 2018”, or VALID Act, was released for discussion. The draft bill proposes a risk-based approach to regulate LDTs and creates a new in vitro clinical test, or IVCT, category of regulated products, which includes LDTs, and a regulatory structure under the FDA. As proposed, the draft bill grandfathers many existing tests from the proposed premarket approval, quality systems, and labeling requirements, respectively, but would require such tests to comply with other regulatory requirements (e.g., registration and notification, adverse event reporting). 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 (either as medical devices or as part of a new stand-alone regulatory category for IVCTs), 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 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 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. 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 out-of-state laboratory licenses to conduct testing on specimens from Maryland, New York, Pennsylvania and Rhode Island.

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 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;
- 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;
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the federal false claims law, 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 may also be 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 are 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 are 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. The payment rates calculated under PAMA went into effect starting January 1, 2018. Where applicable, 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 (following a second round of private payer rate reporting in 2020 to establish rates for 2021 through 2023).

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 March 2018, CMS published a final national coverage determination, or NCD, for next generation sequencing, or NGS, tests for patients with advanced cancer. The final NCD establishes full coverage for FDA-approved or FDA-cleared NGS-based companion diagnostic assays when offered for their FDA-approved or FDA-cleared use(s), ordered by the patient's treating physician for Medicare beneficiaries with advanced cancer (recurrent, relapsed, refractory, metastatic, or advanced stage III or IV cancer) who have not have previously been tested with the same test for the same primary diagnosis of cancer or are seeking repeat testing for a new primary cancer diagnosis, and have decided to seek further cancer treatment. The final NCD also gives MACs the authority to establish local coverage for NGS-based assays that are not FDA-approved or FDA-cleared companion diagnostics when offered to patients meeting the above-referenced criteria. It is unclear, however, whether MACs retain the authority to establish local coverage for NGS-based tests provided for patients with cancer that do not meet the above-referenced criteria - e.g., patients with earlier stage cancers or patients with a personal history of cancer - or if such tests are nationally non-covered under the NCD. If CMS interprets the final NCD to exclude coverage for patients with earlier stage cancers or personal history of cancer, MACs will no longer have discretion to cover our current tests when offered to such patients, notwithstanding historical Medicare coverage for

such tests. An interpretation of the NCD that results in Medicare non-coverage for our current and future assays would have significant negative impact on our business, financial condition and results of operations.

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. In 2018, we decommissioned our laboratory in Cambridge, Massachusetts; however, we could be held liable for any damages resulting from our prior use of hazardous chemicals and biological materials at this facility. 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. We use a limited number of independent distributors to sell our tests internationally, which requires 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, 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 addition, the Dodd-Frank Wall Street Reform and Consumer Protection Act, or the Dodd-Frank Act, enacted in 2010, includes significant corporate governance and executive-compensation-related provisions. 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 compiled the system and process documentation necessary to perform the evaluation needed to comply with Section 404 of the Sarbanes-Oxley Act. We need to maintain and enhance these processes and controls as we grow and we have required, and may continue to 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, as described below, 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 have elected 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 have chosen 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 because we have chosen 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 is volatile, and you may not be able to sell shares of our common stock at or above the price you paid.***

The trading price of our common stock is 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, 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.

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

At December 31, 2018, our total gross deferred tax assets were \$131.9 million. Due to our lack of earnings history and uncertainties surrounding our ability to generate future taxable income, the net deferred tax assets have been fully offset by a valuation allowance. The deferred tax assets were primarily comprised of federal and state tax net operating losses and tax credit carryforwards. Furthermore, under Section 382 of the Internal Revenue Code of 1986, as amended, or the Internal Revenue Code, if a corporation undergoes an "ownership change," the corporation's ability to use its pre-change net operating loss carryforwards, or NOLs, and other pre-change tax attributes (such as research tax credits) to offset its future taxable income may be limited. In general, an "ownership change" occurs if there is a cumulative change in our ownership by "5% shareholders" that exceeds 50 percentage points over a rolling three-year period. Our existing NOLs and tax credit carryovers may be subject to limitations arising from previous ownership changes, and if we undergo one or more ownership changes in connection with 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 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 2018 Note Purchase Agreement limits our ability to pay 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.

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***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 headquarters and main production facility is located in San Francisco, California, where we currently lease and occupy approximately 103,000 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.

Our subsidiary Good Start leases approximately 67,000 square feet of laboratory and office space in Massachusetts, and our subsidiary CombiMatrix leases approximately 12,000 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 February 28, 2019, are as follows:

<b>Name</b>	<b>Age</b>	<b>Position</b>
<b>Executive officers</b>		
Randal W. Scott, Ph.D.	61	Executive Chairman and Director
Sean E. George, Ph.D.	45	President, Chief Executive Officer, Director and Co-Founder
Lee Bendekgey	61	Chief Operating Officer and Secretary
Thomas R. Brida	48	General Counsel
Shelly D. Guyer	58	Chief Financial Officer
Robert L. Nussbaum, M.D.	69	Chief Medical Officer
Katherine A. Stueland	43	Chief Commercial Officer

*Randal W. Scott, Ph.D.* has served as our Executive Chairman since January 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 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 2004. Mr. Bendekgey holds a B.A. in French and Political Science from Kalamazoo College and a J.D. from Stanford Law School.

*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 the U.C. Berkeley School of Law.

*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 National Academy 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 B.S. 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.

*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.

## **PART II**

### **ITEM 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 “NVTX” since February 12, 2015. Prior to that time, there was no public market for our common stock.

As of February 22, 2019, there were 48 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. In addition, our 2018 Note Purchase Agreement limits our ability to pay 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.

#### **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.

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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, 2018 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	12/31/2018
Invitae Corporation	\$100.00	\$48.15	\$46.57	\$53.26	\$64.87
S&P 500	\$100.00	\$97.87	\$107.20	\$128.02	\$120.03
S&P 500 Healthcare Index	\$100.00	\$102.41	\$97.94	\$117.53	\$123.05

**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, 2018 and 2017 and the selected consolidated statements of operations data for each of the years ended December 31, 2018, 2017, and 2016 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, 2016, 2015 and 2014 and the selected consolidated statement of operations data for the years ended December 31, 2015 and 2014 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,				
	2018 <sup>(1)</sup>	2017 <sup>(2)</sup>	2016	2015 <sup>(3)</sup>	2014
	(In thousands except per share data)				
<b>Consolidated Statements of Operations Data</b>					
Test revenue	\$144,560	\$65,169	\$24,840	\$8,378	\$1,604
Other revenue	3,139	3,052	208	—	—
Total revenue	147,699	68,221	25,048	8,378	1,604
Costs and operating expenses:					
Cost of revenue <sup>(4)</sup>	80,105	50,142	27,878	16,523	5,624
Research and development <sup>(4)</sup>	63,496	46,469	44,630	42,806	22,063
Selling and marketing <sup>(4)</sup>	74,428	53,417	28,638	22,479	8,669
General and administrative <sup>(4)</sup>	52,227	39,472	24,085	16,047	12,600
Total costs and operating expenses	270,256	189,500	125,231	97,855	48,956
Loss from operations	(122,557 )	(121,279 )	(100,183 )	(89,477 )	(47,352 )
Other income (expense), net	(2,568 )	(303 )	348	(94 )	(79 )
Interest expense	(7,030 )	(3,654 )	(421 )	(211 )	(61 )
Net loss before taxes	(132,155 )	(125,236 )	(100,256 )	(89,782 )	(47,492 )
Income tax benefit	(2,800 )	(1,856 )	—	—	—
Net loss	\$(129,355)	\$(123,380)	\$(100,256)	\$(89,782)	\$(47,492)
Net loss per share, basic and diluted <sup>(5)</sup>	\$(1.94 )	\$(2.65 )	\$(3.02 )	\$(3.18 )	\$(56.14 )
Shares used in computing net loss per share, basic and diluted	66,747	46,512	33,176	28,213	846

	As of December 31,				
	2018 <sup>(1)</sup>	2017 <sup>(2)</sup>	2016	2015 <sup>(3)</sup>	2014
	(In thousands)				
<b>Consolidated Balance Sheet Data:</b>					
Cash and cash equivalents	\$112,158	\$12,053	\$66,825	\$73,238	\$107,027
Working capital	129,127	53,294	87,047	120,433	102,020
Total assets	282,959	211,078	130,651	156,676	128,778
Capital lease obligations	3,312	5,412	1,575	3,164	3,535
Debt	74,477	39,084	12,102	7,040	—
Total liabilities	121,120	89,284	31,577	18,300	10,049
Convertible preferred stock	—	—	—	—	202,305
Accumulated deficit	(516,712 )	(398,598)	(275,218)	(174,962)	(85,180 )
Total stockholders' equity (deficit)	161,839	121,794	99,074	138,376	(83,576 )

(1)On January 1, 2018, we adopted ASC Topic 606 using the modified retrospective transition method. Prior period amounts are presented as originally reported based upon the accounting standards in effect for those periods.

(2)In 2017, we completed the acquisition of four businesses which are included in our selected consolidated financial data as of each acquisition date.

(3)Upon the closing of our initial public offering in February 2015, 141,131,524 shares of convertible preferred stock then outstanding converted into 23,521,889 shares of common stock.

(4)Includes employee stock based compensation as follows:

	Year Ended December 31,				
	2018	2017	2016	2015	2014
	(In thousands)				
Cost of revenue	\$2,960	\$2,093	\$1,353	\$368	\$102
Research and development	7,017	6,158	4,976	1,545	382
Selling and marketing	4,887	3,956	1,709	688	216
General and administrative	5,986	7,014	2,661	876	271
Total stock-based compensation	\$20,850	\$19,221	\$10,699	\$3,477	\$971

(5)See Note 2, "Summary of significant accounting policies," and Note 13, "Net loss per share," in our audited consolidated financial statements included elsewhere in this report for an explanation of the calculations of our basic and diluted net loss per share.

## **ITEM 7. Management's Discussion and Analysis of Financial Condition and Results of Operations.**

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

### **Business overview**

We offer high-quality, comprehensive, affordable genetic testing across multiple clinical areas, including hereditary cancer, cardiology, neurology, pediatrics, metabolic conditions and rare diseases. To augment our offering and realize our mission, we have acquired multiple assets. We acquired four businesses in 2017 and in doing so expanded our suite of genome management offerings and completed our entry into prenatal and perinatal genetic testing.

In 2017, we established a leading position in family health genetic information services through the strategic acquisition of reproductive health testing capabilities. 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. This acquisition was complemented by the acquisition in June 2017 of Ommdom, Inc. and its product, CancerGene Connect, an end-to-end platform for collecting and managing genetic family histories to deliver personalized genetic risk information. In August 2017, we acquired Good Start Genetics, Inc., or Good Start, a molecular diagnostics company focused on preimplantation and carrier screening for inherited disorders. In November 2017, we completed our acquisition of CombiMatrix Corporation (CombiMatrix), a company specializing in prenatal diagnosis, miscarriage analysis and pediatric developmental disorders.

We have experienced rapid growth. For the years ended December 31, 2018, 2017 and 2016, our revenue was \$147.7 million, \$68.2 million and \$25.0 million, respectively and we incurred net losses of \$129.4 million, \$123.4 million and \$100.3 million, respectively. At December 31, 2018, our accumulated deficit was \$516.7 million. We increased our number of employees to 788 at December 31, 2018 from 594 on December 31, 2017. Our sales force grew to 128 at December 31, 2018 from 103 at December 31, 2017. We expect headcount will continue to increase in 2019 as we add staff to support anticipated growth. Sales of our tests have grown significantly. In 2018, 2017 and 2016, we generated approximately 292,000, 145,000 and 57,000 billable tests, respectively. Through December 31, 2018, approximately 29% of the billable tests we performed have been billable to institutions and patients, and the remainder have been billable to third-party payers. Many of the gene tests on our assays are tests for which private insurers reimburse. However, when we do not have reimbursement policies or contracts with private insurers, our claims for reimbursement may be denied upon submission, and we must appeal the claims. The appeals process is time consuming and expensive, and may not result in payment. Even if we are successful in achieving reimbursement, we may be paid at lower rates than if we were under contract with the third-party payer. When there is not a contracted rate for reimbursement, there is typically a greater coinsurance or copayment requirement from the patient which may result in further delay or decreased likelihood of collection.

We expect to incur operating losses for the near-term future and may need to raise additional capital in order to fund our operations. If we are unable to achieve our revenue growth objectives and successfully manage our costs, we may not be able to achieve profitability.

We believe that the keys to our future growth will be to increase billable test volumes, achieve broad reimbursement coverage for our tests from third-party payers, consistently drive down the price for genetic analysis and interpretation, steadily increase the amount of genetic content we offer, consistently improve the client experience, drive physician and patient utilization of our website for ordering and delivery of results and increase the number of strategic partners working with us to add value for our clients.

### **Factors affecting our performance**

#### ***Number of billable tests***

The growth in our genetic testing business is tied to the number of tests for which we bill third-party payers, institutions, partners or patients, which we refer to as billable tests. We typically bill for our services following delivery of the billable test report derived from testing samples and interpreting the results. We incur the expenses associated with a test in the period in which the test is processed regardless of when payment is received with respect to that test. We believe the number of billable tests in any period is the most important indicator of the growth in our business, and with time, this will translate into the number of customers we add to the platform and the revenue generated per customer.

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***Success obtaining and maintaining reimbursement***

Our ability to increase the number of billable tests and our revenue will depend in part on our success achieving broad reimbursement coverage and laboratory service contracts for our tests from third-party payers and agreements with institutions and partners. Reimbursement may depend on a number of factors, including a payer's determination that a test is appropriate, medically necessary and cost-effective, as well as whether we are in contract, where we get paid more consistently and at higher rates. Because each payer makes its own decision as to whether to establish a policy or enter into a contract to reimburse for our testing services, seeking these approvals is a time-consuming and costly process. In addition, clinicians may decide not to order our tests if the cost of the test is not covered by insurance. Our revenue growth also depends on our ability to successfully promote the adoption of our testing services and expand our base of ordering clinicians. We believe that establishing coverage and obtaining contracts from third-party payers is an important factor in gaining adoption by ordering clinicians. As of December 2018, we have entered in to contracts for laboratory services with payers covering approximately 264 million lives, comprised of Medicare, most national health plans, and Medicaid in 37 states, including California (Medi-Cal), our home state.

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, tests provided by companies we acquire and any future tests we may develop. However, if we are not able to continue to obtain and maintain adequate reimbursement from third-party payers and institutions for our testing services and expand the base of clinicians ordering our tests, we may not be able to effectively increase the number of billable tests or our revenue.

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

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

***Ability to expand our genetic content***

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

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

We plan to continue to invest in our genetic testing and information management business. We deploy state-of-the-art and costly technologies in our genetic testing services, and we intend to continue to scale our infrastructure, including our testing capacity and information systems. We also expect to incur software development costs as we seek to further automate our laboratory processes and our genetic interpretation

and report sign-out procedures, scale our customer service capabilities and expand the functionality of our website. We plan to hire additional personnel as necessary to support anticipated growth, including software engineers, sales and marketing personnel, billing personnel, research and development personnel, medical specialists, biostatisticians and geneticists. We will also incur additional costs related to the expansion of our production facility in San Francisco to accommodate growth. In addition, we expect to incur ongoing expenses as a result of operating as a public company. The expenses we incur may vary significantly by quarter, as we focus on building out different aspects of our business.



### ***How we recognize revenue***

From inception through December 31, 2017, we recognized revenue principally when cash was received. Effective January 1, 2018, we implemented Financial Accounting Standards Board Accounting Standards Codification Topic 2014-09, *Revenue from Contracts with Customers* ("Topic 606"), using the modified retrospective method. (See Note 3, "Revenue, accounts receivable and deferred revenue" in the Notes to Consolidated Financial Statements included elsewhere in this report.) Prior period amounts are not adjusted and continue to be reported under the accounting standards in effect for those periods. Under Topic 606, we generally recognize revenue on an accrual basis, which is when a customer obtains control of the promised goods or services, typically a test report. Accrual amounts recognized are based on estimates of the consideration that we expect to receive and such estimates will be adjusted and subsequently recorded until fully settled. Changes to such estimates may increase or decrease revenue recognized in future periods. Revenue from our tests may not be equal to billed amounts due to a number of factors, including differences in reimbursement rates, the amounts of patient copayments, the existence of secondary payers and claims denials.

### **Financial overview**

#### ***Revenue***

We primarily generate revenue from the sale of our tests, which provide the analysis and associated interpretation of the sequencing of parts of the genome. Clients are billed upon delivery of test results to the physician. Our ability to increase our revenue will depend on our ability to increase our market penetration, obtain contracted reimbursement coverage from third-party payers, enter into contracts with institutions and partners, and increase the rate at which we are paid for tests performed.

#### ***Cost of revenue***

Cost of revenue reflects the aggregate costs incurred in delivering test results to clinicians and includes expenses for materials and supplies, personnel-related costs, equipment and infrastructure expenses associated with testing and allocated overhead including rent, equipment depreciation and utilities. Costs associated with performing our test are recorded as the patient's sample is processed. We expect cost of revenue to generally increase in line with the increase in the number of tests we perform. However, we expect that the cost per test will decrease over time due to the efficiencies we expect to gain as test volume increases and from automation and other cost reductions, but it could fluctuate quarter-to-quarter.

#### ***Operating expenses***

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

#### ***Research and development***

Research and development expenses represent costs incurred to develop our technology and future tests. These costs are principally for process development associated with our efforts to expand the number of genes we can evaluate in our tests and with our efforts to lower the cost of performing our test. In addition, we incur process development costs to further develop the software we use to operate our laboratory, analyze the data it generates, process customer orders, deliver reports and automate our business processes. These costs consist of personnel-related costs, laboratory supplies and equipment expenses, consulting costs, amortization of acquired intangibles, and allocated overhead including rent, information technology, equipment depreciation and utilities.

We expense all research and development costs in the periods in which they are incurred. We expect our research and development expenses to increase as we continue our efforts to develop additional tests, make investments to reduce testing costs and work on scaling the business.

#### ***Selling and marketing***

Selling and marketing expenses consist of personnel-related costs, client service expenses, advertising and marketing expenses, educational and promotional expenses, market research and analysis, amortization of acquisition-related intangible assets and allocated overhead including rent, information technology, equipment depreciation and utilities. We expect our selling and marketing expenses to significantly increase as we expand our salesforce and increase our advertising.

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*General and administrative*

General and administrative expenses include executive, finance and accounting, billing and collections, legal and human resources functions. These expenses include personnel-related costs, audit and legal expenses, consulting costs, amortization of acquisition-related intangible assets, losses incurred in relation to collaboration agreements and allocated overhead including rent, information technology, equipment depreciation and utilities. We expect our general and administrative expenses to increase at a moderate growth rate as we support continued growth of operations.

***Other income (expense), net***

Other income (expense), net, primarily consists of interest income, offset by losses on extinguishment of debt, adjustments to fair value of acquisition liabilities, and losses on disposal of assets.

***Interest expense***

Interest expense is attributable to debt financing and capital leases. See Note 9 “Commitments and contingencies” in the Notes to Consolidated Financial Statements included elsewhere in this report.

***Income tax benefit***

Income tax benefit primarily consists of tax impacts of our deferred income tax asset assessments resulting from our acquisitions.

**Critical accounting policies and estimates**

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

***Revenue recognition***

We generate test revenue primarily from delivery of test reports generated from our assays. Other revenue consists primarily of revenue from genome network subscription services which we recognize on a straight-line basis over the subscription term, and from revenue from collaboration agreements. Effective January 1, 2018, we adopted ASC Topic 606. Under Topic 606 we generally recognize revenue on an accrual basis, that is when a customer obtains control of the promised goods or services which for us is delivery of a test report. Accrual amounts recognized under Topic 606 are based on an estimate of the consideration that we expect to receive, and such estimates will be adjusted and subsequently recorded until fully settled. The estimate of the consideration that we expect to receive requires significant judgment by management and any adjustments may be material. Prior period amounts are not adjusted and continue to be reported under the accounting standards in effect for those periods.

***Business Combinations - Purchase Accounting***

We apply ASC 805, *Business Combinations*, or ASC 805, which is the accounting guidance related to business combinations. The standard requires recognition of assets acquired, liabilities assumed, and contingent consideration at their fair value on the acquisition date with subsequent changes recognized in earnings; requires acquisition-related expenses and restructuring costs to be recognized separately from the business combination and expensed as incurred; requires in-process research and development to be capitalized at fair value as an indefinite-lived intangible asset until completion or abandonment; and

requires that changes in accounting for deferred tax asset valuation allowances and acquired income tax uncertainties after the measurement period be recognized as a component of provision for taxes.

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We account for acquisitions of entities that include inputs and processes and have the ability to create outputs as business combinations. The purchase prices of acquisitions are allocated to tangible assets, liabilities and identifiable intangible assets acquired based on their estimated fair values. The excess of purchase prices over those fair values is recorded as goodwill. Acquisition-related expenses are expensed as incurred. While we use our best estimates and assumptions as a part of the process to accurately value assets acquired and liabilities assumed at the business combination date, these estimates and assumptions are inherently uncertain and subject to refinement. Our key assumptions used have included projected revenue, cost of goods sold and operating expenses for the acquired entities, as well as discount rates. As a result, during the measurement period, which may be up to one year from the business combination date, we may record adjustments to the assets acquired and liabilities assumed, with the corresponding offset to goodwill. After the measurement period, we record adjustments to assets acquired or liabilities assumed subsequent to the measurement period in our operating results in the period in which the adjustments were determined.

### **Goodwill**

In accordance with ASC 350, *Intangibles - Goodwill and Other*, or ASC 350, we do not amortize goodwill or other intangible assets with indefinite lives but rather test them for impairment. ASC 350 requires us to perform an impairment review of our goodwill balance at least annually, which we do in the fourth quarter of each year for our single consolidated reporting unit, and whenever events or changes in circumstances indicate that the carrying amount of these assets may not be recoverable.

### **Stock-based compensation**

Stock-based compensation expense is measured at the date of grant and is based on the estimated fair value of the award. Compensation cost is recognized as expense on a straight-line basis over the vesting period for options and restricted stock unit, or RSU, awards and on an accelerated basis for performance-based restricted stock unit, or PRSU, awards. We recognize stock-based compensation expense associated with PRSU grants when we determine the achievement of performance conditions is probable. In determining the fair value of stock options and Employee Stock Purchase Plan, or ESPP, purchases, we estimate the grant date fair value, and the resulting stock-based compensation expense, using the Black-Scholes option-pricing model. We estimate the grant date fair value of RSU and PRSU awards based on the grant date share price.

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

For the years ended December 31, 2018, 2017 and 2016, we recorded stock-based compensation expense of \$20.9 million, \$19.2 million and \$10.7 million, respectively. At December 31, 2018, unrecognized compensation expense related to unvested stock options was \$4.5 million, which we expect to recognize over a weighted-average period of 1.8 years. Unrecognized compensation expense related to RSUs at December 31, 2018, net of estimated forfeitures, was \$22.6 million, which we expect to recognize on a straight-line basis over a weighted-average period of 2.1 years.

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

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

*Expected volatility*—Because we were privately held until our initial public offering in February 2015 and did not have any trading history for our common stock, we have estimated expected volatility using our own

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

stock price becomes available. We estimate expected volatility for ESPP purchases using our own stock price volatility over the expected six-month term of the ESPP purchase period.

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

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

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

**Results of Operations****Comparison of the Years Ended December 31, 2018 and 2017**

	Year Ended December 31,		Dollar	%
	2018	2017	Change	Change
Revenue:				
Test revenue	\$144,560	\$65,169	\$79,391	122%
Other revenue	3,139	3,052	87	3%
Total revenue	147,699	68,221	79,478	117%
Operating expenses:				
Cost of revenue	80,105	50,142	29,963	60%
Research and development	63,496	46,469	17,027	37%
Selling and marketing	74,428	53,417	21,011	39%
General and administrative	52,227	39,472	12,755	32%
Total operating expenses	270,256	189,500	80,756	43%
Loss from operations	(122,557)	(121,279)	(1,278)	1%
Other income (expense), net	(2,568)	(303)	(2,265)	748%
Interest expense	(7,030)	(3,654)	(3,376)	92%
Net loss before taxes	(132,155)	(125,236)	(6,919)	6%
Income tax benefit	(2,800)	(1,856)	(944)	51%
Net loss	\$(129,355)	\$(123,380)	\$(5,975)	5%

**Revenue**

The increase in revenue of \$79.5 million for the year ended December 31, 2018 compared to the same period in 2017 was due primarily to increased test volume from growth in our historical business as well as the full year impact from our acquisitions of AltaVoice, Good Start Genetics and CombiMatrix completed in 2017. Billable test volumes increased to approximately 292,000 during the year ended December 31, 2018 compared to 145,000 in the same period in 2017. Average revenue per test increased to \$495 per test during the year ended December 31, 2018 compared to \$449 in the same period in 2017. Test revenue during the year ended December 31, 2018 included \$4.3 million of revenue recognized in 2018 relating to notification from Medicare of approval for payment of certain Current Procedure Terminology (CPT) codes and \$2.0 million in cash received from customers which exceeded our estimated collections.

**Cost of revenue**

The increase in the cost of revenue of \$30.0 million for the year ended December 31, 2018 compared to the same period in 2017 was primarily due to costs associated with increased test volume partially offset by the effect of cost efficiencies. For the year ended December 31, 2018, the number of samples accessioned increased to approximately 303,000 from approximately 150,000 for the same period in 2017. Cost per sample accessioned was \$264 in 2018 compared to \$335 in 2017. The decrease in the cost per sample accessioned was primarily attributable to increased volume which resulted in lower labor costs and to production improvements which resulted in material efficiencies, and to automation and software improvements which reduced the medical interpretation time per report.



*Research and development*

The increase in research and development expense of \$17.0 million for the year ended December 31, 2018 compared to the same period in 2017 was due to growth in the business and the effect of business acquisitions in 2017 and principally consisted of the following elements: personnel costs which increased by \$19.2 million due primarily to increases in headcount; lab expenses increased by \$4.8 million due to increases in development activities; depreciation and amortization expense increased by \$1.9 million principally due to amortization of intangible assets associated with business acquisitions; professional fees increased by \$1.5 million reflecting increased utilization of outside consultants; information technology costs increased by \$1.4 million due to increased spending on networking equipment and software licenses; and stock-based compensation costs increased by \$0.9 million and travel-related costs increased by \$0.6 million, both due to increases in headcount. These cost increases were partially offset by an increase of \$14.4 million in allocations of resources from research and development to cost of revenue, to support the increase in production volumes.

*Selling and marketing*

The increase in selling and marketing expenses of \$21.0 million for the year ended December 31, 2018 compared to the same period in 2017 was due to growth in the business and the effect of business acquisitions in 2017 and principally consisted of the following elements: increases in personnel costs of \$11.5 million due to increases in headcount, marketing costs, principally for branding initiatives, increased by \$3.2 million, travel expenses increased by \$2.3 million due to our growing sales force, amortization expense increased by \$1.5 million due to amortization of intangible assets associated with business acquisitions, stock-based compensation increased by \$0.9 million due to increases in headcount, and information technology costs increased by \$0.8 million.

*General and administrative*

The increase in general and administrative expenses of \$12.8 million for the year ended December 31, 2018 compared to the same period in 2017 was primarily due to the growth of the business and the effect of business acquisitions in 2017 and principally consisted of the following elements: personnel-related costs increased by \$6.5 million principally due to increases in headcount, including an internal billings and collections team hired to replace third-party billings and collection contractors; \$2.9 million of losses related to our collaboration agreement with KEW, Inc. with no similar expense in 2017; right of first refusal payments relating to the collaboration agreement with KEW and a separate co-development agreement with a different privately held genetics company were \$2.6 million with no similar costs in 2017 (see Note 8, "Investment in privately held company," and Note 9, "Commitments and contingencies," in the Notes to Consolidated Financial Statements included elsewhere in this report for further details on these arrangements); professional fees increased by \$2.3 million principally due to the utilization of outside consultants to augment existing staff; occupancy costs increased by \$2.2 million, due principally to costs related to facilities acquired through business acquisitions; information technology costs increased by \$1.5 million due primarily to computer equipment and software purchases to support headcount growth; and travel expenses increased by \$0.7 million due to increases in headcount.

These cost increases were offset by increased allocations of technology and facilities-related expenses to other functional areas of \$2.9 million, reduction of depreciation and amortization costs of \$1.5 million and a decrease in stock-based compensation of \$1.0 million.

*Other income (expense), net*

The increase in other expense, net of \$2.3 million for the year ended December 31, 2018 compared to the same period in 2017 was principally due to a loss on extinguishment of debt of \$5.3 million recorded in November 2018 compared to \$0.7 million in 2017. This charge in November 2018 related to our repayment in full, and prior to the scheduled maturity date, of the balance of our obligations under a Loan and Security Agreement entered into in 2017 ("2017 Loan Agreement"). This was partially offset by a gain on

remeasurement of an acquisition-related liability from AltaVoice of \$1.6 million in the first quarter of 2018 as well as an increase in interest income of \$0.7 million.

*Interest expense*

The increase in interest expense of \$3.4 million for the year ended December 31, 2018 compared to the same period in 2017 was due principally to the impact of borrowings under the 2017 Loan Agreement entered into in March 2017 as well as borrowings under a separate arrangement in November 2018. See Note 9, "Commitments and contingencies" in the Notes to Consolidated Financial Statements included elsewhere in this report.

*Income tax benefit*

The increase in income tax benefit of \$0.9 million for the year ended December 31, 2018 compared to the same period in 2017 was due primarily to changes in our deferred income taxes during 2017 resulting from the completion of our analyses associated with the acquisitions of AltaVoice and Ommdom as compared to changes in our deferred income taxes during 2018 resulting from the completion of our analysis of historical net operating losses for CombiMatrix.

**Comparison of the Years Ended December 31, 2017 and 2016**

	Year Ended December 31,		Dollar	%	
	2017	2016	Change	Change	
Revenue:					
Test revenue	\$65,169	\$24,840	\$40,329	162	%
Other revenue	3,052	208	2,844	1,367	%
Total revenue	68,221	25,048	43,173	172	%
Operating expenses:					
Cost of revenue	50,142	27,878	22,264	80	%
Research and development	46,469	44,630	1,839	4	%
Selling and marketing	53,417	28,638	24,779	87	%
General and administrative	39,472	24,085	15,387	64	%
Total operating expenses	189,500	125,231	64,269	51	%
Loss from operations	(121,279 )	(100,183 )	(21,096 )	21	%
Other income (expense), net	(303 )	348	(651 )	(187 )	%
Interest expense	(3,654 )	(421 )	(3,233 )	768	%
Net loss before taxes	(125,236 )	(100,256 )	(24,980 )	25	%
Income tax benefit	(1,856 )	—	(1,856 )	(100 )	%
Net loss	\$(123,380)	\$(100,256)	\$(23,124)	23	%

*Revenue*

The increase in total revenue of \$43.2 million for the year ended December 31, 2017 compared to the same period in 2016 was due primarily to increased test volume from our historical business and test and other revenues from our acquisitions of AltaVoice, Good Start Genetics and CombiMatrix. Revenue recognized on a cash basis was \$46.4 million in the year ended December 31, 2017 compared to \$21.3 million in the same period in 2016, and this increase was principally attributable to increased test volumes from our historical business. Revenue recognized on an accrual basis was \$21.8 million in the year ended December 31, 2017 compared to \$3.6 million in the same period in 2016. Of this increase, \$7.2 million was attributable to increased test volumes from our historical business, \$6.2 million was attributable to revenues relating to our acquisition of Good Start Genetics, \$2.8 million was attributable to genome network revenues relating to our acquisition of AltaVoice and \$2.0 million was attributable to revenues relating to our acquisition of CombiMatrix.

*Cost of revenue*

The increase in the cost of revenue of \$22.3 million for the year ended December 31, 2017 compared to the same period in 2016 was primarily due to costs associated with increased test volume partially offset by the effect of cost efficiencies. For the year ended December 31, 2017, the number of samples accessioned increased to approximately 150,000 from approximately 59,000 for the same period in 2016. This increase included approximately 13,000 Good Start Genetics samples and 2,000 CombiMatrix samples. Cost per sample accessioned was \$335 in 2017 compared to \$473 in 2016. The decrease in the cost per sample was primarily attributable to increased volume, which led to higher labor efficiencies, to production improvements which resulted in lower materials costs, and to automation and software improvements

which have reduced the medical interpretation time per report.

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*Research and development*

The increase in research and development expense of \$1.8 million for the year ended December 31, 2017 compared to the same period in 2016 was due primarily to personnel costs which increased by \$3.3 million principally reflecting the acquisitions of Good Start Genetics and CombiMatrix. Facilities and information technology costs increased by \$2.8 million reflecting costs associated with our new production facility and headquarters, which became fully operational in February 2017. Stock-based compensation costs increased by \$1.2 million and depreciation expense increased by \$0.7 million. These cost increases were partially offset by an increase of \$6.5 million in allocations of resources from research and development to cost of revenue, reflecting increased test volumes.

*Selling and marketing*

The increase in selling and marketing expenses of \$24.8 million for the year ended December 31, 2017 compared to the same period in 2016 was due primarily to increased personnel costs of \$16.1 million including increases of \$12.4 million in salaries and benefits, \$2.8 million in sales commissions and \$0.9 million in other payroll related costs. Facilities and information technology costs increased by \$4.7 million, reflecting costs associated with our new production facility and headquarters, which became fully operational in February 2017. Stock-based compensation increased by \$2.2 million and travel costs increased by \$2.1 million reflecting our growing sales force. In addition, marketing costs increased by \$1.0 million and professional services costs increased by \$0.4 million.

These cost increases were partially offset by an increase of \$1.9 million in allocations of resources from sales and marketing to cost of revenue, reflecting increased test volumes and sign-out activity. In addition, depreciation and amortization costs decreased by \$0.2 million.

*General and administrative*

The increase in general and administrative expenses of \$15.4 million for the year ended December 31, 2017 compared to the same period in 2016 was primarily due to increased personnel costs of \$5.7 million. Headcount increased principally due to hiring an internal billings and collection team to replace third-party billings and collections contractors. Headcount also increased due to the acquisitions of Good Start Genetics and CombiMatrix. Stock-based compensation increased by \$4.4 million due principally to acquisition-related stock compensation expense for Good Start Genetics and CombiMatrix. Depreciation and amortization expense increased by \$2.3 million, due primarily to intangible asset amortization of \$1.6 million in 2017 and increased depreciation expense of \$0.7 million principally for leasehold improvements associated with our new production facility and headquarters. Occupancy costs increased by \$2.1 million, principally reflecting costs associated with our new production facility and headquarters. Acquisition-related legal and accounting fees increased by \$1.8 million, internal billing and collection costs increased by \$1.5 million and legal costs increased by \$1.2 million. Professional fees increased by \$1.4 million, principally due to third-party billings and collection costs reflecting increased sales volumes and costs related to running dual billing systems for a portion of 2017 as we moved from a third-party billing agency to in-house billing. Information technology costs increased by \$1.1 million due principally to computer equipment and software purchases to support headcount growth.

These cost increases were offset by increased allocations of technology and facilities-related expenses to other functional areas of \$7.5 million, reflecting the allocation of costs associated with our new production facility and headquarters, which became fully operational in February 2017. From February 2016 to January 2017, we recorded rent expense for our new production facility and headquarters as general and administrative expense. Beginning in February 2017, we began allocating this cost across our organization.

*Other income (expense), net*

The decrease in other income (expense), net of \$0.7 million for the year ended December 31, 2017 compared to the same period in 2016 was principally due to a loss on extinguishment of debt of \$0.7 million recorded in March 2017. This charge related to our repayment in full, and prior to the scheduled maturity

date, of the balance of our obligations under an agreement entered into in July 2015, or the 2015 Loan Agreement.

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*Interest expense*

The increase in interest expense of \$3.2 million for the year ended December 31, 2017 compared to the same period in 2016 was due principally to borrowings, under the 2017 Loan Agreement. See Note 9, "Commitments and contingencies" in the Notes to Consolidated Financial Statements included elsewhere in this report. We borrowed \$40.0 million pursuant to the 2017 Loan Agreement in March 2017.

*Income tax benefit*

The income tax benefit of \$1.9 million recorded in the year ended December 31, 2017 was due to changes in our deferred income tax asset valuation allowances resulting from our acquisitions of AltaVoice in January 2017 and Ommdom in June 2017.

**Liquidity and capital resources**

***Liquidity and capital expenditures***

We have incurred net losses since our inception. For the years ended December 31, 2018, 2017 and 2016, our net losses were \$129.4 million, \$123.4 million and \$100.3 million, respectively, and we expect to incur additional losses in the near term. At December 31, 2018, we had an accumulated deficit of \$516.7 million. While our revenue has increased over time, we may never achieve revenue sufficient to offset our expenses.

Since inception, our operations have been financed primarily by net proceeds from sales of our capital stock, fees collected from our customers as well as borrowing from debt facilities.

From inception through December 31, 2018, we have entered into various capital lease agreements for an aggregate financing amount of \$15.2 million to obtain laboratory equipment. The terms of our capital leases are typically three years and are secured by the underlying equipment.

In November 2018, we entered into a Note Purchase Agreement (the "2018 Note Purchase Agreement") pursuant to which we are eligible to borrow an aggregate principal amount up to \$200.0 million over its maturity term of 7 years which includes an initial borrowing of \$75.0 million in November 2018 which we used to extinguish our previous debt. The outstanding principal amount under the 2018 Note Purchase Agreement bears interest at a rate of 8.75% annually. In addition, beginning on January 1, 2020 and continuing until the maturity date, we will make quarterly payments of 0.5% of our annual net revenues subject to a maximum annual amount of such payments of \$1.6 million which will be recognized as interest expense. Through the fixed interest charges and the quarterly revenue payments, we are required to pay total amounts to generate an 11% internal rate of return to the lender on any outstanding principal balances due in a lump-sum upon the repayment or maturity of any outstanding principal. See more details on the 2018 Note Purchase Agreement in Note 9, "Commitments and contingencies" in the Notes to Consolidated Financial Statements included elsewhere in this report.

The 2018 Note Purchase Agreement contains quarterly covenants to achieve certain revenue levels as well as additional covenants, including limits on our ability to dispose of assets, undergo a change of 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.

In connection with the 2018 Note Purchase Agreement, in November 2018, we entered into a Securities Purchase Agreement pursuant to which the lender purchased 373,524 shares of our common stock at a price of \$13.39 per share for an aggregate amount of \$5.0 million. The price paid by the lender was calculated based on the 15-day average closing share price prior to the issuance. The fair value of the common stock purchased by the lender was \$5.4 million.

At December 31, 2018 and 2017, we had \$131.9 million and \$76.0 million, respectively, of cash, cash equivalents, restricted cash and marketable securities.

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

expenses. We estimate our capital expenditures for the full year 2019 will be approximately \$10.0 million. We have incurred substantial losses since our inception, and we expect to continue to incur losses in the near term. We believe our existing cash, cash equivalents and marketable securities as of December 31, 2018, revenue from the sale of our tests, and notes available to us pursuant to the 2018 Note Purchase Agreement, will be sufficient to meet our anticipated cash requirements for the foreseeable future.

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We may need additional funding to finance operations prior to achieving profitability or should we make additional acquisitions. We regularly consider fundraising opportunities and will determine the timing, nature and size of future financings based upon various factors, including market conditions and our operating plans. We may in the future elect to finance operations by selling equity or debt securities or borrowing money. We also may elect to finance future acquisitions. If we issue equity securities, dilution to stockholders may result. Any equity securities issued may also provide for rights, preferences or privileges senior to those of holders of our common stock. If we raise funds by issuing debt securities, these debt securities would have rights, preferences and privileges senior to those of holders of our common stock. In addition, the terms of debt securities or borrowings could impose significant restrictions on our operations. If additional funding is required, there can be no assurance that additional funds will be available to us on acceptable terms on a timely basis, if at all. If we are unable to obtain additional funding when needed, we will need to curtail planned activities to reduce costs. Doing so will likely have an unfavorable effect on our ability to execute on our business plan, and have an adverse effect on our business, results of operations and future prospects.

The following table summarizes our cash flows (in thousands):

	Year Ended December 31,		
	2018	2017	2016
Cash used in operating activities	\$(92,220 )	\$(97,981 )	\$(76,317 )
Cash provided by (used in) investing activities	35,773	(36,953 )	16,061
Cash provided by financing activities	157,152	80,871	53,709
Net increase (decrease) in cash, cash equivalents and restricted cash	\$100,705	\$(54,063 )	\$(6,547 )

***Cash flows from operating activities***

For the year ended December 31, 2018, cash used in operating activities of \$92.2 million principally resulted from our net loss of \$129.4 million offset by non-cash charges of \$20.9 million for stock-based compensation, \$13.5 million for depreciation and amortization, \$5.3 million related to debt extinguishment costs, \$2.9 million of impairment losses related to our collaboration agreement with KEW, \$0.8 million of other non-cash adjustments and \$0.4 million for remeasurements of liabilities associated with business combinations, all partially offset by a \$2.9 million benefit from income taxes resulting from the completion of our analysis of historical net operating losses for CombiMatrix. The net effect on cash of changes in net operating assets was a use of cash of \$3.8 million due principally to the effect of increase in accounts receivable due to timing of collections partially offset by an increase in accrued and other liabilities.

For the year ended December 31, 2017, cash used in operating activities of \$98.0 million principally resulted from our net loss of \$123.4 million and non-cash income tax benefits offset by non-cash charges of \$19.2 million for stock-based compensation, \$9.2 million for depreciation and amortization and \$1.8 million for remeasurements of liabilities associated with business combinations. The net effect on cash of changes in net operating assets was a use of cash of \$3.4 million due principally to the effect of increase in accounts receivable.

For the year ended December 31, 2016, cash used in operating activities of \$76.3 million principally resulted from our net loss of \$100.3 million offset by non-cash charges of \$10.7 million for stock-based compensation, \$6.6 million for depreciation and amortization and \$1.0 million for asset impairment charges. The net effect on cash of changes in net operating assets was \$5.3 million and was due principally to the effect of increases in accrued expenses and other assets.

***Cash flows from investing activities***

For the year ended December 31, 2018, cash provided by investing activities of \$35.8 million resulted primarily from proceeds from maturities and sales of marketable securities exceeding purchases of marketable securities by \$42.7 million and purchases of property and equipment of \$6.0 million.

For the year ended December 31, 2017, cash used in investing activities of \$37.0 million resulted primarily from purchases of marketable securities exceeding proceeds from maturities of marketable securities by \$33.1 million and purchases of property and equipment of \$6.7 million, partially offset by \$2.8 million cash acquired from acquisition of businesses.

For the year ended December 31, 2016, cash provided by investing activities of \$16.1 million resulted primarily from proceeds from maturities of marketable securities exceeding purchases of marketable securities by \$27.7 million, partially offset by purchases of property and equipment of \$11.6 million.

**Cash flows from financing activities**

For the year ended December 31, 2018, cash provided by financing activities of \$157.2 million consisted of net proceeds from the public offerings of common stock of \$112.4 million, net proceeds of \$93.9 million from the second term loan under the Amended 2017 Loan Agreement and from the 2018 Note Purchase Agreement, and cash received from issuances of common stock totaling \$17.5 million (which includes \$6.5 million received from exercises of warrants issued pursuant to the acquisition of CombiMatrix (see Note 4, "Business combinations," in the Notes to Consolidated Financial Statements included elsewhere in this report), \$5.0 million received pursuant to the Securities Purchase Agreement entered into in connection with our 2018 Note Purchase Agreement, employee stock purchases of \$3.2 million, and stock option exercises of \$2.7 million). These cash inflows were partially offset by loan payments of \$60.0 million to extinguish our 2017 Loan Agreement, payments of \$4.6 million related to the extinguishment of our 2017 Loan Agreement and related amendments and capital lease payments of \$2.1 million.

For the year ended December 31, 2017, cash provided by financing activities of \$80.9 million consisted of net proceeds of \$68.9 million from a private placement, net proceeds of \$39.7 million from an initial term loan under the 2017 Loan Agreement and cash received from employee stock plan purchases, exercises of stock options and exercises of warrants totaling \$5.7 million. These cash inflows were partially offset by a cash payment of \$18.4 million to settle loan obligations assumed in the Good Start acquisition, other loan payments of \$12.1 million and capital lease obligations payments of \$3.0 million.

For the year ended December 31, 2016, cash provided by financing activities of \$53.7 million resulted from net proceeds from an underwritten public offering of common stock of \$47.1 million, borrowings of \$7.5 million under the a loan agreement and cash received from exercises of stock options of \$3.1 million, partially offset by loan payments of \$2.4 million and capital lease obligations payments of \$1.6 million.

**Contractual obligations**

The following table summarizes our contractual obligations, including interest, as of December 31, 2018 (in thousands):

Contractual obligations:	2019	2020 and 2021	2022 and 2023	2024 and beyond	Total
Operating leases <sup>(1)</sup>	\$10,774	\$21,969	\$19,965	\$25,715	\$78,423
Capital leases	2,087	1,413	—	—	3,500
Debt	6,654	16,576	16,558	89,998	129,786
Purchase commitments	3,040	4,480	—	—	7,520
Total	\$22,555	\$44,438	\$36,523	\$115,713	\$219,229

<sup>(1)</sup> Operating lease commitments are net of total sublease payments of \$0.2 million.

In September 2015, we entered into a lease agreement for our current production facility and headquarters in San Francisco, California, in which we commenced occupancy and operations in January 2017. This lease expires in July 2026. Leases for other facilities in California and Massachusetts expire at various dates from 2019 through 2026. Aggregate future minimum lease payments for these facilities are included in the table above.

Debt in the table above includes principal and interest payments pertaining our 2018 Note Purchase Agreement.

In the normal course of business, we enter into various purchase commitments primarily related to service agreements, laboratory supplies and a co-development agreement. Our total future payments under noncancelable unconditional purchase commitments having a remaining term of over one year are included above.

See Note 9, "Commitments and contingencies" in the Notes to Consolidated Financial Statements for additional details regarding our leases, debt, and purchase commitments.

**Off-balance sheet arrangements**

We have not entered into any off-balance sheet arrangements. See Note 8, "Investments in privately held company" in the Notes to Consolidated Financial Statements included elsewhere in this report for a discussion of our holding in a variable interest entity.

**Recent accounting pronouncements**

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See “Recent accounting pronouncements” in Note 2, “Summary of significant accounting policies” in the Notes to Consolidated Financial Statements for a discussion of recently adopted accounting pronouncements and accounting pronouncements not yet adopted, and their expected effect on our financial position and results of operations.

**ITEM 7A. Quantitative and Qualitative Disclosures about Market Risk.**

We are exposed to market risks in the ordinary course of our business. These risks primarily relate to interest rates. We had loan obligations under our 2018 Note Purchase Agreement of \$74.5 million at December 31, 2018. This loan is subject to a fixed interest rate, plus beginning on January 1, 2020 and continuing until the maturity date, quarterly payments of 0.5% of our annual net revenues subject to a maximum annual amount of such payments of \$1.6 million. We had capital lease obligations of \$3.3 million as of December 31, 2018, which result from various capital lease agreements to obtain laboratory equipment. Our capital lease obligations carry fixed rates of interest. Our cash, cash equivalents, restricted cash and marketable securities totaled \$131.9 million at December 31, 2018, and consisted of bank deposits, commercial paper, money market funds, U.S. treasury notes, and U.S. government agency securities. Such interest-bearing instruments carry a degree of risk; however, because our investments are primarily short-term in duration, we have not been exposed to, nor do we anticipate being exposed to, material risks due to changes in interest rates. At December 31, 2018, a hypothetical 1% (100 basis points) increase or decrease in interest rates would not have resulted in a material change in the fair value of our cash equivalents and portfolio of marketable securities. Fluctuations in the value of our cash equivalents and portfolio of marketable securities caused by a change in interest rates (gains or losses on the carrying value) are recorded in other comprehensive gain (loss) and are realized only if we sell the underlying securities prior to maturity or declines in fair value are determined to be other-than-temporary.

**ITEM 8. Consolidated Financial Statements and Supplementary Data.**

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**Report of Independent Registered Public Accounting Firm**

To the Stockholders and Board of Directors of Invitae Corporation

**Opinion on the Financial Statements**

We have audited the accompanying consolidated balance sheets of Invitae Corporation (the Company) as of December 31, 2018 and 2017, the related consolidated statements of operations, comprehensive loss, convertible preferred stock and stockholders' equity and cash flows for each of the three years in the period ended December 31, 2018, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2018 and 2017, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2018, in conformity with U.S. generally accepted accounting principles.

**Adoption of ASU No. 2014-09**

As discussed in Note 2 to the consolidated financial statements, the Company changed its method of accounting for revenue in 2018 due to the adoption of Accounting Standards Update (ASU) No. 2014-09, Revenue from Contracts with Customers (Topic 606), and the related amendments.

**Basis for Opinion**

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB. We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ Ernst & Young LLP

We have served as the Company's auditor since 2013.

Redwood City, California

February 28, 2019

**INVITAE CORPORATION**  
**Consolidated Balance Sheets**

(in thousands, except par value data)

	December 31, 2018	December 31, 2017
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$112,158	\$12,053
Marketable securities	13,727	52,607
Accounts receivable	26,296	10,422
Prepaid expenses and other current assets	13,258	11,599
Total current assets	165,439	86,681
Property and equipment, net	27,886	30,341
Restricted cash	6,006	5,406
Marketable securities, non-current	—	5,983
Intangible assets, net	30,469	35,516
Goodwill	50,095	46,575
Other assets	3,064	576
Total assets	\$282,959	\$211,078
<b>Liabilities and stockholders' equity</b>		
Current liabilities:		
Accounts payable	\$7,812	\$8,606
Accrued liabilities	26,563	22,742
Capital lease obligation, current portion	1,937	2,039
Total current liabilities	36,312	33,387
Capital lease obligation, net of current portion	1,375	3,373
Debt	74,477	39,084
Other long-term liabilities	8,956	13,440
Total liabilities	121,120	89,284
Commitments and contingencies (Note 9)		
Stockholders' equity:		
Preferred stock, \$0.0001 par value: 20,000 shares authorized; 3,459 shares issued and outstanding as of December 31, 2018 and 2017	—	—
Common stock, \$0.0001 par value: 400,000 shares authorized; 75,481 and 53,597 shares issued and outstanding as of December 31, 2018 and 2017, respectively	8	5
Accumulated other comprehensive loss	(5	) (171
Additional paid-in capital	678,548	520,558
Accumulated deficit	(516,712	) (398,598
Total stockholders' equity	161,839	121,794
Total liabilities and stockholders' equity	\$282,959	\$211,078

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



**INVITAE CORPORATION**  
**Consolidated Statements of Operations**

(in thousands, except per share data)

	Year Ended December 31,		
	2018	2017	2016
Revenue:			
Test revenue	\$144,560	\$65,169	\$24,840
Other revenue	3,139	3,052	208
Total revenue	147,699	68,221	25,048
Costs and operating expenses:			
Cost of revenue	80,105	50,142	27,878
Research and development	63,496	46,469	44,630
Selling and marketing	74,428	53,417	28,638
General and administrative	52,227	39,472	24,085
Total costs and operating expenses	270,256	189,500	125,231
Loss from operations	(122,557 )	(121,279 )	(100,183 )
Other income (expense), net	(2,568 )	(303 )	348
Interest expense	(7,030 )	(3,654 )	(421 )
Net loss before taxes	(132,155 )	(125,236 )	(100,256 )
Income tax benefit	(2,800 )	(1,856 )	—
Net loss	\$(129,355)	\$(123,380)	\$(100,256)
Net loss per share, basic and diluted	\$(1.94 )	\$(2.65 )	\$(3.02 )
Shares used in computing net loss per share, basic and diluted	66,747	46,512	33,176

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

**INVITAE CORPORATION****Consolidated Statements of Comprehensive Loss**

(in thousands)

	Year Ended December 31,		
	2018	2017	2016
Net loss	\$(129,355)	\$(123,380)	\$(100,256)
Other comprehensive income (loss):			
Unrealized income (loss) on available-for-sale marketable securities, net of tax	166	(171)	15
Comprehensive loss	\$(129,189)	\$(123,551)	\$(100,241)

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

**INVITAE CORPORATION****Consolidated Statements of Convertible Preferred Stock and Stockholders' Equity**

(in thousands)

	Convertible Preferred Stock		Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Income (Loss)		Total Accumulated Stockholders' Equity
	Shares	Amount	Shares	Amount		Income (Loss)	Deficit	
Balance as of December 31, 2015	—	\$ —	31,935	\$ 4	\$ 313,349	\$ (15 )	\$ (174,962 )	\$ 138,376
Common stock issued on exercise of stock options	—	—	244	—	744	—	—	744
Common stock issued pursuant to vesting of restricted stock units	—	—	157	(1 )	—	—	—	(1 )
Common stock issued pursuant to employee stock purchase plan	—	—	370	—	2,391	—	—	2,391
Common stock issued in connection with underwritten public offering, net of offering costs of \$3,498	—	—	8,433	1	47,101	—	—	47,102
Vesting of common stock related to early exercise of options	—	—	5	—	4	—	—	4
Stock-based compensation expense	—	—	—	—	10,699	—	—	10,699
Unrealized income (loss) on available-for-sale marketable securities, net of tax	—	—	—	—	—	15	—	15
Net loss	—	—	—	—	—	—	(100,256 )	(100,256 )
Balance as of December 31, 2016	—	—	41,144	4	374,288	—	(275,218 )	99,074
Common and convertible preferred stock issued in private placement, net of offering costs of \$4,599	3,459	—	5,188	1	68,896	—	—	68,897
Common stock issued on exercise of stock options, net	—	—	387	—	1,706	—	—	1,706
Common stock issued pursuant to vesting of restricted stock units, net	—	—	925	—	—	—	—	—
Common stock issued pursuant to acquisition-related transaction bonus	—	—	4	—	—	—	—	—
Common stock issued pursuant to exercises of warrants	—	—	232	—	1,381	—	—	1,381
Common stock issued pursuant to employee stock purchase plan	—	—	379	—	2,635	—	—	2,635
Common stock issued pursuant to business combinations	—	—	5,176	—	50,808	—	—	50,808
Common stock issued to settle assumed liabilities	—	—	162	—	1,272	—	—	1,272
Warrants issued pursuant to the 2017 Loan Agreement	—	—	—	—	740	—	—	740
Stock-based compensation expense	—	—	—	—	18,832	—	—	18,832
Unrealized income (loss) on available-for-sale marketable securities, net of tax	—	—	—	—	—	(171 )	—	(171 )
Net loss	—	—	—	—	—	—	(123,380 )	(123,380 )
Balance as of December 31, 2017	3,459	—	53,597	5	520,558	(171 )	(398,598 )	121,794
Cumulative effect of accounting change	—	—	—	—	—	—	11,241	11,241
Common stock issued in connection with public offering, net of offering costs of \$6,183	—	—	17,103	3	112,438	—	—	112,441
Common stock issued on exercise of stock options, net	—	—	351	—	2,741	—	—	2,741
Common stock issued pursuant to vesting of restricted stock units, net	—	—	1,369	—	—	—	—	—
Common stock issued pursuant to exercises of warrants	—	—	1,099	—	6,539	—	—	6,539
Common stock issued pursuant to employee stock purchase plan	—	—	566	—	3,231	—	—	3,231
Common stock issued pursuant to business combinations	—	—	1,022	—	6,455	—	—	6,455
Warrants issued pursuant to 2017 Loan Agreement	—	—	—	—	383	—	—	383
Common stock issued pursuant to Securities Purchase Agreement (see Note 9)	—	—	374	—	5,353	—	—	5,353

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Stock-based compensation expense	—	—	—	—	20,850	—	—	20,850							
Unrealized income (loss) on available-for-sale marketable securities, net of tax	—	—	—	—	—	166	—	166							
Net loss	—	—	—	—	—	—	(129,355 )	(129,355 )							
Balance as of December 31, 2018	3,459	\$	—75,481	\$	8	\$	678,548	\$	(5 )	)	\$	(516,712 )	)	\$	161,839

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

**INVITAE CORPORATION**  
**Consolidated Statements of Cash Flows**  
(in thousands)

	<b>Year Ended December 31,</b>		
	<b>2018</b>	<b>2017</b>	<b>2016</b>
<b>Cash flows from operating activities:</b>			
Net loss	\$(129,355)	\$(123,380)	\$(100,256)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	13,540	9,181	6,553
Stock-based compensation	20,850	19,221	10,699
Impairment losses	2,925	—	—
Remeasurements of liabilities associated with business combinations	362	1,810	—
Benefit from income taxes	(2,862)	(1,856)	—
Debt extinguishment costs	5,266	—	—
Other	806	404	1,341
Changes in operating assets and liabilities, net of effects of business combination:			
Accounts receivable	(5,291)	(1,963)	(843)
Prepaid expenses and other current assets	(1,445)	(641)	(1,149)
Other assets	(163)	(185)	1,465
Accounts payable	(417)	(535)	(111)
Accrued expenses and other liabilities	3,564	(37)	5,984
Net cash used in operating activities	(92,220)	(97,981)	(76,317)
<b>Cash flows from investing activities:</b>			
Purchases of marketable securities	(9,680)	(101,867)	(90,236)
Proceeds from sales of marketable securities	19,965	—	—
Proceeds from maturities of marketable securities	32,458	68,768	117,922
Acquisition of businesses, acquired cash	—	2,821	—
Purchases of property and equipment	(5,970)	(6,675)	(11,625)
Other	(1,000)	—	—
Net cash provided by (used in) investing activities	35,773	(36,953)	16,061
<b>Cash flows from financing activities:</b>			
Proceeds from public offering of common stock, net of issuance costs	112,441	—	47,102
Proceeds from issuance of common stock	17,511	74,619	3,134
Net proceeds from issuance of debt	93,909	39,661	7,500
Payments for debt extinguishment costs	(4,609)	—	—
Loan payments	(60,000)	(30,457)	(2,438)
Capital lease principal payments	(2,100)	(2,952)	(1,589)
Net cash provided by financing activities	157,152	80,871	53,709
<b>Net increase (decrease) in cash, cash equivalents and restricted cash</b>	<b>100,705</b>	<b>(54,063)</b>	<b>(6,547)</b>
<b>Cash, cash equivalents and restricted cash at beginning of period</b>	<b>17,459</b>	<b>71,522</b>	<b>78,069</b>
<b>Cash, cash equivalents and restricted cash at end of period</b>	<b>\$118,164</b>	<b>\$17,459</b>	<b>\$71,522</b>
<b>Supplemental cash flow information:</b>			
Interest paid	\$6,231	\$2,852	\$421
<b>Supplemental cash flow information of non-cash investing and financing activities:</b>			

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Equipment acquired through capital leases	\$—	\$6,789	\$—
Purchases of property and equipment in accounts payable and accrued liabilities	\$510	\$200	\$1,644
Amounts related to co-development agreement in other assets and accrued liabilities	\$2,000	\$—	\$—
Warrants issued pursuant to 2017 Loan Agreement	\$383	\$740	\$—
Common stock issued for acquisition of businesses	\$6,445	\$50,808	\$—
Consideration payable for acquisition of businesses	\$—	\$13,276	\$—
Common stock issued to settle assumed liabilities	\$—	\$1,272	\$—

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

## **INVITAE CORPORATION**

### **Notes to Consolidated Financial Statements**

#### **1. Organization and description of business**

Invitae Corporation (the "Company") was incorporated in the State of Delaware on January 13, 2010, as Locus Development, Inc. and changed its name to Invitae Corporation in 2012. The Company utilizes an integrated portfolio of laboratory processes, software tools and informatics capabilities to process DNA-containing samples, analyze information about patient-specific genetic variation and generate test reports for clinicians and their patients. The Company's headquarters and main production facility is located in San Francisco, California. The Company currently has more than 20,000 genes in production and provides a variety of diagnostic tests that can be used in multiple indications. The Company's tests include genes associated with hereditary cancer, neurological disorders, cardiovascular disorders, pediatric disorders, metabolic disorders and other hereditary conditions. In addition, and as a result of the acquisitions of Good Start Genetics ("Good Start") in August 2017 and CombiMatrix Corporation ("CombiMatrix") in November 2017, the Company's services also include screening and testing in reproductive health, including preimplantation and carrier screening for inherited disorders, prenatal diagnosis, miscarriage analysis and pediatric developmental disorders. The Company operates in one segment.

#### **2. Summary of significant accounting policies**

##### ***Principles of consolidation***

The consolidated financial statements include the accounts of the Company and its wholly owned subsidiaries. All intercompany balances and transactions have been eliminated in consolidation.

##### ***Use of estimates***

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent liabilities as of the date of the financial statements and the reported amounts of revenue and expenses during the reporting period. The Company bases these estimates on historical and anticipated results, trends and various other assumptions that the Company believes are reasonable under the circumstances, including assumptions as to future events. Actual results could differ materially from those estimates and assumptions.

Significant estimates and assumptions made by management include the determination of: revenue recognition (See Note 3, "Revenue, accounts receivable and deferred revenue" for further information);

the fair value of assets acquired and liabilities assumed for business combinations;

the fair value of goodwill and intangible assets;

the recoverability of long-lived assets;

stock-based compensation expense and the fair value of awards issued; and

income tax uncertainties.

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

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

Significant customers are those that represent 10% or more of the Company's total revenue for each year presented on the statements of operations. For the significant customer, revenue as a percentage of total revenue were as follows:

December 31,

<b>Customers</b>	2018	2017	2016
Medicare	22%	13%	11%

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Medicare represented 21% and 13% of accounts receivable as of December 31, 2018 and 2017.

**Cash, cash equivalents, and restricted cash**

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

Restricted cash consists of money market funds that serve as collateral for security deposits for the Company's facility lease and sublease agreements and collateral for a credit card agreement at one of the Company's financial institutions.

The following table provides a reconciliation of cash, cash equivalents and restricted cash reported within the consolidated balance sheets that sum to the total of the same amounts shown in the statements of cash flows (in thousands):

	December 31, 2018	December 31, 2017
Cash and cash equivalents	\$ 112,158	\$ 12,053
Restricted cash	6,006	5,406
Total cash, cash equivalents and restricted cash	\$ 118,164	\$ 17,459

**Marketable securities**

All marketable securities have been classified as "available-for-sale" and are carried at estimated fair value as determined based upon quoted market prices or pricing models for similar securities. Management determines the appropriate classification of its marketable debt securities at the time of purchase and reevaluates such designation at each balance sheet date. Short-term marketable securities have maturities less than 365 days at the balance sheet date. Unrealized gains and losses are excluded from earnings and are reported as a component of other comprehensive loss. Realized gains and losses and declines in fair value judged to be other than temporary, if any, on available-for-sale securities are included in interest and other income (expense), net. The cost of securities sold is based on the specific-identification method. Interest on marketable securities is included in interest and other income (expense), net.

**Accounts receivable**

The Company receives payment for its tests from partners, patients, institutional customers and third-party payers. See Note 3, "Revenue, accounts receivable and deferred revenue" for further information.

**Inventory**

The Company maintains test reagents and other consumables primarily used in sample collection kits which are valued at the lower of cost or market value. Cost is determined using actual costs on a first-in, first-out basis. The Company's inventory was \$8.3 million and \$5.4 million as of December 31, 2018 and 2017, respectively, and was recorded in prepaid expenses and other current assets in the Company's consolidated balance sheets.

**Business combinations**

The tangible and identifiable intangible assets acquired and liabilities assumed in a business combination are recorded based on their estimated fair values as of the business combination date, including identifiable intangible assets which either arise from a contractual or legal right or are separable from goodwill. The Company bases the estimated fair value of identifiable intangible assets acquired in a business combination on independent valuations that use information and assumptions provided by management, which consider management's estimates of inputs and assumptions that a market participant would use. Any excess purchase price over the estimated fair value assigned to the net tangible and identifiable intangible assets acquired and liabilities assumed is recorded to goodwill. The use of alternative valuation assumptions, including estimated revenue projections, growth rates, cash flows, discount rates, estimated useful lives and probabilities surrounding the achievement of contingent milestones could result in different

purchase price allocations and amortization expense in current and future periods.

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In circumstances where an acquisition involves a contingent consideration arrangement that meets the definition of a liability under Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") Topic 480 *Distinguishing Liabilities from Equity*, the Company recognizes a liability equal to the fair value of the contingent payments the Company expects to make as of the acquisition date. The Company remeasures this liability each reporting period and records changes in the fair value as a component of operating expenses.

Transaction costs associated with acquisitions are expensed as incurred in general and administrative expenses. Results of operations and cash flows of acquired companies are included in the Company's operating results from the date of acquisition.

#### ***Intangible assets***

Amortizable intangible assets include trade names, non-compete agreements, developed technology and customer relationships acquired as part of business combinations. Customer relationships are amortized on an accelerated basis, utilizing free cash flows, over periods ranging from five to 11 years. All other intangible assets subject to amortization are amortized using the straight-line method over their estimated useful lives ranging from two to 15 years. All intangible assets subject to amortization are reviewed for impairment in accordance with ASC 360, *Property, Plant and Equipment*.

#### ***Goodwill***

In accordance with ASC 350, *Intangibles-Goodwill and Other* ("ASC 350"), the Company's goodwill is not amortized but is tested for impairment on an annual basis or whenever events or changes in circumstances indicate that the carrying amount of these assets may not be recoverable. Under ASC 350, the Company performs annual impairment reviews of its goodwill balance during the fourth fiscal quarter. In testing for impairment, the Company compares the fair value of its reporting unit to its carrying value including the goodwill of that unit. If the carrying value, including goodwill, exceeds the reporting unit's fair value, the Company will recognize an impairment loss for the amount by which the carrying amount exceeds the reporting unit's fair value. The loss recognized cannot exceed the total amount of goodwill allocated to that reporting unit. The Company did not incur any goodwill impairment losses in any of the periods presented.

#### ***Leases***

The Company rents its facilities under operating lease agreements and recognizes related rent expense on a straight-line basis over the term of the applicable lease agreement. Some of the lease agreements contain rent holidays, scheduled rent increases, lease incentives, and renewal options. Rent holidays and scheduled rent increases are included in the determination of rent expense to be recorded over the lease term. Lease incentives are recognized as a reduction of rent expense on a straight-line basis over the term of the lease. Renewals are not assumed in the determination of the lease term unless they are deemed to be reasonably assured at the inception of the lease. The Company recognizes rent expense beginning on the date it obtains the legal right to use and control the leased space.

#### ***Property and equipment, net***

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



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

Furniture and fixtures	7 years
Automobiles	7 years
Laboratory equipment	5 years
Computer equipment	3 years
Software	3 years
Leasehold improvements	Shorter of lease term or estimated useful life

### ***Long lived assets***

The Company reviews long lived assets for impairment whenever events or changes in circumstances indicate that the carrying amount of the assets may not be recoverable. An impairment loss is recognized when the total estimated future undiscounted cash flows expected to result from the use of the asset and its eventual disposition are less than its carrying amount. Impairment, if any, is assessed using discounted cash flows or other appropriate measures of fair value. Other than impairment losses of \$1.0 million in 2016 relating to leasehold improvements and to the shutdown of the Company's Chilean operations, there were no long-lived asset impairment losses recorded for any period presented. All impairment losses were charged to general and administrative expense.

### ***Variable interest entity***

The Company had a variable interest in a variable interest entity ("VIE") through an investment in convertible notes issued by the VIE. The convertible notes do not provide the Company with voting rights in the VIE or with power to direct the activities of the VIE which most significantly affect its economic performance. The Company is not the VIE's primary beneficiary and it does not consolidate the VIE.

### ***Fair value of financial instruments***

The Company's financial instruments consist principally of cash and cash equivalents, marketable securities, accounts payable, accrued liabilities, capital leases and debt. The carrying amounts of certain of these financial instruments, including cash and cash equivalents, accounts receivable, accounts payable and accrued and other current liabilities approximate their current fair value due to the relatively short-term nature of these accounts. Based on borrowing rates available to the Company, the carrying value of capital leases and debt approximate their fair values.

### ***Revenue recognition***

The Company recognizes revenue when control of the promised goods or services is transferred to the customer in an amount that reflects the consideration it expects to be entitled to in exchange for those goods or services. All revenues are generated from contracts with customers.

Test revenue is generated primarily from the sale of tests that provide analysis and associated interpretation of the sequencing of parts of the genome.

Other revenue consists primarily of revenue from genome network subscription services which is recognized on a straight-line basis over the subscription term, and revenue from collaboration agreements.

### ***Cost of revenue***

Cost of revenue reflects the aggregate costs incurred in delivering the genetic testing results to clinicians and includes expenses for personnel-related costs including stock-based compensation, materials and supplies, equipment and infrastructure expenses associated with testing and allocated overhead including rent, equipment depreciation and utilities.

***Income taxes***

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

***Stock-based compensation***

The Company measures its stock-based payment awards made to employees and directors based on the estimated fair values of the awards and recognizes the compensation expense over the requisite service period. The Company uses the Black-Scholes option-pricing model to estimate the fair value of its stock option awards and employee stock purchase plan (“ESPP”) purchases. The fair value of restricted stock unit (“RSU”) awards with time-based vesting terms is based on the grant date share price. The Company grants performance-based restricted stock unit (“PRSU”) awards to certain employees which vest upon the achievement of certain performance conditions, subject to the employees’ continued service relationship with the Company. The probability of vesting is assessed at each reporting period and compensation cost is adjusted based on this probability assessment. The Company recognizes such compensation expense on an accelerated vesting method.

Stock-based compensation expense for awards without a performance condition is recognized using the straight-line method. Stock-based compensation expense is based on the value of the portion of stock-based payment awards that is ultimately expected to vest. As such, the Company’s stock-based compensation is reduced for estimated forfeitures at the date of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates.

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

The Company accounts for stock issued as compensation in connection with business combinations based on the fair value of the Company’s common stock on the date of issuance.

***Advertising***

Advertising expenses are expensed as incurred. The Company incurred advertising expenses of \$0.6 million, \$0.6 million and \$0.5 million during the years ended December 31, 2018, 2017 and 2016, respectively.

***Comprehensive loss***

Comprehensive loss is composed of two components: net loss and other comprehensive income (loss). Other comprehensive income (loss) refers to gains and losses that under U.S. GAAP are recorded as an element of stockholders’ equity, but are excluded from net loss. The Company’s other comprehensive income (loss) consists of unrealized gains or losses on investments in available-for-sale securities.

***Net loss per share***

Basic net loss per share is calculated by dividing net loss by the weighted-average number of common shares outstanding during the period, without consideration of common stock equivalents. Diluted net loss per share is computed by dividing net loss by the weighted-average number of common share equivalents outstanding for the period determined using the treasury stock method. Potentially dilutive securities, consisting of preferred stock, options to purchase common stock, common stock warrants, RSUs and PRSUs, are considered to be common stock equivalents and were excluded from the calculation of diluted net loss per share because their effect would be antidilutive for all periods presented.

***Recent accounting pronouncements***

The Company evaluates all Accounting Standards Updates (“ASUs”) issued by the FASB for consideration of their applicability. ASUs not included in the disclosures in this report were assessed and determined to be

either not applicable or are not expected to have a material impact on the Company's consolidated financial statements.

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**Recently issued accounting pronouncements not yet adopted**

In November 2018, the FASB issued ASU 2018-18, *Collaborative Arrangements (Topic 808): Clarifying the Interaction between Topic 808 and Topic 606*, which clarifies that certain transactions between participants in a collaborative arrangement should be accounted for under Accounting Standards Codification ("ASC") 606 when the counterparty is a customer. In addition, Topic 808 precludes an entity from presenting consideration from a transaction in a collaborative arrangement as revenue from contracts with customers if the counterparty is not a customer for that transaction. This guidance will be effective for the Company beginning January 1, 2020. The Company is currently evaluating the impact of the adoption of this standard on its consolidated financial statements.

In June 2016, the FASB issued ASU No. 2016-13, *Financial Instruments - Credit Losses (Topic 326)*, which replaces the incurred loss impairment methodology in current U.S. GAAP with a methodology that reflects expected credit losses. The amended guidance is effective for fiscal years, and interim periods within those years, beginning after December 15, 2019, with early adoption permitted for the fiscal years, and interim periods within those fiscal years, beginning after December 15, 2018. The Company is currently evaluating the impact of the adoption of this standard on its consolidated financial statements.

In February 2016, the FASB issued ASU 2016-02, *Leases (Topic 842)* and in July 2018 issued ASU 2018-10, *Codification Improvements to Topic 842, Leases* and ASU 2018-11, *Leases (Topic 842): Targeted Improvements* (the foregoing ASUs collectively referred to as "Topic 842"). Under the new guidance, lessees are required to recognize a lease liability and a right-of-use asset for all leases (with the exception of short-term leases) at the commencement date and also requires expanded disclosures about leasing arrangements. Topic 842 is effective for annual and interim periods beginning on or after December 15, 2018 and early adoption is permitted. Entities may initially apply the new leases standard at the adoption date and recognize a cumulative-effect adjustment to the opening balance of retained earnings in the period of adoption.

The Company is evaluating the final effect that Topic 842 and related standards will have on its consolidated financial statements, related disclosures and ongoing financial reporting, but expects implementation of Topic 842 to result in the recognition of material right of use assets and corresponding lease liabilities in its consolidated balance sheets as of the implementation of Topic 842 on January 1, 2019, principally relating to facilities leases. The Company does not have any material embedded leases and the implementation of Topic 842 is primarily focused on the treatment of the Company's previously identified leases. As of December 31, 2018, the Company's total future undiscounted capital lease payments were \$3.5 million and future undiscounted non-cancelable minimum operating lease payments, net of subleases were \$78.4 million

**Recently adopted accounting pronouncements**

In May 2014, the FASB issued ASU 2014-09, *Revenue from Contracts with Customers (Topic 606)*, designed to enable users of financial statements to better understand the nature, amount, timing and uncertainty of revenue and cash flows arising from contracts with customers. On January 1, 2018, the Company adopted the provisions of Topic 606 using the modified retrospective method. From adoption to date, the Company has recognized all its revenue from contracts with customers within the scope of Topic 606. In connection with the adoption, the Company recognized the cumulative effect of initially applying this standard as an adjustment to retained earnings on the date of adoption. Comparative information prior to the date of adoption has not been restated and continues to be reported under the accounting standards in effect for those periods.

In connection with the adoption of Topic 606, the Company amended its revenue recognition policy to provide for the recognition of certain variable consideration related to diagnostic tests that was previously deferred pending cash collection. Under Topic 606, the Company records variable consideration based on an estimate of the consideration to which it will be entitled.



The Company recognizes revenue when control of the promised goods or services is transferred to the customer in an amount that reflects the consideration it expects to be entitled to in exchange for those goods or services. All revenues are generated from contracts with customers.

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#### *Diagnostic tests*

The majority of the Company's revenue is generated from genetic testing services that provide analysis and associated interpretation of the sequencing of parts of the genome. Test orders are placed under signed requisitions, and the Company often enters into contracts with institutions (e.g., hospitals and clinics) and insurance companies that include pricing provisions under which such tests are billed. Billing terms are generally net thirty days.

While the transaction price of diagnostic tests is originally established either via contract or pursuant to the Company's standard list price, the Company often provides concessions for tests billed to insurance carriers, and therefore the transaction price for patient insurance-billed tests is considered to be variable and revenue is recognized based on an estimate of the consideration to which the Company will be entitled at an amount for which it is probable that a reversal of cumulative consideration will not occur. Making these estimates requires significant judgments based upon such factors as length of payer relationship, historical payment patterns, changes in contract provisions and insurance reimbursement policies. These judgments are reviewed quarterly and revenue recognized is updated, as necessary, until the Company's obligations are fully settled.

In connection with some diagnostic test orders, the Company offers limited re-requisition rights ("Re-Requisition Rights") that are considered distinct at contract inception, and therefore certain diagnostic test orders contain two performance obligations, the performance of the original test and the Re-Requisition Rights. When Re-Requisition Rights are granted, the Company allocates the transaction price to each performance obligation based on the relative estimated standalone selling prices. In order to comply with loss contract rules, the allocations are adjusted, if necessary, to ensure the amount deferred for Re-Requisition Rights is no less than the estimated cost of fulfilling the Company's related obligations. The Company looks to transfer of control in assessing timing of recognition of revenue in connection with each performance obligation. In general, revenue in connection with diagnostic tests is recognized upon delivery of the underlying clinical report or when the report is made available on the Company's web portal. Outstanding performance obligations pertaining to orders received but for which the underlying report has not been issued are generally satisfied within a thirty-day period. Revenue in connection with Re-Requisition Rights is recognized as the rights are exercised or expire unexercised, which is generally within ninety days of initial deferral.

#### *Other contracts*

The Company also enters into collaboration and genome network contracts. Collaboration agreements provide customers with diagnostic testing and related data aggregation reporting services that are provided over the contract term. Collaboration revenue is recognized as the testing and reporting services are delivered to the customer. Genome network offerings consist of subscription services related to a proprietary software platform designed to connect patients, clinicians, advocacy organizations, researchers and therapeutic developers to accelerate the understanding, diagnosis and treatment of hereditary disease. Such services are recognized on a straight-line basis over the subscription periods.

Amounts due under collaboration and genome network agreements are typically billable on net thirty-day terms.

### **3. Revenue, accounts receivable and deferred revenue**

As described in Note 2, "Summary of significant accounting policies," the Company adopted Topic 606 effective January 1, 2018. In connection with the adoption the Company utilized the following practical expedients and exemptions:

- Certain information about remaining performance obligations is not disclosed because the underlying contracts have an original expected duration of one year or less.

- Costs to obtain or fulfill a contract are expensed when incurred because the amortization period would have been one year or less.

No adjustments to promised consideration were made for financing as the Company expects, at contract inception, that the period between the transfer of a promised good or service and when the customer pays for that good or service will be one year or less.

The adoption of Topic 606 resulted in a cumulative-effect adjustment to accounts receivable and accumulated deficit of \$11.2 million as of January 1, 2018 primarily related to the recognition of uncollected

diagnostic test variable consideration as of the date of adoption. Test revenue without adoption of Topic 606 for the year ended December 31, 2018 includes cash collections related to accounts receivable recorded as of January 1, 2018 in connection with the Topic 606 cumulative-effect adjustment. The effect of the adoption of Topic 606 on financial statement line items in the Company's consolidated statement of operations for the year ended December 31, 2018, and the Company's consolidated balance sheet as of December 31, 2018 was as follows (in thousands, except per share amounts):

	Year Ended December 31, 2018		
		Without	Effect of
	As Reported	Adoption of Topic 606	Adoption Higher/(Lower)
Test revenue	\$144,560	\$144,222	\$ 338
Net loss	\$(129,355)	\$(129,693)	\$ 338
Net loss per share, basic and diluted	\$(1.94 )	\$(1.94 )	\$ —

	As of December 31, 2018		
		Without	Effect of
	As Reported	Adoption of Topic 606	Adoption Higher/(Lower)
Accounts receivable	\$26,296	\$14,150	\$ 12,146
Accumulated deficit	\$(516,712)	\$(528,291)	\$ 11,579
Stockholders' equity	\$161,839	\$150,260	\$ 11,579

#### *Disaggregation of revenue*

Test revenue is generated from sales of diagnostic tests to three groups of customers: institutions, such as hospitals, clinics and partners; patients who pay directly; and patients' insurance carriers. Amounts billed and collected, and the timing of collections, vary based on whether the payer is an institution, an insurance carrier or a patient. Other revenue consists principally of revenue recognized under collaboration and genome network agreements.

The following table includes the Company's revenues as disaggregated by payer category (in thousands):

	Year Ended December	
	31, 2018	2017 <sup>(1)</sup>
Test revenue:		
Institutions	\$34,618	\$17,238
Patient - direct	13,589	5,638
Patient - insurance	96,353	42,293
Total test revenue	144,560	65,169
Other revenue	3,139	3,052
Total revenue	\$147,699	\$68,221

<sup>(1)</sup> As noted above, prior period amounts are presented as originally reported based upon the accounting standards in effect for those periods.

Included in revenue in the Company's consolidated statements of operations for the year ended December 31, 2018 was \$0.3 million that was included in deferred revenue at January 1, 2018.

The Company recognizes revenue related to billings based on estimates of the amount that will ultimately be realized. The estimate of the transaction price of test revenue is based on many factors such as length of payer relationship, historical payment patterns, changes in contract provisions and insurance

reimbursement policies. Cash collections for certain tests delivered may differ from rates originally estimated. As a result of new information, the Company updated its estimate of the amounts to be recognized for previously delivered tests which resulted in

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an additional \$4.5 million of test revenue for the year ended December 31, 2018. These changes in estimates decreased the Company's loss from operations by \$4.5 million and decreased basic and diluted net loss per share by approximately \$0.07 for the year ended December 31, 2018.

*Accounts receivable*

The majority of the Company's accounts receivable represents amounts billed to institutions (e.g., hospitals, clinics) and estimated amounts to be collected from third-party insurance payers for test revenue recognized. Also included is amounts due under the terms of collaboration and genome network agreements for diagnostic testing and data aggregation reporting services provided and proprietary platform access rights transferred.

*Deferred revenues*

The Company records deferred revenues when cash payments are received or due in advance of its performance related to one or more performance obligations. The amounts deferred to date primarily consist of consideration received pertaining to the estimated exercise of certain Re-Requisition Rights. The Company defers revenue related to Re-Requisition Rights in amounts no less than the estimated cost of fulfilling its related obligations. The Company recognizes revenue related to Re-Requisition Rights as the rights are exercised or expire unexercised, which is generally within 90 days of initial deferral.

#### **4. Business combinations**

***AltaVoice***

On January 6, 2017, the Company acquired AltaVoice (formerly PatientCrossroads, Inc.), a privately-owned patient-centered data company with a global platform for collecting, curating, coordinating and delivering safeguarded data from patients and clinicians. The acquisition, complemented by several other strategic partnerships, expanded the Company's genome network, designed to connect patients, clinicians, advocacy organizations, researchers and therapeutic developers to accelerate the understanding, diagnosis, and treatment of hereditary disease. Pursuant to the terms of the Stock Purchase Agreement, the Company acquired all of the outstanding shares of AltaVoice for total purchase consideration of \$12.4 million, payable in the Company's common stock, as follows:

- (a) payment of \$5.5 million through the issuance of 641,126 shares of the Company's common stock; payment of \$5.0 million in the Company's common stock, payable on March 31, 2018, with the common shares deliverable equal to \$5.0 million divided by the trailing average share price of the Company's
- (b) common stock for the 30 days preceding March 31, 2018. This payment was made in April 2018 through the issuance of 716,332 shares of the Company's common stock; payment of \$5.0 million in the Company's common stock, which was contingently payable on March 31, 2018 if a milestone based on a certain threshold of revenue was achieved during 2017, with the shares deliverable equal to \$5.0 million divided by the trailing average share price of the Company's common stock for the 30 days preceding March 31, 2018. As the foregoing milestone was not achieved, there was a new contingent milestone based on achieving a revenue target during 2017 and 2018. Since this
- (c) new contingent milestone was achieved, on March 31, 2019, a payment of \$5.0 million in the Company's common stock will be payable. The actual payout is dependent upon meeting the 2017 and 2018 revenue targets (capped at \$14.0 million) times 75% less \$5.5 million. This formula in effect caps the possible payout amount at \$5.0 million in the Company's common shares. The number of shares to be issued will be equal to the payout amount divided by the trailing average share price of the Company's common stock for the 30 days preceding March 31, 2019.

The first payment of \$5.5 million was classified as equity. The second payment was discounted to \$4.7 million as of the acquisition date, recorded as a liability, and was accreted to fair value at each reporting date until the extinguishment of the liability in April 2018. The third payment, representing contingent consideration, was determined to have a fair value of \$2.2 million as of the acquisition date and was recorded as a liability. In accordance with ASC Topic 805, *Business Combinations*, the contingent

consideration of \$2.2 million was remeasured to fair value at each reporting date until the contingency was resolved, with changes in fair value recognized in earnings.

For the second payment, the acquisition-date fair value was \$4.7 million, and the Company recorded accretion gains (losses) of \$1.6 million and \$(0.2) million in other income (expense), net, for the years ended December 31, 2018 and 2017, respectively. The accretion gains in 2018 resulted from an adjustment to the value of

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the second payment as of March 31, 2018, and principally reflected the difference between the value of the common shares deliverable, based upon the closing price of the Company's stock on March 29, 2018, and the value per share used to calculate the number of common shares deliverable. The accretion losses in 2017 resulted from adjustments to the discounted value of the second payment, reflecting the passage of time.

For the third payment, the acquisition-date fair value was \$2.2 million, and the Company recorded remeasurement losses of \$1.2 million and \$1.6 million in general and administrative expense for the years ended December 31, 2018 and 2017, respectively. The remeasurement losses in 2018 reflect updated estimations of fair value of the third payment, based upon achieving a revenue target during 2017 and 2018, as the milestone based on a certain threshold of revenue to be achieved during 2017 was not met. The principal inputs affecting those estimations have been updates to the Company's revenue forecasts and the passage of time.

Assets acquired and liabilities assumed are recorded based on valuations derived from estimated fair value assessments and assumptions used by the Company. While the Company believes that its estimates and assumptions underlying the valuations are reasonable, different estimates and assumptions could result in different valuations assigned to the individual assets acquired and liabilities assumed, and the resulting amount of goodwill. The following table summarizes the fair values of assets acquired and liabilities assumed at the date of acquisition (in thousands):

Cash	\$54
Accounts receivable	274
Prepaid expense and other assets	52
Non-compete agreement	286
Developed technology	570
Customer relationships	3,389
Total identifiable assets acquired	4,625
Accounts payable	(28 )
Deferred revenue	(202 )
Accrued expenses	(21 )
Deferred tax liability	(1,422 )
Total liabilities assumed	(1,673 )
Net identifiable assets acquired	2,952
Goodwill	9,432
Net assets acquired	\$12,384

Acquisition-related intangibles included in the above table are finite-lived. Customer relationships are being amortized on an accelerated basis, utilizing free cash flows, over a period of ten years. All other acquisition-related intangibles are being amortized on a straight-line basis over their estimated lives, which approximates the pattern in which the economic benefits of the intangible assets are expected to be realized, as follows (in thousands):

	Gross Purchased Intangible Assets	Estimated Useful Life (in Years)
Non-compete agreement	\$ 286	5
Developed technology	570	6
Customer relationships	3,389	10
	\$ 4,245	



Goodwill represents the excess of the purchase price over the fair value of the net tangible and intangible assets acquired. The acquisition of AltaVoice resulted in \$9.4 million of goodwill which the Company believes consists principally of expected synergies to be realized by combining capabilities, technology and data to accelerate the use of genetic information for the diagnosis and treatment of hereditary diseases. In accordance with ASC 350, goodwill will not be amortized but will be tested for impairment at least annually. Goodwill created as a result of the acquisition is not deductible for tax purposes. The Company has finalized its assessment of fair value of the assets and liabilities assumed at the acquisition date.

**Ommodom**

On June 11, 2017, the Company acquired Ommodom, Inc. (“Ommodom”), a privately held company that develops, commercializes and sells hereditary risk assessment and management software, including CancerGene Connect, a cancer genetic counseling platform. The acquisition expanded Invitae’s suite of genome management offerings designed to help patients and clinicians use genetic information as part of mainstream medical care. CancerGene Connect is a platform for collecting and managing genetic family histories.

Pursuant to the terms of a Stock Exchange Agreement, the Company acquired all of the outstanding shares of Ommodom for consideration of \$6.1 million, payable entirely in the Company’s common stock. There was no cash consideration nor any contingent payments associated with the acquisition, other than a hold-back amount of \$0.6 million. Per the terms of the agreement, the Company was obligated to issue shares of its common stock as follows:

- (a) payment of \$5.5 million through the issuance of 600,108 shares of the Company’s common stock on the acquisition date; and
- (b) payment of \$0.6 million through the issuance of 66,582 shares of the Company’s common stock, representing a hold-back amount, and payable on the twelve-month anniversary of the acquisition date.

The first payment of \$5.5 million was classified as equity. The second payment of \$0.6 million was recorded as a stock payable liability on the acquisition date and was reclassified to equity upon the issuance of 66,582 shares of the Company’s common stock in June 2018.

Assets acquired and liabilities assumed are recorded based on valuations derived from estimated fair value assessments and assumptions used by the Company. While the Company believes that its estimates and assumptions underlying the valuations are reasonable, different estimates and assumptions could result in different valuations assigned to the individual assets acquired and liabilities assumed, and the resulting amount of goodwill. The following table summarizes the fair values of assets acquired and liabilities assumed at the date of acquisition (in thousands):

Cash	\$53
Accounts receivable	10
Prepaid expense and other assets	4
Trade name	13
Developed technology	2,335
Customer relationships	147
Total identifiable assets acquired	2,562
Accounts payable	(16 )
Accrued expenses	(17 )
Deferred tax liability	(434 )
Total liabilities assumed	(467 )
Net identifiable assets acquired	2,095
Goodwill	4,045
Net assets acquired	\$6,140

Finite-lived intangibles included in the above table are being amortized on a straight-line basis over their estimated lives, which approximates the pattern in which the economic benefits of the intangible assets are expected to be realized, as follows (in thousands):

	Gross Purchased Intangible Assets	Estimated Useful Life (in Years)
Trade name	\$ 13	5

Developed technology	2,335	5
Customer relationships	147	5
	\$ 2,495	

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Goodwill represents the excess of the purchase price over the fair value of the net tangible and intangible assets acquired. The acquisition of Ommdom resulted in the recognition of \$4.0 million of goodwill which the Company believes consists principally of expected synergies to be realized by expanding the Company's suite of genome management offerings. In accordance with ASC 350, goodwill will not be amortized but rather will be tested for impairment at least annually. Goodwill created as a result of the acquisition is not deductible for tax purposes. The Company has finalized its assessment of fair value of the assets and liabilities assumed at the acquisition date.

**Good Start Genetics**

On August 4, 2017, the Company acquired 100% of the fully diluted equity of Good Start, a privately held molecular diagnostics company focused on preimplantation and carrier screening for inherited disorders. The acquisition of Good Start was intended to further Invitae's plan to create a comprehensive genetic information platform providing high-quality, affordable genetic information coupled with world-class clinical expertise to inform healthcare decisions throughout every stage of an individual's life. The purchase consideration for the Good Start acquisition consisted of the assumption of the net liabilities of Good Start of \$24.4 million at the acquisition date.

Immediately subsequent to the acquisition of Good Start, the Company paid \$18.4 million in cash to settle outstanding notes payable, accrued interest and related costs. In addition, and immediately subsequent to the acquisition, the Company settled outstanding convertible promissory notes payable through:

- (a) payment of \$11.9 million through the issuance of 1,148,283 shares of the Company's common stock; and
- (b) payment of \$3.6 million through the issuance of 343,986 shares of the Company's common stock, representing a hold-back amount payable on the one-year anniversary of the acquisition date. In September 2018, the Company issued 212,260 shares in partial payment of the hold-back amount payable. The remainder of the hold-back amount payable, approximately \$1.3 million as of December 31, 2018, will be settled upon resolution of outstanding claims from Good Start customers, of which \$0.6 million was settled in January 2019.

Also in connection with the acquisition of Good Start and immediately subsequent to the acquisition, the Company paid bonuses to certain members of Good Start's management team through:

- (a) payment of \$0.9 million through the issuance of 83,025 shares of the Company's common stock; and
- (b) payment of \$0.4 million through the issuance of 37,406 shares of the Company's common stock, representing a hold-back amount payable on the one-year anniversary of the acquisition date. In September 2018, the Company issued 27,784 shares in partial payment of the hold-back amount payable to settle bonuses to Good Start's management team. The remainder of the hold-back amount payable, approximately \$0.2 million as of December 31, 2018, will be settled upon resolution of outstanding claims from Good Start customers, of which \$0.1 million was settled in January 2019.

These bonus payments were recorded as general and administrative expense.

Assets acquired and liabilities assumed are recorded based on valuations derived from estimated fair value assessments and assumptions used by the Company. While the Company believes that its estimates and assumptions underlying the valuations are reasonable, different estimates and assumptions could result in different valuations assigned to the individual assets acquired and liabilities assumed, and the resulting amount of goodwill.

At acquisition date, the Company also recorded \$4.8 million as a provisional amount for a deferred tax liability because certain information and analysis related to Good Start's historical net operating losses that could have affected the Company's initial valuation was still being obtained or reviewed at that time. This provisional amount for the deferred tax liability was subsequently reversed during the fourth quarter of 2017 based on the results of further analysis of Good Start's historical net operating losses.



The following table summarizes the fair values of assets acquired and liabilities assumed at the date of acquisition (in thousands):

Cash and restricted cash	\$ 1,381
Accounts receivable	2,246
Prepaid expense and other assets	1,579
Property and equipment	1,320
Trade name	460
Developed technology	5,896
Customer relationships	7,830
Total identifiable assets acquired	20,712
Accounts payable	(5,418 )
Accrued expenses	(6,802 )
Notes payable	(17,904 )
Convertible promissory notes payable	(15,430 )
Other liabilities	(222 )
Total liabilities assumed	(45,776 )
Net identifiable assets acquired	(25,064 )
Goodwill	25,064
Net assets acquired	\$—

During the year ended December 31, 2018, the Company recorded adjustments to its accounting for the amount recorded as accounts receivable at acquisition. Accordingly, the fair value of accounts receivable was decreased by \$0.7 million during the year ended December 31, 2018, with corresponding increases to goodwill.

Customer relationships are being amortized on an accelerated basis, utilizing free cash flows, over a period of eight years. All other finite-lived intangibles included in the above table are being amortized on a straight-line basis over their estimated lives, which approximates the pattern in which the economic benefits of the intangible assets are expected to be realized, as follows (in thousands):

	Gross Purchased Intangible Assets	Estimated Useful Life (in Years)
Trade name	\$460	3
Developed technology	5,896	5
Customer relationships	7,830	8
	\$14,186	

Goodwill represents the excess of the purchase price over the fair value of the net tangible and intangible assets acquired. The acquisition of Good Start resulted in the recognition of \$25.1 million of goodwill which the Company believes consists principally of expected synergies to be realized by expanding the Company's suite of genome management offerings. In accordance with ASC 350, goodwill will not be amortized but rather will be tested for impairment at least annually. Goodwill created as a result of the acquisition is not deductible for tax purposes. The Company has finalized its assessment of fair value of the assets and liabilities assumed at the acquisition date.

### **CombiMatrix**

On November 14, 2017, the Company completed its acquisition of CombiMatrix in accordance with the terms of the Agreement and Plan of Merger and Reorganization, dated as of July 31, 2017 (the "Merger

Agreement”), by and among the Company, Coronado Merger Sub, Inc., a wholly owned subsidiary of the Company (“Merger Sub”), and CombiMatrix, pursuant to which Merger Sub merged with and into CombiMatrix, with CombiMatrix surviving as a wholly owned subsidiary of the Company (the “Merger”). At the closing of the Merger, the Company issued shares of its common stock to (i) CombiMatrix’s common stockholders, at an exchange ratio of 0.8692 of a share of the Company’s common stock (the “Merger Exchange

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Ratio”) for each share of CombiMatrix common stock outstanding immediately prior to the Merger, (ii) CombiMatrix’s Series F preferred stockholders, at the Merger Exchange Ratio for each share of CombiMatrix common stock underlying Series F preferred stock outstanding immediately prior to the Merger, (iii) holders of outstanding and unexercised in-the-money CombiMatrix stock options, which were fully accelerated to the extent of any applicable vesting period and converted into the right to receive the number of shares of the Company’s common stock equal to the Merger Exchange Ratio multiplied by the number of shares of CombiMatrix common stock issuable upon exercise of such option, minus the number of shares of the Company’s common stock determined by dividing the aggregate exercise price for such option by \$9.491, and (iv) holders of outstanding and unsettled CombiMatrix restricted stock units, which were fully accelerated to the extent of any applicable vesting period and converted into the right to receive a number of shares of the Company’s common stock determined by multiplying the number of shares of CombiMatrix common stock that were subject to such restricted stock unit by the Merger Exchange Ratio. In addition, at the closing of the Merger, (a) all outstanding and unexercised out-of-the money CombiMatrix stock options were cancelled and terminated without the right to receive any consideration, (b) all CombiMatrix Series D Warrants and Series F Warrants outstanding and unexercised immediately prior to the closing of the Merger were assumed by the Company and converted into warrants to purchase the number of shares of the Company’s common stock determined by multiplying the number of shares of CombiMatrix common stock subject to such warrants by the Merger Exchange Ratio, and with the exercise price adjusted by dividing the per share exercise price of the CombiMatrix common stock subject to such warrants by the Merger Exchange Ratio, and (c) certain entitlements under CombiMatrix’s executive compensation transaction bonus plan (the “Transaction Bonus Plan”) were paid in shares of the Company’s common stock or RSUs to be settled in shares of the Company’s common stock. All outstanding and unexercised CombiMatrix Series A, Series B, Series C, Series E, and PIPE warrants were repurchased by CombiMatrix prior to closing pursuant to that certain CombiMatrix Common Stock Purchase Warrants Repurchase Agreement dated July 11, 2016.

Pursuant to the Merger Agreement, the Company issued an aggregate of 2,703,389 shares of its common stock as follows:

- (a) payment of \$20.5 million through the issuance of 2,611,703 shares of the Company’s common stock to holders of CombiMatrix common stock outstanding;
- (b) payment of \$0.7 million through the issuance of 85,219 shares of the Company’s RSUs to holders of outstanding and unsettled CombiMatrix restricted stock units;
- (c) payment of \$0.1 million through the issuance of 3,323 shares of the Company’s common stock to holders of outstanding and unexercised in-the-money CombiMatrix stock options; and
- (d) payment of \$0.1 million through the issuance of 3,144 shares of the Company’s common stock to holders of CombiMatrix Series F preferred stock.

In addition, and pursuant to the Merger Agreement, the Company issued warrants to purchase an aggregate of 2,077,273 shares of its common stock as follows:

- (a) payment of \$7.4 million through the issuance of warrants to purchase a total of 1,739,689 shares of the Company’s common stock in exchange for all outstanding CombiMatrix Series F warrants; and
- (b) payment of \$1,000 through the issuance of warrants to purchase a total of 337,584 shares of the Company’s common stock in exchange for all outstanding CombiMatrix Series D warrants.

In connection with the acquisition of CombiMatrix, the Company paid bonuses to certain members of CombiMatrix’s management team through:

- (a) payment of \$1.7 million through the issuance of common stock and RSUs totaling 214,976 shares of the Company’s common stock to settle payments pursuant to CombiMatrix’s executive compensation transaction bonus plan (the “Transaction Bonus Plan”), recorded as post-combination compensation expense and included in general and administrative expense; and



payment of \$0.2 million through the issuance of 22,966 shares of the Company's common stock to settle (b) payments pursuant to the Transaction Bonus Plan, recorded as an assumed liability at the acquisition date.

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Assets acquired and liabilities assumed are recorded based on valuations derived from estimated fair value assessments and assumptions used by the Company. While the Company believes that its estimates and assumptions underlying the valuations are reasonable, different estimates and assumptions could result in different valuations assigned to the individual assets acquired and liabilities assumed, and the resulting amount of goodwill. The following table summarizes the fair values of assets acquired and liabilities assumed at the date of acquisition (in thousands):

Cash and restricted cash	\$1,333
Accounts receivable	4,118
Prepaid expense and other assets	1,299
Property and equipment	437
Other assets - non current	30
Favorable leases	247
Trade name	103
Patent licensing agreement	496
Developed technology	3,162
Customer relationships	12,397
Total identifiable assets acquired	23,622
Accounts payable	(276 )
Accrued expenses	(3,925 )
Deferred tax liability	(2,862 )
Other liabilities	(180 )
Total liabilities assumed	(7,243 )
Net identifiable assets acquired	16,379
Goodwill	11,554
Net assets acquired	\$27,933

During the year ended December 31, 2018, upon the completion of the Company's analysis of CombiMatrix's historical net operating losses, the Company recorded a deferred tax liability of \$2.9 million with corresponding increases to goodwill. The \$2.9 million net deferred tax liability represents the excess of the financial reporting over tax basis in acquired intangibles over the amount of CombiMatrix's historical net operating loss carryovers that were determined to be available to offset future income due to change in ownership operating loss carryover limitation rules under Internal Revenue Code section 382.

Customer relationships are being amortized on an accelerated basis, utilizing free cash flows, over a period of eleven years. All other finite-lived intangibles included in the above table are being amortized on a straight-line basis over their estimated lives, which approximates the pattern in which the economic benefits of the intangible assets are expected to be realized, as follows (in thousands):

	Gross Purchased Intangible Assets	Estimated Useful Life (in Years)
Favorable leases	\$247	2
Trade name	103	1
Patent licensing agreement	496	15
Developed technology	3,162	4
Customer relationships	12,397	11
	\$16,405	



Goodwill represents the excess of the purchase price over the fair value of the net tangible and intangible assets acquired. The acquisition of CombiMatrix resulted in the recognition of \$11.6 million of goodwill which the Company believes consists principally of expected synergies to be realized by expanding the Company's suite of genome management offerings. In accordance with ASC 350, goodwill will not be amortized but rather will be tested for impairment at least annually. Goodwill created as a result of the acquisition is not deductible for tax purposes. The Company has finalized its assessment of fair value of the assets and liabilities assumed at the acquisition date.

## 5. Goodwill and intangible assets

### Goodwill

Details of the Company's goodwill for the year ended December 31, 2018 are as follows (in thousands):

	AltaVoice	Ommdom	Good Start	CombiMatrix	Total
Balance as of December 31, 2017	\$9,432	\$4,045	\$24,406	\$8,692	\$46,575
Goodwill adjustment	—	—	658	2,862	3,520
Balance as of December 31, 2018	\$9,432	\$4,045	\$25,064	\$11,554	\$50,095

The goodwill adjustments were principally due to changes in the fair value of accounts receivable for Good Start as well as the recognition of a \$2.9 million deferred tax liability for CombiMatrix resulting from the completion of the Company's analysis of historical net operating losses.

### Intangible assets

The following table presents details of the Company's finite-lived intangible assets as of December 31, 2018 (in thousands):

	Cost	Accumulated Amortization	Net	Weighted Average Useful Life (in Years)	Weighted Average Estimated Remaining Useful Life (in Years)
Customer relationships	\$23,763	\$(2,783)	\$20,980	10.0	8.6
Developed technology	11,963	(3,482)	8,481	4.8	3.4
Non-compete agreement	286	(114)	172	5.0	3.0
Trade name	576	(329)	247	2.7	1.4
Patent licensing agreement	496	(37)	459	15.0	13.9
Favorable leases	247	(117)	130	2.2	1.1
	\$37,331	\$(6,862)	\$30,469	8.2	6.8

Acquisition-related intangibles included in the above table are finite-lived. Customer relationships are being amortized on an accelerated basis, in proportion to estimated cash flows, over periods ranging from five to eleven years. All other acquisition-related intangibles are being amortized on a straight-line basis over their estimated lives, which approximates the pattern in which the economic benefits of the intangible assets are realized. Amortization expense was \$5.0 million, \$1.8 million, and nil for the years ended December 31, 2018, 2017, and 2016, respectively. Intangible assets are carried at cost less accumulated amortization. Amortization expense is recorded to research and development, sales and marketing and general and administrative expense.

The following table summarizes the Company's estimated future amortization expense of intangible assets with finite lives as of December 31, 2018 (in thousands):

	<b>Amount</b>
2019	\$5,250
2020	5,525
2021	5,829
2022	4,124
2023	3,111
Thereafter	6,630
Total estimated future amortization expense	\$30,469

## **6. Balance sheet components**

### ***Property and equipment, net***

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

	<b>December 31, 2018</b>	<b>December 31, 2017</b>
Leasehold improvements	\$13,034	\$12,623
Laboratory equipment	22,149	17,705
Equipment under capital lease	7,129	11,446
Computer equipment	4,723	4,023
Software	2,594	2,520
Furniture and fixtures	784	569
Automobiles	20	20
Construction-in-progress	1,962	965
Total property and equipment, gross	52,395	49,871
Accumulated depreciation and amortization (24,509 )	(24,509 )	(19,530 )
Total property and equipment, net	\$27,886	\$30,341

Depreciation expense was \$8.5 million, \$7.2 million and \$6.6 million for the years ended December 31, 2018, 2017 and 2016, respectively.

### ***Accrued liabilities***

Accrued liabilities consisted of the following (in thousands):

	<b>December 31, 2018</b>	<b>December 31, 2017</b>
Accrued compensation and related expenses	\$7,917	\$7,406
Deferred revenue	761	307
Liabilities associated with business combinations	6,460	9,497
Liability associated with co-development agreement	2,000	—
Other	9,425	5,532
Total accrued liabilities	\$26,563	\$22,742

**Other long-term liabilities**

Other long-term liabilities consisted of the following (in thousands):

	December 31, 2018	December 31, 2017
Lease incentive obligation, non-current	\$3,280	\$3,831
Deferred rent, non-current	5,495	5,153
Liabilities associated with business combinations	—	3,779
Other non-current liabilities	181	677
Total other long-term liabilities	\$8,956	\$13,440

**7. Fair value measurements**

Financial assets and liabilities are recorded at fair value. Fair value is defined as the price that would be received to sell an asset or paid to transfer a liability (an exit price) in an orderly transaction between market participants at the reporting date. The authoritative guidance establishes a three-level valuation hierarchy that prioritizes the inputs to valuation techniques used to measure fair value based upon whether such inputs are observable or unobservable. Observable inputs reflect market data obtained from independent sources, while unobservable inputs reflect market assumptions made by the reporting entity.

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

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

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

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

The following tables set forth the fair value of the Company's consolidated financial instruments that were measured at fair value on a recurring basis (in thousands):

	December 31, 2018						
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value	Level 1	Level 2	Level 3
<b>Financial assets:</b>							
Money market funds	\$93,934	\$	—\$ —	\$93,934	\$93,934	\$—	\$—
Certificates of deposit	300	—	—	300	—	300	—
Commercial paper	10,908	—	(1 )	10,907	—	10,907	—
U.S. treasury notes	9,990	—	—	9,990	9,990	—	—
U.S. government agency securities	6,001	—	(4 )	5,997	—	5,997	—
Total financial assets	\$121,133	\$	—\$ (5 )	\$121,128	\$103,924	\$17,204	\$—
<b>Financial liabilities:</b>							
Contingent consideration				\$4,998	\$—	\$—	\$4,998
Total financial liabilities				\$4,998	\$—	\$—	\$4,998

	December 31, 2018
Reported as:	
Cash equivalents	\$101,395
Restricted cash	6,006
Marketable securities	13,727
Total cash equivalents, restricted cash, and marketable securities	\$121,128
Accrued liabilities	\$4,998

	December 31, 2017						
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value	Level 1	Level 2	Level 3
<b>Financial assets:</b>							
Money market funds	\$5,998	\$	—\$	\$5,998	\$5,998	\$—	\$—
Certificates of deposit	300	—	—	300	300	—	—
U.S. treasury notes	12,010	—	(19 )	11,991	11,991	—	—
U.S. government agency securities	46,451	—	(152 )	46,299	—	46,299	—
Total financial assets	\$64,759	\$	—\$(171 )	\$64,588	\$18,289	\$46,299	\$—
<b>Financial liabilities:</b>							
Contingent consideration				\$3,779	\$—	\$—	\$3,779
Total financial liabilities				\$3,779	\$—	\$—	\$3,779
					<b>December 31, 2017</b>		
Reported as:							
Cash equivalents						\$592	
Restricted cash						5,406	
Marketable securities						58,590	
Total cash equivalents, restricted cash, and marketable securities						\$64,588	
Accrued liabilities						\$3,779	

There were no transfers between Level 1, Level 2 and Level 3 during the periods presented. The total fair value of investments with unrealized losses at December 31, 2018 was \$13.4 million. None of the available-for-sale securities held as of December 31, 2018 has been in a material continuous unrealized loss position for more than one year. At December 31, 2018, unrealized losses on available-for-sale investments are not attributed to credit risk and are considered to be temporary. The Company believes it is more likely than not that investments in an unrealized loss position will be held until maturity or the recovery of the cost basis of the investment. To date, the Company has not identified any other-than-temporary declines in market value and thus has not recorded any impairment charges on its financial assets other than on the convertible notes which are described in Note 8, "Investment in privately held company." At December 31, 2018, the remaining contractual maturities of available-for-sale securities ranged from less than one to 4 months. For the years ended December 31, 2018, 2017 and 2016, there were no realized gains or losses on available-for-sale securities.

The Company's certificates of deposit, commercial paper, and debt securities of U.S. government agency entities are classified as Level 2 as they are valued based upon quoted market prices for similar instruments in active markets, quoted prices for identical or similar instruments in markets that are not active and model-based valuation techniques for which all significant inputs are observable in the market or can be corroborated by observable market data for substantially the full term of the assets. Where applicable, these models project future cash flows and discount the future amounts to a present value using market-based observable inputs obtained from various third party data providers, including but not limited to benchmark yields, interest rate curves, reported trades, broker/dealer quotes and reference data.



The following table presents the Company's Level 3 financial instruments that are measured at fair value on a recurring basis (in thousands):

	<b>Level 3 Contingent Consideration Liability</b>
Balance as of December 31, 2017	\$ 3,779
Change in estimate of fair value	1,219
Balance as of December 31, 2018	\$ 4,998

As of December 31, 2018, the Company had a contingent obligation of up to \$5.0 million payable in the Company's common stock to the former owners of AltaVoice in conjunction with the Company's acquisition of AltaVoice in January 2017. The contingency was dependent upon future revenues attributable to AltaVoice. If the revenue attributable to AltaVoice for the combined period of 2017 and 2018 was at least \$10 million, the Company would make a payment of up to \$5.0 million in the Company's common stock in March 2019. The Company estimated the fair value of the contingent consideration at \$2.2 million at the acquisition date in January 2017, based on a Monte Carlo simulation, as well as estimates of the 30-day trailing price of its stock at certain dates, its volatility assumptions and its revenue forecasts, all of which were significant inputs in the Level 3 measurement not supported by market activity. The value of the liability was subsequently remeasured to fair value at each reporting date. Changes in estimated fair value are recorded as general and administrative expense until the contingency is paid or expires. The change in the fair value of the contingent consideration between the acquisition date and December 31, 2018 was an increase of \$2.8 million.

The fair value of the Company's outstanding debt is estimated using the net present value of future debt payments, discounted at an interest rate that is consistent with market interest rates, which is a Level 2 input. The carrying amount of the Company's outstanding debt at December 31, 2018 approximated its fair value and as of December 31, 2017, the Company's debt carrying amount and fair value were as follows (in thousands):

<b>December 31, 2017</b>	
<b>Carrying Amount</b>	<b>Fair Value</b>
Debt	\$39,084 \$40,526

## **8. Investment in privately held company**

On March 15, 2018, the Company entered into a collaboration agreement with KEW, Inc. ("KEW"), a privately held comprehensive genomic profiling company. The Company determined it had a variable interest in a VIE through its investment in a convertible note issued by KEW. During the year ended December 31, 2018, the Company incurred losses relating to this collaboration agreement with KEW of \$2.9 million which were recognized in general and administrative expenses in the Company's consolidated statements of operations. As of December 31, 2018, the Company fulfilled its obligations with respect to the collaboration agreement and there are no balances recorded in the Company's consolidated balance sheets pertaining to this arrangement.

## 9. Commitments and contingencies

### *Operating leases*

In September 2015, the Company entered into a lease agreement for its headquarters and main production facility in San Francisco, California. This lease expires in July 2026 and the Company may renew the lease for an additional ten years. The Company has determined the lease term to be a ten-year period expiring in 2026. The lease term commenced when the Company took occupancy of the facility in February 2016. In connection with the execution of the lease, the Company provided a security deposit of approximately \$4.6 million which is included in restricted cash in the Company's consolidated balance sheets. Minimum annual rent under the lease is subject to increases based on stated rental adjustment terms. In addition, per the terms of the lease, the Company received a \$5.2 million lease incentive in the form of reimbursement from the landlord for a portion of the costs of leasehold improvements the Company has made to the facility. The assets purchased with the lease incentive are included in property and equipment, net, in the Company's consolidated balance sheets and the lease incentive is recognized as a reduction of rental expense on a straight-line basis over the term of the lease. At December 31, 2018, all of the lease incentive had been utilized by the Company and all related reimbursements had been received from the landlord. Aggregate future minimum lease payments for this facility at December 31, 2018 were approximately \$57.8 million. Future minimum payments under non-cancelable operating leases and future minimum payments to be received from non-cancelable subleases as of December 31, 2018 are as follows (in thousands):

	<b>Amounts</b>
2019	\$10,948
2020	10,860
2021	11,109
2022	11,067
2023	8,898
Thereafter	25,715
Future non-cancelable minimum operating lease payments	78,597
Less: minimum payments to be received from non-cancelable subleases	(174 )
Total future non-cancelable minimum operating lease payments, net	\$78,423

The following table summarizes rent expense related to non-cancelable operating leases (in thousands):

	<b>Year Ended December 31,</b>		
	<b>2018</b>	<b>2017</b>	<b>2016</b>
Rent expense	\$9,720	\$8,950	\$8,901
Sublease income	227	398	257
Rent expense, net of sublease income	\$9,493	\$8,552	\$8,644

### *Debt financing*

In March 2017, the Company entered into a Loan and Security Agreement (the "2017 Loan Agreement") with a lender pursuant to which the Company borrowed an initial term loan of \$40.0 million, and received net proceeds of approximately \$39.7 million. Subject to certain conditions, the Company was eligible to borrow a second term loan pursuant to the 2017 Loan Agreement of \$20.0 million in the first quarter of 2018 and did so in March 2018, receiving net proceeds of approximately \$19.8 million.

In February 2018 and June 2018, the Company entered into amendments to the 2017 Loan Agreement (the "2018 Amendments") pursuant to which the Company, subject to certain conditions, was eligible to borrow a third term loan of \$20.0 million during the period from April 2, 2018 to December 31, 2018. Pursuant to the 2018 Amendments, since the third term loan became available and the Company did not draw upon the third term loan, a fee of 1% was applied to the difference between \$20.0 million and the

amount drawn, or \$0.2 million.

Term loans under the amended 2017 Loan Agreement bore interest at a floating rate equal to an index rate plus 7.73%, where the index rate was the greater of 0.77% or the 30-day U.S. Dollar London Interbank Offered Rate ("LIBOR") as reported in *The Wall Street Journal*, with the floating rate resetting monthly subject to a floor of 8.5%.

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The Company could make monthly interest-only payments until May 1, 2019 (or, subject to certain conditions, May 1, 2020), and thereafter monthly payments of principal and interest were required to fully amortize the borrowed amount by a final maturity date of March 1, 2022. A fee of 5% of each funded draw was due at the earlier of prepayment or loan maturity, a facility fee of 0.5% was due upon funding for each draw, and a prepayment fee of between 1% and 3% of the outstanding balance applied in the event of a prepayment. Concurrent with each term loan, the Company granted to the lender a warrant to acquire shares of the Company's common stock equal to the quotient of 3% of the funded amount divided by a per share exercise price equal to the lower of the average closing price for the previous ten days of trading (calculated on the day prior to funding) or the closing price on the day prior to funding. In connection with the initial term loan, in 2017, the Company issued the lender warrants to purchase 116,845 shares of common stock at an exercise price of \$10.27 per share. The Company classified these warrants as equity with a fair value of \$0.7 million. In connection with the second term loan, in 2018, the Company issued the lender warrants to purchase 85,482 shares of common stock at an exercise price of \$7.02 per share. The Company classified these warrants as equity with a fair value of \$0.4 million. All warrants issued pursuant to the amended 2017 Loan Agreement have a term of ten years from the date of issuance and include a cashless exercise provision.

In November 2018, the Company entered into a Note Purchase Agreement (the "2018 Note Purchase Agreement") pursuant to which the Company was eligible to borrow an aggregate principal amount up to \$200.0 million over a seven year maturity term which included an initial borrowing of \$75.0 million in November 2018. The Company received net proceeds of \$10.3 million after terminating and repaying the balance of its obligations of approximately \$64.7 million under the 2017 Loan Agreement and associated amendments with its previous lender. The Company incurred \$5.3 million of debt extinguishment costs upon terminating its previous debt facility which the Company recorded as other income (expense), net in its consolidated statements of operations during the year ended December 31, 2018.

At December 31, 2018, obligations under the 2018 Note Purchase Agreement were \$75.0 million which are required to be repaid to the lender in a balloon payment no later than 2025. If the Company repays prior to the three year anniversary following the initial borrowing, the amount due will be: 117.5% of the principal amount if payment is made within 12 months after the borrowing; 132.5% of the principal amount if payment is made between 12 and 24 months after the borrowing; and 145.0% of the principal amount if payment is made between 24 and 36 months after the borrowing.

The outstanding principal amount under the 2018 Note Purchase Agreement bears interest at a rate of 8.75% annually. In addition, beginning on January 1, 2020 and continuing until repayment or maturity of any outstanding principal, the Company will make quarterly payments of 0.5% of the Company's annual net revenues subject to a maximum annual amount of such payments of \$1.6 million which will be recognized as interest expense. Through the fixed interest charges and the quarterly revenue payments, the Company is required to pay total amounts to generate an 11% internal rate of return to the lender on any outstanding principal balances due in a lump-sum upon the repayment or maturity of any outstanding principal. During the year ended December 31, 2018, the 2018 Note Purchase Agreement bore interest at an average interest rate of 10.6%.

The 2018 Note Purchase Agreement contains quarterly covenants to achieve certain revenue levels as well as additional covenants, including limits on the Company's ability to dispose of assets, undergo a change of control, merge with or acquire other entities, incur debt, incur liens, pay dividends or other distributions to holders of its capital stock, repurchase stock and make investments, in each case subject to certain exceptions. The Company's obligations under the 2018 Note Purchase Agreement are secured by a security interest on substantially all of its and certain of its subsidiaries' assets.

In connection with the 2018 Note Purchase Agreement, in November 2018, the Company entered into a Securities Purchase Agreement with the lender pursuant to which the Company issued 373,524 shares of

its common stock at a price of \$13.39 per share for an aggregate amount of \$5.0 million. The share price paid by the lender was calculated based on the 15-day average closing share price prior to the issuance. The relative fair value method was used to allocate the proceeds between the common stock issued and the note proceeds; the fair value of the common stock issued to the lender was determined to be \$5.4 million.

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Debt discounts, including debt issuance costs, related to the 2018 Note Purchase Agreement of \$0.7 million were recorded as a direct deduction from the debt liability and are being amortized to interest expense over the term of the 2018 Note Purchase Agreement. Future estimated payments under the 2018 Note Purchase Agreement as of December 31, 2018 are as follows (in thousands):

	<b>Amounts</b>
2019	\$6,654
2020	8,297
2021	8,279
2022	8,279
2023	8,279
Thereafter	89,998
Total remaining payments	129,786
Less: amount representing debt discount	(721 )
Less: amount representing interest	(54,588 )
Total non-current debt obligation	\$74,477

Interest expense related to the Company's debt financings was \$6.7 million, \$3.5 million and \$0.3 million for the years ended December 31, 2018, 2017 and 2016, respectively.

#### **Capital leases**

The Company has entered into various capital lease agreements to obtain laboratory equipment. The terms of the Company's capital leases are typically three years and are secured by the underlying equipment. The portion of the future payments designated as principal repayment was classified as a capital lease obligation on the consolidated balance sheets.

Future payments under capital leases at December 31, 2018 were as follows (in thousands):

	<b>Amounts</b>
2019	\$2,087
2020	1,392
2021	21
Total capital lease obligations	3,500
Less: amount representing interest	(188 )
Present value of net minimum capital lease payments	3,312
Less: current portion	(1,937 )
Total non-current capital lease obligations	\$1,375

Interest expense related to capital leases was \$0.3 million, \$0.2 million and \$0.1 million for the years ended December 31, 2018, 2017 and 2016, respectively.

Property and equipment under capital leases was \$7.1 million and \$11.4 million as of December 31, 2018 and 2017, respectively. Accumulated depreciation, collectively, on these assets was \$2.0 million and \$3.0 million at December 31, 2018 and 2017, respectively.

#### **Guarantees and indemnifications**

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

2018 or December 31, 2017.

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**Other commitments**

In the normal course of business, the Company enters into various purchase commitments primarily related to service agreements, laboratory supplies, and a co-development agreement. At December 31, 2018, the Company's total future payments under noncancelable unconditional purchase commitments having a remaining term of over one year were as follows (in thousands):

Amount
2019\$3,040
20203,040
2021 1,440
Total\$7,520

In addition, in September 2018, the Company entered into a co-development agreement with a privately held genetics testing company. The co-development agreement grants the Company the right of first refusal to enter into an agreement for an acquisition of the entity in return for total fees of \$3.0 million over the term of the 12-month agreement, of which \$1.0 million has been paid by the Company as of December 31, 2018. The unpaid fees of \$2.0 million were paid in January 2019, and as of December 31, 2018, were recorded as an accrued liability in the Company's consolidated balance sheets.

**Contingencies**

The Company was not a party to any material legal proceedings at December 31, 2018, or at the date of this report. The Company may from time to time become involved in various legal proceedings arising in the ordinary course of business, and the resolution of any such claims could be material.

**10. Stockholders' Equity****Common stock**

As of December 31, 2018 and 2017, the Company had reserved shares of common stock, on an as if converted basis, for issuance as follows (in thousands):

	As of December 31,	
	2018	2017
Options issued and outstanding	3,855	4,115
RSU awards issued and outstanding	4,031	2,387
Shares available for grant under stock option plans	118	2,397
Shares reserved for issuance under the 2015 Employee Stock Purchase Plan	278	308
Common stock underlying warrants	611	1,962
Common stock issuable upon conversion of preferred stock	3,459	3,459
Common stock underlying stock payable liabilities	132	689
Common stock payable as contingent consideration	452	551
Total	12,936	15,868

**Private placement**

In August 2017, in a private placement to certain accredited investors, the Company issued 5.2 million shares of its common stock at a price of \$8.50 per share, and 3.5 million shares of its Series A convertible preferred stock at a price of \$8.50 per share, for gross proceeds of approximately \$73.5 million and net proceeds of \$68.9 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. The Series A Preferred Stock has the right to receive dividends first or simultaneously with payment of dividends on common stock,



in an amount equal to the product of (i) the dividend payable on each share of common stock and (ii) the number of shares of common stock issuable upon conversion

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of a share of Series A Preferred Stock. The Series A Preferred Stock has no voting rights except as required by law, as modified by the Company's Amended and Restated Certificate of Incorporation. In the event of any liquidation or dissolution of the Company, the Series A Preferred Stock is entitled to receive \$0.001 per share prior to the payment of any amount to any holders of capital stock of the Company ranking junior to the Series A Preferred Stock and thereafter shall participate pari passu with the holders of the Company's common stock (on an as-if-converted-to-common-stock basis). During January and February 2019, 1.1 million shares of Series A convertible preferred stock were converted to 1.1 million shares of common stock.

#### **Public offering**

In April 2018, the Company issued, in an underwritten public offering, an aggregate of 12.8 million shares of its common stock at a price of \$4.50 per share, for gross proceeds of \$57.5 million and net proceeds of \$53.5 million.

#### **2018 Sales Agreement**

In August 2018, the Company entered into a Common Stock Sales Agreement (the "2018 Sales Agreement") with Cowen and Company, LLC ("Cowen"), under which the Company may offer and sell from time to time at its sole discretion shares of its common stock through Cowen as its sales agent, in an aggregate amount not to exceed \$75.0 million. Cowen may sell the shares by any method permitted by law deemed to be an "at the market" offering as defined in Rule 415 of the Securities Act, including without limitation sales made directly on The New York Stock Exchange, and also may sell the shares in privately negotiated transactions, subject to the Company's prior approval. The Company is obligated to pay Cowen a commission equal to 3% of the gross proceeds of the sales price of all shares sold through it as sales agent under the 2018 Sales Agreement. During the year ended December 31, 2018, the Company issued a total of 4.3 million shares of common stock under the 2018 Sales Agreement for aggregate gross proceeds of \$61.1 million and net proceeds of \$58.9 million.

#### **Common stock warrants**

As of December 31, 2018, the Company had outstanding warrants to purchase common stock as follows:

Warrant	Issuance Date	Expiration Date	Exercise Price Per Share	Number of Shares of Common Stock Underlying Warrants
Warrants issued in exchange for CombiMatrix Series F warrants	November 2017	March 2021	\$5.95	408,548
Warrants issued to lender under 2017 Loan Agreement	March 2017	March 2027	\$10.27	116,845
Warrants issued to lender under 2017 Loan Agreement - 2018 Amendments	March 2018	March 2028	\$7.02	85,482
				610,875

The exercise price of warrants issued in exchange for CombiMatrix Series F warrants was determined pursuant to the terms of the Merger Agreement (See Note 4, "Business Combinations"). The CombiMatrix Series D warrants expired during the year ended December 31, 2018. The exercise price of the warrants issued to the lender under the 2017 Loan Agreement was the closing price of the Company's common stock on the date of the agreements. During the year ended December 31, 2018, the Company received \$6.5 million from exercises 1.0 million shares of common stock under these warrants.

### **11. Stock incentive plans**

#### **Stock incentive plans**

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

In January 2015, the Company adopted the 2015 Stock Incentive Plan (the “2015 Plan”), which became effective upon the closing of the Company’s initial public offering (“IPO”). Shares outstanding under the 2010 Plan were transferred to the 2015 Plan upon effectiveness of the 2015 Plan. The 2015 Plan provides for automatic annual increases in shares available for grant, beginning on January 1, 2016 through January 1, 2025. In addition, shares subject to awards under the 2010 Plan that are forfeited or terminated will be added to the 2015 Plan. The 2015 Plan provides for the grant of incentive stock options, nonstatutory stock options, restricted stock awards, stock units, stock appreciation rights and other forms of equity compensation, all of which may be granted to employees, including officers, non-employee directors and consultants. Additionally, the 2015 Plan provides for the grant of cash-based awards.

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

RSUs generally vest over a period of three years. Typically, the vesting schedule for RSUs provides that one third of the award vests upon each anniversary of the grant date.

In February 2016, the Company granted PRSUs under the 2015 Plan, which PRSUs could be earned based on the achievement of specified performance conditions measured over a period of approximately 12 months. In February 2017, upon the Audit Committee’s determination of the level of achievement, 352,045 fully vested stock units were awarded to holders of PRSUs. The Company has not granted any PRSUs since 2016.

Based on its evaluations of the probability of achieving performance conditions, the Company recorded stock-based compensation expense of nil, \$0.4 million, and \$1.9 million for the years ended December 31, 2018, 2017, and 2016, respectively, related to the PRSUs.

Activity under the 2010 Plan and the 2015 Plan is set forth below (in thousands, except per share amounts and years):

	Shares Available For Grant	Stock Options Outstanding	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Life (years)	Aggregate Intrinsic Value
Balance at December 31, 2017	2,397	4,115	\$ 8.51	7.6	\$ 5,128
Additional shares reserved	754	—			
Options granted	(260 )	260	\$ 8.50		
Options cancelled	169	(169 )	\$ 9.35		
Options exercised	—	(351 )	\$ 7.73		
RSUs granted	(3,282 )	—			
RSUs cancelled	340	—			
Balance at December 31, 2018	118	3,855	\$ 8.54	6.8	\$ 9,927
Options exercisable at December 31, 2018		2,737	\$ 8.27	6.4	\$ 7,787
Options vested and expected to vest at December 31, 2018		3,710	\$ 8.52	6.8	\$ 9,626

The aggregate intrinsic value is calculated as the difference between the exercise price of the underlying stock options and the fair value of the Company’s common stock for stock options that were in-the-money. The weighted-average fair value of options to purchase common stock granted was \$4.87, \$5.82 and \$6.18 in the years ended December 31, 2018, 2017 and 2016, respectively. The weighted-average fair value of RSUs granted was \$7.46, \$10.03 and \$9.80 in the years ended December 31, 2018, 2017 and 2016, respectively. No PRSUs were granted in the years ended December 31, 2018 or 2017 and the weighted

average fair value of PRSUs granted in the year ended December 31, 2016 was \$6.50.

The total grant-date fair value of options to purchase common stock vested was \$5.9 million, \$6.9 million and \$5.6 million in the year ended December 31, 2018, 2017, and 2016, respectively.

The intrinsic value of options to purchase common stock exercised was \$1.7 million, \$2.1 million and \$1.4 million in the years ended December 31, 2018, 2017 and 2016, respectively.

The following table summarizes RSU activity for the year ended December 31, 2018 (in thousands, except per share data):

	Number of Shares	Weighted-Average Grant Date Fair Value
Balance at December 31, 2017	2,387	\$ 9.91
RSUs granted	3,282	\$ 7.46
RSUs vested	(1,298)	\$ 8.84
RSUs cancelled	(340 )	\$ 8.84
Balance at December 31, 2018	4,031	\$ 8.35

### **2015 employee stock purchase plan**

In January 2015, the Company adopted the 2015 Employee Stock Purchase Plan (the “ESPP”), which became effective upon the closing of the IPO. Employees participating in the ESPP may purchase common stock at 85% of the lesser of the fair market value of common stock on the purchase date or last trading day preceding the offering date. At December 31, 2018, cash received from payroll deductions pursuant to the ESPP was \$0.6 million.

The ESPP provides for automatic annual increases in shares available for grant, beginning on January 1, 2016 and continuing through January 1, 2025. At December 31, 2018, a total of 277,577 shares of common stock are reserved for issuance under the ESPP.

### **Stock-based compensation**

The Company uses the grant date fair value of its common stock to value both employee and non-employee options when granted. The Company revalues non-employee options each reporting period using the fair market value of the Company’s common stock as of the last day of each reporting period. In determining the fair value of stock options and ESPP purchases, the Company uses the Black-Scholes option-pricing model and, for stock options, the assumptions discussed below. Each of these inputs is subjective and its determination generally requires significant judgment. The fair value of RSU and PRSU awards is based on the grant date share price. Compensation cost is recognized as expense on a straight-line basis over the vesting period for options and RSUs and on an accelerated basis for PRSUs. In 2016, the Company modified certain stock options and RSU awards. The terms of the stock option modifications included acceleration of vesting and extensions of post-termination exercise periods. The terms of the RSU award modifications included acceleration of vesting. A total of 14 employees were affected by the stock option and RSU modifications and the total incremental compensation cost relating to these modifications was \$0.3 million.

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

*Expected volatility*—Because the Company was privately held until its initial public offering in February 2015 and did not have any trading history for its common stock, the Company estimates expected volatility using its own stock price volatility when available as well as the average volatility for comparable publicly traded life sciences companies, including molecular diagnostics companies, over a period equal to the expected term of stock option grants and RSUs. When selecting comparable publicly-traded biopharmaceutical companies, including molecular diagnostics companies, the Company selected companies with comparable characteristics, including enterprise value, risk profiles, position within the industry and with historical share price information sufficient to meet the expected life of the stock-based awards. The Company computed historical volatility data using daily closing prices for the selected companies’ shares during the equivalent period of the calculated expected term of the stock-based awards. The Company will continue to apply this process until a sufficient amount of historical information regarding the volatility of its own stock price

becomes available. The Company estimates expected volatility for ESPP purchases using its own stock price volatility over the expected six-month term ESPP purchase periods.

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

*Dividend yield*—The Company has never paid dividends on its common stock and has no plans to pay dividends on its common stock. Therefore, the Company used an expected dividend yield of zero. The fair value of share-based payments for stock options granted to employees and directors was estimated on the date of grant using the Black-Scholes option-pricing model based on the following assumptions:

	Year Ended December 31,		
	2018	2017	2016
Expected term (in years)	6.00	6.03	6.03
Expected volatility	59.58%	72.64%	71.42%
Risk-free interest rate	2.80%	2.01%	1.37%

Stock-based compensation related to stock options granted to non-employees is recognized as the stock options vest. The fair value of the stock options granted is calculated at each reporting date using the Black-Scholes option-pricing model based on the following assumptions:

	Year Ended December 31,		
	2018	2017	2016
Expected term (in years)	—	8.41 – 8.83	6.25 – 10.00
Expected volatility	—	69.9 – 78.70%	76.92%
Risk-free interest rate	—	1.83 – 2.04%	1.55 – 2.37%

No stock options granted to non-employees vested during the year ended December 31, 2018. The fair value of shares purchased pursuant to the ESPP is estimated using the Black-Scholes option pricing model. For the years ended December 31, 2018, 2017 and 2016, the weighted average grant date fair value per share for the ESPP was \$3.26, \$2.51 and \$2.66, respectively and stock based compensation expense for the ESPP was \$1.4 million, \$1.1 million and \$0.9 million, respectively. The fair value of the shares purchased pursuant to the ESPP was estimated using the following assumptions:

	Year Ended December 31,		
	2018	2017	2016
Expected term (in years)	0.5	0.5	0.5
Expected volatility	71.66%	52.50%	66.31%
Risk-free interest rate	2.09%	1.23%	0.50%

The following table summarizes stock-based compensation expense for the years ended December 31, 2018, 2017 and 2016, included in the consolidated statements of operations (in thousands):

	Year Ended December 31,		
	2018	2017	2016
Cost of revenue	\$2,960	\$2,093	\$1,353
Research and development	7,017	6,158	4,976
Selling and marketing	4,887	3,956	1,709
General and administrative	5,986	7,014	2,661
Total stock-based compensation expense	\$20,850	\$19,221	\$10,699

At December 31, 2018, unrecognized compensation expense related to unvested stock options, net of estimated forfeitures, was \$4.5 million, which the Company expects to recognize on a straight-line basis



over a weighted-average period of 1.8 years. Unrecognized compensation expense related to RSUs at December 31, 2018, net of estimated forfeitures, was \$22.6 million, which the Company expects to recognize on a straight-line basis over a weighted-average period of 2.1 years. At December 31, 2018, there was no unrecognized compensation expense related to PRSUs and no capitalized stock-based employee compensation.

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**12. Income taxes**

The Company recorded a benefit for income taxes in the years ended December 31, 2018 and 2017. The Company did not record a provision or benefit for income taxes during the year ended December 31, 2016. The components of net loss before taxes by U.S. and foreign jurisdictions are as follows (in thousands):

	Year Ended December 31,		
	2018	2017	2016
United States	\$132,194	\$124,108	\$99,793
Foreign	(39 )	1,128	463
Total	\$132,155	\$125,236	\$100,256

The components of the provision for income taxes are as follows (in thousands):

	Year Ended December 31,		
	2018	2017	2016
Current:			
Foreign	62	—	—
Total current benefit for income taxes	62	—	—
Deferred:			
Federal	(2,862 )	(1,704 )	—
State	—	(152 )	—
Total deferred benefit for income taxes	(2,862 )	(1,856 )	—
Total income tax benefit	\$(2,800)	\$(1,856)	\$ —

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

	Year Ended December 31,			
	2018	2017	2016	
U.S. federal taxes at statutory rate	21.0 %	34.0 %	34.0 %	%
State taxes (net of federal benefit)	5.2 %	3.3 %	1.4 %	%
Stock-based compensation	(0.7 )%	(1.1 )%	(1.7 )%	%
Research and development credits	2.7 %	— %	— %	%
Non-deductible expenses	(0.6 )%	— %	0.2 %	%
Foreign tax differential	— %	(0.3 )%	(0.2 )%	%
Other	— %	— %	1.1 %	%
Change in valuation allowance	(25.5)%	(34.4)%	(34.8)%	%
Change in deferred—Tax Reform	— %	(39.0)%	— %	%
Change in valuation allowance—Tax Reform	— %	39.0 %	— %	%
Total	2.1 %	1.5 %	— %	%

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

	As of December 31,	
	2018	2017
Deferred tax assets:		
Net operating loss carryforwards	\$76,972	\$70,825
Tax credits	15	15
Revenue recognition differences	47,650	29,819
Accruals and other	7,262	5,544
Gross deferred tax assets	131,899	106,203
Valuation allowance	(121,954)	(95,687)
Total deferred tax assets	9,945	10,516
Deferred tax liabilities:		
Property and equipment	(9,945)	(10,516)
Total deferred tax liabilities	(9,945)	(10,516)
Net deferred tax assets	\$—	\$—

On December 22, 2017, the Tax Cuts and Jobs Act of 2017 (the "Tax Act") was signed into law making significant changes to the Internal Revenue Code. Changes included among other items, a reduction of the corporate tax rate from a top marginal rate of 35% to a flat rate of 21%. Although the Tax Act was generally effective January 1, 2018, GAAP required 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, during 2017, the Company recorded a provisional estimate to reduce deferred tax assets by \$48.8 million offset by a corresponding reduction in the valuation allowance resulting in no net impact to the Company's income tax benefit or expense.

On December 22, 2017, the Securities and Exchange Commission issued Staff Accounting Bulletin No. 118 ("SAB 118") to address the application of U.S. GAAP in situations when a registrant does not have the necessary information available, prepared, or analyzed (including computations) in reasonable detail to complete the accounting for certain income tax effects of the Tax Act. In accordance with SAB 118, during 2017, the Company recorded a provisional estimate which resulted in a \$48.8 million reduction in deferred tax assets and in the fourth quarter of 2018, the Company completed its analysis of the impact of the Tax Act and determined that no material adjustments were required to the provisional amounts previously recorded.

The Company has established a full valuation allowance against its deferred tax assets due to the uncertainty surrounding realization of such assets. The Company's valuation allowance increased by \$26.3 million, \$2.0 million, and \$33.4 million during the years ended December 31, 2018, 2017, and 2016, respectively.

As of December 31, 2018, the Company had net operating loss carryforwards of approximately \$318.7 million and \$134.3 million available to reduce future taxable income, if any, for Federal and state income tax purposes, respectively. Of the \$318.7 million, \$277.3 million will begin to expire in 2030 while \$41.4 million have no expiration date. The state net operating loss carryforwards will begin to expire in 2030.

As of December 31, 2018, the Company had research and development credit carryforwards of approximately \$9.0 million and \$7.4 million available to reduce its future tax liability, if any, for Federal and state income tax purposes, respectively. The Federal credit carryforwards begin to expire in 2030.

California credit carryforwards have no expiration date.

Internal Revenue Code ("IRC") section 382 places a limitation (the "Section 382 limitation" or "annual limitation") on the amount of taxable income that can be offset by net operating loss carryforwards after a

change in control (generally greater than 50% change in ownership) of a loss corporation. Similar provisions exist for states. In addition, and as a result of the acquisitions of Good Start Genetics and CombiMatrix in 2017, tax loss carryforwards from acquired entities are also subject to the Section 382 limitation due to the change in control in the acquired entities in the current year.

The Company performed a section 382 analysis for Good Start Genetics and CombiMatrix and concluded that a substantial portion of the acquired operating loss and credit carryovers would expire unused as a result of

annual limitations under IRC sections 382 and 383 in 2017. As a result, the federal and state operating loss and credit carryforwards acquired in connection with the Good Start Genetics and CombiMatrix acquisitions were reduced by the amount of tax attributes estimated to expire during their respective carryforward periods. In addition, as a result of equity issued in connection with its 2017 acquisitions, the Company also performed a section 382 analysis with respect to its legacy operating loss and credit carryforwards. The Company concluded while an ownership change occurred in 2017 as defined under IRC section 382, none of the Company's legacy carryforwards would expire unused solely as a result of annual limitations imposed on the use of the carryforwards under IRC sections 382 and 383.

As of December 31, 2018, the Company had unrecognized tax benefits of \$16.4 million, which primarily relates to research and development credits, none of which would currently affect the Company's effective tax rate if recognized due to the Company's deferred tax assets being fully offset by a valuation allowance. Unrecognized tax benefits are not expected to change in the next 12 months.

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

	Year ended December 31,		
	2018	2017	2016
Unrecognized tax benefits, beginning of period	\$10,561	\$7,791	\$11,429
Gross increases—current period tax positions	5,686	2,552	782
Gross increases (decreases)—prior period tax position	\$28	218	(4,420 )
Unrecognized tax benefits, end of period	\$16,375	\$10,561	\$7,791

The Company's policy is to include penalties and interest expense related to income taxes as a component of tax expense. The Company has not accrued interest and penalties related to the unrecognized tax benefits reflected in the financial statements for the years ended December 31, 2018, 2017 and 2016.

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

### 13. Net loss per share

The following table presents the calculation of basic and diluted net loss per share for the years ended December 31, 2018, 2017 and 2016 (in thousands, except per share data):

	Year ended December 31,		
	2018	2017	2016
Net loss	\$(129,355)	\$(123,380)	\$(100,256)
Shares used in computing net loss per share, basic and diluted	66,747	46,512	33,176
Net loss per share, basic and diluted	\$(1.94 )	\$(2.65 )	\$(3.02 )

The following common stock equivalents have been excluded from diluted net loss per share for the years ended December 31, 2018, 2017 and 2016 because their inclusion would be anti-dilutive (in thousands):

	Year Ended December 31,		
	2018	2017	2016
Shares of common stock subject to outstanding options	3,855	4,115	4,491
Shares of common stock subject to outstanding warrants	611	1,962	—
Shares of common stock subject to outstanding RSUs	4,031	2,387	892
Shares of common stock subject to outstanding PRSUs	—	—	530
Shares of common stock pursuant to ESPP	63	59	55
Shares of common stock underlying Series A convertible preferred stock	3,459	3,459	—
Total shares of common stock equivalents	12,019	11,982	5,968

#### 14. Geographic information

Revenue by country is determined based on the billing address of the customer and is summarized as follows (in thousands):

	Year Ended December 31,		
	2018	2017	2016
United States	\$138,239	\$62,446	\$20,758
Canada	4,206	3,226	2,526
Rest of world	5,254	2,549	1,764
Total revenue	\$147,699	\$68,221	\$25,048

As of December 31, 2018 and 2017, all long-lived assets were located in the United States.

#### 15. Selected quarterly data (unaudited)

The following table summarizes the Company's quarterly financial information for 2018 and 2017 (in thousands, except per share amounts):

	Three Months Ended			
	March 31, 2018	June 30, 2018	September 30, 2018	December 31, 2018
Revenue	\$27,671	\$37,306	\$37,366	\$45,356
Cost of revenue	\$18,076	\$20,447	\$20,441	\$21,141
Loss from operations	\$(36,475)	\$(30,068)	\$(30,110)	\$(25,904)
Net loss <sup>(2)</sup>	\$(36,120)	\$(31,671)	\$(31,723)	\$(29,841)
Net loss per share, basic and diluted <sup>(1)</sup>	\$(0.66)	\$(0.47)	\$(0.45)	\$(0.40)

	Three Months Ended			
	March 31, 2017	June 30, 2017	September 30, 2017	December 31, 2017
Revenue	\$10,338	\$14,336	\$18,148	\$25,399
Cost of revenue	\$9,329	\$10,490	\$13,274	\$17,049
Loss from operations	\$(27,337)	\$(28,075)	\$(30,976)	\$(34,891)
Net loss <sup>(2)</sup>	\$(26,928)	\$(28,557)	\$(27,402)	\$(40,493)
Net loss per share, basic and diluted <sup>(1)</sup>	\$(0.64)	\$(0.66)	\$(0.57)	\$(0.78)

(1) Net loss per share is computed independently for each of the quarters presented. Therefore, the sum of quarterly net loss per share information may not equal annual net loss per share.



<sup>(2)</sup> Includes \$5.3 million of debt extinguishment costs during the three months ended December 31, 2018. See Note 9, "Commitments and contingencies" for further information.

**ITEM 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure.**

Not applicable.

**ITEM 9A. Controls and Procedures.**

**Evaluation of disclosure controls and procedures**

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

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

**Changes in internal controls**

There was no change in our internal control over financial reporting (as defined in Rule 13a-15(f) under the Exchange Act) identified in connection with the evaluation described in Item 9A above that occurred during our last fiscal quarter that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

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

Our management is responsible for establishing and maintaining internal control over our financial reporting. Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Projections of any evaluation of the effectiveness of internal control to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with policies or procedures may deteriorate. Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, assessed the effectiveness of our internal control over financial reporting as of December 31, 2018. In making this assessment, our management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission, or COSO, in Internal Control—Integrated Framework (2013 Framework). Based on the assessment using those criteria, our management concluded that, as of December 31, 2018, our internal control over financial reporting was effective.

**ITEM 9B. Other Information.**

As of the date of this filing, Patricia E. Dumond has ceased to serve as our Principal Accounting Officer. Shelly D. Guyer, age 58, our Chief Financial Officer since June 2017, has been appointed to serve in the additional position of Principal Accounting Officer. 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. Ms. Guyer has no family relationships with any of our directors or executive officers, and she has no direct or indirect material interest in any transaction required to be disclosed pursuant to Item 404(a) of Regulation S-K. Ms. Dumond will continue as an employee of Invitae working on various matters, including direct offering of product lines into the marketplace.

### **PART III**

#### **ITEM 10. Directors, Executive Officers and Corporate Governance.**

The information required by this item with respect to directors is incorporated by reference from the information under the caption "Election of Directors," contained in our proxy statement to be filed with the Securities and Exchange Commission no later than 120 days from the end of our fiscal year ended December 31, 2018 in connection with the solicitation of proxies for our 2019 Annual Meeting of Stockholders, or the Proxy Statement. Certain information required by this item concerning executive officers is set forth in Part I of this Report under the caption "Executive Officers of the Registrant" and is incorporated herein by reference.

There have been no material changes to the procedures by which stockholders may recommend nominees to our Board of Directors.

Item 405 of Regulation S-K calls for disclosure of any known late filing or failure by an insider to file a report required by Section 16(a) of the Exchange Act. This disclosure is contained in the section entitled "Section 16(a) Beneficial Ownership Reporting Compliance" in the Proxy Statement and is incorporated herein by reference.

Our board of directors has adopted a code of ethics for senior financial officers applicable to our Chief Executive Officer and Chief Financial Officer as well as other key management employees addressing ethical issues. The code of business conduct and the code of ethics are each posted on our website [www.invitae.com](http://www.invitae.com). The code of business conduct and the code of ethics can only be amended by the approval of a majority of our board of directors. Any waiver to the code of business conduct for an executive officer or director or any waiver of the code of ethics may only be granted by our board of directors or our nominating and corporate governance committee and must be timely disclosed as required by applicable law. We have implemented whistleblower procedures that establish formal protocols for receiving and handling complaints from employees. Any concerns regarding accounting or auditing matters reported under these procedures will be communicated promptly to our audit committee. Stockholders may request a free copy of our code of business conduct and code of ethics by contacting Invitae Corporation, Attention: Chief Financial Officer, 1400 16th Street, San Francisco, California 94103.

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

Our Board of Directors has appointed an Audit Committee, comprised of Eric Aguiar, Geoffrey S. Crouse and Christine M. Gorjanc. The Board of Directors has determined that each of the members of our Audit Committee qualifies as an Audit Committee Financial Expert under the definition outlined by the Securities and Exchange Commission. In addition, each of the members of the Audit Committee qualifies as an "independent director" under the current rules of the New York Stock Exchange and Securities and Exchange Commission rules and regulations.

#### **ITEM 11. Executive Compensation.**

The information required by this item is incorporated by reference from the information under the captions "Election of Directors-Director Compensation" and "Executive Compensation" contained in the Proxy Statement.

#### **ITEM 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.**

The information required by this item is incorporated by reference to the disclosure appearing under the headings "Security Ownership of Certain Beneficial Owners and Management" and "Executive Compensation-Equity Compensation Plan Information" contained in the Proxy Statement.

#### **ITEM 13. Certain Relationships and Related Transactions, and Director Independence.**

The information required by this item is incorporated by reference from the information under the caption “Election of Directors-Certain Relationships and Related Transactions” and “Director Independence” contained in the Proxy Statement.

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**ITEM 14. Principal Accountant Fees and Services.**

The information required by this item is incorporated by reference from the information under the caption “Ratification of the Appointment of Independent Registered Public Accounting Firm” contained in the Proxy Statement.

**PART IV**

**ITEM 15. Exhibits and Financial Statement Schedules.**

(a) Documents filed as part of this report

1. *Financial Statements:* Reference is made to the Index to Financial Statements of Invitae Corporation included in Item 8 of Part II hereof.

2. *Financial Statement Schedules:* All schedules have been omitted because they are not required, not applicable, or the required information is included in the financial statements or notes thereto.

3. *Exhibits:* See Item 15(b) below. Each management contract or compensating plan or arrangement required to be filed has been identified.

(b) Exhibits

Exhibit Number	Description
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2.1&@	<u>Stock Purchase Agreement dated as of January 6, 2017 by and among Invitae Corporation, each of the selling shareholders listed on Schedule 1 thereto, and the sellers' agent (incorporated by reference to Exhibit 2.1 to the Registrant's Current Report on Form 8-K filed January 6, 2017).</u>
2.2@	<u>Form of Stock Exchange Agreement dated as of June 11, 2017 by and among Invitae Corporation, each of the selling stockholders listed on Schedule 1 thereto, and the sellers' agent (incorporated by reference to Exhibit 2.1 to the Registrant's Current Report on Form 8-K filed June 13, 2017).</u>
2.3@	<u>Agreement and Plan of Merger and Reorganization, dated as of July 31, 2017, by and among Invitae Corporation, Coronado Merger Sub, Inc. and CombiMatrix Corporation (incorporated by reference to Exhibit 2.1 to the Registrant's Current Report on Form 8-K filed August 1, 2017).</u>
2.4@	<u>Agreement and Plan of Merger, dated as of July 31, 2017, by and among Invitae Corporation, Bueno Merger Sub, Inc., Good Start Genetics, Inc., the Noteholders, the Management Carveout Plan Participants, and OrbiMed Private Investments III, LP as the Holders' Representative (incorporated by reference to Exhibit 2.2 to the Registrant's Current Report on Form 8-K filed August 1, 2017).</u>
2.5	<u>Securities Purchase Agreement, dated as of November 6, 2018, by and among Invitae Corporation and the investors party thereto (incorporated by reference to Exhibit 10.2 to the Registrant's Current Report on Form 8-K filed November 7, 2018).</u>
3.1	<u>Restated Certificate of Incorporation of the Registrant (incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K filed February 23, 2015).</u>
3.1.1	<u>Certificate of Designation of Preferences, Rights and Limitations of Series A Convertible Preferred Stock of Invitae Corporation (incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K filed August 1, 2017).</u>
3.2	<u>Amended and Restated Bylaws of the Registrant (incorporated by reference to Exhibit 3.2 to the Registrant's Current Report on Form 8-K filed February 23, 2015).</u>
4.1	<u>Form of Common Stock Certificate (incorporated by reference to Exhibit 4.1 to the Registrant's Registration Statement on Form S-1 (File No. 333-201433), as amended, declared effective on February 11, 2015).</u>
4.2	<u>Registration Rights Agreement, dated as of July 31, 2017 (incorporated by reference to Exhibit 10.2 to the Registrant's Current Report on Form 8-K filed August 1, 2017).</u>
4.3	<u>Amended and Restated Registration Rights Agreement, dated as of July 31, 2017 (incorporated by reference to Exhibit 10.4 to the Registrant's Current Report on Form 8-K filed August 1, 2017).</u>
4.4	

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Form of Invitae Corporation Series D Warrant (incorporated by reference to Exhibit 4.2 to the Registrant's Registration Statement on Form S 4 (File No. 333 220447), as amended, filed September 13, 2017).

4.5 Form of Invitae Corporation Series D Warrant Agent Agreement (incorporated by reference to Exhibit 4.3 to the Registrant's Registration Statement on Form S 4 (File No. 333 220447), as amended, filed September 13, 2017).

4.6 Form of Invitae Corporation Series F Warrant (incorporated by reference to Exhibit 4.4 to the Registrant's Registration Statement on Form S 4 (File No. 333 220447), as amended, filed September 13, 2017).

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Exhibit Number	Description
4.7	<u>Form of Invitae Corporation Series F Warrant Agent Agreement (incorporated by reference to Exhibit 4.5 to the Registrant's Registration Statement on Form S-4 (File No. 333-220447), as amended, filed September 13, 2017).</u>
10.1	<u>Form of Indemnification Agreement between the Registrant and its officers and directors (incorporated by reference to Exhibit 10.1 to the Registrant's Registration Statement on Form S-1 (File No. 333-201433), as amended, declared effective on February 11, 2015).</u>
10.2#	<u>2010 Stock Plan (incorporated by reference to Exhibit 10.2 to the Registrant's Registration Statement on Form S-1 (File No. 333-201433), as amended, declared effective on February 11, 2015).</u>
10.3#	<u>Form of Notice of Stock Option Grant and Stock Option Agreement—Standard Exercise for awards granted under 2010 Stock Incentive Plan (incorporated by reference to Exhibit 10.3 to the Registrant's Registration Statement on Form S-1 (File No. 333-201433), as amended, declared effective on February 11, 2015).</u>
10.4#	<u>Form of Notice of Stock Option Grant and Stock Option Agreement—Early Exercise for awards granted under 2010 Stock Incentive Plan (incorporated by reference to Exhibit 10.4 to the Registrant's Registration Statement on Form S-1 (File No. 333-201433), as amended, declared effective on February 11, 2015).</u>
10.5#	<u>2015 Stock Incentive Plan (incorporated by reference to Exhibit 10.5 to the Registrant's Registration Statement on Form S-1 (File No. 333-201433), as amended, declared effective on February 11, 2015).</u>
10.6#	<u>Form of Notice of Stock Option Grant and Non-Qualified Stock Option Agreement for awards granted under the 2015 Stock Incentive Plan (incorporated by reference to Exhibit 10.6 to the Registrant's Registration Statement on Form S-1 (File No. 333-201433), as amended, declared effective on February 11, 2015).</u>
10.7#	<u>Form of Notice of Restricted Stock Award and Restricted Stock Agreement for awards granted under the 2015 Stock Incentive Plan (incorporated by reference to Exhibit 10.7 to the Registrant's Registration Statement on Form S-1 (File No. 333-201433), as amended, declared effective on February 11, 2015).</u>
10.8#	<u>Form of Notice of Restricted Stock Unit Award and Restricted Stock Unit Agreement for Awards Granted under the 2015 Stock Incentive Plan (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed August 6, 2015).</u>
10.9#	<u>Employee Stock Purchase Plan (incorporated by reference to Exhibit 10.8 to the Registrant's Registration Statement on Form S-1 (File No. 333-201433), as amended, declared effective on February 11, 2015).</u>
10.10	<u>Lease Agreement dated as of September 2, 2015 by and between 1400 16th Street LLC, a Delaware limited liability company, and Invitae Corporation (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed September 4, 2015).</u>
10.11	<u>Loan and Security Agreement dated as of July 17, 2015 between Silicon Valley Bank and Invitae Corporation (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed July 22, 2015).</u>
10.12 <sup>&amp;</sup>	<u>Loan and Security Agreement dated as of March 15, 2017 between Oxford Capital, LLC and Invitae Corporation (incorporated by reference to Exhibit 10.13 to the Registrant's Amendment No. 2 to Annual Report on Form 10-K for the year ended December 31, 2016).</u>
10.13	<u>First Amendment to Loan and Security Agreement entered into as February 26, 2018 between Oxford Finance LLC and Invitae Corporation together with its subsidiaries PatientCrossroads, Inc., Good Start Genetics, Inc., Ommdom Inc., Combimatrix Corporation and Combimatrix Molecular Diagnostics, Inc. (incorporated by reference to Exhibit 10.2 to the Registrant's Current Report on Form 8-K filed February 28, 2018).</u>

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- 10.14 Second Amendment to Loan and Security Agreement entered into as of June 29, 2018 between Oxford Finance LLC and Invitae Corporation together with its subsidiaries PatientCrossroads, Inc., Good Start Genetics, Inc., Ommdom Inc., Combimatrix Corporation and Combimatrix Molecular Diagnostics, Inc. (incorporated by reference to Exhibit 10.3 to the Registrant's Current Report on Form 8-K filed June 29, 2018).
- 10.15 Form of Warrant to Purchase Common Stock between Oxford Capital, LLC and Invitae Corporation (incorporated by reference to Exhibit 10.14 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2016).
- 10.16 Note Purchase Agreement, dated as of November 6, 2018, by and among Invitae Corporation, the guarantors from time to time party thereto, INN SA LLC, as collateral agent, and the purchasers listed therein or otherwise party thereto from time to time (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed November 7, 2018).
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Exhibit Number	Description
10.17#	<u>Offer Letter, dated May 19, 2017, between Invitae Corporation and Shelly Guyer (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed June 1, 2017).</u>
10.18	<u>Marketing and Laboratory Services Agreement dated as of September 25, 2017 by and between Invitae Corporation, Good Start Genetics, Inc. and CombiMatrix Molecular Diagnostics, Inc. (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed September 27, 2017).</u>
10.19*	<u>Sales Agreement dated August 9, 2018 between Invitae Corporation and Cowen and Company, LLC.</u>
21.1*	<u>List of Subsidiaries.</u>
23.1*	<u>Consent of Independent Registered Public Accounting Firm.</u>
24.1*	Power of Attorney (contained on the signature page to this Form 10 K).
31.1*	<u>Principal Executive Officer's Certifications Pursuant to Section 302 of the Sarbanes Oxley Act of 2002.</u>
31.2*	<u>Principal Financial Officer's Certifications Pursuant to Section 302 of the Sarbanes Oxley Act of 2002.</u>
32.1+	<u>Certification Pursuant to 18 U.S.C. § 1350 (Section 906 of Sarbanes Oxley Act of 2002).</u>
32.2+	<u>Certification Pursuant to 18 U.S.C. § 1350 (Section 906 of Sarbanes Oxley Act of 2002).</u>
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema
101.CAL	XBRL Taxonomy Extension Calculation Linkbase
101.DEF	XBRL Taxonomy Extension Definition Linkbase
101.LAB	XBRL Taxonomy Extension label Linkbase
101.PRE	XBRL Taxonomy Extension Presentation Linkbase

# Indicates management contract or compensatory plan or arrangement.

\* Filed herewith.

@ The schedules and exhibits to this agreement have been omitted pursuant to Item 601(b)(2) of Regulation S-K. A copy of any omitted schedule and/or exhibit will be furnished to the SEC upon request.

In accordance with Item 601(b)(32)(ii) of Regulation S K and SEC Release No. 34 47986, the certifications furnished in Exhibits 32.1 and 32.2 hereto are deemed to accompany this Form 10 K and will not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934 (the "Exchange Act") or deemed to be incorporated by reference into any filing under the Exchange Act or the Securities Act of 1933 except to the extent that the registrant specifically incorporates it by reference.

+ Confidential treatment has been granted with respect to certain portions of this exhibit.

Copies of the above exhibits not contained herein are available to any stockholder, upon payment of a reasonable per page fee, upon written request to: Chief Financial Officer, Invitae Corporation, 1400 16th Street, San Francisco, California 94103.

(c) Financial Statement Schedules: Reference is made to Item 15(a) 2 above.

**ITEM 16. Form 10-K Summary.**

Not applicable.

**SIGNATURES**

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

INVITAE CORPORATION

By: /s/ Sean E. George, Ph.D.

Sean E. George, Ph.D.

*President and Chief Executive Officer*

Date: February 28, 2019

**POWER OF ATTORNEY**

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Sean E. George and Shelly D. Guyer, and each of them, his true and lawful attorneys in fact, each with full power of substitution, for him or her in any and all capacities, to sign any amendments to this report on Form 10 K and to file the same, with exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, hereby ratifying and confirming all that each of said attorneys in fact or their substitute or substitutes may do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons, on behalf of the registrant on the dates and the capacities indicated.

Signature	Title	Date
/s/ Sean E. George, Ph.D. Sean E. George, Ph.D.	President and Chief Executive Officer (Principal Executive Officer) and Director	February 28, 2019
/s/ Shelly D. Guyer Shelly D. Guyer	Chief Financial Officer (Principal Financial and Accounting Officer)	February 28, 2019
/s/ Randal W. Scott, Ph.D. Randal W. Scott, Ph.D.	Executive Chairman of the Board of Directors	February 28, 2019
/s/ Eric Aguiar, M.D. Eric Aguiar, M.D.	Director	February 28, 2019
/s/ Geoffrey S. Crouse Geoffrey S. Crouse	Director	February 28, 2019
/s/ Christine M. Gorjanc Christine M. Gorjanc	Director	February 28, 2019
/s/ Chitra Nayak Chitra Nayak	Director	February 28, 2019

