UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

	For	rm 10-K		
X	NNUAL 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) For the transition purchased to the commission of the transition purchased to the commission of the commi			
		NVITAE Corporation		
		trant as specified in its charter)		
	Delaware	27-1701898		
	(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)		
	1400 16th Street, San	Francisco, California 94103 executive offices, Zip Code)		
		5) 374-7782		
		number, including area code) suant 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 pursua	nt to Section 12(g) of the Act: None		
Indic	cate by check mark if the registrant is a well-known seasoned issue	r, as defined in Rule 405 of the Securities Act. Yes ☒ No ☐		
Indic	cate by check mark if the registrant is not required to file reports pur	suant to Section 13 or 15(d) of the Act. Yes □ No 区		
1934		equired to be filed by Section 13 or 15(d) of the Securities Exchange Act of e registrant was required to file such reports), and (2) has been subject to		
of Re		ally every Interactive Data File required to be submitted pursuant to Rule 40 onths (or for such shorter period that the registrant was required to submit		

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.

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	X					
Non-accelerated filer		Smaller reporting company						
		Emerging growth company	X					
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 t	he registrant is a shell company (as defined	n Rule 12b-2 of the Act). Yes □ No 区						
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 INCORPORA	TED 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.

TABLE OF CONTENTS

		Page No.
PART I		
Item 1.	<u>Business</u>	<u>2</u>
Item 1A.	Risk Factors	<u>15</u>
Item 1B.	<u>Unresolved Staff Comments</u>	<u>36</u>
Item 2.	<u>Properties</u>	<u>36</u>
Item 3.	<u>Legal Proceedings</u>	<u>37</u>
Item 4.	Mine Safety Disclosure	<u>37</u>
PART II		
Item 5.	Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities	<u>39</u>
Item 6.	Selected Financial Data	<u>40</u>
Item 7.	Management's Discussion and Analysis of Financial Condition and Results of Operations	<u>42</u>
Item 7A.	Qualitative and Quantitative Disclosures About Market Risk	<u>55</u>
Item 8.	Consolidated Financial Statements and Supplementary Data	<u>56</u>
Item 9.	Changes in and Disagreements with Accountants on Accounting and Financial Disclosure	<u>96</u>
Item 9A.	Controls and Procedures	<u>96</u>
Item 9B.	Other Information	<u>96</u>
PART III		
<u>Item 10.</u>	<u>Directors, Executive Officers and Corporate Governance</u>	<u>97</u>
<u>Item 11.</u>	Executive Compensation	<u>97</u>
<u>Item 12.</u>	Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters	<u>97</u>
<u>Item 13.</u>	Certain Relationships and Related Transactions, and Director Independence	<u>97</u>
<u>Item 14.</u>	Principal Accountant Fees and Services	<u>98</u>
PART IV		
<u>Item 15.</u>	Exhibits, Financial Statement Schedules	99
<u>Item 16.</u>	Form 10-K Summary	<u>101</u>
SIGNATURES		

i

PART I

ITEM 1. Business.

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

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

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.

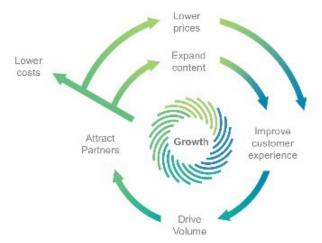
Mission and strategy

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.
- 2) Genome network: sharing genetic information on a global scale to advance science and medicine. We are focusing our efforts on partnering with patients, family members, healthcare professionals, payers, industry professionals, researchers, and clinical trial sponsors to advance the development of our

genome network. 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.

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

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.

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.

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.e., Mayo Collaborative v. Prometheus Laboratories (2012), or Mayo, Association for Molecular Pathology v. Myriad Genetics (2013), or Myriad, and Alice Corporation v. CLS Bank (2014), or Alice. As discussed below, we believe the Mayo, Myriad and Alice decisions bring clarity to the limits to which patents may cover specific genes, mutations of such genes, or gene-specific technology for determining a patient's genomic information.

Patents

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

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

ITEM 1A. Risk Factors.

Risks related to our business and strategy

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

We have incurred substantial losses since our inception. For the years ended December 31, 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

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

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 Heath Act, or HITECH, state data security and data breach notification laws, and related regulatory penalties. Although we have implemented security measures and a formal, dedicated enterprise security program to prevent unauthorized access to patient data, our Invitae Family History Tool, PIN and CancerGene Connect platform are currently accessible through our online portal and/or through our mobile

applications, and there is no guarantee we can protect our online portal or our mobile applications from breach. Unauthorized access, loss or dissemination could also disrupt our operations (including our ability to conduct our analyses, provide test results, bill payers or patients, process claims and appeals, provide customer assistance, conduct research and development activities, collect, process and prepare company financial information, provide information about our tests and other patient and physician education and outreach efforts through our website, and manage the administrative aspects of our business) and damage our reputation, any of which could adversely affect our business.

In addition to security risks, we also face privacy risks. While we have policies that govern our privacy practices and procedures that aim to keep our practices consistent with such policies, such procedures are not invulnerable to human error. Should we inadvertently break the privacy promises we make to patients or consumers, we could receive a complaint from an affected individual or interested privacy regulator, such as the FTC or a state Attorney General. This risk is heightened given the sensitivity of the data we collect.

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

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.

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;
- 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.

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:

Name	Age	Position
Executive officers		
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 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 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities.

Our common stock has been publicly traded on the New York Stock Exchange under the symbol "NVTA" since February 12, 2015. Prior to that time, there was no public market for our common stock.

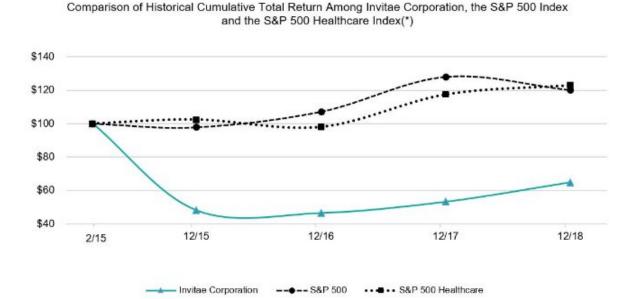
As of February 22, 2019, there were 48 stockholders of record of our common stock. The actual number of stockholders is greater than this number of record holders and includes stockholders who are beneficial owners but whose shares are held in street name by brokers and other nominees.

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.



^(*) 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 (1)		2017 (2)		2016		2015 ⁽³⁾		2014
				(In thou	sand	s except per sl	hare	data)		
Consolidated Statements of Operations Data										
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 (4)		80,105		50,142		27,878		16,523		5,624
Research and development (4)		63,496		46,469		44,630		42,806		22,063
Selling and marketing (4)		74,428		53,417		28,638		22,479		8,669
General and administrative (4)		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 (5)	\$	(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 Dec	ember 31	l,		
	2018 (1)	2017 (2)	20	16		2015 (3)	2014
			(In tho	usands)			
Consolidated Balance Sheet Data:							
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	1	30,651		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)	(2	75,218)		(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.

(4) Includes employee stock-based compensation as follows:

	Year Ended December 31,										
	2018			2017 20		2016	2016			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.

⁽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.

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.

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 innetwork 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.

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.

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 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.

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.

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.

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		2	2022 and 2023	2024 and beyond			Total
Operating leases (1)	\$ 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

⁽¹⁾ 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

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.

Index to Consolidated Financial Statements

	Page
Report of independent registered public accounting firm	<u>57</u>
Consolidated balance sheets	<u>58</u>
Consolidated statements of operations	<u>59</u>
Consolidated statements of comprehensive loss	<u>60</u>
Consolidated statements of convertible preferred stock and stockholders' equity	<u>61</u>
Consolidated statements of cash flows	<u>62</u>
Notes to consolidated financial statements	<u>63</u>
56	

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

Consolidated Balance Sheets

(in thousands, except par value data)

	Dec	ember 31, 2018	Dec	ember 31, 2017
Assets				
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
Liabilities and stockholders' equity				
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

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 52,227 24,085 General and administrative 39,472 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

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)			

Consolidated Statements of Convertible Preferred Stock and Stockholders' Equity (in thousands)

						Accumulated		
	Convertible Additional Other			Total				
	Prefer	red Stock	Comn	non Stock	Paid-In	Comprehensive Accumula		Stockholders'
	Shares	Amount	Shares	Amount	Capital	Income (Loss)	Deficit	Equity
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
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	<u> </u>	75,481	\$ 8	\$ 678,548	\$ (5)	\$ (516,712)	\$ 161,839

Consolidated Statements of Cash Flows

(in thousands)

				Year Ended December 3		
		2018		2017		2016
Cash flows from operating activities:						
Net loss	\$	(129,355)	\$	(123,380)	\$	(100,25
Adjustments to reconcile net loss to net cash used in operating activities:						
Depreciation and amortization		13,540		9,181		6,55
Stock-based compensation		20,850		19,221		10,69
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		1,34
Changes in operating assets and liabilities, net of effects of business combination:						
Accounts receivable		(5,291)		(1,963)		(84
Prepaid expenses and other current assets		(1,445)		(641)		(1,149
Other assets		(163)		(185)		1,46
Accounts payable		(417)		(535)		(11
Accrued expenses and other liabilities		3,564		(37)		5,98
Net cash used in operating activities		(92,220)	_	(97,981)		(76,31
		•		•		, .
Cash flows from investing activities:						
Purchases of marketable securities		(9,680)		(101,867)		(90,23
Proceeds from sales of marketable securities		19,965		_		_
Proceeds from maturities of marketable securities		32,458		68,768		117,92
Acquisition of businesses, acquired cash		_		2,821		_
Purchases of property and equipment		(5,970)		(6,675)		(11,62
Other		(1,000)		_		
Net cash provided by (used in) investing activities		35,773		(36,953)		16,06
				(00,000)		,
Cash flows from financing activities:						
Proceeds from public offering of common stock, net of issuance costs		112,441		_		47,10
Proceeds from issuance of common stock		17,511		74,619		3,13
Net proceeds from issuance of debt		93,909		39,661		7,50
Payments for debt extinguishment costs		(4,609)		_		_
Loan payments		(60,000)		(30,457)		(2,43
Capital lease principal payments		(2,100)		(2,952)		(1,58
Net cash provided by financing activities		157,152		80,871		53,70
		.0.,.02				00,.0
Net increase (decrease) in cash, cash equivalents and restricted cash		100,705		(54,063)		(6,54
Cash, cash equivalents and restricted cash at beginning of period		17,459		71,522		78,06
Cash, cash equivalents and restricted cash at end of period	\$	118,164	\$	17,459	\$	71,52
Supplemental cash flow information:	•	-, -	<u> </u>	,	÷	,-
Interest paid	\$	6,231	\$	2,852	\$	42
	Ψ	0,201	Ψ	2,002	Ψ	42
Supplemental cash flow information of non-cash investing and financing activities:	•		¢.	0.700	C	
Equipment acquired through capital leases	\$		\$	6,789	\$	
Purchases of property and equipment in accounts payable and accrued liabilities	\$	510	\$	200	\$	1,64
Amounts related to co-development agreement in other assets and accrued liabilities	\$	2,000	\$	<u> </u>	\$	_
Warrants issued pursuant to 2017 Loan Agreement	\$	383	\$	740	\$	<u> </u>

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	\$ _

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 disord ers, 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 C ompany'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,			
Customers	2018	2017	2016	
Medicare	22%	13%	11%	

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.

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.

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.

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):

	 Ye	Year Ended December 31, 2018 Without Effect of							
			Without		Effect of				
			Adoption of		Adoption				
	As Reported		Topic 606		Higher/(Lower)				
evenue	\$ 144,560	\$	144,222	\$	338				
oss	\$ (129,355)	\$	(129,693)	\$	338				
oss per share, basic and diluted	\$ (1.94)	\$	(1.94)	\$	_				

		<u>.</u>	As o	f December 31, 20	18	
				Without		Effect of
				Adoption of		Adoption
	Α	s Reported	Topic 606		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 (1)		
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		

⁽¹⁾ 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

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;
- (b) 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 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;
- (c) 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 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

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.

Ommdom

On June 11, 2017, the Company acquired Ommdom, Inc. ("Ommdom"), 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 Ommdom 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	

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	Ψ	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):

	Ir	Gross urchased itangible 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"

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

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				
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):

	1	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):

	Amount
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):

	Dece	mber 31, 2018	December 31, 2017		
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	<u>-</u>	52,395		49,871	
Accumulated depreciation and amortization		(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):

	December 31, 2018		Decen	nber 31, 2017
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):

	Decer	December 31, 2018		nber 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):

Gross

Unrealized Losses

Gross Unrealized Gains

Amortized Cost

Financial assets:

Accrued liabilities

December 31, 2018

Estimated Fair Value

Level 1

Level 2

\$

Level 3

4,998

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	\$	_
Financial liabilities:										
Contingent consideration						\$ 4,998	\$ _	\$ _	\$	4,998
Total financial liabilities						\$ 4,998	\$ _	\$ 	\$	4,998
								Decembe	r 31, 2	2018
Reported as:										
Cash equivalents								\$	1	01,395
Restricted cash										6,006
Marketable securities										13,727
Total cash equivalents, restricted of	ash, and	d marketabl	e secu	ırities				\$	1	21,128

		December 31, 2017											
	A	mortized Cost		Gross Unrealized Gains		Gross nrealized Losses		Estimated Fair Value	Level 1		Level 2	ı	_evel 3
Financial assets:													
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	\$	
Financial liabilities:													
Contingent consideration							\$	3,779	\$ 	\$	_	\$	3,779
Total financial liabilities							\$	3,779	\$ 	\$		\$	3,779
Reported as:											Decembe	r 31, 2	2017
Cash equivalents										\$			592
Restricted cash													5,406
Marketable securities													58,590
Total cash equivalents, restricted cash,	and	marketable	sec	curities						\$			64,588
A company to be the second										Φ.			0.770
Accrued liabilities										\$			3,779

December 31 2017

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):

	<u></u>	Level 3
	Contingent Co	nsideration Liability
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):

	Carrying Amount		Fair Value	
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):

	 Amounts
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):

	Year Ended December 31,							
		2018		2017		2016		
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%.

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.

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):

	Amounts
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):

Δ	mounts
\$	2,087
	1,392
	21
-	3,500
	(188)
	3,312
	(1,937)
\$	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.

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
2020	3,040
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 Dece	mber 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

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	_	xercise Price er 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	ghted-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			
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.

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)%	<u> </u>	0.2 %
Foreign tax differential	— %	(0.3)%	(0.2)%
Other	— %	<u> </u>	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 %	<u> </u>

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 positions	128		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):

	Ye	ear Ended December 3	1,
	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	<u> </u>
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					
ted States	\$ 138,239	\$	62,446	\$	20,758				
nada	4,206		3,226		2,526				
st 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

			Three i	vioni	ns Ended	
	Marc	ch 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 (2)	\$	(36,120)	\$ (31,671)	\$	(31,723)	\$ (29,841)
Net loss per share, basic and diluted (1)	\$	(0.66)	\$ (0.47)	\$	(0.45)	\$ (0.40)

		Three Months Ended							
	Mar	ch 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 (2)	\$	(26,928)	\$	(28,557)	\$	(27,402)	\$	(40,493)	
Net loss per share, basic and diluted (1)	\$	(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.

(2) 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. 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 16 th 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.

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

4.6

Number	Description
2.1 &@	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).
2.2 @	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).
2.3 [@]	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).
2.4 @	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).
2.5	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).
3.1	Restated Certificate of Incorporation of the Registrant (incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K filed February 23, 2015).
3.1.1	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).
3.2	Amended and Restated Bylaws of the Registrant (incorporated by reference to Exhibit 3.2 to the Registrant's Current Report on Form 8-K filed February 23, 2015).
4.1	Form of Common Stock Certificate (incorporated by reference to Exhibit 4.1 to the Registrant's Registration Statement on Form S-1 (File No. 333-201433), as amended, declared effective on February 11, 2015).
4.2	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).
4.3	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).
4.4	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).

(File No. 333-220447), as amended, filed September 13, 2017).

Form of Invitae Corporation Series F Warrant (incorporated by reference to Exhibit 4.4 to the Registrant's Registration Statement on Form S-4

Exhibit Number	Description
4.7	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).
10.1	Form of Indemnification Agreement between the Registrant and its officers and directors (incorporated by reference to Exhibit 10.1 to the Registrant's Registration Statement on Form S-1 (File No. 333-201433), as amended, declared effective on February 11, 2015).
10.2 #	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).
10.3 #	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).
10.4 #	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).
10.5 #	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).
10.6 #	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).
10.7 #	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).
10.8 #	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).
10.9 #	Employee Stock Purchase Plan (incorporated by reference to Exhibit 10.8 to the Registrant's Registration Statement on Form S-1 (File No. 333-201433), as amended, declared effective on February 11, 2015).
10.10	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).
10.11	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).
10.12 &	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).
10.13	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).
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,

Exhibit Number	Description
10.17 #	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).
10.18	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).
10.19*	Sales Agreement dated August 9, 2018 between Invitae Corporation and Cowen and Company, LLC.
21.1*	List of Subsidiaries.
23.1*	Consent of Independent Registered Public Accounting Firm.
24.1*	Power of Attorney (contained on the signature page to this Form 10-K).
31.1*	Principal Executive Officer's Certifications Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2*	Principal Financial Officer's Certifications Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1 +	Certification Pursuant to 18 U.S.C. § 1350 (Section 906 of Sarbanes-Oxley Act of 2002).
32.2 +	Certification Pursuant to 18 U.S.C. § 1350 (Section 906 of Sarbanes-Oxley Act of 2002).
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 16 th 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	_ Chief Financial Officer	February 28, 2019
Shelly D. Guyer	(Principal Financial and Accounting Officer)	
/s/ Randal W. Scott, Ph.D.	Executive Chairman of the Board of Directors	February 28, 2019
Randal W. Scott, Ph.D.		
/s/ Eric Aguiar, M.D.	— Director	February 28, 2019
Eric Aguiar, M.D.		
/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

INVITAE CORPORATION \$75,000,000

COMMON STOCK

SALES AGREEMENT

August 9, 2018

Cowen and Company, LLC 599 Lexington Avenue New York, NY 10022

Ladies and Gentlemen:

Invitae Corporation, a Delaware corporation (the "Company"), confirms its agreement (this "Agreement") with Cowen and Company, LLC ("Cowen"), as follows:

1. <u>Issuance and Sale of Shares</u>. The Company agrees that, from time to time during the term of this Agreement, on the terms and subject to the conditions set forth herein, it may issue and sell through Cowen, acting as agent and/or principal, shares of the Company's common stock, \$0.0001 par value per share (the "<u>Common Stock</u>"), having an aggregate offering price of up to \$75,000,000.00 (the "<u>Placement Shares</u>"). Notwithstanding anything to the contrary contained herein, the parties hereto agree that compliance with the limitation set forth in this <u>Section 1</u> on the number of shares of Common Stock issued and sold under this Agreement shall be the sole responsibility of the Company, and Cowen shall have no obligation in connection with such compliance. The issuance and sale of Common Stock through Cowen will be effected pursuant to the Registration Statement (as defined below) being filed by the Company and which will be declared effective by the Securities and Exchange Commission (the "<u>Commission</u>"), although nothing in this Agreement shall be construed as requiring the Company to use the Registration Statement (as defined below) to issue the Common Stock.

The Company has filed or will file, in accordance with the provisions of the Securities Act of 1933, as amended, and the rules and regulations thereunder (collectively, the "Securities Act"), with the Commission a registration statement on Form S-3, including a base prospectus, relating to certain securities, including the Common Stock, to be issued from time to time by the Company, and which incorporates by reference documents that the Company has filed or will file in accordance with the provisions of the Securities Exchange Act of 1934, as amended, and the rules and regulations thereunder (collectively, the "Exchange Act"). The Company has prepared a prospectus supplement specifically relating to the Placement Shares (the "Prospectus Supplement") to the base prospectus

included as part of such registration statement. Following the date that such registration statement is declared effective, the Company shall furnish to Cowen, for use by Cowen, copies of the base prospectus included as part of such registration statement, as supplemented by the Prospectus Supplement, relating to the Placement Shares. Except where the context otherwise requires, such registration statement, as amended when it becomes effective, including all documents filed as part thereof or incorporated by reference therein, and including any information contained in a Prospectus (as defined below) subsequently filed with the Commission pursuant to Rule 424(b) under the Securities Act or deemed to be a part of such registration statement pursuant to Rule 430B or 462(b) of the Securities Act, is herein called the "Registration Statement." The base prospectus, including all documents incorporated therein by reference, included in the Registration Statement, as it may be supplemented by the Prospectus Supplement, in the form in which such base prospectus and/or Prospectus Supplement have most recently been filed by the Company with the Commission pursuant to Rule 424(b) under the Securities Act, together with any "issuer free writing prospectus," as defined in Rule 433 of the Securities Act regulations (" Rule 433"), relating to the Placement Shares that (i) is required to be filed with the Commission by the Company or (ii) is exempt from filing pursuant to Rule 433(d)(5)(i), in each case in the form filed or required to be filed with the Commission or, if not required to be filed, in the form retained in the Company's records pursuant to Rule 433(g), is herein called the "Prospectus." Any reference herein to the Registration Statement, the Prospectus or any amendment or supplement thereto shall be deemed to refer to and include the documents incorporated by reference therein, and any reference herein to the terms "amend," "amendment" or "supplement" with respect to the Registration Statement or the Prospectus shall be deemed to refer to and include the filing after the execution hereof of any document with the Commission deemed to be incorporated by reference therein. For purposes of this Agreement, all references to the Registration Statement, the Prospectus or to any amendment or supplement thereto shall be deemed to include any copy filed with the Commission pursuant to the Electronic Data Gathering, Analysis, and Retrieval system or any successor thereto ("EDGAR").

Placement Shares hereunder (each, a "Placement"), it will notify Cowen by email notice (or other method mutually agreed to in writing by the parties) (a "Placement Notice") containing the parameters in accordance with which it desires the Placement Shares to be sold, which shall at a minimum include the number of Placement Shares to be issued, the time period during which sales are requested to be made, any limitation on the number of Placement Shares that may be sold in any one Trading Day (as defined in Section 3) and any minimum price below which sales may not be made, a form of which containing such minimum sales parameters necessary is attached hereto as Schedule 1. The Placement Notice shall originate from any of the individuals from the Company set forth on Schedule 2 (with a copy to each of the other individuals from the Company listed on such schedule), and shall be addressed to each of the individuals from Cowen set forth on Schedule 2 may be amended from time to time. The Placement Notice shall be effective upon receipt by Cowen unless and until (i) in accordance with the notice requirements set forth in Section 4, Cowen declines to accept the terms contained therein for any reason, in its sole discretion, (ii) the entire amount of the Placement Shares thereunder have been sold, (iii) in accordance with the notice requirements set forth in Section 4, the Company suspends or terminates the Placement Notice, (iv) the Company issues a subsequent Placement Notice with parameters superseding those

on the earlier dated Placement Notice, or (v) this Agreement has been terminated under the provisions of <u>Section 11</u>. The amount of any discount, commission or other compensation to be paid by the Company to Cowen in connection with the sale of the Placement Shares shall be calculated in accordance with the terms set forth in <u>Schedule 3</u>. It is expressly acknowledged and agreed that neither the Company nor Cowen will have any obligation whatsoever with respect to a Placement or any Placement Shares unless and until the Company delivers a Placement Notice to Cowen and Cowen does not decline such Placement Notice pursuant to the terms set forth above, and then only upon the terms specified therein and herein. In the event of a conflict between the terms of this Agreement and the terms of a Placement Notice, the terms of the Placement Notice will control.

3. Sale of Placement Shares by Cowen. Subject to the terms and conditions herein set forth, upon the Company's delivery of a Placement Notice, and unless the sale of the Placement Shares described therein has been declined, suspended, or otherwise terminated in accordance with the terms of this Agreement, Cowen, for the period specified in the Placement Notice, will use its commercially reasonable efforts consistent with its normal trading and sales practices and applicable state and federal laws, rules and regulations and the rules of the New York Stock Exchange (the "NYSE") to sell such Placement Shares up to the amount specified in such Placement Notice, and otherwise in accordance with the terms of such Placement Notice. Cowen will provide written confirmation to the Company (including by email correspondence to each of the individuals of the Company set forth on Schedule 2 , if receipt of such correspondence is actually acknowledged by any of the individuals to whom the notice is sent, other than via auto-reply) no later than the opening of the Trading Day (as defined below) immediately following the Trading Day on which it has made sales of Placement Shares hereunder setting forth the number of Placement Shares sold on such day, the volume-weighted average price of the Placement Shares sold, and the Net Proceeds (as defined below) payable to the Company. Subject to the terms of a Placement Notice, Cowen may sell Placement Shares by any method permitted by law deemed to be an "at the market offering" as defined in Rule 415(a)(4) of the Securities Act, including without limitation sales made through the NYSE or on any other existing trading market for the Common Stock. Notwithstanding the provisions of Section 6(ddd), Cowen shall not purchase Placement Shares for its own account as principal unless expressly authorized to do so by the Company in a Placement Notice. The Company acknowledges and agrees that (i) there can be no assurance that Cowen will be successful in selling Placement Shares, and (ii) Cowen will incur no liability or obligation to the Company or any other person or entity if it does not sell Placement Shares for any reason other than a failure by Cowen to use its commercially reasonable efforts consistent with its normal trading and sales practices to sell such Placement Shares as required under this Section 3. For the purposes hereof, "Trading Day" means any day on which the Company's Common Stock is purchased and sold on the principal market on which the Common Stock is listed or quoted.

4. Suspension of Sales.

(a) The Company or Cowen may, upon notice to the other party in writing (including by email correspondence to each of the individuals of the other party set forth on **Schedule 2**, if receipt of such correspondence is actually acknowledged by any of the individuals to whom the notice is sent, other than via auto-reply) or by telephone (confirmed immediately by verifiable

facsimile transmission or email correspondence to each of the individuals of the other party set forth on <u>Schedule 2</u>), suspend any sale of Placement Shares; *provided, however*, that such suspension shall not affect or impair either party's obligations with respect to any Placement Shares sold hereunder prior to the receipt of such notice. Each of the parties agrees that no such notice under this <u>Section 4</u> shall be effective against the other unless it is made to one of the individuals named on <u>Schedule 2</u> hereto, as such schedule may be amended from time to time.

- (b) Notwithstanding any other provision of this Agreement, during any period in which the Company is in possession of material non-public information, the Company and Cowen agree that (i) no sale of Placement Shares will take place, (ii) the Company shall not request the sale of any Placement Shares, and (iii) Cowen shall not be obligated to sell or offer to sell any Placement Shares.
- (c) If either Cowen or the Company has reason to believe that the exemptive provisions set forth in Rule 101(c)(1) of Regulation M under the Exchange Act are not satisfied with respect to the Common Stock, it shall promptly notify the other party, and Cowen may, at its sole discretion, suspend sales of the Placement Shares under this Agreement.
- (d) Notwithstanding any other provision of this Agreement, during any period in which the Registration Statement is no longer effective under the Securities Act, the Company shall promptly notify Cowen, the Company shall not request the sale of any Placement Shares, and Cowen shall not be obligated to sell or offer to sell any Placement Shares.

5. <u>Settlement.</u>

- (a) <u>Settlement of Placement Shares</u>. Unless otherwise specified in the applicable Placement Notice, settlement for sales of Placement Shares will occur on the second (2nd) Trading Day (or such earlier day as is industry practice for regular-way trading) following the date on which such sales are made (each, a "<u>Settlement Date</u>" and the first such settlement date, the "<u>First Delivery Date</u>"). The amount of proceeds to be delivered to the Company on a Settlement Date against receipt of the Placement Shares sold (the "<u>Net Proceeds</u>") will be equal to the aggregate sales price received by Cowen at which such Placement Shares were sold, after deduction for (i) Cowen's commission, discount or other compensation for such sales payable by the Company pursuant to <u>Section 2</u> hereof, (ii) any other amounts due and payable by the Company to Cowen hereunder pursuant to <u>Section 7(g)</u> (Expenses) hereof, and (iii) any transaction fees imposed by any governmental or self-regulatory organization in respect of such sales.
- (b) <u>Delivery of Placement Shares</u>. On or before each Settlement Date, the Company will, or will cause its transfer agent to, electronically transfer the Placement Shares being sold by crediting Cowen's or its designee's account (*provided* that Cowen shall have given the Company written notice of such designee at least one Trading Day prior to the Settlement Date) at The Depository Trust Company through its Deposit and Withdrawal at Custodian System or by such other means of delivery as may be mutually agreed upon by the parties hereto which in all cases shall be freely tradeable, transferable, registered shares in good deliverable form. On each

Settlement Date, Cowen will deliver the related Net Proceeds in same day funds to an account designated by the Company on, or prior to, the Settlement Date. The Company agrees that if the Company, or its transfer agent (if applicable), defaults in its obligation to deliver duly authorized Placement Shares on a Settlement Date, the Company agrees that in addition to and in no way limiting the rights and obligations set forth in Section 9(a) (Indemnification and Contribution) hereto, it will (i) hold Cowen harmless against any loss, claim, damage, or reasonable and documented expense (including reasonable and documented legal fees and expenses), as incurred, arising out of or in connection with such default by the Company and (ii) pay to Cowen (without duplication) any commission, discount, or other compensation to which it would otherwise have been entitled absent such default.

- 6. <u>Representations and Warranties of the Company</u>. The Company represents and warrants to, and agrees with, Cowen that, unless such representation and warranty specifies a different time, as of the date of this Agreement, each Representation Date (as defined in <u>Section 7(m)</u>), each date on which a Placement Notice is given, and any date on which Placement Shares are sold hereunder:
- (a) <u>Compliance with Registration Requirements</u>. The Registration Statement and any Rule 462(b) Registration Statement has been or will be declared effective by the Commission under the Securities Act prior to the delivery of any Placement Notice by the Company. The Company has complied to the Commission's satisfaction with all requests of the Commission for additional or supplemental information in connection therewith. No stop order suspending the effectiveness of the Registration Statement or any Rule 462(b) Registration Statement is in effect and no proceedings for such purpose have been instituted or are pending or, to the knowledge of the Company, threatened by the Commission. The Company meets the requirements for use of Form S-3 under the Securities Act. The sale of the Placement Shares hereunder meets the requirements of General Instruction I.B.1 of Form S-3.
- (b) No Misstatement or Omission. The Prospectus when filed complied and, as amended or supplemented, if applicable, will comply in all material respects with the Securities Act. Each of the Registration Statement, any Rule 462(b) Registration Statement, the Prospectus and any post-effective amendments or supplements thereto, at the time it became effective or its date, as applicable, complied and as of each of the Settlement Dates, if any, will comply in all material respects with the Securities Act and did not and, as of each Settlement Date, if any, will not contain any untrue statement of a material fact or omit to state a material fact required to be stated therein or necessary to make the statements therein not misleading. The Prospectus, as amended or supplemented, as of its date, did not and, as of each of the Settlement Dates, if any, will not contain any untrue statement of a material fact or omit to state a material fact necessary in order to make the statements therein, in the light of the circumstances under which they were made, not misleading. The representations and warranties set forth in the two immediately preceding sentences do not apply to statements in or omissions from the Registration Statement, any Rule 462(b) Registration Statement, or any post-effective amendment thereto, or the Prospectus, or any amendments or supplements thereto, made in reliance upon and in conformity with information relating to Cowen furnished to the Company in writing by Cowen expressly for use therein. There are no contracts or other documents required

to be described in the Prospectus or to be filed as exhibits to the Registration Statement which have not been described or filed as required.

- (c) <u>Offering Materials Furnished to Cowen</u>. The Company has delivered to Cowen one complete copy of the Registration Statement and a copy of each consent and certificate of experts filed as a part thereof, and conformed copies of the Registration Statement (without exhibits) and the Prospectus, as amended or supplemented, in such quantities and at such places as Cowen has reasonably requested.
- (d) <u>Emerging Growth Company</u>. From the time of initial confidential submission of the registration statement relating to the Company's initial public offering to the Commission (or, if earlier, the first date on which the Company engaged directly or through any person authorized to act on its behalf in any Testing-the-Waters Communication) through the date hereof, the Company has been and is an "emerging growth company," as defined in Section 2(a) of the Securities Act (an "<u>Emerging Growth Company</u>").
- (e) <u>Incorporated Documents</u>. The documents incorporated by reference in the Registration Statement and the Prospectus, when they were filed with the Commission conformed in all material respects to the requirements of the Exchange Act, and none of such documents contained any untrue statement of a material fact or omitted to state a material fact necessary to make the statements therein, in the light of the circumstances under which they were made, not misleading; and any further documents so filed and incorporated by reference in the Registration Statement or the Prospectus, when such documents are filed with the Commission, will conform in all material respects to the requirements of the Exchange Act and will not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements therein, in the light of the circumstances under which they were made, not misleading.
- (f) Financial Statements. The financial statements (including the related notes thereto) of the Company and its consolidated subsidiaries and CombiMatrix Corporation included or incorporated by reference in the Registration Statement and the Prospectus comply in all material respects with the applicable requirements of the Securities Act and the Exchange Act, as applicable, and present fairly, in all material respects, the financial position of the Company and its consolidated subsidiaries and CombiMatrix Corporation as of the dates indicated and the results of their operations and the changes in their cash flows for the periods specified; such financial statements have been prepared in conformity with generally accepted accounting principles in the United States ("GAAP") applied on a consistent basis throughout the periods covered thereby, and any supporting schedules included or incorporated by reference in the Registration Statement present fairly, in all material respects, the information required to be stated therein; and the other financial information included or incorporated by reference in the Registration Statement and the Prospectus has been derived from the accounting records of the Company and its consolidated subsidiaries and CombiMatrix Corporation and presents fairly the information shown thereby.
- (g) <u>No Material Adverse Change</u>. Since the date of the most recent financial statements of the Company included or incorporated by reference in the Registration Statement and the Prospectus, (i) there has not been any change in the capital stock (other than the issuance of shares

of Common Stock upon exercise of stock options and warrants described as outstanding in, the grant of options and awards under existing equity incentive plans described in, and the issuance of Common Stock in connection with acquisitions described in, the Registration Statement and the Prospectus), short-term debt or long-term debt of the Company or any of its subsidiaries, or any dividend or distribution of any kind declared, set aside for payment, paid or made by the Company on any class of capital stock, or any material adverse change, or any development that would reasonably be expected to result in a material adverse change, in or affecting the business, properties, management, financial position, stockholders' equity, results of operations or prospects of the Company and its subsidiaries taken as a whole; (ii) neither the Company nor any of its subsidiaries has entered into any transaction or agreement (whether or not in the ordinary course of business) that is material to the Company and its subsidiaries taken as a whole or incurred any liability or obligation, direct or contingent, that is material to the Company and its subsidiaries taken as a whole; and (iii) neither the Company nor any of its subsidiaries has sustained any loss or interference with its business that is material to the Company and its subsidiaries taken as a whole and that is either from fire, explosion, flood or other calamity, whether or not covered by insurance, or from any labor disturbance or dispute or any action, order or decree of any court or arbitrator or governmental or regulatory authority, except in each case as otherwise disclosed in the Registration Statement and the Prospectus.

- (h) Organization and Good Standing. The Company and each of its subsidiaries have been duly organized and are validly existing and in good standing under the laws of their respective jurisdictions of organization, are duly qualified to do business and are in good standing in each jurisdiction in which their respective ownership or lease of property or the conduct of their respective businesses requires such qualification, and have all power and authority necessary to own or hold their respective properties and to conduct the businesses in which they are engaged, except where the failure to be so qualified or in good standing or have such power or authority would not, individually or in the aggregate, have a material adverse effect on the business, properties, management, financial position, stockholders' equity, results of operations or prospects of the Company and its subsidiaries taken as a whole or on the performance by the Company of its obligations under this Agreement (a "Material Adverse Effect"). Except as disclosed in the Registration Statement and the Prospectus, the Company does not own or control, directly or indirectly, any corporation, association or other entity other than the subsidiaries listed in Exhibit 21 to the Company's most recently filed Annual Report on Form 10-K. The subsidiaries listed in Schedule 4 to this Agreement are the only significant subsidiaries of the Company as of the end of the Company's most recently completed fiscal year.
- (i) <u>Capitalization</u>. The Company has an authorized capitalization as set forth in the Registration Statement and the Prospectus under the heading "Description of Capital Stock"; all the outstanding shares of capital stock of the Company have been duly and validly authorized and issued and are fully paid and non-assessable and are not subject to any pre-emptive or similar rights; except as described in or expressly contemplated by the Prospectus, there are no outstanding rights (including, without limitation, pre-emptive rights), warrants or options to acquire, or instruments convertible into or exchangeable for, any shares of capital stock or other equity interest in the Company or any of its subsidiaries, or any contract, commitment, agreement, understanding or

arrangement of any kind relating to the issuance of any capital stock of the Company or any such subsidiary, any such convertible or exchangeable securities or any such rights, warrants or options; the capital stock of the Company conforms in all material respects to the description thereof contained in the Registration Statement and the Prospectus; and all the outstanding shares of capital stock or other equity interests of each subsidiary owned, directly or indirectly, by the Company have been duly and validly authorized and issued, are fully paid and non-assessable (except, in the case of any foreign subsidiary, for directors' qualifying shares) and are owned directly or indirectly by the Company, free and clear of any lien, charge, encumbrance, security interest, restriction on voting or transfer or any other claim of any third party.

- (j) Stock Options. With respect to the stock options (the "Stock Options") granted pursuant to the stock-based compensation plans of the Company and its subsidiaries (the "Company Stock Plans"), (i) each Stock Option intended to qualify as an "incentive stock option" under Section 422 of the Internal Revenue Code of 1986, as amended (the "Code") so qualifies, (ii) each grant of a Stock Option was duly authorized no later than the date on which the grant of such Stock Option was by its terms to be effective by all necessary corporate action, including, as applicable, approval by the board of directors of the Company (or a duly constituted and authorized committee thereof) and any required stockholder approval by the necessary number of votes or written consents, and the award agreement governing such grant (if any) was duly executed and delivered by each party thereto, (iii) each such grant was made in accordance with the terms of the Company Stock Plans and, to the extent applicable, the Exchange Act and the rules of the NYSE, and (iv) each such grant was properly accounted for in accordance with GAAP in the financial statements (including the related notes) of the Company. Each Company Stock Plan is accurately described in all material respects in the Registration Statement and the Prospectus.
- (k) <u>Due Authorization</u>. The Company has full right, power and authority to execute and deliver this Agreement and to perform its obligations hereunder; and all action required to be taken for the due and proper authorization, execution and delivery by it of this Agreement and the consummation by it of the transactions contemplated hereby has been duly and validly taken.
 - (1) <u>Sales Agreement</u>. This Agreement has been duly authorized, executed and delivered by the Company.
- (m) <u>The Placement Shares</u>. The Placement Shares to be issued and sold by the Company hereunder have been duly authorized by the Company and, when issued and delivered and paid for as provided herein, will be duly and validly issued, will be fully paid and nonassessable and will conform to the descriptions thereof in the Registration Statement and the Prospectus; and the issuance of the Placement Shares is not subject to any preemptive or similar rights.
- (n) No Violation or Default. Neither the Company nor any of its subsidiaries is (i) in violation of its charter or by-laws or similar organizational documents; (ii) in default, and no event has occurred that, with notice or lapse of time or both, would constitute such a default, in the due performance or observance of any term, covenant or condition contained in any indenture, mortgage, deed of trust, loan agreement or other agreement or instrument to which the Company or any of its subsidiaries is a party or by which the Company or any of its subsidiaries is bound or to which any

of the property or assets of the Company or any of its subsidiaries is subject; or (iii) in violation of any law or statute or any judgment, order, rule or regulation of any court or arbitrator or governmental or regulatory authority, except, in the case of clauses (ii) and (iii) above, for any such default or violation that would not, individually or in the aggregate, have a Material Adverse Effect.

- (o) No Conflicts. The execution, delivery and performance by the Company of this Agreement, the issuance and sale of the Placement Shares and the consummation by the Company of the transactions contemplated by this Agreement will not (i) conflict with or result in a breach or violation of any of the terms or provisions of, or constitute a default under, or result in the creation or imposition of any lien, charge or encumbrance upon any property or assets of the Company or any of its subsidiaries pursuant to, any indenture, mortgage, deed of trust, loan agreement or other agreement or instrument to which the Company or any of its subsidiaries is a party or by which the Company or any of its subsidiaries is bound or to which any of the property or assets of the Company or any of its subsidiaries is subject, (ii) result in any violation of the provisions of the charter or by-laws or similar organizational documents of the Company or any of its subsidiaries or (iii) result in the violation of any law or statute or any judgment, order, rule or regulation of any court or arbitrator or governmental or regulatory authority, except, in the case of clauses (i) and (iii) above, for any such conflict, breach, violation or default that would not, individually or in the aggregate, have a Material Adverse Effect.
- (p) No Consents Required. No consent, filing, approval, authorization, order, license, registration or qualification of or with any court or arbitrator or governmental or regulatory authority is required for the execution, delivery and performance by the Company of this Agreement, the issuance and sale of the Placement Shares and the consummation of the transactions contemplated by this Agreement, except for the registration of the Placement Shares under the Securities Act and such consents, approvals, authorizations, orders and registrations or qualifications as may be required by the Financial Industry Regulatory Authority, Inc. ("
 FINRA"), the NYSE and under applicable state securities laws in connection with the purchase and distribution of the Placement Shares by Cowen.
- (q) <u>Legal Proceedings</u>. Except as described in the Registration Statement and the Prospectus: (x) there are no legal, governmental or regulatory investigations, actions, suits or proceedings pending to which the Company or any of its subsidiaries is or may be a party or to which any property of the Company or any of its subsidiaries, could reasonably be expected to have a Material Adverse Effect or have a material adverse effect on the power or ability of the Company to perform its obligations under this Agreement or to consummate the transactions contemplated hereby; (y) to the knowledge of the Company, no such investigations, actions, suits or proceedings are threatened or contemplated by any governmental or regulatory authority or threatened by others; and (z) (i) there are no current or pending legal, governmental or regulatory actions, suits or proceedings that are required under the Securities Act to be described in the Registration Statement or the Prospectus that are not so described in the Registration Statement and the Prospectus and (ii) there are no statutes, regulations or contracts or other documents that are required under the Securities Act to be filed as exhibits to the Registration

Statement or described in the Registration Statement or the Prospectus that are not so filed as exhibits to the Registration Statement or described in the Registration Statement and the Prospectus.

- (r) <u>Independent Accountants</u>. Ernst & Young LLP, who has certified certain financial statements of the Company and its subsidiaries, is an independent registered public accounting firm with respect to the Company and its subsidiaries within the applicable rules and regulations adopted by the Commission and the Public Company Accounting Oversight Board (United States) and as required by the Securities Act.
- (s) <u>Title to Real and Personal Property</u>. The Company and its subsidiaries have good and marketable title in fee simple (in the case of real property) to, or have valid and marketable rights to lease or otherwise use, all items of real and personal property and assets that are material to the respective businesses of the Company and its subsidiaries, in each case free and clear of all liens, encumbrances, claims and defects and imperfections of title except those that (i) do not materially interfere with the use made and proposed to be made of such property by the Company and its subsidiaries, (ii) could not reasonably be expected, individually or in the aggregate, to have a Material Adverse Effect or (iii) result from the lease of such property and assets, to the extent applicable.
- Title to Intellectual Property. Except as described in the Registration Statement and the Prospectus or as could not reasonably be expected to result in a Material Adverse Effect, to the Company's knowledge (i) the Company and its subsidiaries own, possess, license or can acquire or license on reasonable terms all material patents, patent applications, trademarks, service marks, trade names, trademark registrations, service mark registrations, copyrights, licenses and know-how (including trade secrets and other unpatented and/or unpatentable proprietary or confidential information, systems or procedures) necessary for the conduct of their respective businesses as currently conducted and as proposed to be conducted in the manner described in the Registration Statement and the Prospectus (collectively, "Intellectual Property"), and (ii) the conduct of their respective businesses does not and will not conflict in any material respect with any valid and enforceable Intellectual Property rights of others. Except as described in the Registration Statement and the Prospectus, the Company and its subsidiaries have not received any notice of any claim of infringement, misappropriation or conflict with any intellectual property rights of another in connection with its patents, patent applications, patent rights, licenses, inventions, trademarks, service marks, trade names, copyrights and know-how which could reasonably be expected to result in a Material Adverse Effect, and the Company is unaware of any facts which would form a reasonable basis for any such notice or claim. To the Company's knowledge, (i) there are no third party rights to any of the Intellectual Property that is disclosed in the Registration Statement and the Prospectus as owned by the Company (the "Company <u>Intellectual Property</u>"); and (ii) there is no material infringement by third parties of any of the Company Intellectual Property. Except as disclosed in the Registration Statement and the Prospectus or as could not reasonably be expected to result in a Material Adverse Effect, there is no pending or, to the Company's knowledge, threatened action, suit, proceeding or claim by others; (A) challenging the Company's rights in or to any Intellectual Property, and the Company is unaware of any facts which would form a reasonable basis for any such action, suit, proceeding or claim; (B) challenging the validity, enforceability or

scope of any Intellectual Property, and the Company is unaware of any facts which would form a reasonable basis for any such action, suit, proceeding or claim; or (C) asserting that the Company or its subsidiaries infringe, misappropriate, or otherwise violate, or would, upon the commercialization of any product or service described in the Registration Statement and the Prospectus as under development, infringe, misappropriate, or otherwise violate, any intellectual property rights of others, and the Company is unaware of any facts which would form a reasonable basis for any such action, suit, proceeding or claim. To the knowledge of the Company, the Company and its subsidiaries have complied with the terms of each agreement pursuant to which Intellectual Property has been licensed to the Company or its subsidiaries, and all such agreements are in full force and effect. To the Company's knowledge, and except as is disclosed in the Registration Statement and the Prospectus, there are no material defects in any of the patents or patent applications included in the Company Intellectual Property.

- (u) <u>Trade Secrets</u>. The Company and its subsidiaries have taken reasonable and customary actions to protect their rights in and prevent the unauthorized use and disclosure of material trade secrets and confidential business information (including confidential source code, ideas, research and development information, know-how, formulas, compositions, technical data, designs, drawings, specifications, research records, records of inventions, test information, financial, marketing and business data, customer and supplier lists and information, pricing and cost information, business and marketing plans and proposals) owned by the Company and its subsidiaries, and, to the knowledge of the Company, there has been no material unauthorized use or disclosure.
- (v) <u>IT Assets</u>. Except as could not reasonably be expected to have a Material Adverse Effect, (i) the computers, software, servers, networks, data communications lines, and other information technology systems owned, licensed, leased or otherwise used by the Company or its subsidiaries (excluding any public networks) (collectively, the "<u>IT Assets</u>") operate and perform as is reasonably necessary for the operation of the business of the Company and its subsidiaries as currently conducted and as proposed to be conducted as described in the Registration Statement and the Prospectus, and (ii) to the Company's knowledge such IT Assets are not infected by viruses, disabling code or other harmful code.
- (w) <u>Data Privacy and Security Laws</u>. The Company and its subsidiaries are, and at all prior times were, in material compliance with all applicable state and federal data privacy and security laws and regulations, including without limitation the Health Insurance Portability and Accountability Act of 1996 ("<u>HIPAA</u>") as amended by the Health Information Technology for Economic and Clinical Health Act (the "<u>HITECH Act</u>") (collectively, the "<u>Privacy Laws</u>"). To ensure compliance with the Privacy Laws, the Company and its subsidiaries have in place, comply with, and take appropriate steps reasonably designed to ensure compliance in all material respects with their policies and procedures relating to data privacy and security and the collection, storage, use, disclosure, handling, and analysis of Personal Data (the "<u>Policies</u>"). "Personal Data" means (i) a natural person's name, street address, telephone number, e-mail address, photograph, social security number or tax identification number, driver's license number, passport number, credit card number, bank information, or customer or account number; (ii) any information which would qualify

as "personally identifying information" under the Federal Trade Commission Act, as amended; (iii) Protected Health Information as defined by HIPAA; and (iv) any other piece of information that allows the identification of such natural person, or his or her family, or permits the collection or analysis of any data related to an identified person's health or sexual orientation. The Company and its subsidiaries have at all times made all disclosures to users or customers required by applicable laws and regulatory rules or requirements, and no disclosure made pursuant to any Policy has, to the knowledge of the Company, been inaccurate or in violation of any applicable laws and regulatory rules or requirements in any material respect. The Company further certifies that neither it nor any subsidiary: (i) has received notice of any actual or potential material liability under or relating to, or actual or potential material violation of, any of the Privacy Laws, and has no knowledge of any event or condition that would reasonably be expected to result in any such notice; (ii) is currently conducting or paying for, in whole or in part, any investigation, remediation or other corrective action pursuant to any Privacy Law; or (iii) is a party to any order, decree, or agreement that imposes any obligation or liability under any Privacy Law.

- (x) <u>No Complaints</u>. There is no complaint, audit, proceeding, investigation (formal or informal) or claim currently pending against the Company or its subsidiaries, or to the knowledge of the Company, any of its customers (specific to the customer's use of the products or services of the Company) by the Federal Trade Commission, the U.S. Department of Health and Human Services and any office contained therein ("<u>HHS</u>"), or any similar authority in any jurisdiction other than the United States or any other governmental entity, or by any person with respect to the collection, use or disclosure of Personal Data by the Company or its subsidiaries, and, to the knowledge of the Company, no such complaint, audit, proceeding, investigation or claim is threatened.
- (y) <u>Clinical Data</u>. The descriptions of the results of any studies and tests conducted by or on behalf of, or sponsored by, the Company or its subsidiaries, or in which the Company has participated, that are described in the Registration Statement and the Prospectus, or the results of which are referred to in the Registration Statement and the Prospectus do not contain any misstatement of material fact or omit to state a material fact necessary to make such statements not misleading. The Company has no knowledge of any studies or tests not described in the Registration Statement and the Prospectus the results of which reasonably call into question in any material respect the results of the studies, tests and trials described in the Registration Statement or Prospectus.
- (z) Compliance with Health Care Laws. The Company and its subsidiaries are, and at all times have been, in compliance in all material respects with all applicable Health Care Laws. For purposes of this Agreement, "Health Care Laws" means: (i) the Federal Food, Drug, and Cosmetic Act and the regulations promulgated thereunder; (ii) all applicable federal, state, local and foreign health care laws, including, without limitation, the Clinical Laboratory Improvement Amendments of 1988 (42 U.S.C. Section 263a et seq.), the U.S. Anti-Kickback Statute (42 U.S.C. Section 1320a-7b(b)), the Anti-Inducement Law (42 U.S.C. § 1320a-7a(a)(5)), the U.S. Civil False Claims Act (31 U.S.C. Section 3729 et seq.), the criminal False Statements Law (42 U.S.C. Section 1320a-7b(a)), 18 U.S.C. Sections 286 and 287, the health care fraud criminal provisions under HIPAA (42 U.S.C. Section 1320d et seq.), the Stark Law (42 U.S.C. Section 1395nn), the civil

monetary penalties law (42 U.S.C. Section 1320a-7a), the exclusion laws, laws governing government funded or sponsored healthcare programs, and the directives and regulations promulgated pursuant to such statutes and any state or non-U.S. counterpart thereof; (iii) HIPAA, as amended by the HITECH Act (42 U.S.C. Section 17921 et seq.); (iv) the Patient Protection and Affordable Care Act of 2010, as amended by the Health Care and Education Affordability Reconciliation Act of 2010, the regulations promulgated thereunder; (v) licensure, quality, safety and accreditation requirements under applicable federal, state, local or foreign laws or regulatory bodies; and (vi) all other local, state, federal, national, supranational and foreign laws, relating to the regulation of the Company or its subsidiaries. Neither the Company, any of its subsidiaries, nor to the Company's knowledge, any of its officers, directors, employees or agents have engaged in activities which are, as applicable, cause for material liability under a Health Care Law. Neither the Company nor any of its subsidiaries has received written notice of any claim, action, suit, proceeding, hearing, enforcement, investigation, arbitration or other action from any court or arbitrator or governmental or regulatory authority or third party alleging a material violation of any Health Care Laws nor, to the Company's knowledge, is any such claim, action, suit, proceeding, hearing, enforcement, investigation, arbitration or other action threatened. The Company and its subsidiaries have filed, maintained or submitted all material reports, documents, forms, notices, applications, records, claims, submissions and supplements or amendments as required by the applicable Health Care Laws, and all such reports, documents, forms, notices, applications, records, claims, submissions and supplements or amendments were complete and accurate on the date filed in all material respects (or were corrected or supplemented by a subsequent submission). Neither the Company nor any of its subsidiaries is a party to any corporate integrity agreements, monitoring agreements, consent decrees, settlement orders, or similar agreements with or imposed by any governmental or regulatory authority. Additionally, neither the Company, any of its subsidiaries nor any of their respective employees, officers, directors, or agents has been excluded, suspended or debarred from participation in any U.S. federal health care program or human clinical research or, to the knowledge of the Company, is subject to a governmental inquiry, investigation, proceeding, or other similar action that could reasonably be expected to result in debarment, suspension, or exclusion.

- (aa) <u>Clinical Laboratory Tests</u>. The Company's clinical laboratory tests are conducted in compliance in all material respects with all applicable Health Care Laws, and, to the extent applicable, the respective counterparts thereof promulgated by governmental authorities in countries outside the United States. The Company has not received notice from the FDA, HHS or other governmental authority alleging or asserting material noncompliance with any applicable Health Care Law. To the Company's knowledge, neither the FDA nor any other governmental authority is considering such action.
- (bb) <u>No Undisclosed Relationships</u>. No relationship, direct or indirect, exists between or among the Company or any of its subsidiaries, on the one hand, and the directors, officers or stockholders of the Company or, to the knowledge of the Company, the customers or suppliers of the Company or any of its subsidiaries, on the other, that is required by the Securities Act to be described in the Registration Statement and the Prospectus and that is not so described in such documents.

- (cc) <u>Investment Company Act</u>. The Company is not and, after giving effect to the offering and sale of the Placement Shares and the application of the proceeds thereof as described in the Registration Statement and the Prospectus, will not be required to register as an "investment company" or an entity "controlled" by an "investment company" within the meaning of the Investment Company Act of 1940, as amended, and the rules and regulations of the Commission thereunder (collectively, the "<u>Investment Company Act</u>").
- (dd) <u>Taxes</u>. The Company and its subsidiaries have paid all federal, state, local and foreign taxes and filed all tax returns required to be paid or filed through the date hereof; and except as otherwise disclosed in the Registration Statement and the Prospectus, there is no tax deficiency that has been, or could reasonably be expected to be, asserted against the Company or any of its subsidiaries or any of their respective properties or assets.
- Licenses and Permits. The Company and its subsidiaries possess all licenses, certificates, permits and other authorizations issued by, and have made all declarations and filings with, the appropriate federal, state, local or foreign governmental or regulatory authorities that are necessary for the ownership or lease of their respective properties or the conduct of their respective businesses as described in the Registration Statement and the Prospectus, except where the failure to possess or make the same would not, individually or in the aggregate, have a Material Adverse Effect; and except as described in the Registration Statement and the Prospectus, neither the Company nor any of its subsidiaries has received notice of any revocation or modification of any such license, certificate, permit or authorization will not be renewed in the ordinary course. To the Company's knowledge, no party granting any such licenses, certificates, permits and other authorizations has taken any action to limit, suspend or revoke the same in any material respect. The Company and its subsidiaries have filed, obtained, maintained or submitted all material reports, documents, forms, notices, applications, records, claims, submissions and supplements or amendments were materially complete and correct on the date filed (or were corrected or supplemented by a subsequent submission) as required for maintenance of their licenses, certificates, permits and other authorizations that are necessary for the conduct of their respective businesses.
- (ff) <u>No Labor Disputes</u>. No labor disturbance by or dispute with employees of the Company or any of its subsidiaries exists or, to the knowledge of the Company, is contemplated or threatened, and the Company is not aware of any existing or imminent labor disturbance by, or dispute with, the employees of any of its or its subsidiaries' principal suppliers, contractors or customers, except as would not have a Material Adverse Effect.
- (gg) <u>Compliance with and Liability under Environmental Laws</u>. (i) The Company and its subsidiaries (a) are, and at all prior times were, in material compliance with any and all applicable federal, state, local and foreign laws, rules, regulations, requirements, decisions, judgments, decrees, orders and the common law relating to pollution or the protection of the environment, natural resources or human health or safety, including those relating to the generation, storage, treatment, use, handling, transportation, Release or threat of Release of Hazardous Materials (collectively,

- "Environmental Laws"), (b) have received and are in compliance with all permits, licenses, certificates or other authorizations or approvals required of them under applicable Environmental Laws to conduct their respective businesses, (c) have not received notice of any actual or potential liability under or relating to, or actual or potential violation of, any Environmental Laws, including for the investigation or remediation of any Release or threat of Release of Hazardous Materials, and have no knowledge of any event or condition that would reasonably be expected to result in any such notice, (d) are not conducting or paying for, in whole or in part, any investigation, remediation or other corrective action pursuant to any Environmental Law at any location, and (e) are not a party to any order, decree or agreement that imposes any obligation or liability under any Environmental Law, and (ii) there are no costs or liabilities associated with Environmental Laws of or relating to the Company or its subsidiaries, except in the case of each of (i) and (ii) above, for any such matter, as would not, individually or in the aggregate, reasonably be expected to have a Material Adverse Effect; and (iii) except as described in the Registration Statement and the Prospectus, (a) there are no proceedings that are pending, or that are known to be contemplated, against the Company or any of its subsidiaries under any Environmental Laws in which a governmental entity is also a party, other than such proceedings regarding which it is reasonably believed no monetary sanctions of \$100,000 or more will be imposed, (b) the Company and its subsidiaries are not aware of any facts or issues regarding the Company's or its subsidiaries' compliance with Environmental Laws, or liabilities or other obligations under Environmental Laws, including the Release or threat of Release of Hazardous Materials, that could reasonably be expected to have a material effect on the capital expenditures, earnings or competitive position of the Company and its subsidiaries, and (c) none of the Company and its subsidiaries anticipates material capital expenditures relating to any Environmental Laws.
- (hh) <u>Hazardous Materials</u>. There has been no storage, generation, transportation, use, handling, treatment, Release or threat of Release of Hazardous Materials by, relating to or caused by the Company or any of its subsidiaries (or, to the knowledge of the Company and its subsidiaries, any other entity (including any predecessor) for whose acts or omissions the Company or any of its subsidiaries is or could reasonably be expected to be liable) at, on, under or from any property or facility now or previously owned, operated or leased by the Company or any of its subsidiaries, or at, on, under or from any other property or facility, in violation of any Environmental Laws or in a manner or amount or to a location that could reasonably be expected to result in any liability under any Environmental Law, except for any violation or liability which would not, individually or in the aggregate, reasonably be expected to have a Material Adverse Effect. "<u>Hazardous Materials</u>" means any material, chemical, substance ,waste, pollutant, contaminant, compound, mixture, or constituent thereof, in any form or amount, including petroleum (including crude oil or any fraction thereof) and petroleum products, natural gas liquids, asbestos and asbestos containing materials, naturally occurring radioactive materials, brine, and drilling mud, regulated or which can give rise to liability under any Environmental Law. "Release" means any spilling, leaking, seepage, pumping, pouring, emitting, emptying, discharging, injecting, escaping, leaching, dumping, disposing, depositing, dispersing, or migrating in, into or through the environment, or in, into from or through any building or structure.

- Compliance with ERISA. (i) Each employee benefit plan, within the meaning of Section 3(3) of the Employee Retirement Income Security Act of 1974, as amended (" ERISA"), for which the Company or any member of its "Controlled Group" (defined as any organization which is a member of a controlled group of corporations within the meaning of Section 414 of the Code) would have any liability (each, a "Plan") has been maintained in compliance with its terms and the requirements of any applicable statutes, orders, rules and regulations, including but not limited to ERISA and the Code, except for noncompliance that could not reasonably be expected to result in material liability to the Company or its subsidiaries; (ii) no prohibited transaction, within the meaning of Section 406 of ERISA or Section 4975 of the Code, has occurred with respect to any Plan excluding transactions effected pursuant to a statutory or administrative exemption that could reasonably be expected to result in a material liability to the Company or its subsidiaries; (iii) for each Plan that is subject to the funding rules of Section 412 of the Code or Section 302 of ERISA, the minimum funding standard of Section 412 of the Code or Section 302 of ERISA, as applicable, has been satisfied (without taking into account any waiver thereof or extension of any amortization period) and is reasonably expected to be satisfied in the future (without taking into account any waiver thereof or extension of any amortization period); (iv) the fair market value of the assets of each Plan exceeds the present value of all benefits accrued under such Plan (determined based on those assumptions used to fund such Plan); (v) no "reportable event" (within the meaning of Section 4043(c) of ERISA) has occurred or is reasonably expected to occur that either has resulted, or could reasonably be expected to result, in material liability to the Company or its subsidiaries; (vi) neither the Company nor any member of the Controlled Group has incurred, nor reasonably expects to incur, any liability under Title IV of ERISA (other than contributions to the Plan or premiums to the PBGC, in the ordinary course and without default) in respect of a Plan (including a "multiemployer plan", within the meaning of Section 4001(a)(3) of ERISA); and (vii) there is no pending audit or investigation by the Internal Revenue Service, the U.S. Department of Labor, the Pension Benefit Guaranty Corporation or any other governmental agency or any foreign regulatory agency with respect to any Plan that could reasonably be expected to result in material liability to the Company or its subsidiaries. None of the following events has occurred or is reasonably likely to occur: (x) a material increase in the aggregate amount of contributions required to be made to all Plans by the Company or its subsidiaries in the current fiscal year of the Company and its subsidiaries compared to the amount of such contributions made in the Company and its subsidiaries' most recently completed fiscal year; or (y) a material increase in the Company and its subsidiaries' "accumulated post-retirement benefit obligations" (within the meaning of Statement of Financial Accounting Standards 106) compared to the amount of such obligations in the Company and its subsidiaries' most recently completed fiscal year.
- (jj) <u>Disclosure Controls</u>. The Company and its subsidiaries maintain a system of disclosure controls and procedures (as defined in Rule 13a-15(e) of the Exchange Act) that are designed to comply with the requirements of the Exchange Act and that has been designed to ensure that information required to be disclosed by the Company in reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the Commission's rules and forms, including controls and procedures designed to ensure that such information is accumulated and communicated to the Company's management as appropriate to allow timely decisions regarding required disclosure. The Company and its subsidiaries have

carried out evaluations of the effectiveness of their disclosure controls and procedures as required by Rule 13a-15 of the Exchange Act.

- (kk) Accounting Controls. The Company and its subsidiaries maintain a system of internal control over financial reporting (as defined in Rule 13a-15(f) of the Exchange Act) that comply with the requirements of the Exchange Act and have been designed by, or under the supervision of, their respective principal executive and principal financial officers, or persons performing similar functions, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with GAAP, including, but not limited to, internal accounting controls sufficient to provide reasonable assurance that (i) transactions are executed in accordance with management's general or specific authorizations: (ii) transactions are recorded as necessary to permit preparation of financial statements in conformity with GAAP and to maintain asset accountability; (iii) access to assets is permitted only in accordance with management's general or specific authorization; (iv) the recorded accountability for assets is compared with the existing assets at reasonable intervals and appropriate action is taken with respect to any differences and (v) interactive data in eXtensible Business Reporting Language included or incorporated by reference in the Registration Statement fairly presents the information called for in all material respects and is prepared in accordance with the Commission's rules and guidelines applicable thereto. Except as disclosed in the Registration Statement and the Prospectus, there are no material weaknesses in the Company's internal controls over financial reporting. The Company's auditors and the Audit Committee of the Board of Directors of the Company have been advised of: (i) all significant deficiencies and material weaknesses in the design and operation of internal controls over financial reporting which have adversely affected or are reasonably likely to adversely affect the Company's ability to record, process, summarize and report financial information; and (ii) any fraud, whether or not material, that involves management or other employees who have a significant role in the Company's internal accounting controls over financial reporting.
- (II) <u>eXtensible Business Reporting Language</u>. The interactive data in eXtensible Business Reporting Language included or incorporated by reference in the Registration Statement fairly presents the information called for in all material respects and has been prepared in accordance with the Commission's rules and guidelines applicable thereto.
- (mm) <u>Insurance</u>. The Company and its subsidiaries have insurance covering their respective properties, operations, personnel and businesses, including business interruption insurance, which insurance is in amounts and insures against such losses and risks the Company reasonably believes as are adequate to protect the Company and its subsidiaries and their respective businesses; and neither the Company nor any of its subsidiaries has (i) received notice from any insurer or agent of such insurer that capital improvements or other expenditures are required or necessary to be made in order to continue such insurance or (ii) any reason to believe that it will not be able to renew its existing insurance coverage as and when such coverage expires or to obtain similar coverage at reasonable cost from similar insurers as may be necessary to continue its business.
- (nn) <u>No Unlawful Contributions or Other Payments</u>. Neither the Company nor any of its subsidiaries nor, to the Company's knowledge, any director, officer, employee, agent, affiliate or other person acting on behalf of the Company or any subsidiary has (i) used any corporate funds

for any unlawful contribution, gift, entertainment or other unlawful expense relating to political activity; (ii) made any direct or indirect unlawful payment to any foreign or domestic government officials or employees, political parties or campaigns, political party officials, or candidates for political office from corporate funds; (iii) violated or is in violation of any provision of the U.S. Foreign Corrupt Practices Act of 1977, as amended, or any applicable anti-corruption laws, rules, or regulations of any other jurisdiction in which the Company or any subsidiary conducts business; or (iv) made any other unlawful bribe, rebate, payoff, influence payment, kickback or other unlawful payment to any person.

(oo) <u>Compliance with Money Laundering Laws</u>. The operations of the Company and its subsidiaries are and have been conducted at all times in compliance with all applicable financial recordkeeping and reporting requirements, including those of the U.S. Bank Secrecy Act, as amended by Title III of the Uniting and Strengthening America by Providing Appropriate Tools Required to Intercept and Obstruct Terrorism Act of 2001 (USA PATRIOT Act), and the applicable anti-money laundering statutes of jurisdictions where the Company and its subsidiaries conduct business, the rules and regulations thereunder and any related or similar rules, regulations or guidelines, issued, administered or enforced by any governmental agency (collectively, the "<u>Anti-Money Laundering Laws</u>"), and no action, suit or proceeding by or before any court or governmental agency, authority, body or any arbitrator involving the Company or any of its subsidiaries with respect to Anti-Money Laundering Laws is pending, or to the knowledge of the Company, threatened.

(pp) <u>Compliance with OFAC</u>.

- a. (i) Neither the Company nor any of its subsidiaries, nor to the Company's knowledge, any director, officer or employee thereof, any agent, affiliate, representative, or other person acting on behalf of the Company or any of its subsidiaries, is an individual or entity ("Person") that is, or is 50% or more owned, in the aggregate, by one or more Persons that is the subject of any sanctions administered or enforced by the U.S. Department of Treasury's Office of Foreign Assets Control ("OFAC"), the United Nations Security Council ("UNSC"), the European Union ("EU"), Her Majesty's Treasury ("HMT"), or other relevant sanctions authority (collectively, "Sanctions"), and (ii) neither the Company nor any of its subsidiaries is located, organized, or resident in a country or territory that is the subject of a U.S. government embargo (currently including, without limitation, Cuba, Iran, North Korea, Syria and the Crimea Region of Ukraine).
- (A) The Company will not, directly or indirectly, use the Net Proceeds, or knowingly lend, contribute or otherwise make available such Net Proceeds to any subsidiary, joint venture partner or other Person: (i) to fund or facilitate any activities or business of or with any Person that, at the time of such funding or facilitation, is the subject of Sanctions, or in any country or territory that, at the time of such funding or facilitation, is the subject of a U.S. government embargo; or (ii) in

- any other manner, in each case of clause (i) or (ii), that would result in a violation of Sanctions by any Person (including Cowen)
- (B) For the past five (5) years, the Company and its subsidiaries have not knowingly engaged in, are not now knowingly engaged in, any direct or indirect dealings or transactions with any Person that at the time of the dealing or transaction is or was the subject of Sanctions or any country or territory that, at the time of the dealing or transaction is or was the subject of a U.S. government embargo.
- (qq) No Restrictions on Subsidiaries. No subsidiary of the Company is currently prohibited, directly or indirectly, under any agreement or other instrument to which it is a party or is subject, from paying any dividends to the Company, from making any other distribution on such subsidiary's capital stock, from repaying to the Company any loans or advances to such subsidiary from the Company or from transferring any of such subsidiary's properties or assets to the Company or any other subsidiary of the Company.
- (rr) No Broker's Fees. Neither the Company nor any of its subsidiaries is a party to any contract, agreement or understanding with any person (other than this Agreement) that would give rise to a valid claim against the Company or any of its subsidiaries or Cowen for a brokerage commission, finder's fee or like payment in connection with the offering and sale of the Placement Shares.
- (ss) No Registration Rights. Except as disclosed in the Registration Statement and the Prospectus and as have been duly waived or satisfied, no person has the right to require the Company or any of its subsidiaries to register any securities for sale under the Securities Act by reason of the filing of the Registration Statement with the Commission or the issuance and sale of the Placement Shares.
- (tt) <u>No Stabilization</u>. The Company has not taken, directly or indirectly, any action designed to or that could reasonably be expected to cause or result in any stabilization or manipulation of the price of the Placement Shares.
- (uu) <u>Margin Rules</u>. The application of the proceeds received by the Company from the issuance, sale and delivery of the Placement Shares as described in the Registration Statement, and the Prospectus will not violate Regulation T, U or X of the Board of Governors of the Federal Reserve System or any other regulation of such Board of Governors.
- (vv) <u>Forward-Looking Statements</u>. No forward-looking statement (within the meaning of Section 27A of the Securities Act and Section 21E of the Exchange Act) contained in the Registration Statement or the Prospectus has been made without a reasonable basis or has been disclosed other than in good faith.
- (ww) <u>Statistical and Market Data</u>. Nothing has come to the attention of the Company that has caused the Company to believe that the statistical and market-related data included or

incorporated by reference in the Registration Statement and the Prospectus is not based on or derived from sources that are reliable and accurate in all material respects.

- (xx) <u>Sarbanes-Oxley Act</u>. There is and has been no failure on the part of the Company or, to the knowledge of the Company, any of the Company's directors or officers, in their capacities as such, to comply with any provision of the Sarbanes-Oxley Act of 2002, as amended, and the rules and regulations promulgated in connection therewith (the "<u>Sarbanes-Oxley Act</u>") applicable to the Company or any of the Company's directors or officers, in their capacities as such, including Section 402 related to loans and Sections 302 and 906 related to certifications.
- (yy) <u>Status under the Securities Act</u>. The Company currently is not an "ineligible issuer," as defined in Rule 405 of the rules and regulation of the Commission. The Company has paid the registration fee for this offering pursuant to Rule 456(b)(1) under the Securities Act or will pay such fee within the time period required by such rule (without giving effect to the proviso therein) and in any event prior to any Settlement Date.
- (zz) <u>No Ratings</u>. There are no debt securities or preferred stock issued or guaranteed by the Company or any of its subsidiaries that are rated by a "nationally recognized statistical rating organization", as such term is defined in Section 3(a)(62) of the Exchange Act.
 - ([[) Required Filings. The Company has timely made all filings required to be made by it under the Exchange Act.
- (aaa) <u>No Reliance</u>. The Company has not relied upon Cowen or legal counsel for Cowen for any legal, tax or accounting advice in connection with the offering and sale of the Placement Shares.
- (bbb) <u>Cowen Purchases</u>. The Company acknowledges and agrees that Cowen has informed the Company that Cowen may, to the extent permitted under the Securities Act and the Exchange Act, purchase and sell shares of Common Stock for its own account while this Agreement is in effect.
- (ccc) <u>Listing</u>. The Company is subject to and in compliance in all material respects with the reporting requirements of Section 13 or Section 15(d) of the Exchange Act. The Common Stock is registered pursuant to Section 12(b) or Section 12(g) of the Exchange Act and is listed on the NYSE, and the Company has taken no action designed to, or reasonably likely to have the effect of, terminating the registration of the Common Stock under the Exchange Act or delisting the Common Stock from the NYSE, nor has the Company received any notification that the Commission or NYSE is contemplating terminating such registration or listing.
- (ddd) <u>FINRA Exemption</u>. To enable Cowen to rely on Rule 5110(b)(7)(C)(i) of FINRA, the Company represents that the Company (i) has a non-affiliate, public common equity float of at least \$150 million or a non-affiliate, public common equity float of at least \$100 million and annual trading volume of at least three million shares and (ii) has been subject to the Exchange Act reporting requirements for a period of at least 36 months.

Any certificate signed by an officer of the Company and delivered to Cowen or to counsel for Cowen in connection with this Agreement shall be deemed to be a representation and warranty by the Company to Cowen as to the matters set forth therein.

The Company acknowledges that Cowen and, for purposes of the opinions to be delivered pursuant to <u>Section 7</u> hereof, counsel to the Company and counsel to Cowen, will rely upon the accuracy and truthfulness of the foregoing representations and hereby consents to such reliance.

- 7. <u>Covenants of the Company</u>. The Company covenants and agrees with Cowen that:
- Registration Statement Amendments. After the date of this Agreement and during any period in which a (a) Prospectus relating to any Placement Shares is required to be delivered by Cowen under the Securities Act (including in circumstances where such requirement may be satisfied pursuant to Rule 172 under the Securities Act or similar rule), (i) the Company will notify Cowen promptly of the time when any subsequent amendment to the Registration Statement, other than documents incorporated by reference, has been filed with the Commission and/or has become effective or any subsequent supplement to the Prospectus has been filed and of any request by the Commission for any amendment or supplement to the Registration Statement or Prospectus or for additional information (insofar as such request relates to the transactions contemplated hereby), (ii) the Company will prepare and file with the Commission, promptly upon Cowen's reasonable request, any amendments or supplements to the Registration Statement or Prospectus that, in Cowen's reasonable opinion, may be necessary or advisable in connection with the distribution of the Placement Shares by Cowen (provided, however, that the failure of Cowen to make such request shall not relieve the Company of any obligation or liability hereunder, or affect Cowen's right to rely on the representations and warranties made by the Company in this Agreement; provided, further, that the only remedy Cowen shall have with respect to the failure by the Company to comply with Cowen's request shall be to cease making sales under this Agreement); (iii) the Company will not file any amendment or supplement to the Registration Statement or Prospectus, other than documents incorporated by reference, relating to the Placement Shares or a security convertible into the Placement Shares unless a copy thereof has been submitted to Cowen within a reasonable period of time before the filing and Cowen has not reasonably objected thereto (provided, however, that (A) the failure of Cowen to make such objection shall not relieve the Company of any obligation or liability hereunder, or affect Cowen's right to rely on the representations and warranties made by the Company in this Agreement, (B) the Company has no obligation to provide Cowen any advance copy of such filing or to provide Cowen an opportunity to object to such filing if the filing does not name Cowen or does not relate to the transaction herein provided and (C) the only remedy Cowen shall have with respect to the failure by the Company to provide Cowen with such copy or the filing of such amendment or supplement despite Cowen's objection shall be to cease making sales under this Agreement) and the Company will furnish to Cowen at the time of filing thereof a copy of any document that upon filing is deemed to be incorporated by reference into the Registration Statement or Prospectus, except for those documents available via EDGAR; (iv) the Company will cause each amendment or supplement to the Prospectus, other than documents incorporated by reference, to be filed with the Commission as required pursuant to the applicable paragraph of Rule 424(b) of the Securities Act; and (v) prior to the termination of this Agreement, the Company will

notify Cowen if at any time the Registration Statement shall no longer be effective as a result of the passage of time pursuant to Rule 415 under the Securities Act or otherwise.

- (b) <u>Notice of Commission Stop Orders</u>. The Company will advise Cowen, promptly after it receives notice or obtains knowledge thereof, of the issuance or threatened issuance by the Commission of any stop order suspending the effectiveness of the Registration Statement, of the suspension of the qualification of the Placement Shares for offering or sale in any jurisdiction, or of the initiation or threatening of any proceeding for any such purpose; and it will promptly use its commercially reasonable efforts to prevent the issuance of any stop order or to obtain its withdrawal if such a stop order should be issued.
- Company of Prospectus; Subsequent Changes. During any period in which a Prospectus relating to the Placement Shares is required to be delivered by Cowen under the Securities Act with respect to a pending sale of the Placement Shares (including in circumstances where such requirement may be satisfied pursuant to Rule 172 under the Securities Act or similar rule), the Company will comply with all the requirements imposed upon it by the Securities Act, as from time to time in force, and to file on or before their respective due dates (taking into account any extensions available under the Exchange Act) all reports and any definitive proxy or information statements required to be filed by the Company with the Commission pursuant to Sections 13(a), 13(c), 14, 15(d) or any other provision of or under the Exchange Act. If during such period any event occurs as a result of which the Prospectus as then amended or supplemented would include an untrue statement of a material fact or omit to state a material fact necessary to make the statements therein, in the light of the circumstances then existing, not misleading, or if during such period it is necessary to amend or supplement the Registration Statement or Prospectus to comply with the Securities Act, the Company will promptly notify Cowen to suspend the offering of Placement Shares during such period and the Company will promptly amend or supplement the Registration Statement or Prospectus (at the expense of the Company) so as to correct such statement or omission or effect such compliance; provided, however, that the Company may delay the filing of any amendment or supplement if, in the reasonable judgment of the Company, it is in the best interest of the Company to do so.
- (d) <u>Listing of Placement Shares</u>. During any period in which the Prospectus relating to the Placement Shares is required to be delivered by Cowen under the Securities Act with respect to a pending sale of the Placement Shares (including in circumstances where such requirement may be satisfied pursuant to Rule 172 under the Securities Act or similar rule), the Company will use its commercially reasonable efforts to cause the Placement Shares to be listed on the NYSE and to qualify the Placement Shares for sale under the securities laws of such jurisdictions as Cowen reasonably designates and to continue such qualifications in effect so long as required for the distribution of the Placement Shares; *provided, however*, that the Company shall not be required in connection therewith to qualify as a foreign corporation or dealer in securities or file a general consent to service of process in any jurisdiction.
- (e) <u>Delivery of Registration Statement and Prospectus</u>. Following the date that the Registration Statement is declared effective by the Commission, the Company will furnish to Cowen and its counsel (at the expense of the Company) copies of the Registration Statement, the

Prospectus (including all documents incorporated by reference therein) and all amendments and supplements to the Registration Statement or Prospectus that are filed with the Commission during any period in which a Prospectus relating to the Placement Shares is required to be delivered under the Securities Act (including all documents filed with the Commission during such period that are deemed to be incorporated by reference therein), in each case as soon as reasonably practicable and in such quantities as Cowen may from time to time reasonably request and, at Cowen's reasonable request, will also furnish copies of the Prospectus to each exchange or market on which sales of the Placement Shares may be made; *provided, however*, that the Company shall not be required to furnish any document (other than the Prospectus) to Cowen to the extent such document is available on EDGAR.

- (f) <u>Earnings Statement</u>. The Company will make generally available to its security holders as soon as practicable, but in any event not later than 15 months after the end of the Company's current fiscal quarter, an earnings statement covering a 12-month period that satisfies the provisions of Section 11(a) and Rule 158 of the Securities Act.
- Expenses. The Company, whether or not the transactions contemplated hereunder are consummated or this Agreement is terminated, in accordance with the provisions of Section 11 hereunder, will pay the following expenses all incident to the performance of its obligations hereunder, including, but not limited to, expenses relating to (i) the preparation, printing and filing of the Registration Statement and each amendment and supplement thereto, and of each Prospectus and of each amendment and supplement thereto, (ii) the preparation, issuance and delivery of the Placement Shares, (iii) the qualification of the Placement Shares under securities laws in accordance with the provisions of Section 7(d) of this Agreement, including filing fees (provided, however, that any fees or disbursements of counsel for Cowen in connection therewith shall be paid by Cowen except as set forth in (vii) below), (iv) the printing and delivery to Cowen of copies of the Prospectus and any amendments or supplements thereto, and of this Agreement, (v) the fees and expenses incurred in connection with the listing or qualification of the Placement Shares for trading on the NYSE, (vi) the filing fees and expenses, if any, of the Commission, (vii) the filing fees and associated legal expenses of Cowen's outside counsel for filings with the FINRA Corporate Financing Department, such legal expense reimbursement not to exceed \$10,000 in the aggregate and (viii) the reasonable fees and disbursements of Cowen's outside counsel in an amount not to exceed \$50,000 in the aggregate.
- (h) <u>Use of Proceeds</u>. The Company will use the Net Proceeds as described in the Prospectus in the section entitled "Use of Proceeds."
- (i) <u>Notice of Other Sales</u>. During the pendency of any Placement Notice given hereunder, and for three (3) trading days following the termination of any Placement Notice given hereunder, the Company shall provide Cowen notice as promptly as reasonably practicable before it offers to sell, contracts to sell, sells, grants any option to sell or otherwise disposes of any shares of Common Stock (other than Placement Shares offered pursuant to the provisions of this Agreement) or securities convertible into or exchangeable for Common Stock, warrants or any rights to purchase or acquire Common Stock; *provided*, that such notice shall not be required in connection with (i) the issuance, grant or sale of Common Stock, options to purchase shares of

Common Stock or any other equity awards, or Common Stock issuable upon the exercise of options or other equity awards pursuant to any equity incentive plan, stock option, stock bonus, employee stock purchase or other stock plan or arrangement described in the Prospectus, (ii) warrants that may be issued by the Company in connection with that certain Loan and Security Agreement dated as of March 15, 2017 among the Company, Oxford Capital, LLC and PatientCrossroads, Inc., as amended, (iii) the issuance of securities in connection with an acquisition, merger or sale or purchase of assets, (iv) the issuance or sale of Common Stock pursuant to any dividend reinvestment plan that the Company may adopt from time to time provided the implementation of such is disclosed to Cowen in advance, or (v) the issuance of any shares of Common Stock issuable upon the exchange, conversion or redemption of securities or the exercise of warrants, options or other rights in effect or outstanding.

- (j) <u>Change of Circumstances</u>. The Company will, at any time during a fiscal quarter in which the Company intends to tender a Placement Notice or sell Placement Shares, advise Cowen promptly after it shall have received notice or obtained knowledge thereof, of any information or fact that would alter or affect in any material respect any opinion, certificate, letter or other document provided to Cowen pursuant to this Agreement.
- (k) <u>Due Diligence Cooperation</u>. During the term of this Agreement, the Company will cooperate with any reasonable due diligence review conducted by Cowen or its agents in connection with the transactions contemplated hereby, including, without limitation, providing information and making available documents and senior corporate officers, during regular business hours and at the Company's principal offices, as Cowen may reasonably request.
- Required Filings Relating to Placement of Placement Shares. The Company agrees that on such dates as the Securities Act shall require, the Company will (i) file a prospectus supplement with the Commission under the applicable paragraph of Rule 424(b) under the Securities Act (each and every filing under Rule 424(b), a "Filing Date"), which prospectus supplement will set forth, within the relevant period, the amount of Placement Shares sold through Cowen, the Net Proceeds to the Company and the compensation payable by the Company to Cowen with respect to such Placement Shares, and (ii) deliver such number of copies of each such prospectus supplement to each exchange or market on which such sales were effected as may be required by the rules or regulations of such exchange or market.
- (m) Representation Dates; Certificate. During the term of this Agreement, on or prior to the First Delivery Date and each time the Company (i) files the Prospectus relating to the Placement Shares or amends or supplements the Registration Statement or the Prospectus relating to the Placement Shares (other than a prospectus supplement filed in accordance with Section 7(1) of this Agreement) by means of a post-effective amendment, sticker, or supplement but not by means of incorporation of document(s) by reference to the Registration Statement or the Prospectus relating to the Placement Shares; (ii) files an Annual Report on Form 10-K under the Exchange Act; (iii) files its Quarterly Reports on Form 10-Q under the Exchange Act; or (iv) files a Current Report on Form 8-K containing amended financial information (other than an earnings release) under the Exchange Act (each date of filing of one or more of the documents referred to in clauses (i) through (iv) shall be a "Representation Date"); the Company shall furnish Cowen with a certificate, in the

form attached hereto as **Exhibit 7(m)** within three (3) Trading Days of any Representation Date if requested by Cowen. The requirement to provide a certificate under this <u>Section 7(m)</u> shall be automatically waived for any Representation Date occurring at a time at which no Placement Notice is pending, which waiver shall continue until the earlier to occur of the date the Company delivers a Placement Notice hereunder (which for such calendar quarter shall be considered a Representation Date) and the next occurring Representation Date; *provided*, *however*, that such waiver shall not apply for any Representation Date on which the Company files its Annual Report on Form 10-K. Notwithstanding the foregoing, if the Company subsequently decides to sell Placement Shares following a Representation Date when the Company relied on such waiver and did not provide Cowen with a certificate under this <u>Section 7(m)</u>, then before the Company delivers the Placement Notice or Cowen sells any Placement Shares, the Company shall provide Cowen with a certificate, in the form attached hereto as <u>Exhibit 7(m)</u>, dated the date of the Placement Notice.

- (n) <u>Legal Opinion</u>. On or prior to the First Delivery Date and within three (3) Trading Days of each Representation Date with respect to which the Company is obligated to deliver a certificate in the form attached hereto as <u>Exhibit 7(m)</u> for which no waiver is applicable, the Company shall cause to be furnished to Cowen a written opinion of Pillsbury Winthrop Shaw Pittman LLP ("<u>Company Counsel</u>"), or other counsel satisfactory to Cowen, in form and substance reasonably satisfactory to Cowen and its counsel, dated the date that the opinion is required to be delivered, modified, as necessary, to relate to the Registration Statement and the Prospectus as then amended or supplemented; *provided, however*, that in lieu of such opinion for subsequent Representation Dates, counsel may furnish Cowen with a letter (a "<u>Reliance Letter</u>") to the effect that Cowen may rely on a prior opinion delivered under this <u>Section 7(n)</u> to the same extent as if it were dated the date of such letter (except that statements in such prior opinion shall be deemed to relate to the Registration Statement and the Prospectus as amended or supplemented at such Representation Date).
- On or prior to the First Delivery Date and within three (3) Trading Days of each Representation Date with respect to which the Company is obligated to deliver a certificate in the form attached hereto as **Exhibit 7(m)** for which no waiver is applicable, the Company shall cause its independent accountants to furnish Cowen letters (the "**Comfort Letters**"), dated the date the Comfort Letter is delivered, in form and substance reasonably satisfactory to Cowen, (i) confirming that they are an independent registered public accounting firm within the meaning of the Securities Act and the PCAOB, (ii) stating, as of such date, the conclusions and findings of such firm with respect to the financial information and other matters ordinarily covered by accountants' "comfort letters" to Cowen in connection with registered public offerings (the first such letter, the "**Initial Comfort Letter**") and (iii) updating the Initial Comfort Letter with any information that would have been included in the Initial Comfort Letter had it been given on such date and modified as necessary to relate to the Registration Statement and the Prospectus, as amended and supplemented to the date of such letter.
- (p) <u>Market Activities</u>. The Company will not, directly or indirectly, (i) take any action designed to cause or result in, or that constitutes or might reasonably be expected to constitute, the stabilization or manipulation of the price of any security of the Company to facilitate the sale

or resale of the Placement Shares or (ii) sell, bid for, or purchase the Placement Shares to be issued and sold pursuant to this Agreement, or pay anyone any compensation for soliciting purchases of the Placement Shares other than Cowen; *provided*, *however*, that the Company may bid for and purchase shares of its Common Stock in accordance with Rule 10b-18 under the Exchange Act.

- (q) <u>Insurance</u>. The Company and its subsidiaries shall maintain, or cause to be maintained, insurance in such amounts and covering such risks as is reasonable and customary for the business for which it is engaged.
- (r) <u>Compliance with Laws</u>. The Company and each of its subsidiaries shall use commercially reasonable efforts to maintain, or cause to be maintained, all material environmental permits, licenses and other authorizations required by federal, state and local law in order to conduct their businesses as described in the Prospectus, and the Company and each of its subsidiaries shall conduct their businesses, or cause their businesses to be conducted, in substantial compliance with such permits, licenses and authorizations and with applicable environmental laws, except where the failure to maintain or be in compliance with such permits, licenses and authorizations could not reasonably be expected to result in a Material Adverse Effect.
- (s) <u>Investment Company Act</u>. The Company will conduct its affairs in such a manner so as to reasonably ensure that neither it nor its subsidiaries will be or become, at any time prior to the termination of this Agreement, an "investment company," as such term is defined in the Investment Company Act, assuming no change in the Commission's current interpretation as to entities that are not considered an investment company.
- (t) <u>Securities Act and Exchange Act</u>. The Company will use commercially reasonable efforts to comply with all requirements imposed upon it by the Securities Act and the Exchange Act as from time to time in force, so far as necessary to permit the continuance of sales of, or dealings in, the Placement Shares as contemplated by the provisions hereof and the Prospectus.
- (u) No Offer to Sell. Other than a free writing prospectus (as defined in Rule 405 under the Securities Act) approved in advance by the Company and Cowen in its capacity as principal or agent hereunder, neither Cowen nor the Company (including its agents and representatives, other than Cowen in its capacity as such) will make, use, prepare, authorize, approve or refer to any written communication (as defined in Rule 405 under the Securities Act), required to be filed with the Commission, that constitutes an offer to sell or solicitation of an offer to buy Placement Shares hereunder.
- (v) <u>Sarbanes-Oxley Act</u>. The Company and its subsidiaries will use commercially reasonable efforts to comply with all effective applicable provisions of the Sarbanes-Oxley Act.
- (w) <u>Status under the Securities Act</u>. The Company shall notify Cowen promptly upon the Company becoming an "ineligible issuer," as defined in Rule 405 of the rules and regulations of the Commission.

- 8. <u>Conditions to Cowen's Obligations</u>. The obligations of Cowen hereunder with respect to a Placement will be subject to the continuing accuracy and completeness of the representations and warranties made by the Company herein, to the due performance by the Company of its obligations hereunder, to the completion by Cowen of a due diligence review satisfactory to Cowen in its reasonable judgment, and to the continuing satisfaction (or waiver by Cowen in its sole discretion) of the following additional conditions:
- (a) <u>Registration Statement Effective</u>. The Registration Statement shall be effective and shall be available for (i) all sales of Placement Shares issued pursuant to all prior Placement Notices and (ii) the sale of all Placement Shares contemplated to be issued by any Placement Notice.
- (b) No Material Notices. None of the following events shall have occurred and be continuing: (i) receipt by the Company or any of its subsidiaries of any request for additional information from the Commission or any other federal or state governmental authority during the period of effectiveness of the Registration Statement, the response to which would require any post-effective amendments or supplements to the Registration Statement or the Prospectus; (ii) the issuance by the Commission or any other federal or state governmental authority of any stop order suspending the effectiveness of the Registration Statement or the initiation of any proceedings for that purpose; (iii) receipt by the Company of any notification with respect to the suspension of the qualification or exemption from qualification of any of the Placement Shares for sale in any jurisdiction or the initiation or threatening of any proceeding for such purpose; or (iv) the occurrence of any event that makes any material statement made in the Registration Statement or the Prospectus or any material document incorporated or deemed to be incorporated therein by reference untrue in any material respect or that requires the making of any changes in the Registration Statement, related Prospectus or such documents so that, in the case of the Registration Statement, it will not contain any materially untrue statement of a material fact or omit to state any material fact required to be stated therein or necessary to make the statements therein not misleading and, that in the case of the Prospectus, it will not contain any materially untrue statement of a material fact or omit to state any material fact required to be stated therein or necessary to make the statements under which they were made, not misleading.
- (c) <u>No Misstatement or Material Omission</u>. Cowen shall not have advised the Company that the Registration Statement or Prospectus, or any amendment or supplement thereto, contains an untrue statement of fact that in Cowen's reasonable opinion is material, or omits to state a fact that in Cowen's reasonable opinion is material and is required to be stated therein or is necessary to make the statements therein not misleading.
- (d) <u>Material Changes</u>. Except as contemplated in the Prospectus, or disclosed in the Company's reports filed with the Commission, there shall not have been any material adverse change, on a consolidated basis, in the authorized capital stock of the Company or any Material Adverse Effect or any development that could reasonably be expected to result in a Material Adverse Effect, or any downgrading in or withdrawal of the rating assigned to any of the Company's securities (other than asset backed securities) by any rating organization or a public announcement by any rating organization that it has under surveillance or review its rating of any of the Company's

securities (other than asset backed securities), the effect of which, in the case of any such action by a rating organization described above, in the reasonable judgment of Cowen (without relieving the Company of any obligation or liability it may otherwise have), is so material as to make it impracticable or inadvisable to proceed with the offering of the Placement Shares on the terms and in the manner contemplated in the Prospectus.

- (e) <u>Company Counsel Legal Opinion</u>. Cowen shall have received the opinion of Company Counsel required to be delivered pursuant to <u>Section 7(n)</u> on or before the date on which such delivery of such opinion is required pursuant to <u>Section 7(n)</u>.
- (f) <u>Cowen Counsel Legal Opinion</u>. Cowen shall have received from Cooley LLP, counsel for Cowen, such opinion or opinions, on or before the date on which the delivery of the Company Counsel legal opinion is required pursuant to <u>Section 7(n)</u>, with respect to such matters as Cowen may reasonably require, and the Company shall have furnished to such counsel such documents as they request for enabling them to pass upon such matters.
- (g) <u>Comfort Letter</u>. Cowen shall have received the Comfort Letter required to be delivered pursuant to <u>Section 7(o)</u> on or before the date on which such delivery of such Comfort Letter is required pursuant to <u>Section 7(o)</u>.
- (h) <u>Representation Certificate</u>. Cowen shall have received the certificate required to be delivered pursuant to <u>Section 7(m)</u> on or before the date on which delivery of such certificate is required pursuant to <u>Section 7(m)</u>.
- (i) <u>Secretary's Certificate</u>. On or prior to the First Delivery Date, Cowen shall have received a certificate, signed on behalf of the Company by its corporate Secretary, in form and substance satisfactory to Cowen and its counsel.
 - (j) <u>No Suspension</u>. Trading in the Common Stock shall not have been suspended on the NYSE.
- (k) Other Materials. On each date on which the Company is required to deliver a certificate pursuant to Section 7(m), the Company shall have furnished to Cowen such appropriate further information, certificates and documents as Cowen may have reasonably requested. All such opinions, certificates, letters and other documents shall have been in compliance with the provisions hereof. The Company will furnish Cowen with such conformed copies of such opinions, certificates, letters and other documents as Cowen shall have reasonably requested.
- (l) <u>Securities Act Filings Made</u>. All filings with the Commission required by Rule 424 under the Securities Act to have been filed prior to the issuance of any Placement Notice hereunder shall have been made within the applicable time period prescribed for such filing by Rule 424.
- (m) <u>Approval for Listing</u>. The Placement Shares shall have been approved for listing on the NYSE, subject only to notice of issuance.

- (n) <u>No Termination Event</u>. There shall not have occurred any event that would permit Cowen to terminate this Agreement pursuant to <u>Section 11(a)</u>.
 - 9. <u>Indemnification and Contribution</u>.
- (a) Company Indemnification. The Company agrees to indemnify and hold harmless Cowen, the directors, officers, partners, employees and agents of Cowen and each person, if any, who (i) controls Cowen within the meaning of Section 15 of the Securities Act or Section 20 of the Exchange Act, or (ii) is controlled by or is under common control with Cowen from and against any and all losses, claims, liabilities, expenses and damages (including, but not limited to, any and all reasonable investigative, legal and other expenses incurred in connection with, and any and all amounts paid in settlement (in accordance with Section 9(c)) of, any action, suit or proceeding between any of the indemnified parties and any indemnifying parties or between any indemnified party and any third party, or otherwise, or any claim asserted), as and when incurred, to which Cowen, or any such person, may become subject under the Securities Act, the Exchange Act or other federal or state statutory law or regulation, at common law or otherwise, insofar as such losses, claims, liabilities, expenses or damages arise out of or are based, directly or indirectly, on (x) any untrue statement or alleged untrue statement of a material fact contained in the Registration Statement or the Prospectus or any amendment or supplement to the Registration Statement or the Prospectus or in any free writing prospectus or in any application or other document executed by or on behalf of the Company or based on written information furnished by or on behalf of the Company filed in any jurisdiction in order to qualify the Placement Shares under the securities laws thereof or filed with the Commission or (y) the omission or alleged omission to state in any such document a material fact required to be stated in it or necessary to make the statements in it not misleading; provided, however, that this indemnity agreement shall not apply to the extent that such loss, claim, liability, expense or damage arises from the sale of the Placement Shares pursuant to this Agreement and is caused directly or indirectly by an untrue statement or omission made in reliance upon and in conformity with the Agent's Information. This indemnity agreement will be in addition to any liability that the Company might otherwise have.
- (b) <u>Cowen Indemnification</u>. Cowen agrees to indemnify and hold harmless the Company and its directors and each officer of the Company that signed the Registration Statement, and each person, if any, who controls the Company within the meaning of Section 15 of the Securities Act or Section 20 of the Exchange Act against any and all loss, liability, claim, damage and expense described in the indemnity contained in <u>Section 9(a)</u>, as incurred, but only with respect to untrue statements or omissions, or alleged untrue statements or omissions, made in the Registration Statement (or any amendments thereto) or the Prospectus (or any amendment or supplement thereto) in reliance upon and in conformity with the Agent's Information.
- (c) <u>Procedure</u>. Any party that proposes to assert the right to be indemnified under this <u>Section 9</u> will, promptly after receipt of notice of commencement of any action against such party in respect of which a claim is to be made against an indemnifying party or parties under this <u>Section 9</u>, notify each such indemnifying party of the commencement of such action, enclosing a copy of all papers served, but the omission so to notify such indemnifying party will not relieve the indemnifying party from (i) any liability that it might have to any indemnified party otherwise

than under this Section 9 and (ii) any liability that it may have to any indemnified party under the foregoing provision of this Section 9 unless, and only to the extent that, such omission results in the forfeiture of substantive rights or defenses by the indemnifying party. If any such action is brought against any indemnified party and it notifies the indemnifying party of its commencement, the indemnifying party will be entitled to participate in and, to the extent that it elects by delivering written notice to the indemnified party promptly after receiving notice of the commencement of the action from the indemnified party, jointly with any other indemnifying party similarly notified, to assume the defense of the action, with counsel reasonably satisfactory to the indemnified party, and after notice from the indemnifying party to the indemnified party of its election to assume the defense, the indemnifying party will not be liable to the indemnified party for any legal or other expenses except as provided below and except for the reasonable costs of investigation subsequently incurred by the indemnified party in connection with the defense. The indemnified party will have the right to employ its own counsel in any such action, but the fees, expenses and other charges of such counsel will be at the expense of such indemnified party unless (1) the employment of counsel by the indemnified party has been authorized in writing by the indemnifying party, (2) the indemnified party has reasonably concluded (based on advice of counsel) that there may be legal defenses available to it or other indemnified parties that are different from or in addition to those available to the indemnifying party, (3) a conflict or potential conflict exists (based on advice of counsel to the indemnified party) between the indemnified party and the indemnifying party (in which case the indemnifying party will not have the right to direct the defense of such action on behalf of the indemnified party) or (4) the indemnifying party has not in fact employed counsel to assume the defense of such action within a reasonable time after receiving notice of the commencement of the action, in each of which cases the reasonable fees, disbursements and other charges of counsel will be at the expense of the indemnifying party or parties. It is understood that the indemnifying party or parties shall not, in connection with any proceeding or related proceedings in the same iurisdiction, be liable for the reasonable fees, disbursements and other charges of more than one separate firm admitted to practice in such jurisdiction at any one time for all such indemnified party or parties. All such fees, disbursements and other charges will be reimbursed by the indemnifying party promptly as they are incurred. An indemnifying party will not, in any event, be liable for any settlement of any action or claim effected without its written consent. No indemnifying party shall, without the prior written consent of each indemnified party, settle or compromise or consent to the entry of any judgment in any pending or threatened claim, action or proceeding relating to the matters contemplated by this <u>Section 9</u> (whether or not any indemnified party is a party thereto), unless such settlement, compromise or consent includes an unconditional release of each indemnified party from all liability arising or that may arise out of such claim, action or proceeding.

(d) <u>Contribution</u>. In order to provide for just and equitable contribution in circumstances in which the indemnification provided for in the foregoing paragraphs of this <u>Section 9</u> is applicable in accordance with its terms but for any reason is held to be unavailable from the Company or Cowen, the Company and Cowen will contribute to the total losses, claims, liabilities, expenses and damages (including any investigative, legal and other expenses reasonably incurred in connection with, and any amount paid in settlement of, any action, suit or proceeding or any claim asserted, but after deducting any contribution received by the Company from persons other

than Cowen, such as persons who control the Company within the meaning of the Securities Act, officers of the Company who signed the Registration Statement and directors of the Company, who also may be liable for contribution) to which the Company and Cowen may be subject in such proportion as shall be appropriate to reflect the relative benefits received by the Company on the one hand and Cowen on the other. The relative benefits received by the Company on the one hand and Cowen on the other hand shall be deemed to be in the same proportion as the total Net Proceeds from the sale of the Placement Shares (before deducting expenses) received by the Company bear to the total compensation received by Cowen from the sale of Placement Shares on behalf of the Company. If, but only if, the allocation provided by the foregoing sentence is not permitted by applicable law, the allocation of contribution shall be made in such proportion as is appropriate to reflect not only the relative benefits referred to in the foregoing sentence but also the relative fault of the Company, on the one hand, and Cowen, on the other, with respect to the statements or omission that resulted in such loss, claim, liability, expense or damage, or action in respect thereof, as well as any other relevant equitable considerations with respect to such offering. Such relative fault shall be determined by reference to, among other things, whether the untrue or alleged untrue statement of a material fact or omission or alleged omission to state a material fact relates to information supplied by the Company or Cowen, the intent of the parties and their relative knowledge, access to information and opportunity to correct or prevent such statement or omission. The Company and Cowen agree that it would not be just and equitable if contributions pursuant to this Section 9(d) were to be determined by pro rata allocation or by any other method of allocation that does not take into account the equitable considerations referred to herein. The amount paid or payable by an indemnified party as a result of the loss, claim, liability, expense, or damage, or action in respect thereof, referred to above in this Section 9(d) shall be deemed to include, for the purpose of this Section 9(d), any legal or other expenses reasonably incurred by such indemnified party in connection with investigating or defending any such action or claim to the extent consistent with Section 9(c) hereof. Notwithstanding the foregoing provisions of this Section 9(d), Cowen shall not be required to contribute any amount in excess of the commissions received by it under this Agreement and no person found guilty of fraudulent misrepresentation (within the meaning of Section 11(f) of the Securities Act) will be entitled to contribution from any person who was not guilty of such fraudulent misrepresentation. For purposes of this Section 9(d), any person who controls a party to this Agreement within the meaning of the Securities Act, and any officers, directors, partners, employees or agents of Cowen, will have the same rights to contribution as that party, and each director of the Company and each officer of the Company who signed the Registration Statement will have the same rights to contribution as the Company, subject in each case to the provisions hereof. Any party entitled to contribution, promptly after receipt of notice of commencement of any action against such party in respect of which a claim for contribution may be made under this Section 9(d), will notify any such party or parties from whom contribution may be sought, but the omission to so notify will not relieve that party or parties from whom contribution may be sought from any other obligation it or they may have under this Section 9(d) except to the extent that the failure to so notify such other party materially prejudiced the substantive rights or defenses of the party from whom contribution is sought. Except for a settlement entered into pursuant to the last sentence of Section 9(c) hereof, no party will be liable for contribution with respect to any action or claim settled without its written consent if such consent is required pursuant to Section 9(c) hereof.

10. Representations and Agreements to Survive Delivery. The indemnity and contribution agreements contained in Section 9 of this Agreement and all representations and warranties of the Company herein or in certificates delivered pursuant hereto shall survive, as of their respective dates, regardless of (i) any investigation made by or on behalf of Cowen, any controlling persons, or the Company (or any of their respective officers, directors or controlling persons), (ii) delivery and acceptance of the Placement Shares and payment therefor or (iii) any termination of this Agreement.

11. <u>Termination.</u>

- (a) Cowen shall have the right by giving written notice as hereinafter specified at any time to terminate this Agreement if (i) any Material Adverse Effect, or any development that could reasonably be expected to result in a Material Adverse Effect has occurred that, in the reasonable judgment of Cowen, may materially impair the ability of Cowen to sell the Placement Shares hereunder, (ii) the Company shall have failed, refused or been unable to perform any agreement on its part to be performed hereunder; *provided, however*, in the case of any failure of the Company to deliver (or cause another person to deliver) any certification, opinion, or letter required under Sections 7(m), 7(n), or 7(o), Cowen's right to terminate shall not arise unless such failure to deliver (or cause to be delivered) continues for more than thirty (30) days from the date such delivery was required, (iii) any other condition of Cowen's obligations hereunder is not fulfilled or (iv), any suspension or limitation of trading in the Placement Shares or in securities generally on the NYSE shall have occurred. Any such termination shall be without liability of any party to any other party except that the provisions of Section 7(g) (Expenses), Section 9 (Indemnification and Contribution), Section 10 (Representations and Agreements to Survive Delivery), Section 16 (Applicable Law; Consent to Jurisdiction) and Section 17 (Waiver of Jury Trial) hereof shall remain in full force and effect notwithstanding such termination. If Cowen elects to terminate this Agreement as provided in this Section 11(a), Cowen shall provide the required notice as specified in Section 12 (Notices).
- (b) The Company shall have the right, by giving five (5) days' notice as hereinafter specified to terminate this Agreement in its sole discretion at any time after the date of this Agreement. Any such termination shall be without liability of any party to any other party except that the provisions of Section 7(g), Section 9, Section 10, Section 16 and Section 17 hereof shall remain in full force and effect notwithstanding such termination.
- (c) Cowen shall have the right, by giving five (5) days' notice as hereinafter specified to terminate this Agreement in its sole discretion at any time after the date of this Agreement. Any such termination shall be without liability of any party to any other party except that the provisions of Section 7(g), Section 9, Section 10, Section 16 and Section 17 hereof shall remain in full force and effect notwithstanding such termination.
- (d) Unless earlier terminated pursuant to this <u>Section 11</u>, this Agreement shall automatically terminate upon the issuance and sale of all of the Placement Shares through Cowen on the terms and subject to the conditions set forth herein; *provided* that the provisions of Section

- 7(g), Section 9, Section 10, Section 16 and Section 17 hereof shall remain in full force and effect notwithstanding such termination.
- (e) This Agreement shall remain in full force and effect unless terminated pursuant to Sections 11(a), (b), (c), or (d) above or otherwise by mutual agreement of the parties; provided, however, that any such termination by mutual agreement shall in all cases be deemed to provide that Section 7(g), Section 9, Section 10, Section 16 and Section 17 shall remain in full force and effect.
- (f) Any termination of this Agreement shall be effective on the date specified in such notice of termination; *provided, however,* that such termination shall not be effective until the close of business on the date of receipt of such notice by Cowen or the Company, as the case may be. If such termination shall occur prior to the Settlement Date for any sale of Placement Shares, such Placement Shares shall settle in accordance with the provisions of this Agreement.
- 12. Notices. All notices or other communications required or permitted to be given by any party to any other party pursuant to the terms of this Agreement shall be in writing, unless otherwise specified in this Agreement, and if sent to Cowen, shall be delivered to Cowen at Cowen and Company, LLC, 599 Lexington Avenue, New York, NY 10022, fax no. 646-562-1124, Attention: General Counsel, with a copy to Cooley LLP, 1114 Avenue of the Americas, New York, NY 10036, fax no. (212) 479-6275, Attention: Daniel I. Goldberg; or if sent to the Company, shall be delivered to Invitae Corporation, 1400 16th Street, San Francisco, California 94103, fax no. (415) 276-4164, Attention: General Counsel, with a copy to Pillsbury Winthrop Shaw Pittman LLP, 2550 Hanover Street, Palo Alto, CA 94304, fax no. (650) 233-4545, Attention: Gabriella A. Lombardi. Each party to this Agreement may change such address for notices by sending to the parties to this Agreement written notice of a new address for such purpose. Each such notice or other communication shall be deemed given (i) when delivered personally or by verifiable facsimile transmission (with an original to follow) on or before 4:30 p.m., New York City time, on a Business Day (as defined below), or, if such day is not a Business Day on the next succeeding Business Day, (ii) on the next Business Day after timely delivery to a nationally-recognized overnight courier, (iii) on the Business Day actually received if deposited in the U.S. mail (certified or registered mail, return receipt requested, postage prepaid), and (iv) when delivered by electronic communication (" Electronic Notice"), at the time the party sending Electronic Notice receives verification of receipt by the receiving party, other than via auto reply. For purposes of this Agreement, "Business Day" shall mean any day on which the NYSE and commercial banks in the City of New York are open for business.
- 13. <u>Successors and Assigns</u>. This Agreement shall inure to the benefit of and be binding upon the Company and Cowen and their respective successors and the affiliates, controlling persons, officers and directors referred to in <u>Section 9</u> hereof. References to any of the parties contained in this Agreement shall be deemed to include the successors and permitted assigns of such party. Nothing in this Agreement, express or implied, is intended to confer upon any party other than the parties hereto or their respective successors and permitted assigns any rights, remedies, obligations or liabilities under or by reason of this Agreement, except as expressly provided in this Agreement. Neither party may assign its rights or obligations under this Agreement without the prior written

consent of the other party; *provided*, *however*, that Cowen may assign its rights and obligations hereunder to an affiliate of Cowen without obtaining the Company's consent.

- 14. <u>Adjustments for Share Splits</u>. The parties acknowledge and agree that all share-related numbers contained in this Agreement shall be adjusted to take into account any share split, share dividend or similar event effected with respect to the Common Stock.
- 15. Entire Agreement; Amendment; Severability. This Agreement (including all schedules and exhibits attached hereto and Placement Notices issued pursuant hereto) constitutes the entire agreement and supersedes all other prior and contemporaneous agreements and undertakings, both written and oral, among the parties hereto with regard to the subject matter hereof. Neither this Agreement nor any term hereof may be amended except pursuant to a written instrument executed by the Company and Cowen. In the event that any one or more of the provisions contained herein, or the application thereof in any circumstance, is held invalid, illegal or unenforceable as written by a court of competent jurisdiction, then such provision shall be given full force and effect to the fullest possible extent that it is valid, legal and enforceable, and the remainder of the terms and provisions herein shall be construed as if such invalid, illegal or unenforceable term or provision was not contained herein, but only to the extent that giving effect to such provision and the remainder of the terms and provisions hereof shall be in accordance with the intent of the parties as reflected in this Agreement.
- Applicable Law; Consent to Jurisdiction. This Agreement shall be governed by, and construed in accordance with, the internal laws of the State of New York without regard to the principles of conflicts of laws. Each party hereby irrevocably submits to the non-exclusive jurisdiction of the state and federal courts sitting in the City of New York, borough of Manhattan, for the adjudication of any dispute hereunder or in connection with any transaction contemplated hereby, and hereby irrevocably waives, and agrees not to assert in any suit, action or proceeding, any claim that it is not personally subject to the jurisdiction of any such court, that such suit, action or proceeding is brought in an inconvenient forum or that the venue of such suit, action or proceeding is improper. Each party hereby irrevocably waives personal service of process and consents to process being served in any such suit, action or proceeding by mailing a copy thereof (certified or registered mail, return receipt requested) to such party at the address in effect for notices to it under this Agreement and agrees that such service shall constitute good and sufficient service of process and notice thereof. Nothing contained herein shall be deemed to limit in any way any right to serve process in any manner permitted by law.
- 17. <u>Waiver of Jury Trial</u>. The Company and Cowen each hereby irrevocably waives any right it may have to a trial by jury in respect of any claim based upon or arising out of this Agreement or any transaction contemplated hereby.
 - 18. <u>Absence of Fiduciary Relationship</u>. The Company acknowledges and agrees that:
- (a) Cowen has been retained solely to act as sales agent in connection with the sale of the Placement Shares and that no fiduciary, advisory or agency relationship between the

Company and Cowen has been created in respect of any of the transactions contemplated by this Agreement, irrespective of whether Cowen has advised or is advising the Company on other matters;

- (b) the Company is capable of evaluating and understanding and understands and accepts the terms, risks and conditions of the transactions contemplated by this Agreement;
- (c) the Company has been advised that Cowen and its affiliates are engaged in a broad range of transactions which may involve interests that differ from those of the Company and that Cowen has no obligation to disclose such interests and transactions to the Company by virtue of any fiduciary, advisory or agency relationship; and
- (d) the Company waives, to the fullest extent permitted by law, any claims it may have against Cowen, for breach of fiduciary duty or alleged breach of fiduciary duty in connection with the sale of the Placement Shares under this Agreement and agrees that Cowen shall have no liability (whether direct or indirect) to the Company in respect of such a fiduciary claim or to any person asserting a fiduciary duty claim on behalf of or in right of the Company, including stockholders, partners, employees or creditors of the Company.
- 19. <u>Counterparts</u>. This Agreement may be executed in two or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. Delivery of an executed Agreement by one party to the other may be made by Electronic Notice or facsimile transmission.
 - 20. Definitions . As used in this Agreement, the following term has the meaning set forth below:
- (a) "Applicable Time" means the date of this Agreement, each Representation Date, the date on which a Placement Notice is given, and any date on which Placement Shares are sold hereunder.
- (b) "Agent's Information" means, solely the following information in the Prospectus: the third sentence of the eighth paragraph under the caption "Plan of Distribution" in the Prospectus.

[Remainder of Page Intentionally Blank]

If the foregoing correctly sets forth the understanding between the Company and Cowen, please so indicate in the space provided below for that purpose, whereupon this letter shall constitute a binding agreement between the Company and Cowen.
Very truly yours,
COWEN AND COMPANY, LLC

By: /s/ E. James Streator, III

Name: E. James Streator, III Title: Managing Director

ACCEPTED as of the date first-above written:

INVITAE CORPORATION

By: <u>_/s/ Shelly D. Guyer _</u> Name: Shelly D. Guyer

Title: CFO

[Signature Page to Invitae Corporation Sales Agreement]

FORM OF PLACEMENT NOTICE

From:	: [•]
Cc:	[•]	
To:	[•]	
Date:			

Subject: Cowen and Company, LLC – At the Market Offering – Placement Notice

Ladies and Gentlemen:

Pursuant to the terms and subject to the conditions contained in the Sales Agreement between Invitae Corporation (the "Company"), and Cowen and Company, LLC ("Cowen") dated August 9, 2018 (the "Agreement"), I hereby request on behalf of the Company that Cowen sell up to [•] shares of the Company's common stock, \$0.0001 par value per share, at a minimum market price of \$[•] per share. Sales should begin on the date of this Notice and shall continue until [DATE] [all shares are sold].

SCHEDULE 2

Placement Notice Individuals

The Company

Sean E. George

Shelly D. Guyer

Patty Dumond

Cowen and Company, LLC

Michael Murphy, Director

SCHEDULE 3

Compensation

Cowen shall be paid compensation equal to 3.0% of the gross proceeds from the sales of Common Stock pursuant to the terms of this Agreement.

Schedule of Subsidiaries

CombiMatrix Corporation, a Delaware corporation

Exhibit 7(m)

OFFICER CERTIFICATE

The undersigned, the duly qualified and elected President and Chief Executive Officer of Invitae Corporation, a Delaware corporation (the "Company"), does hereby certify in such capacity and on behalf of the Company, pursuant to Section 7(m) of the Sales Agreement dated August 9 2018 (the "Sales Agreement") between the Company and Cowen and Company, LLC, that to the best of the knowledge of the undersigned:

- (i) The representations and warranties of the Company in Section 6 of the Sales Agreement (A) to the extent such representations and warranties are subject to qualifications and exceptions contained therein relating to materiality or Material Adverse Effect, are true and correct on and as of the date hereof with the same force and effect as if expressly made on and as of the date hereof, except for those representations and warranties that speak solely as of a specific date and which were true and correct as of such date, and (B) to the extent such representations and warranties are not subject to any qualifications or exceptions, are true and correct in all material respects as of the date hereof as if made on and as of the date hereof with the same force and effect as if expressly made on and as of the date hereof except for those representations and warranties that speak solely as of a specific date and which were true and correct as of such date; and
- (ii) The Company has complied with all agreements and satisfied all conditions on its part to be performed or satisfied pursuant to the Sales Agreement at or prior to the date hereof.

Capitalized terms used but not defined herein shall have the meanings ascribed to them in the Sales Agreement.

Dy		
Name:		
Title:		
Date:		

Bw.

LIST OF SUBSIDIARIES OF INVITAE CORPORATION

Subsidiary	Jurisdiction
Good Start Genetics, Inc.	Delaware
CombiMatrix Corporation	Delaware
CombiMatrix Molecular Diagnostics, Inc.	California
PatientCrossroads, Inc.	California
Ommdom Inc.	Delaware
Invitae Canada Inc.	British Colombia, Canada

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in the following Registration Statements:

- (1) Registration Statements on Form S-3 (Nos. 333-220053, 333-220054 and 333-226756) of Invitae Corporation and the related prospectuses
- (2) Registration Statement on Form S-4 (No. 333-220447) of Invitae Corporation, including any post-effective amendments thereto on Form S-3 or Form S-8
- (3) Registration Statement on Form S-8 (No. 333-202066) pertaining to the 2015 Stock Incentive Plan, the Employee Stock Purchase Plan, and the 2010 Stock Incentive Plan of Invitae Corporation
- (4) Registration Statements on Form S-8 (Nos. 333-216761 and 333-223455) pertaining to the 2015 Stock Incentive Plan and the Employee Stock Purchase Plan of Invitae Corporation

of our report dated February 28, 2019, with respect to the consolidated financial statements of Invitae Corporation included in this Annual Report (Form 10-K) for the year ended December 31, 2018.

/s/ Ernst & Young LLP

Redwood City, California February 28, 2019

PRINCIPAL EXECUTIVE OFFICER'S CERTIFICATION PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

- I, Sean E. George, certify that:
 - 1. I have reviewed this annual report on Form 10-K of Invitae Corporation;
- 2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report:
- 3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
- 4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
- a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
- b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
- c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
- d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
- 5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
- a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
- b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: February 28, 2019

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

Sean E. George, Ph.D.

Chief Executive Officer (Principal Executive Officer) and Director

PRINCIPAL FINANCIAL OFFICER'S CERTIFICATION PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

- I, Shelly D. Guyer, certify that:
 - 1. I have reviewed this annual report on Form 10-K of Invitae Corporation;
- 2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report:
- 3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
- 4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
- a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
- b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles:
- c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
- d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
- 5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
- a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
- b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: February 28, 2019

/s/ Shelly D. Guyer

Shelly D. Guver

Chief Financial Officer (Principal Financial and Accounting Officer)

CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the annual report of Invitae Corporation (the "Company") on Form 10-K for the year ended December 31, 2018, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned officer of the Company certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to such officer's knowledge:

- (1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: February 28, 2019

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

Sean E. George, Ph.D.
Chief Executive Officer (Principal Executive Officer) and Director

CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the annual report of Invitae Corporation (the "Company") on Form 10-K for the year ended December 31, 2018, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned officer of the Company certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to such officer's knowledge:

- (1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: February 28, 2019

/s/ Shelly D. Guyer

Shelly D. Guyer Chief Financial Officer (Principal Financial and Accounting Officer)