UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2019

OR

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

For the transition period from to

Commission File Number 001-37894

FULGENT GENETICS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**81-2621304**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
4978 Santa Anita Avenue, Suite 205 Temple City, CA	**91780**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (626) 350-0537

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	**Name of each exchange on which registered**
Common Stock, par value $0.0001 per share	The Nasdaq Stock Market (Nasdaq Global Market)

Securities registered pursuant to Section 12(g) of the Act: **None**

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. YES ☐ NO ☒

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. YES ☐ NO ☒

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. YES ☒ NO ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). YES ☒ NO ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☒
		Emerging growth company	☒

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

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). YES ☐ NO ☒

The aggregate market value of the registrant's voting and non-voting common equity held by non-affiliates as of June 30, 2019 (computed by reference to the price at which the registrant's common stock was last sold on such date, the last business day of the registrant's most recently completed second fiscal quarter, as reported by the Nasdaq Global Market) was approximately $38.8 million. For purposes of this calculation, it has been assumed that all shares of the registrant's common stock held by directors, executive officers and persons beneficially owning 10% or more of the registrant's common stock are held by affiliates; however, the treatment of these persons as affiliates for purposes of this calculation is not, and shall not be considered, a determination as to whether such persons are affiliates of the registrant for any other purpose.

As of March 1, 2020, there were 21,564,971 outstanding shares of the registrant's common stock.

DOCUMENTS INCORPORATED BY REFERENCE

Certain portions of the registrant's definitive proxy statement for its 2020 annual meeting of stockholders are incorporated by reference in Part III of this report.

TABLE OF CONTENTS

		Page
Cautionary Note Regarding Forward-Looking Statements		i
PART I		1
Item 1.	Business	1
Item 1A.	Risk Factors	18
Item 1B.	Unresolved Staff Comments	43
Item 2.	Properties	43
Item 3.	Legal Proceedings	43
Item 4.	Mine Safety Disclosures	43
PART II		44
Item 5.	Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities	44
Item 6.	Selected Financial Data	44
Item 7.	Management's Discussion and Analysis of Financial Condition and Results of Operations	45
Item 7A.	Quantitative and Qualitative Disclosures About Market Risk	56
Item 8.	Financial Statements and Supplementary Data	57
Item 9.	Changes in and Disagreements with Accountants on Accounting and Financial Disclosure	57
Item 9A.	Controls and Procedures	57
Item 9B.	Other Information	57
PART III		58
Item 10.	Directors, Executive Officers and Corporate Governance	58
Item 11.	Executive Compensation	58
Item 12.	Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters	58
Item 13.	Certain Relationships and Related Transactions, and Director Independence	58
Item 14.	Principal Accounting Fees and Services	58
PART IV		59
Item 15.	Exhibits, Financial Statement Schedules	59
Item 16.	Form 10-K Summary	59

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This report contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, or Securities Act, and Section 21E of the Securities Exchange Act of 1934, as amended, or Exchange Act. Forward-looking statements are statements other than historical facts and relate to future events or circumstances or our future performance, and they are based on our current assumptions, expectations and beliefs concerning future developments and their potential effect on our business. The words “believe,” “may,” “will,” “potentially,” “estimate,” “continue,” “anticipate,” “intend,” “could,” “would,” “project,” “plan,” “expect,” “possible,” “likely,” “probable,” and similar expressions that convey uncertainty of future events or outcomes identify forward-looking statements.

The forward-looking statements in this report include statements about, among other things:

- developments, projections and trends relating to us, our competitors and our industry;
- our strategic plans for our business;
- our operating performance, including our ability to achieve equal or higher levels of revenue, stabilize the historical fluctuations in our performance and achieve or grow profitability;
- the rate and degree of market acceptance and adoption of our tests and genetic testing generally and other anticipated trends in our industry;
- our ability to remain competitive, particularly if the genetic testing market continues to expand and competition becomes more acute;
- our ability to continue to expand the number of genes covered by our tests and introduce other improvements to our tests;
- our continued ability to offer affordable pricing for our tests, in spite of recent price degradation in our industry, and our ability to maintain the low internal costs of our business model and record acceptable margins on our sales;
- our ability to strengthen our existing base of hospital and medical institution customers by maintaining or increasing demand from these customers;
- our ability to grow and diversify our customer base, including our plans to target new institutional and individual customer groups;
- our reliance on a limited number of suppliers and ability to adapt to possible disruptions in their operations;
- our use of our sole laboratory facility and ability to adapt in the event it is damaged or rendered inoperable;
- the level of success of our efforts to increase our global presence, including strengthening relationships with existing and new international customers and establishing other types of arrangements, including our joint venture in the People’s Republic of China, or PRC, or other international joint venture or distributor relationships we may pursue;
- the impact on our business of our recent investments in building and restructuring our sales and marketing strategies and teams, and our plans for future sales and marketing efforts;
- advancements in technology by us and our competitors;
- our use of technology and ability to prevent security breaches, loss of data and other disruptions;
- our ability to effectively manage any growth we may experience, including expanding our infrastructure, developing increased efficiencies in our operations and hiring additional skilled personnel in order to support any such growth;
- developments with respect to U.S. and foreign regulations applicable to our business, and our ability to comply with these regulations;
- our ability to prevent errors in interpreting the results of our tests so as to avoid product liability and professional liability claims;
- our ability to obtain and maintain coverage and adequate reimbursement for our tests and to manage the complexity of billing and collecting such reimbursement;
- the state of the U.S. and foreign healthcare markets, including the role of governments in the healthcare industry generally and pressures or incentives to reduce healthcare costs while expanding individual benefits, as well as the impact of general uncertainty in the U.S. healthcare regulatory environment;

- our ability to attract, retain and motivate key scientific and management personnel;
- our expectations regarding our ability to obtain and maintain protection of our trade secrets and other intellectual property rights and not infringe the rights of others;
- our expectations regarding our future expense levels and our ability to appropriately forecast and plan our expenses;
- our expectations regarding our future capital requirements and our ability to obtain additional capital if and when needed; and
- the impact of the above factors and other future events on the market price of our common stock.

These forward-looking statements are subject to a number of risks and uncertainties, including, among others, those described under Item1A. “Risk Factors” and elsewhere in this report. Moreover, we operate in a competitive and rapidly evolving industry and new risks emerge from time to time. It is not possible for us to predict all of the risks we may face, nor can we assess the impact of all factors on our business or the extent to which any factor or combination of factors could cause actual results to differ from our expectations. In light of these risks and uncertainties, the forward-looking events and circumstances described in this report may not occur, and actual results could differ materially and adversely from those described in or implied by any forward-looking statements we make. Although we have based our forward-looking statements on assumptions and expectations we believe are reasonable, we cannot guarantee future results, levels of activity, performance or achievements or other future events. As a result, forward-looking statements should not be relied on or viewed as predictions of future events, and this report should be read with the understanding that our actual future results, levels of activity, performance and achievements or other future events may be materially different than what we currently expect.

The forward-looking statements in this report speak only as of the date of this document, and except as required by law, we undertake no obligation to update publicly any forward-looking statements for any reason after the date of this report to conform these statements to actual results or to changes in our expectations.

We qualify all of our forward-looking statements by this cautionary note.

* * * * * * *

We own registered or unregistered trademark rights to Fulgent®, Picture Genetics® and our company name and logo. Any other service marks, trademarks and trade names appearing in this report are the property of their respective owners. We do not use the ® or ™ symbol in each instance in which one of our trademarks appears in this report, but this should not be construed as any indication that we will not assert our rights thereto to the fullest extent under applicable law.

PART I

Item 1. Business.

Overview

Fulgent is a growing technology company offering comprehensive genetic testing and providing physicians with clinically actionable diagnostic information they can use to improve the quality of patient care. We have developed a proprietary technology platform that allows us to offer a broad and flexible test menu and continually expand and improve our proprietary genetic reference library, while maintaining accessible pricing, high accuracy and competitive turnaround times. Combining next generation sequencing, or NGS, with our technology platform, we perform full-gene sequencing with deletion/duplication analysis in single-gene tests; pre-established, multi-gene, disease-specific panels; and customized panels that can be tailored to meet specific customer needs. We believe our test menu offers more genes for testing than our competitors in today's market, which enables us to provide expansive options for test customization and clinically actionable results. After launching our first commercial genetic tests in 2013, we have expanded our test menu to include approximately 18,000 single-gene tests and more than 900 panels that collectively test for approximately 5,700 genetic conditions, including various cancers, cardiovascular diseases, neurological disorders and pediatric conditions. A cornerstone of our business is our ability to provide expansive options and flexibility for all clients' unique genetic testing needs.

Genetic testing offers the possibility of early identification of a disease or a genetic predisposition to a disease and enhanced disease treatment and prognosis. As a result, we believe widespread genetic testing could enable significant health improvements and healthcare cost reductions by providing patients and clinicians with more advanced knowledge and options for personal health management plans. Due to these and other potential benefits, genetic testing has experienced significant growth in recent years. If this growth trend continues, we believe genetic testing will become part of standard medical care and the knowledge of a person's unique genetic makeup could play a more important role in the practice of medicine. We believe this growth has been tempered in prior years, however, because many tests are prohibitively expensive, are produced through inefficient processes and often do not result in clinically actionable data. Through our technology platform, we have developed an offering that we believe addresses these industry challenges and provides a sustainable competitive advantage, both in today's genetic testing market and as we seek to implement new diagnostic tools in the future.

Our technology platform, which integrates sophisticated data comparison and suppression algorithms, adaptive learning software, advanced genetic diagnostics tools and integrated laboratory processes, allows us to offer a test menu with expansive genetic coverage. We believe the comprehensive data output and high detection rates of our tests, both made possible by this expansive genetic coverage, provide physicians with information they can readily incorporate into treatment decisions for their patients, which we refer to as clinical actionability. In addition, our technology platform facilitates our ability to perform customized genetic tests using our expansive library of genes, and we believe this flexibility increases the utility of the genetic data we produce. Further, our technology platform provides us with operating efficiencies that help lower our internal costs, which allows us to offer our tests at accessible price points. As a result, our efforts to build and continually enhance our technology platform allow us to deliver comprehensive, adaptable, clinically actionable and affordable genetic analysis while maintaining a low cost per billable test, enabling us to efficiently meet the needs of our growing base of customers. These features of our offering have resulted in rapid volume growth since our commercial launch, with 58,573 billable tests delivered in 2019, compared to 22,298 billable tests delivered in 2018, and an aggregate of over 117,774 billable tests delivered to approximately 1,100 customers from inception through December 31, 2019.

Genetic Testing Industry

Genetic testing identifies mutations in genes or chromosomal abnormalities. The results of genetic tests can be used to confirm or rule out a diagnosis of a suspected genetic condition, to predict a person's likelihood of developing a genetic condition, and to improve the selection and implementation of drug treatment programs targeting specific diseases.

The availability and accessibility of genetic testing has grown significantly in recent years, due in large part to improvements in testing technologies, particularly next generation sequencing. NGS technology, a genetic testing technique that enables millions of DNA fragments to be sequenced in parallel, has dramatically lowered the cost and improved the quality of genetic testing. As technology advances continue to drive costs down and improve testing quality, the availability and accessibility of genetic tests is expected to continue to accelerate. This expansion of testing availability and accessibility, as well as a growing and aging population; increasing overall incidence of disease; innovations in genomic medicine that enable the selection and implementation of drug treatment programs based on genetic information, or pharmacogenomics; and other factors all contribute to expectations of continued growth in the global market for genetic testing.

While adoption of genetic testing has increased in recent years, we believe widespread utilization has been tempered because of certain challenges and barriers to adoption that exist in today's market. These industry challenges include: the continued high prices of some genetic tests, in spite of declining prices in recent periods; largely inadequate reimbursement options, due to third-party payors' restrictions on reimbursement to only a narrow subset of genetic tests and certain patients who meet specific criteria; the limited scope of some genetic analysis, which may test only a small portion of the genes in the human genome and thus may fail to diagnose or identify a predisposition to a condition that is linked to mutations in untested genes; inefficient testing processes, which often involve sequential retesting from multiple different laboratories in order to obtain comprehensive results; and the cumbersome and time-consuming nature of test results interpretation, which requires significant expertise and time to review proprietary and publicly available information about individual genetic disorders, genes and variants and understand the implications of genetic mutations that are identified in a genetic test. In addition, the increased competition in our industry in recent years, due in large part to the growth of genetic testing, as well as the cost-saving initiatives on the part of government entities and other third-party payors, have resulted in downward pressure on the price for genetic analysis and interpretation, which have posed challenges to genetic testing laboratories as they seek to maintain both competitive pricing and acceptable revenue levels and margins on test sales. We have approached these competitive and operational industry challenges by building and continually advancing a multi-faceted, scalable technology platform that we believe will facilitate our ability to address many of these challenges.

Our Technology Platform

Our technology-driven approach to the challenges facing our industry has resulted in our development of an integrated technology platform featuring the following proprietary tools and processes:

Proprietary Gene Probes

Many genetic testing providers use gene probes in the sequencing process to extract and target specific genomic regions. A gene probe is a single strand of DNA or RNA that has a base sequence complementary to the base sequence of a targeted gene and that binds to this complementary base sequence when introduced during the sequencing process, thereby identifying the presence and location of the targeted gene. Many companies obtain these gene probes from third-party suppliers. We have developed technologies to design and formulate our own proprietary gene probes, which, when combined with our proprietary genetic reference library and publicly available genetic databases, support our ability to sequence DNA regions we believe laboratories using commercial probes cannot sequence and improve the detection rate of our test data. In turn, we believe this enables us to produce clinically actionable results physicians can use to improve care for their patients. In addition, our proprietary gene probes are specifically engineered to generate genetic data optimized for our software, which enables us to rapidly incorporate new genes into our test menu, develop new panels of disease-specific tests and customize tests for our customers. Moreover, once we develop a probe for a new gene, we can efficiently reproduce, validate and assure the quality of that probe under applicable guidelines and standards, which allows us to continuously and rapidly expand our library of genetic content while increasing the breadth of our test menu. Additionally, we believe our probes more effectively enrich the targeted genes to improve the quality of the sequenced data we produce.

Advanced Database Algorithms

After DNA is sequenced using all appropriate equipment and tools, the fully sequenced genes are analyzed in a process known as curation, in which every DNA sequence is aligned with a known reference sequence and differences between the DNA sequence and the reference sequence are identified. These differences, which represent potential genomic alterations, are then compared to publicly available genetic databases and proprietary genetic libraries to identify pathogenic alterations associated with disease or disease risk. We have developed proprietary data comparison and data suppression algorithms to improve and simplify this curation process by highlighting identified pathogenic mutations. Our advanced data comparison algorithms measure DNA sequences from patient specimens against genetic data available from the broader scientific community and our own proprietary reference library of genetic information, which enables us to rapidly and effectively detect pathogenic mutations. Our advanced data suppression algorithms reduce irrelevant noise in the genetic data we analyze, which improves the efficiency and speed of our data analysis and reduces the reliance upon manual review and comparison in the curation process.

Adaptive Learning Software

We have developed software that automatically incorporates the data from each completed test into our expansive genetic reference library, enabling it to continuously evolve with each set of genes we analyze. This adaptive learning software supports the continuous improvement of our proprietary gene probes and leverages the capabilities of these gene probes to improve the speed and effectiveness of curation and reporting. Our adaptive learning software also communicates with our integrated laboratory systems, which leads to increasing automation processes and other operating efficiencies.

Proprietary Laboratory Information Management Systems

We have developed proprietary laboratory information management systems that are highly integrated with our laboratory processes and adaptive learning software. These systems provide the backbone by which we efficiently manage workflow, monitor quality and ensure the fidelity of information generation and analytics for reporting to our customers. The result is a highly connected platform that allows us to process tests and information in an efficient manner. Our talented team of software engineers continuously iterates with our laboratory and customer-facing personnel to improve the efficiencies of these systems.

Our Solution

The benefits provided by our technology platform include:

Low Internal Cost per Billable Test

We have developed various proprietary technologies that improve our laboratory efficiency and reduce the costs we incur to perform our tests. This technology platform enables us to perform each test and deliver its results at a lower internal cost than many of our competitors, averaging approximately $241 per billable test delivered in 2019. This low cost per billable test allows us to maintain affordable pricing for our customers, averaging approximately $555 per billable test delivered in 2019, which we believe encourages repeat ordering from existing customers and attracts new customers. We believe our low cost per billable test could also facilitate the process for establishing coverage and reimbursement from third-party payors at a level adequate for us to achieve profitability with this payor group.

Broad and Flexible Test Menu

We currently offer single-gene tests on approximately 18,000 genes, which we believe is thousands more than most of our competitors' portfolios. Based on the results of a retrospective study of individuals with a personal or family history of cancer, described below, we believe the breadth of genes in our portfolio allows us to provide more comprehensive genetic information and improves our variant detection rate, which can increase the clinical actionability of the data we produce. The breadth of genes in our portfolio also allows us to provide a flexible and customizable test menu for our customers, which can reduce the need for sequential retesting. We offer single-gene tests on all of the genes in our portfolio, as well as deletion/duplication analysis and site-specific tests. If customers desire a broader test, we offer more than 900 pre-established, multi-gene panels that focus on specified genetic conditions. These panels can be adjusted up or down to include more or fewer genes, or customers can design their own panels to their exact specifications. We also offer clinical and full gene exome testing options. We offer our tests at different price points and turnaround times depending on the size and complexity of the test, which increases optionality for our customers. We believe the flexibility of our offering improves the efficiency and utility of the data output by our tests and decreases overall customer costs. We also offer our customers access to our highly qualified genetic counselors and laboratory experts to assist in interpreting the data we provide, which further increases the utility of our test results for ordering physicians.

The benefit of including multiple genes on a single panel was discussed in a study published in 2016 by the University of Southern California, or USC, Norris Comprehensive Cancer Center in *Cancer Genetics*. The study retrospectively evaluated 475 individuals with a personal or family history of cancer who had undergone a clinically indicated multi-gene panel test of six to 110 genes from one of the following six commercial laboratories: Myriad Genetics (n=354), Ambry Genetics (n=100), Fulgent (n=17), University of Washington Genetics Laboratory (n=2), City of Hope Molecular Diagnostics (n=1) and Baylor Genetics Laboratory (n=1). The study concluded that multi-gene panel testing increases the yield of mutations detected and adds to the capability of providing individualized cancer risk assessment. More specifically, the study reported that deleterious mutations were identified in 15.6% of patients tested on a variety of multi-gene panels, which included 8.6% of patients who would not have a mutation detected if a targeted gene-by-gene-approach had been used. The study also presented evidence that, as the number of genes on a panel increased, a higher proportion of panels identified a mutation. The Fulgent panels evaluated in the study contained over 100 genes compared to less than 30 genes in the next largest panel. Additionally, approximately 35% of our panels identified a genetic mutation, and in comparison, the test with the next highest percentage of detected mutations identified mutations in approximately 17% of its tests.

Expansive and Growing Genetic Library

Using our proprietary gene probes and testing processes, we are able to capture large amounts of genetic information from each test we perform—oftentimes more than is ordered for the test—without an incremental increase in our costs. Through this data collection process, we have developed a proprietary reference library of expansive genetic information. This reference library is automatically curated by our adaptive learning software and supplemented with manual curation by our team of highly trained professionals, which adds to and improves upon the information available in public genetic databases. As a result, our integrated technology systems allow us to leverage publicly available information from the broader scientific community with our internally developed reference library to develop what we believe is a more reliable catalog of genetic information and to accelerate, standardize and improve our curation and reporting process.

Our Genetic Tests

Our offering consists of a wide variety of tests and test types, and our customers have a high degree of choice when selecting a test from our menu. A customer may select a single-gene test of any of the genes in our portfolio or a customer may select one of our pre-established panel tests, which are designed to test particular genes and mutations within these genes that relate to a wide range of specified conditions and diseases. For example, our *Focus* and *Comprehensive* oncology panels test 30 genes and 127 genes, respectively, that relate to various cancers and our *Beacon* carrier screening panels test up to 410 genes covering over 400 inherited conditions. We can perform full-gene sequencing with deletion/duplication analysis in all of these tests. In addition, we continually seek to expand our test menu with new genes and panel tests, including our plans to expand our reproductive testing options, including preimplantation genetic testing, or PGT, and preimplantation genetic diagnosis, or PGD. We also plan to increase the genes available on our expanded Beacon carrier screening panel, which, along with preimplantation genetic testing options and newborn genetic analysis options, will round out our family planning testing options. Our test offerings also included Solid Tumor Molecular Profiling for somatic cancer testing, Rapid Whole Genome testing developed for children in neonatal intensive care units, or NICU, or pediatric intensive care units, or PICU, our Newborn Genetic Analysis panel, and a single front-line test designed to comprehensively detect ataxia-related variants and repeat expansions via sequencing. New test offerings in 2019 included Picture Genetics, a patient-initiated genetic testing offering aimed at individual consumers and which we advertise directly to consumers through a variety of methods including social media and other digital avenues.

We also offer certain research service tests, which we refer to as “sequencing as a service” and which are primarily ordered by research institutions and other similar institutional customers. In addition, we offer whole exome and clinical exome panel tests, which test all genes included in our portfolio and up to 4,701 genes located in the exome, respectively, and produce results that we combine with the individual’s unique clinical presentation and family history to enhance the clinical relevance of the results. Our whole exome and clinical exome tests also include the option for Trio testing, which involves sequencing the genes of a patient’s parents and is thought to enhance the utility of the test results. In addition, we offer whole genome testing, which determines and tests the complete DNA sequence of a genome at a single time. We also provide known mutation testing, which can be used to target familial specific or other desired mutations, as well as repeat expansion testing, which tests for a particular type of mutation known as “copy choice” DNA replication.

Importantly, all of our pre-established panels are customizable, offering customers the ability to add or remove genes at their election. To further increase test option flexibility, as well as to reduce the complexity of ordering tests, we consistently strive to innovate our pricing structure and features for our available tests. We have upgraded many our pre-set panels with additional genes. In addition, if a variant is reported in a proband for whom duo or trio testing was not originally ordered, the ordering physician is given the option of adding complementary familial known mutation testing, or FKMT, for any variant reported by Fulgent in the proband’s final report, for up to two first-degree relatives. We believe these options represent competitive pricing features that will streamline the test ordering process, give customers more flexibility with added value, and reduce barriers to trio and familial testing, which can both increase the clinical utility of genetic testing for a single proband.

Our Customers

Since inception, we have sold our tests to approximately 1,100 total customers. We consider each single billing and paying unit to be an individual customer, even though a unit may represent multiple physicians and healthcare providers ordering tests. Aggregating customers that are under common control or are affiliates, one of our customers contributed 28% of our total revenue in 2019, and one of our customers contributed 13% of our total revenue in 2018.

We have primarily sold our tests to hospitals and medical institutions. We have approached the genetic testing market with a focus on these customers in part because they are frequent and high-volume users of genetic tests. We believe this customer base provides a meaningful opportunity for further growth by acquiring additional hospital and medical institution customers and by deepening our relationships with existing customers to drive increased ordering. Additionally, collection of billings from these institutional customers is generally more attainable than from other types of customers in today's reimbursement environment, as approximately 87% of our test billings that were generated and due in 2019 were paid during that period. In addition, we believe hospitals and medical institutions are early adopters of NGS technology and could influence broader clinical acceptance of genetic testing.

We are also seeking to expand our customer base to include new customer groups. To this end, we have contracted directly with national health insurance companies to become an in-network provider and enrolled as a supplier with the Medicare program and some state Medicaid programs, in an effort to obtain coverage and reimbursement for our tests to make them accessible to more individual physicians. In addition, we are building relationships with research institutions and other similar institutional customers, national clinical laboratories, regional medical networks and various other organizations to facilitate access to physicians, practitioners and other new customer groups, including certain U.S. military and other government agencies. Generally, when we establish these new customer relationships, we agree with the applicable payor, laboratory or other customer to provide certain of our tests at negotiated rates, but, subject to limited exceptions, these relationships do not obligate any party to order our tests.

Much of our business to date has been from non-U.S. customers, with approximately $7.5 million and $8.8 million of our revenue coming from non-U.S. sources in 2019 and 2018, respectively. These customers are located in a variety of geographic markets, including Canada, where we have historically focused much of our international efforts, and other regions, such as Australia, Europe and the Middle East. In addition, we have worked with one of our large stockholders to establish a joint venture to offer genetic testing to customers in the PRC, which was formed in April 2017 and which we refer to as FF Gene Biotech. We believe FF Gene Biotech could expand our long-term opportunities to address the genetic testing market in Asia.

Our customers can generally be divided into three categories based on the party from which we receive payment for our tests: hospitals, medical and other institutions; patients and third-party payors. Hospitals, medical and other institutions are responsible for paying for the vast majority of the tests we have delivered since our inception. We bill these organizations for our tests and they are responsible for paying us directly and either billing their patients separately or obtaining reimbursement from third-party payors in connection with a patient's diagnosis related group, or DRG. A small percentage of our customers are patients, who elect to pay for tests themselves with out-of-pocket payments after their physicians have ordered our tests. Third-party payors, which consist of private health insurers, the Centers for Medicare and Medicaid Services, or CMS, and certain state Medicaid agencies, have been responsible for paying for a small number of the tests we have delivered to date; however, as we seek to expand our customer base to include more individual practitioners, we expect this category of payors would be responsible for many of the tests we deliver to these customers.

Third-party payors require us to identify the test for which we are seeking reimbursement using a Current Procedural Terminology, or CPT, code set maintained by the American Medical Association, or AMA. Where we offer a multi-gene panel and there is no CPT code for the full panel but the panel includes a gene for which the AMA has an established CPT code, we identify the test provided under that CPT code when billing a third-party payor for that test. In cases where there is not a specific CPT code, our test may be billed under a miscellaneous code for an unlisted molecular pathology procedure. Because this miscellaneous code does not describe a specific service, the insurance claim must be examined to determine what service was provided, whether the service was appropriate and medically necessary, and whether payment should be rendered, which may require a letter of medical necessity from the ordering physician. Given the changing CPT coding environment and our development of relationships with third-party payors, we expect that our practices regarding billing these payors will evolve in the future.

Sales and Marketing

Our sales and marketing force currently consists of two lean internal teams of sales and marketing experts, respectively, with deep experience in our industry, as well as a network of independent sales representatives who are knowledgeable about our tests. Historically, we have significantly relied on organic growth and word-of-mouth among our customers to generate interest in our tests, which we believe demonstrates the value of our offering. In recent periods, we have invested significant time and capital to strengthen our sales and marketing efforts, including increasing the size and restructuring the organization of our internal team, re-focusing our initiatives and strategies, and increasing the overall scope of our marketing activities.

Our sales and marketing strategy is designed to expand our brand awareness, grow our customer base and further penetrate our relationships with existing customers. We aim to achieve these objectives by providing education about the benefits and full scale of our offering, both to the medical community in general and to our targeted customer and geographic markets. We plan to expand our presence and test volume in international markets through our own direct sales team, which includes sales people dedicated to international markets, a number of independent contractor sales representatives, and, if opportunities arise, by engaging distributors or establishing other types of arrangements, such as joint ventures or other relationships, to manage or assist with sales, logistics, education and customer support in certain territories.

Our marketing activities also include targeted initiatives, including working with medical professional societies to promote awareness of the benefits of our tests and genetic testing in general, presenting at medical, scientific or industry exhibitions and conferences and pursuing or supporting scientific studies of our tests and publication of results in medical or scientific journals, such as the USC Norris Comprehensive Cancer Center study published in 2016 and discussed above and an evaluation of the clinical utility of proactive genetic screening for healthy individuals, which was presented at the 2018 American Society of Human Genetics conference. In addition, we conduct email advertising campaigns and social media awareness campaigns to existing and potential future customers when we want to send a specific message about our company and our brand, including, for instance, when we launch new tests or new test options and when we add new genes to our test menu. In addition, in 2019, we launched Picture Genetics, a patient-initiated genetic testing offering aimed at individual consumers and which we advertise directly to consumers through a variety of methods including social media and other digital avenues.

Our sales and marketing strategy is also focused on offering differentiated and highly available customer service resources, which we believe is an important factor in maintaining and deepening our customer relationships. Genetic tests are highly complex by nature and we recognize that our customers may want to discuss with us available testing options, specimen collection requirements, expected turnaround times, the cost of our tests and the clinical reports we produce. As a result, we offer comprehensive customer service designed to enable efficient ordering and increase the accessibility of our clinical reports, including customer access to our licensed and qualified laboratory directors who review and approve each report we produce.

Our sales and marketing teams also explore strategic collaboration opportunities with various research and medical institutions. New partnerships formed in 2019 include partnering with the Parkinson’s Foundation on a new genetic testing initiative for individuals living with Parkinson’s Disease. Genetic testing can help determine whether an individual’s genetic makeup indicates a potential genetic cause for Parkinson’s disease. This knowledge can assist patients and physicians in better understanding each case and can help to identify whether a patient qualifies for enrollment in certain clinical trials. Participants will also be able to better understand their genetic test results through free genetic counseling provided by Indiana University and on-site clinicians. Raw data accumulated through the initiative will be captured for future research by scientists to develop improved treatments and precision medicine options for Parkinson’s Disease.

Our Suppliers

We rely on a limited number of suppliers for certain laboratory substances used in the chemical reactions incorporated into our processes, which we refer to as reagents, as well as for the sequencers and various other equipment and materials we use in our laboratory operations. In particular, we rely on Illumina, Inc. as the sole supplier of the next generation sequencers and associated reagents we use to perform our genetic tests and as the sole provider of maintenance and repair services for these sequencers. Our laboratory operations would be interrupted if we encounter delays or difficulties securing these reagents, sequencers, other equipment or materials or maintenance and repair services, which could occur for a variety of reasons, including if we need a replacement or temporary substitute for any of our limited or sole suppliers and are not able to locate and make arrangements with an acceptable replacement or temporary substitute.

Competition

Our competitors include dozens of companies focused on molecular genetic testing services, including specialty and reference laboratories that offer traditional single-gene 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 laboratories. In addition, other established and emerging healthcare, information technology and service companies may develop and sell competitive tests, which may include informatics, analysis, integrated genetic tools and services for health and wellness.

Additionally, participants in closely related markets, such as prenatal testing and clinical trial or companion diagnostic testing, could converge on offerings that are competitive with the type of tests we perform. Instances where potential competitors are aligned with key suppliers or are themselves suppliers could provide these potential competitors with significant advantages. Further, hospitals, research institutions and eventually individual physicians and other practitioners 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, and associated decreases in the cost of, equipment, reagents and other materials and databases and genetic data interpretation services may enable broader direct participation in genetic testing and analysis and drive down the use of third-party testing companies such as ours. Additionally, cost decreases and increased direct participation, as well as cost-saving initiatives on the part of government entities and other third-party payors, could intensify the downward pressure on the price for genetic analysis and interpretation generally. Moreover, the biotechnology and genetic testing fields 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 genetic content;
- flexibility of test customization;
- price of tests;
- quality of results, including their reliability, accuracy and clinical actionability;
- accessibility of results;
- coverage and reimbursement arrangements with third-party payors;
- turnaround time;
- customer service;
- convenience of testing; and
- brand recognition.

We believe we compare favorably with our competitors on the basis of these factors. However, many of our existing and potential future competitors have longer operating histories, larger customer bases, more expansive brand recognition and deeper market penetration, substantially greater financial, technological and research and development resources and selling and marketing capabilities and considerably more experience dealing with third-party payors. As a result, they may be able to respond more quickly to changes in customer requirements or preferences, develop faster and better advancements for their technologies and tests, create and implement more successful strategies for the promotion and sale of their tests, obtain more favorable results from third-party payors regarding coverage and reimbursement for their offerings, adopt more aggressive pricing policies for their tests, secure supplies from vendors on more favorable terms or devote substantially more resources to infrastructure and systems development. 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 NGS for clinical diagnosis and preventative care increases. Further, companies or governments that effectively control access to genetic testing through umbrella contracts or regional preferences could promote our competitors or prevent us from performing certain tests in certain territories. We may not be able to compete effectively against these organizations.

Research and Development

We have assembled a highly-qualified team with expertise in a number of fields important to our business, such as bioinformatics, genetics, software engineering, laboratory management and sales and marketing. We rely on this team to conduct all of our research and development activities, including efforts to develop and curate our expansive library of genetic information and further expand our technology platform.

Intellectual Property

We rely on a combination of registered and unregistered intellectual property rights, including trade secrets, trademarks and customary contractual protections, to protect our core technology and intellectual property.

Trade Secrets

We rely on trade secrets, including unpatented know-how, technology and other proprietary information, to maintain and develop the competitive position afforded by many of our laboratory, analytic and business practices. For example, significant elements of our genetic tests and our testing procedures, including aspects of specimen preparation, our bioinformatics algorithms and related processes and our adaptive learning software, are based on unpatented trade secrets and know-how. We try to protect trade secrets and know-how by taking reasonable steps to keep them confidential, including entering into nondisclosure and confidentiality agreements with parties who have access to them, such as our employees and certain third parties, and entering into invention 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.

Trademarks

We own registered and unregistered trademark and service mark rights under applicable U.S. and foreign law to distinguish and/or protect our brand, including our company name and logo.

Regulation

CLIA

As a clinical laboratory, we are required to hold certain federal licenses, certifications and permits to conduct our business. In 1988, Congress passed the Clinical Laboratory Improvement Amendments of 1988, or CLIA, which establishes quality standards for all laboratory testing designed to ensure the accuracy, reliability and timeliness of patient test results. Our laboratory is CLIA-certified and accredited by the College of American Pathologists, or CAP, a CMS-approved accrediting organization.

Under CLIA, a laboratory is any facility that performs laboratory testing on specimens derived from humans for the purpose of providing information for the diagnosis, prevention or treatment of disease or the impairment or assessment of health. CLIA requires that we hold a certificate applicable to the type of laboratory examinations we perform and that we comply with various standards with respect to personnel qualifications, facility administration, proficiency testing, quality control and assurance and inspections. Laboratories must register and list their tests with CMS, the agency that oversees CLIA, and CLIA compliance and certification is a prerequisite to be eligible to bill government payors and many private payors for our tests.

We are subject to survey and inspection every two years to assess compliance with CLIA's program standards, and we may be subject to additional unannounced inspections. Our CLIA certification was last renewed October 23, 2019 and is valid for two years. If our clinical reference laboratory is found to be out of compliance with CLIA requirements at any of these inspections, we may be subject to sanctions such as suspension, limitation or revocation of our CLIA certificate, a directed plan of correction, on-site monitoring, civil monetary penalties, civil injunctive suits, criminal penalties, exclusion from the Medicare and Medicaid programs and significant adverse publicity.

In addition, we elect to participate in the accreditation program of CAP. CMS has deemed CAP standards to be equally or more stringent than CLIA regulations and has approved CAP as a recognized accrediting organization. Inspection by CAP is performed in lieu of inspection by CMS for CAP-accredited laboratories. Because we are accredited by the CAP Laboratory Accreditation Program, we are deemed to also comply with CLIA.

State and Foreign Laboratory Licensure

Our laboratory is located in Temple City, California. As a result, we are required to maintain a license to conduct testing in the State of California. California laws establish standards for day-to-day operations of our laboratory, including with respect to the training and skills required of personnel, quality control and proficiency testing requirements. If our clinical reference laboratory is out of compliance with California standards, the State of California Department of Public Health, or CA DPH, may suspend, restrict or revoke our license to operate our clinical reference laboratory, assess substantial civil money penalties or impose specific corrective action plans. Any such actions could materially affect our business. We maintain a current license in good standing with CA DPH.

Additionally, several states require the licensure of out-of-state laboratories that accept specimens from those states and/or receive specimens from laboratories in those states. Our laboratory holds the required out-of-state laboratory licenses to perform testing on specimens from Maryland, Rhode Island and Pennsylvania. In addition to having a laboratory license in New York, our laboratory is required to obtain approval on a test-specific basis by the New York State Department of Health, or DOH, before specific testing is performed on specimens from New York. In 2019, we obtained a state laboratory permit for our Temple City laboratory from the New York DOH. The New York state laboratory laws, regulations and rules are equal to or more stringent than the CLIA regulations and establish standards for the operation of a clinical laboratory and performance of test services, including education and experience requirements for laboratory directors and personnel; physical requirements of a laboratory facility; equipment validations; and quality management practices. The laboratory director must also maintain a Certificate of Qualification issued by New York's DOH in permitted categories.

Other states may adopt similar licensure requirements in the future, which could require us to modify, delay or discontinue our operations in such jurisdictions. 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 to comply with such requirements.

We are also subject to regulation in foreign jurisdictions, which we expect will increase as we seek to expand international utilization of our tests or if jurisdictions in which we pursue operations adopt new or modified licensure requirements. Foreign licensure requirements could require review and modification of our tests in order to offer them in certain jurisdictions or could impose other limitations, such as restrictions on the transport of human blood or other tissue necessary for us to perform our tests that may limit our ability to make our tests available outside of the United States on a broad scale.

FDA

Pursuant to its authority under the Federal Food, Drug, and Cosmetic Act, or FDC Act, the U.S. Food and Drug Administration, or FDA, has jurisdiction over medical devices, which are defined to include, among other things, in vitro diagnostic products, or IVDs, used for clinical purposes. The tests that we offer may be considered IVDs and as such, medical devices. The laws and regulations governing the marketing of IVDs are evolving, extremely complex, and in many instances, there are no significant regulatory or judicial interpretations of these laws and regulations. The FDA regulates, among other things, the research, testing, manufacturing, safety, labeling, storage, recordkeeping, premarket clearance or approval, marketing and promotion and sales and distribution of medical devices in the United States to ensure that medical products distributed domestically are safe and effective for their intended uses. In addition, the FDA regulates the import and export of medical devices.

The FDC Act classifies medical devices into one of three categories based on the risks associated with the device and the level of control necessary to provide reasonable assurance of safety and effectiveness. Devices deemed by the FDA to pose the greatest risk, such as life-sustaining, life-supporting or implantable devices or devices deemed not substantially equivalent to a previously 510(k) cleared device, are categorized as Class III. These devices typically require submission and approval of a premarket approval application, or PMA. Devices deemed to pose lower risk are categorized as either Class I or II, which requires the manufacturer to submit to the FDA a 510(k) premarket notification submission requesting clearance of the device for commercial distribution in the United States. Some low-risk devices are exempted from this requirement. When a 510(k) premarket notification submission is required, the manufacturer must submit to the FDA a premarket notification submission demonstrating that the device is "substantially equivalent" to: (i) a device that was legally marketed prior to May 28, 1976, for which PMA approval is not required, (ii) a legally marketed device that has been reclassified from Class III to Class II or Class I, or (iii) another legally marketed, similar device that has been cleared through the 510(k) clearance process.

After the FDA permits a device to enter commercial distribution, numerous regulatory requirements apply. These include: the Quality System Regulation, which requires manufacturers to follow elaborate design, testing, control, documentation and other quality assurance procedures during the manufacturing process; labeling regulations; the FDA's general prohibition against promoting products for unapproved or "off-label" uses; and the Medical Device Reporting regulation, which requires that manufacturers report to the FDA if their device may have caused or contributed to a death or serious injury or malfunctioned in a way that would likely cause or contribute to a death or serious injury if it were to recur. The FDA has broad post-market and regulatory and enforcement powers. Failure to comply with the applicable U.S. medical device regulatory requirements could result in, among other things, warning letters, fines, injunctions, consent decrees, civil penalties, repairs, replacements, refunds, recalls or seizures of products, total or partial suspension of production, the FDA's refusal to grant future premarket clearances or approvals, withdrawals or suspensions of current product applications, and criminal prosecution.

Although the FDA has statutory authority to assure that medical devices, including IVDs, are safe and effective for their intended uses, the FDA has historically exercised its enforcement discretion and not enforced applicable provisions of the FDC Act and regulations with respect to laboratory developed tests, or LDTs, which are a subset of IVDs that are intended for clinical use and designed, manufactured and used within a single laboratory. We believe our tests fall within the definition of an LDT. As a result, we believe our diagnostic tests are not currently subject to the FDA's enforcement of its medical device regulations and the applicable FDC Act provisions.

Even though we commercialize our tests as LDTs, our tests may in the future become subject to more onerous regulation by the FDA. In October 2014, the FDA issued a draft Framework Guidance and Notification Guidance for comment following notice to Congress that it would be doing so. The Framework Guidance stated that the FDA intends to modify its policy of enforcement discretion with respect to LDTs in a risk-based manner consistent with the existing classification of medical devices. The draft guidances resulted in a large number of public comments from interested parties. The FDA subsequently announced in November 2016 that it would not issue a final guidance to allow for further public discussion on an appropriate LDT oversight approach and to give congressional committees the opportunity to develop a legislative solution. In January 2017, the FDA published a Discussion Paper on Laboratory Developed Tests, which provided a synthesis of the feedback the agency had received and which outlined, as part of the synthesis, a new possible approach to LDT oversight. The Discussion Paper noted that the synthesis does not represent the formal position of the FDA, nor is it enforceable. The FDA has not issued any proposed rules, revised proposals, or draft guidance relating to LDTs since January 2017.

In December 2018, members of Congress released a discussion draft of a possible bill to regulate in vitro clinical tests including LDTs, which incorporated suggestions from the FDA and other industry stakeholders. The new bill is called the Verifying Accurate, Leading-edge IVCT Development (VALID) Act and would codify into law the term “in vitro clinical test” (IVCT), a new medical product category separate from medical devices and that includes products currently regulated as IVDs as well as LDTs. One especially notable feature in the discussion draft of the VALID Act is a precertification program that would enable a IVCT developer to be certified by FDA (or potentially by an FDA-accredited body) as having sufficient skill at developing IVCTs as to not require premarket review for each individual test developed and for which marketing is sought. This program would significantly streamline IVCT review but likely would take years to establish following congressional enactment of the VALID Act, the timing of which is subject to the often-unpredictable political process. Moreover, to date the VALID Act has not been formally introduced in Congress and, even if passed by Congress, it would need to be signed by the President in order to become law. If and when the FDA finalizes its position on regulation of LDTs through formal guidance, or new legislation is passed, or if the FDA disagrees with our assessment that our tests fall within the definition of an LDT, we could for the first time be subject to enforcement of regulatory requirements such as registration and listing requirements, medical device reporting requirements and quality control requirements (although the possible approach outlined in the Discussion Paper – as well as in the draft VALID Act – would exempt certain previously marketed LDTs from many requirements, in other words, “grandfather” many existing LDTs). Any new FDA enforcement policies affecting LDTs may result in increased regulatory burdens on our ability to continue marketing our tests and to develop and introduce new tests in the future. Additionally, if and when the FDA begins to actively enforce its premarket submission regulations with respect to LDTs generally or our tests in particular, we may be required to obtain premarket clearance for our tests under Section 510(k) of the FDC Act or approval of a PMA. The process for submitting a 510(k) premarket notification and receiving FDA clearance usually takes from three to 12 months, but it can take significantly longer and clearance is never guaranteed. The process for submitting and obtaining FDA approval of a PMA generally takes from one to three years or even longer and approval is not guaranteed. PMA approval typically requires extensive clinical data and can be significantly longer, more expensive and more uncertain than the 510(k) clearance process. If premarket review is required for some or all of our tests, the FDA could require that we stop selling our products pending clearance or approval and conduct clinical testing prior to making submissions to FDA to obtain premarket clearance or approval. The FDA could also require that we label our tests as investigational or limit the labeling claims we are permitted to make.

While there is also the risk that the FDA does not consider our tests to be LDTs, the draft Framework Guidance stated that, in the interest of ensuring continuity in the testing market and avoiding disruption of access to tests marketed as LDTs that do not meet the FDA’s definition of LDTs, the FDA intends to apply the same risk-based framework described in the Framework Guidance to any IVD that is offered as an LDT by a CLIA-certified laboratory. We would expect the FDA to take the same or similar approach in any new program for the regulation of LDTs. If Congress passes legislation regulating LDTs, then the terms of such legislation would control, subject to FDA’s administration of any such new law.

Additionally, the FDA has recently solicited public input and published two draft guidance documents relating to FDA oversight of NGS-based tests. The two draft guidance documents on NGS-based tests describe the FDA’s current thinking and proposed approach regarding the possible use of FDA-recognized standards to support analytical validity, and public human genetic variant databases to support clinical validity, of these tests. The drafts were published in final form in April 2018. While it appears that the FDA is striving to provide a flexible pathway to device clearance or approval for manufacturers seeking to market NGS-based tests, it is unknown how the FDA may regulate such tests in the future and what testing and data may be required to support such clearance or approval. If premarket review is required for some or all of our tests and the FDA requires more extensive testing such as clinical trials, for example, we could experience significantly increased development costs and delay.

The FDA enforces its medical device requirements by various means, including inspection and market surveillance. If the FDA finds a violation, it can institute a wide variety of enforcement actions, ranging from an Untitled Letter or Warning Letter to more severe sanctions, such as: fines, injunctions and civil penalties; recall or seizure of products; operating restrictions, partial suspension or total shutdown of production; and criminal prosecution.

Legislative proposals addressing the FDA's oversight of LDTs have been introduced by Congress in the past and we expect that new legislative proposals may be introduced from time to time in the future. The likelihood that Congress will pass such legislation and the extent to which such legislation may affect the FDA's plans to enforce its medical device requirements with respect to certain LDTs is difficult to predict at this time. If the FDA ultimately lifts its policy of enforcement discretion over LDTs and begins to enforce its medical device requirements with respect to LDTs, our tests may be subject to additional regulatory requirements imposed by the FDA, the nature and extent of which would depend upon applicable final guidance or regulation by the FDA or instruction by Congress. Failure to comply with any applicable FDA requirements could 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.

Advertising of Laboratory Services or LDTs

Whether regulated by FDA as a Class I or Class II device or subject to FDA's enforcement discretion as an LDT, our advertising for laboratory services and genetic tests is subject to federal truth-in-advertising laws enforced by the Federal Trade Commission, or FTC, as well as comparable state consumer protection laws. Under the Federal Trade Commission Act ("FTC Act"), the FTC is empowered, among other things, to (a) prevent unfair methods of competition and unfair or deceptive acts or practices in or affecting commerce; (b) seek monetary redress and other relief for conduct injurious to consumers; and (c) gather and compile information and conduct investigations relating to the organization, business, practices, and management of entities engaged in commerce. The FTC has very broad enforcement authority, and failure to abide by the substantive requirements of the FTC Act and other consumer protection laws can result in administrative or judicial penalties, including civil penalties, injunctions affecting the manner in which we would be able to market services or products in the future, or criminal prosecution.

Reimbursement

CPT Codes

We bill third-party payors, both commercial and government, using Current Procedural Terminology (CPT) codes, which are published by the American Medical Association (AMA). CPT codes in their current form are not readily applied to many of the genetic tests we conduct. For example, for many of our multi-gene panels, there may not be an appropriate CPT code for any of the genes in a panel, in which case our test would be billed under a miscellaneous code for an unlisted molecular pathology procedure. Many third-party payors do not have set reimbursement fee rates for this miscellaneous code. Prior to starting a test, we negotiate the reimbursement rate with the payor if the benefits investigation has determined the test to be medically necessary and the payor has issued prior authorization. When the test results are delivered, after we file the claim, we may also need to resubmit documentation or appeal a denial, which can cause delay in the reimbursement of the claim.

In September 2014, the AMA published new CPT codes for genomic sequencing procedures that are effective for dates of service on or after January 1, 2015. These include genomic sequencing procedure codes for certain multi-gene panel tests. 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 using the gap-fill process. Under the gap-fill process, local Medicare Administrative Contractors, or MACs, establish rates for the codes that each MAC believes meet the criteria for Medicare coverage and considering laboratory charges and discounts to charges, resources, amounts paid by other third-party payors 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 published codes for genomic sequencing procedures. For the codes for which local gap-filled rates were established in 2015, a national limitation amount for Medicare was established for 2016. For the codes for which local gap-filled rates were not established in 2015, associated procedures are priced by the local MACs in 2016 if 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, which may not be adequate for all of the procedures covered by the applicable codes, including our tests to the extent we are required to report them under these codes.

PAMA

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 priced and paid under Medicare. On June 23, 2016, CMS published the final rule implementing the reporting and rate-setting requirements. Under PAMA, laboratories that receive the majority of their Medicare revenue from payments made under the CLFS or the Physician Fee Schedule are required to report to CMS, beginning in 2017 and every three years thereafter (or annually for an advanced diagnostic laboratory test, or ADLT), private payor payment rates and volumes for clinical diagnostic laboratory tests, or CDLTs. Laboratories that fail to report the required payment information may be subject to substantial civil monetary penalties. We do not believe that any of our tests meet the current definition of ADLTs. We therefore report private payor rates for our tests every three years.

As required under PAMA, CMS uses the data reported by laboratories to develop Medicare payment rates for laboratory tests equal to the volume-weighted median of the private payor payment rates. For tests furnished on or after January 1, 2018, Medicare payments for CDLTs are based upon reported private payor rates. For a CDLT that is assigned a new or substantially revised CPT code, the initial payment rate is assigned using the gap-fill methodology, as under prior law.

On December 20, 2019, the President signed the Further Consolidated Appropriations Act, which included the Laboratory Access for Beneficiaries Act (LAB Act). The LAB Act delays by one year the reporting of payment data under PAMA for CDLTs that are not ADLTs. CDLT data for the collection period of January 1, 2019 through June 30, 2019, which was supposed to be reported in 2020, must now be reported between January 1, 2021 and March 31, 2021. Data reporting will then resume on a three-year cycle, beginning in 2024.

Under PAMA, as amended by the LAB Act, any reduction to a particular payment rate resulting from the new methodology is limited to 10% per test per year in 2020 and to 15% per test per year in each of the years 2021 through 2023.

Privacy and Security Laws

HIPAA and HITECH

Under the Administrative Simplification provisions of the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, as amended by the federal Health Information Technology for Economic and Clinical Health Act, or HITECH, the U.S. Department of Health and Human Services, or HHS, has 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, or PHI, used or disclosed by healthcare providers, health plans, and healthcare clearinghouses that conduct certain healthcare transactions electronically, known as covered entities. The following 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 of HIPAA and HITECH protect medical records and other PHI by limiting their use and release, giving patients a variety of rights, including the right to access their medical records and limiting most disclosures of health information to the minimum amount necessary to accomplish an intended purpose. HIPAA also requires covered entities to enter into business associate agreements to obtain a written assurance of compliance with HIPAA from individuals or organizations who provide services to covered entities involving the use or disclosure of PHI, or also known as business associates. As a general rule, a covered entity or business associate may not use or disclose PHI except as permitted under the privacy regulations of HIPAA and HITECH.

Covered entities must also comply with the security regulations of HIPAA and HITECH, which establish requirements for safeguarding the confidentiality, integrity and availability of electronic PHI. The HIPAA security regulations require the implementation of administrative, physical and technical safeguards and the adoption of written security policies and procedures.

In addition, HITECH established, among other things, certain breach notification requirements with which covered entities must comply. In particular, a covered entity must report breaches of PHI that has not been encrypted or otherwise secured in accordance with guidance from the Secretary of HHS, or the Secretary. Required breach notices must be made as soon as is reasonably practicable, but no later than sixty days following discovery of the breach. Reports must be made to affected individuals, the Secretary, and depending on the size of the breach, the local and national media. Covered entities are also subject to audit under HHS's HITECH-mandated audit program and may be investigated in connection with a privacy or data security complaint.

There are significant civil and criminal fines and other penalties that may be imposed for violating HIPAA. A covered entity or business associate is liable for civil monetary 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. Penalties for failure to comply with a requirement of HIPAA and HITECH vary significantly depending on the failure and include civil monetary penalties of up to $1.5 million per violation of the same requirement per calendar year. A single breach incident can violate multiple requirements, resulting in potential penalties in excess of $1.5 million. Additionally, 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 of imprisonment. These 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. Covered entities are also subject to enforcement by state attorneys general who were given authority to enforce HIPAA under HITECH. Further, 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.

The HIPAA privacy, security, and breach notification regulations establish a uniform federal "floor" but 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 PHI or insofar as such state laws apply to personal information that is broader in scope than PHI as defined under HIPAA. The compliance requirements of these laws, including additional breach reporting requirements, and the penalties for violation vary widely and new privacy and security laws in this area are evolving. For example, several states, such as California, have implemented comprehensive privacy laws and regulations. The California Confidentiality of Medical Information Act imposes restrictive requirements regulating the use and disclosure of health information and other personally identifiable information. In addition to fines and penalties imposed upon violators, some of these state laws also afford private rights of action to individuals who believe their personal information has been misused. California's patient privacy laws, for example, provide for penalties of up to $250,000 and permit injured parties to sue for damages. In addition to the California Confidentiality of Medical Information Act, California recently adopted the California Consumer Privacy Act of 2018, or CCPA, which came into effect on January 1, 2020. The CCPA establishes a new privacy framework for covered businesses by creating an expanded definition of personal information, establishing new data privacy rights for consumers in the State of California, imposing special rules on the collection of consumer data from minors, and creating a new and potentially severe statutory damages framework for violations of the CCPA and for businesses that fail to implement reasonable security procedures and practices to prevent data breaches. There is uncertainty surrounding the application of the CCPA to parts of our business, and amendments to the law before its effective data may have impact on operations. In addition to the CCPA, other states are introducing similar legislation which will impact compliance obligations and increase complexity and cost of compliance.

Many states, such as Massachusetts, have also implemented genetic testing and privacy laws imposing specific patient consent requirements and requirements for protecting test results. The interplay of federal and state laws may be subject to varying interpretations by courts and government agencies, creating complex compliance issues for us and our clients and potentially exposing us to additional expense, adverse publicity, and liability. Further, as regulatory focus on privacy issues continues to increase and laws and regulations concerning the protection of personal information expand and become more complex, these potential risks to our business could intensify. In addition, the interpretation and application of consumer, health-related, and data protection laws are often uncertain, contradictory, and in flux. The applicability and requirements of these laws and penalties for violations vary widely. Failure to maintain compliance, or changes in state or federal laws regarding privacy or security, could result in civil and/or criminal penalties and could have a material adverse effect on our business.

Numerous other federal, state and foreign laws, including consumer protection laws and regulations, govern the collection, dissemination, use, access to, confidentiality and security of patient health information. In addition, Congress and some states are considering new laws and regulations that further protect the privacy and security of medical records or medical information. With the recent increase in publicity regarding data breaches resulting in improper dissemination of consumer information, all 50 states have passed laws regulating the actions that a business must take if it experiences a data breach, as defined by state law, including prompt disclosure within a specified amount of time to affected individuals. Congress has also been considering similar federal legislation relating to data privacy and data protection. The Federal Trade Commission and states' Attorneys General have also brought enforcement actions and prosecuted some data breach cases as unfair and/or deceptive acts or practices under the FTC Act and comparable state laws. In addition to data breach notification laws, some states have enacted statutes and rules requiring businesses to reasonably protect certain types of personal information they hold or to otherwise comply with certain specified data security requirements for personal information. We intend to continue to comprehensively protect all personal information and to comply with all applicable laws regarding the protection of such information.

Foreign Laws

We are also subject to foreign privacy laws in the jurisdictions in which we sell our tests. The interpretation, application and interplay of consumer and health-related data protection laws in the United States, Europe and elsewhere are often uncertain, contradictory and in flux. For example, the new General Data Protection Regulation, or GDPR, and Cybersecurity Directive have been enacted in the European Union and became effective in May 2018. These texts introduced many changes to privacy and security in the European Union, including stricter rules on consent and security duties for critical industries, including for the health sector. The interpretation of some rules is still unclear, and some requirements may be completed by national legislation. This makes it difficult to assess the impact of these new data protection laws on our business at this time. More generally, foreign laws and interpretations governing data privacy and security are constantly evolving and it is possible that laws may be interpreted and applied in a manner that is inconsistent with our current practices, in which case we could be subject to government-imposed fines or orders requiring that we change our practices. These fines can be very high. For instance, the GDPR introduces fines of up to approximately $22 million or 4% of a group's worldwide annual turnover for certain infringements. In addition, privacy regulations differ widely from country to country.

In many activities, including the conduct of clinical trials, we are subject to laws and regulations governing data privacy and the protection of health-related and other personal information. These laws and regulations govern our processing of personal data, including the collection, access, use, analysis, modification, storage, transfer, security breach notification, destruction and disposal of personal data. We must comply with laws and regulations associated with the international transfer of personal data based on the location in which the personal data originates and the location in which it is processed.

If we or our vendors fail to comply with applicable data privacy laws, or if the legal mechanisms we or our vendors rely upon to allow for the transfer of personal data from the European Union to the United States (or other countries not considered by the European Commission to provide an adequate level of data protection) are not considered adequate, we could be subject to government enforcement actions and significant penalties against us, and our business could be adversely impacted if our ability to transfer personal data outside of the European Union is restricted, which could adversely impact our operating results. The GDPR has increased our responsibility and potential liability in relation to European Union personal data that we process, and we may be required to put in place additional mechanisms to ensure compliance with the GDPR. However, our ongoing efforts related to compliance with the GDPR may not be successful and could increase our cost of doing business. In addition, data protection authorities of the different European Union member states may interpret the GDPR, and guidance on implementation and compliance practices are often updated or otherwise revised, which adds to the complexity of processing personal data in the European Union. In addition to the GDPR, other countries have enacted data protection legislation which increase the complexity of doing international business and transferring sensitive personal information from those countries to the United States.

The privacy and security of personally identifiable information stored, maintained, received or transmitted, including electronically, subject to significant regulation in the United States and abroad. While we strive to comply with all applicable privacy and security laws and regulations, legal standards for privacy continue to evolve and any failure or perceived failure to comply may result in proceedings or actions against us by government entities or others, or could cause reputational harm, which could have a material adverse effect on our business.

Fraud and Abuse Laws

In the United States, we must comply with various fraud and abuse laws, and we are subject to regulation by various federal, state and local authorities, including CMS, other divisions of HHS (such as the Office of Inspector General), the U.S. Department of Justice, individual U.S. Attorney's Offices within the Department of Justice and state and local governments. We also may be subject to foreign fraud and abuse laws.

Anti-Kickback and Fraud Statutes

In the United States, the federal Anti-Kickback Statute prohibits, among other things, knowingly and willfully offering, paying, soliciting or receiving remuneration, directly or indirectly, overtly or covertly, in cash or in kind, in order to induce or in return for the referral of an individual for the furnishing of, or the recommending or arranging for the furnishing of, purchasing, leasing, ordering or arranging for or recommending purchasing, leasing or ordering of any good, facility, service or item for which payment may be made in whole or in part by a federal healthcare program. Courts have stated that a financial arrangement may violate the Anti-Kickback Statute if any one purpose of the arrangement is to encourage patient referrals or other federal healthcare program business, regardless of whether there are other legitimate purposes for the arrangement. The definition of "remuneration" has been broadly interpreted to include anything of value, including gifts, discounts, credit arrangements, payments of cash, consulting fees, waivers of co-payments, ownership interests and providing anything at less than its fair market value. The Anti-Kickback Statute is broad and may technically prohibit many innocuous or beneficial arrangements within the healthcare industry, although it does contain several exceptions. HHS has issued a series of regulatory "safe harbors" setting forth certain provisions that, if met, will immunize the parties to the arrangement from prosecution under the Anti-Kickback Statute. Although full compliance with the statutory exceptions or regulatory safe harbors ensures against prosecution under the federal Anti-Kickback Statute, the failure of a transaction or arrangement to fit within a specific statutory exception or regulatory safe harbor does not necessarily mean that the transaction or arrangement is illegal or that prosecution under the Anti-Kickback Statute will be pursued. Furthermore, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. Penalties for violations of the Anti-Kickback Statute are severe and include imprisonment, criminal fines, civil monetary penalties and exclusion from participation in federal healthcare programs. In addition, a violation of the federal Anti-Kickback Statute can serve as a basis of liability under the federal False Claims Act (described below). Many states also have anti-kickback statutes, some of which may apply to items or services reimbursed by any third-party payor, including commercial insurers.

In addition, in October 2018, the Eliminating Kickbacks in Recovery Act of 2018 (EKRA) was enacted as part of the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (SUPPORT Act). EKRA is an all-payer anti-kickback law that makes it a criminal offense to pay any remuneration to induce referrals to, or in exchange for, patients using the services of a recovery home, a substance use clinical treatment facility, or laboratory. However, unlike the federal Anti-Kickback Statute, EKRA is not limited to services covered by federal or state health care programs but applies more broadly to services covered by "health care benefit programs," including commercial insurers. Although it appears that EKRA was intended to

reach patient brokering and similar arrangements to induce patronage of substance use recovery and treatment, the language in EKRA is broadly written. Further, certain of EKRA's exceptions, such as the exception applicable to relationships with employees that effectively prohibits incentive compensation, are inconsistent with the federal anti-kickback statute and regulations, which permit payment of employee incentive compensation, a practice that is common in the industry. Significantly, EKRA permits the U.S. Department of Justice to issue regulations clarifying EKRA's exceptions or adding additional exceptions, but such regulations have not yet been issued. Laboratory industry stakeholders are reportedly seeking clarification regarding EKRA's scope and/or amendments to its language. Because EKRA is a new law, there is no agency guidance or court precedent to indicate how and to what extent it will be applied and enforced. We cannot assure you that our relationships with physicians, sales representatives, hospitals, customers, or any other party will not be subject to scrutiny or will survive regulatory challenge under such laws.

There are also U.S. federal laws related to healthcare fraud and false statements relating to healthcare matters. The healthcare fraud statute prohibits, among other things, knowingly and willfully executing a scheme to defraud any healthcare benefit program, including private payors. A violation of this statute is a felony and may result in fines, imprisonment or exclusion from government payor programs such as the Medicare and Medicaid programs. The false statements statute prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. A violation of this statute is also a felony and may result in fines, imprisonment or exclusion from government payor programs.

False Claims Act

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 to the federal government. The qui tam provisions of the False Claims Act allow a private individual to bring an action under the False Claims Act on behalf of the federal government and permit such an individual to share in any amounts paid by the entity to the government in fines or settlement. In addition, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, which we collectively refer to as the Affordable Care Act, establishes a requirement for providers and suppliers to report and return any overpayments received from government payors under the Medicare and Medicaid programs within 60 days of identification. Failure to identify and return such overpayments exposes the provider or supplier to False Claims Act liability. When an entity is determined to have violated the False Claims Act, it may be required to pay up to three times the actual damages sustained by the government, plus civil penalties ranging from $5,500 to $11,000 for each false claim, as set by statute. However, the civil penalty amounts are adjusted annually for inflation. For civil penalties assessed after January 29, 2018, whose associated violations occurred after November 2, 2015, the civil penalty amount ranges between $11,181 and $22,363 per claim.

In addition, various states have enacted false claim laws analogous to the federal False Claims Act, although many of these state laws apply where a claim is submitted to any third-party payor and not merely a government payor program.

Civil Monetary Penalties Law

The federal Civil Monetary Penalties Law, or the CMP Law, prohibits, among other things, (1) the offering or transfer of remuneration to a Medicare or state health care 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 health care program, unless an exception applies; (2) employing or contracting with an individual or entity that the provider knows or should know is excluded from participation in a federal health care program; (3) billing for services requested by an unlicensed physician or an excluded provider; and (4) billing for medically unnecessary services. The penalties for violating the CMP Law include exclusion, substantial fines, and payment of up to three times the amount billed, depending on the nature of the offense.

Physician Referral Prohibitions

The U.S. federal law directed at "self-referrals," commonly known as the "Stark Law," prohibits a physician from making referrals for certain designated health services, including laboratory services, that are covered by the Medicare program, to an entity with which the physician or an immediate family member has a direct or indirect financial relationship, unless an exception applies. Violation of the Stark Law results in a denial of payment for any services provided 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 $169,153 (which reflects the annual adjustment for inflation effective as of November 5, 2019) 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 $ 23,372 per service (which reflects the annual inflation adjustment effective as of November 5, 2019), an assessment of up to three times the amount claimed and possible exclusion from participation in federal healthcare programs. The Stark Law is a strict liability statute, meaning that a physician's financial relationship with a laboratory must meet an exception under the Stark Law or the referrals are prohibited. Thus, unlike the Anti-Kickback Statute's safe harbors, if a laboratory's financial relationship with a referring physician does not meet the requirements of a Stark Law exception, then the physician is prohibited from making Medicare and Medicaid referrals to the laboratory and any such referrals will result in overpayments to the laboratory and subject the laboratory to the Stark Law's penalties. A violation of the Stark Law can serve as a basis of liability under the federal False Claims Act.

Many states, including California, have comparable laws that are not limited to Medicare referrals. The Stark Law also prohibits state receipt of federal Medicaid matching funds for services furnished pursuant to a prohibited referral, but this provision of the Stark Law has not been implemented by regulations.

Physician Sunshine Laws

The Physician Payments Sunshine Act imposes reporting requirements on manufacturers of certain devices, drugs and biologics for certain payments and transfers of value by them (and in some cases their distributors) to physicians, teaching hospitals and certain advanced non-physician health care practitioners, as well as ownership and investment interests held by physicians and their immediate family members. The reporting program (known as the Open Payments program) is administered by CMS. Because we manufacture our own LDTs solely for use by or within our own laboratory, we believe we are exempt from these reporting requirements. We may become subject to such reporting requirements under the terms of current CMS regulations, however, if the FDA requires us to obtain premarket clearance or approval for our tests.

Anti-Bribery Laws

FCPA

We are subject to U.S. Foreign Corrupt Practices Act, or 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. The sale of our tests internationally demands a high degree of vigilance in maintaining, implementing and enforcing a policy against participation in corrupt activity. Other U.S. companies in the medical device and pharmaceutical fields have faced substantial monetary fines and criminal penalties under the FCPA for allowing their agents to deviate from appropriate practices in doing business with non-U.S. government officials.

Foreign Laws

We are also subject to similar anti-bribery laws in the foreign jurisdictions in which we operate. 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. For instance, in the United Kingdom, under the Bribery Act of 2010, which became effective 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 or private nature. Bribery of foreign public officials also falls within the scope of the Bribery Act of 2010. An individual found in violation of the Bribery Act of 2010 faces imprisonment of up to 10 years and could be subject to an unlimited fine, as could commercial organizations for failure to prevent bribery.

Healthcare Policy Laws

In March 2010, the Affordable Care Act was enacted in the United States. The Affordable Care Act made a number of substantial changes to the way healthcare is financed both by governmental and private payors. Although the Affordable Care Act included a medical device tax, the tax never went into effect and was fully repealed by Congress with enactment of the 2020 federal spending package signed into law by President Trump on December 20, 2019.

Since the ACA's enactment, there have been judicial and Congressional challenges to certain aspects of the Affordable Care Act, and we expect there will be additional challenges and amendments to the Affordable Care Act in the future. The current Presidential administration and members of the US Congress have indicated that they may continue to seek to modify, repeal or otherwise invalidate all, or certain provisions of, the ACA. President Trump has signed two Executive Orders and other directives designed to delay the implementation of certain provisions of the Affordable Care Act or otherwise circumvent some of the requirements for health insurance mandated by the Affordable Care Act. Concurrently, Congress has considered legislation that would repeal or repeal and replace all or part of the Affordable Care Act. While Congress has not passed comprehensive repeal legislation, at least two bills affecting the implementation of certain taxes under the Affordable Care Act have been signed into law. For example, the Tax Cuts and Jobs Act of 2017 repealed the tax-based shared responsibility payment imposed by the Affordable Care Act on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate." In December 2019, the Fifth Circuit Court of Appeals upheld a district court's finding that the individual mandate in the Affordable Care Act is unconstitutional following removal of the penalty provision from the law. However, the Fifth Circuit reversed and remanded the case to the district court to determine if other reforms enacted as part of the Affordable Care Act but not specifically related to the individual mandate or health insurance could be severed from the rest of the Affordable Care Act so as not to have the law declared invalid in its entirety. It is unclear how this decision, subsequent appeals including potentially to the U.S. Supreme Court, and other efforts to repeal and replace the Affordable Care Act will affect the implementation of that law and our business. We continue to evaluate the potential impact of the Affordable Care Act and its possible repeal or replacement on our business.

Corporate Practice of Medicine

Numerous states have enacted laws prohibiting business corporations, such as us, from practicing medicine and employing or engaging physicians 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 the appropriate diagnostic tests for a particular condition and taking responsibility for the ultimate overall care of a 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 the business corporation and/or the professional through licensure proceedings. Typically, such laws are only applicable to entities with a physical presence in the applicable state.

Environmental and Other Regulatory Requirements

Our laboratory is subject on an ongoing basis to federal, state and local laws and regulations governing the use, storage, handling and disposal of regulated medical waste, hazardous waste and biohazardous waste, including chemicals, biological agents and compounds and blood and other tissue specimens. Typically, we use licensed or otherwise qualified outside vendors to dispose of this waste. However, many of these laws and regulations provide for strict liability, holding a party potentially liable without regard to fault or negligence. As a result, we could be held liable for damages and fines if our, or others', business operations or other actions result in contamination of the environment or personal injury due to exposure to hazardous materials. Our costs for complying with these laws and regulations cannot be estimated or predicted and depends on a number of factors, including the amount and nature of waste we produce (which depends in part on the number of tests we perform) and the terms we negotiate with our waste disposal vendors.

Our operations are also subject to extensive requirements established by the U.S. Occupational Safety and Health Administration relating to workplace safety for healthcare employees, including requirements to develop and implement programs to protect workers from exposure to blood-borne pathogens by preventing or minimizing any exposure through needle stick or similar penetrating injuries.

Employees

We believe growing and retaining a strong team is crucial to our success. As of March 1, 2020, we had 139 full-time employees, engaged in bioinformatics, genetics, software engineering, laboratory management, sales and marketing and corporate and administrative activities. None of our employees are represented by a labor union or covered by collective bargaining agreements and we believe our relationship with our employees is good.

Corporate Information

We were incorporated in Delaware on May 13, 2016. We are the holding company of our subsidiaries, including primarily Fulgent LLC, which was initially formed in June 2011. On September 30, 2016, Fulgent LLC became our wholly owned subsidiary in a transaction we refer to as the Reorganization, in which the holders of all equity interests in Fulgent LLC immediately prior to the Reorganization became all of our stockholders immediately following the Reorganization.

Our initial operations focused on Fulgent LLC's former pharmaceutical business, or the Pharma Business, and in 2013 we commenced the genetic testing business we are currently pursuing. In October 2015, we recapitalized Fulgent LLC to establish two series of units, with the Class D units having economic rights based on the genetic testing business we are currently pursuing and the Class P units having economic rights based on the Pharma Business. On April 4, 2016, Fulgent LLC separated the Pharma Business from the genetic testing business we are currently pursuing in a transaction we refer to as the Pharma Split-Off. The operating results of the Pharma Business have been reported as discontinued operations for all periods in our consolidated financial statements included in this report.

Our headquarters and laboratory are located at 4978 Santa Anita Avenue, Temple City, California 91780, and our telephone number is (626) 350-0537. Our website address is *www.fulgentgenetics.com*. The information contained on or that can be accessed through our website is not part of and is not incorporated into this report by this reference.

We qualify as an emerging growth company as defined in the Jumpstart Our Business Startups Act of 2012, as amended, or JOBS Act. As an emerging growth company, we may take advantage of specified reduced disclosure and other requirements that are applicable generally to other public companies. We will remain an emerging growth company until December 31, 2021, unless our gross revenue exceeds $1.07 billion in any fiscal year before that date, we issue more than $1.0 billion of non-convertible debt in any three-year period before that date or the market value of our common stock held by non-affiliates exceeds $700.0 million as of the last business day of the second fiscal quarter of any fiscal year before that date.

Available Information

We file reports with the Securities and Exchange Commission, or the SEC, and make available, free of charge, on or through our website, our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, proxy and information statements and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Exchange Act as soon as reasonably practicable after we electronically file such material with, or furnish it to, the SEC on their website located at www.sec.gov.

Item 1A. Risk Factors.

Investing in our common stock involves a high degree of risk. Before making any investment decision with respect to our common stock, you should carefully consider the risks described below and all of the other information included in this report and the other filings we make with the SEC. We believe the risks and uncertainties described below are the most significant we face; and the occurrence of any of these risks could harm our business, financial condition, results of operations, prospects and reputation and could cause the trading price of our common stock to decline. Additional risks and uncertainties not presently known to us or that we currently deem immaterial may also impair our business.

Business and Strategy Risks

Our results of operations may fluctuate significantly from period to period and can be difficult to predict.

Our results of operations have experienced fluctuations from period to period, which we expect may continue in the future. These fluctuations can occur because of a variety of factors, including, among others, the amount and timing of sales of billable tests; the prices we charge for our tests due to changes in product, customer or payor mix, general price degradation for genetic tests or other competitive factors; the rate and timing of our billings and collections; and the timing and amount of our commitments and other payments, as well as the other risk factors discussed in this report. In addition, in certain prior periods, our results have been impacted by events that may not recur regularly, in the same amounts or at all in the future. Moreover, our limited operating history makes it difficult to determine if fluctuations in our performance reflect seasonality or other trends or are the result of other factors or events. These fluctuations in our operating results may render period-to-period comparisons less meaningful, and investors should not rely on the results of any one period as an indicator of future performance. Additionally, these fluctuations in our operating results could cause our performance in any particular period to fall below the expectations of securities analysts or investors or guidance we have provided to the public, which could negatively affect the price of our common stock.

We have a history of losses, and we may not be able to achieve or sustain profitability.

We have a history of losses. Although we achieved profitability in the first half of 2017, and the second and third quarters of 2019, we recorded losses in all other periods since our inception. As a result, we may not be able to maintain profitability in future periods. Further, we have generated limited revenue to date, and our historical revenue levels may not grow at historical rates or at all, and we may not be able to achieve or sustain profitability. We may incur additional losses in the future, particularly as we focus on investing in and growing our business and operations and experience related increases in expenses. Our prior losses and any future losses have had and will continue to have an adverse effect on our stockholders' equity and working capital, which could negatively impact our operations and your investment in our company. Any failure to sustain or grow our revenue levels and achieve or maintain profitability 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 are an early-stage company with a limited operating history, which could expose us to enhanced risks and increase the difficulty of evaluating our business and prospects.

We began operations in May 2012 and commercially launched our first genetic tests in 2013. As a result, we have only a limited operating history upon which you can evaluate our business and prospects. Our limited operating history makes it difficult to evaluate our current business and hinders our ability to reliably forecast our future operating results, including revenue, cash flows and movement toward sustained profitability. Our revenue levels may not continue to grow at historical rates or at all, and we may not be able to achieve or sustain profitability. We have encountered and will continue to encounter risks and uncertainties frequently experienced by growing companies in the life sciences and technology industries, such as risks related to an evolving and unpredictable industry and business model, management of growth and the other uncertainties described in this report. If our assumptions regarding these risks and uncertainties are incorrect or these risks and uncertainties change due to fluctuations in our markets, or if we do not address these risks successfully, our operating and financial results could differ materially from our expectations and our business could suffer.

Our industry is subject to rapidly changing technology and new and increasing amounts of scientific data, and if we fail to keep pace with these technological advances, we may be unable to compete effectively and our business and prospects could suffer.

In recent years, there have been numerous advances in the ability to analyze large amounts of genomic information and the role of genetics and gene variants in disease diagnosis and treatment. Our industry has been, and we believe will continue to be, characterized by rapid technological change, increasing amounts of data, frequent introductions of new genetic tests and evolving industry standards, all of which could make our tests obsolete if we are not able to enhance our technologies and tests faster and better than our competitors. We believe our future success will depend in part on our ability to keep pace with the evolving needs of our customers in a timely and cost-effective manner and to pursue new market opportunities that develop as a result of technological and scientific advances. If we are not able to keep pace with these advances and increased customer expectations that develop as a result of these advances, we may be unable to sustain or grow our business and our future operations and prospects could suffer.

Our mix of customers can fluctuate from period to period and our revenue may be concentrated among only a small number of customers, and the loss of or a reduction in sales to any of our customers could materially harm our business.

The composition and concentration of our customer base can fluctuate from period to period, and in certain prior periods, a small number of customers accounted for a significant portion of our revenue. In particular, when customers who, to our knowledge, are under common control or otherwise affiliated with each other are aggregated, one customer contributed 28% of our total revenue in the year ended December 31, 2019, and one customer contributed 13% of our total revenue in the year ended December 31, 2018. For these customers and for customers generally, tests are purchased on a test-by-test basis and not pursuant to any long-term purchasing arrangements. As a result, any or all of our customers, including affiliated customers or customers under common control who purchase large quantities of billable tests, could decide at any time to decrease, delay or discontinue their orders from us which could adversely affect our revenue. Although we believe some of these fluctuations in customer demand may be attributable in part to the nature of our business, in which our customers can experience significant volatility in their genetic testing demand from period to period in the ordinary course of their operations, these demand fluctuations, particularly for any key customers, can have a significant impact on our period-to-period performance regardless of their cause. In addition, the failure of any one of our customers or their payors to pay on a timely basis would negatively impact our results and cash flows. Our ability to maintain or increase sales to our existing customers depends on a variety of factors, including the other risk factors discussed in this report, many of which are beyond our control. Because of these and other factors, sales to any of our customers, including any key, affiliated or commonly controlled customers, may not continue in the amounts or at the rates as they have in the past, and such sales may never reach or exceed historical levels in any future period. The loss of any of our customers, or a reduction in orders or difficulties collecting payments for tests ordered by any of them, could significantly reduce our revenue and adversely affect our operating results.

If we are not able to grow and diversify our customer base and increase demand for our tests from existing and new customers, our potential for growth could be limited.

To achieve our desired revenue growth, we must increase test volume by further penetrating our existing hospital and medical institution customers. In addition, we must grow our customer base beyond hospitals, medical institutions and other laboratories and into additional customer groups, such as individual physicians, other practitioners and research institutions. To this end, we are making efforts to diversify our customer market, including building relationships with research institutions and other similar institutional customers, national clinical laboratories and various other organizations to facilitate access to physicians, practitioners and other new customer groups, including certain U.S. government agencies. We are also pursuing relationships with payors, including Medicare, some state Medicaid programs and commercial payors, in an effort to obtain coverage and reimbursement for our tests to make them accessible to more individual physicians. Generally, when we establish these new customer relationships, we agree with the applicable payor, laboratory or other customer to provide certain of our tests at negotiated rates, but, subject to limited exceptions, none of these relationships obligate any party to order our tests at any agreed volume or frequency or at all. Further, any relationships we may develop with any government agencies are subject to unique risks associated with government contracts, including cancellation if adequate appropriations for subsequent performance periods are not made and modification or termination at the government's convenience and without prior notice. In 2019, we launched Picture Genetics, a patient-initiated genetic testing offering aimed at increasing sales volume from individual consumers. Our efforts to pursue individual consumers, new payor or institutional customers or other new customer markets could fail, and even if we are able to develop relationships with new customers in these or any other new customer groups, these relationships may not lead to meaningful or any increases in our customer base, the number of billable tests we deliver or our revenue, and may not improve our ability to achieve or sustain profitability.

We may fail to obtain the customer growth needed to grow volumes and revenue levels as desired or anticipated or at all, which could occur for a variety of reasons, including, among others:

- the genetic testing market generally, and particularly the market for next generation sequencing, or NGS, genetic tests, is relatively new and may not grow as predicted or may decline;
- our efforts to improve our existing tests and develop and launch new tests may be unsuccessful;

- we may not be able to convince additional hospitals, medical institutions and other laboratories or additional customer groups of the utility of our tests and their potential advantages over existing and new alternatives;
- our investments in our sales and marketing functions, including our efforts to increase and restructure our sales force and re-focus and expand our marketing initiatives and strategies, may fail;
- we may be unsuccessful in convincing customers of the benefits of our broad and customizable test menu;
- genetic testing is expensive and many existing and potential new customers may be sensitive to pricing, particularly if we are not able to maintain low prices relative to our competitors;
- potential new customers, particularly individual physicians and other practitioners, may not adopt our tests if coverage and adequate reimbursement are not available;
- negative publicity or regulatory investigations into the actions of companies in our industry could raise doubts about the legitimacy of diagnostic technologies generally, and could result in scrutiny of diagnostic activities by the U.S. Food and Drug Administration, or FDA, or other applicable government agencies; and
- our competitors could introduce new tests that cover more genes or that provide more accurate or reliable results.

If we are unable to address these and other risks associated with growing our customer base and deepening our relationships with existing customers, we may not achieve our desired growth in billable tests and revenue, and our results of operations could be adversely impacted.

We face intense competition, which could intensify further in the future, and we may fail to maintain or increase our revenue levels, maintain the current prices and margins for our billable tests, or achieve or sustain profitability if we cannot compete successfully.

With the development of NGS, the clinical genetic testing market has become increasingly competitive, and we expect this competition to intensify further in the future. We face competition from a variety of sources, including, among others, dozens of companies focused on molecular genetic testing services, such as specialty and reference laboratories that offer traditional single-gene and multi-gene tests, as well as established and emerging healthcare, information technology and service companies that may develop and sell competitive products or services, which may include informatics, analysis, integrated genetic tools and services for health and wellness.

Additionally, participants in closely related markets, such as prenatal testing and clinical trial or companion diagnostic testing, could converge on offerings that are competitive with the type of tests we perform. Instances where potential competitors are aligned with key suppliers or are themselves suppliers could provide these potential competitors with significant advantages. Further, hospitals, research institutions and eventually individual physicians and other practitioners 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, and associated decreases in the cost of, equipment, reagents and other materials and databases and genetic data interpretation services may enable broader direct participation in genetic testing and analysis and drive down the use of third-party testing companies such as ours. Moreover, the biotechnology and genetic testing fields continue to undergo significant consolidation, permitting larger clinical laboratory service providers to increase cost efficiencies and service levels, resulting in more intense competition.

Many of our existing and potential future competitors have longer operating histories, larger customer bases, more expansive brand recognition and deeper market penetration, substantially greater financial, technological and research and development resources and selling and marketing capabilities, and considerably more experience dealing with third-party payors. As a result, they may be able to respond more quickly to changes in customer requirements or preferences, develop faster, better and more expansive advancements for their technologies and tests, create and implement more successful strategies for the promotion and sale of their tests, obtain more favorable results from third-party payors regarding coverage and reimbursement for their offerings, adopt more aggressive pricing and/or price reduction policies for their tests, secure supplies from vendors on more favorable terms or devote substantially more resources to infrastructure and systems development. We may not be able to compete effectively against these organizations.

Additionally, increased competition and cost-saving initiatives on the part of government entities and other third-party payors could result in downward pressure on the price for genetic analysis and interpretation generally, which could harm our revenue levels and sales volume and our ability to gain market share. This downward pricing pressure could intensify in future periods if adoption of genetic testing becomes more widespread, and we may not be able to maintain acceptable margins on our sales if we are forced to reduce prices for our tests to try to remain competitive, especially if we are also experiencing increasing expenses as we make efforts to grow our business or otherwise meet customer demands. The occurrence of these risks could materially harm our ability to achieve or sustain profitability. In addition, competitors may be acquired by, receive investments from or enter into other commercial

relationships with larger, well-established and well-financed companies if and as use of NGS for clinical diagnosis and preventative care increases. Further, companies or governments that effectively control access to genetic testing through umbrella contracts or regional preferences could promote our competitors or prevent us from performing certain tests in certain territories. If we are unable to compete successfully against current and future competitors for these or any other reasons, we may be unable to increase market acceptance and sales volume of our tests, which could prevent us from maintaining or increasing our revenue levels or achieving or sustaining profitability or could otherwise negatively affect our performance.

Our level of commercial success will depend in part on our ability to generate and grow sales with our sales and marketing team, strategies and partnerships, and we may be unsuccessful in these efforts.

We may not be able to market or sell our existing tests or any tests we may develop in the future in order to drive demand sufficiently to support our desired growth. We currently sell our tests through a small internal sales force and a number of contractors who serve as independent sales representatives. Although we have made efforts to enhance and improve our internal sales department, it remains significantly smaller than many of our competitors' sales teams. We have historically relied significantly on organic growth and word-of-mouth among our customers to generate interest in our tests, but our ability to rely on this type of interest in future periods is uncertain.

We believe our ability to maintain and grow sales volume in the future will depend in large part on our ability to further develop our sales team and create and implement effective sales and marketing strategies. We have been focused on these objectives and have taken steps to pursue them in recent periods, including hiring new key members and restructuring the organization of our sales and marketing team, re-focusing our sales and marketing initiatives and strategies and increasing the overall scope of our marketing activities. These efforts have required and will continue to involve significant time and expense. Moreover, these efforts may be unsuccessful. For instance, we may not be able to attract and hire the qualified personnel we need to grow or otherwise improve our sales and marketing team as quickly or as successfully as we would like for various reasons, including intense competition in our industry for qualified personnel and our relative lack of experience selling and marketing our tests. Even if we are able to further develop our sales and marketing team and strategy, and we may not be successful in growing our customer base or increasing order volumes from our existing customers. Further, our reliance on independent sales representatives subjects us to risks, as we have very little control over their activities and they are generally free to market and sell other, potentially competing, products. As a result, these independent sales representatives could devote insufficient time or resources to marketing and selling our tests, could market them in an ineffective manner or could otherwise be unsuccessful in selling adequate or expected quantities of our tests.

In addition, our future sales levels will depend in large part on the effectiveness of our sales and marketing strategies, including our ability to expand our brand awareness by providing education about the benefits and full scale of our offering to the medical community in general and to our targeted geographic and customer markets. We also intend to continue to pursue targeted marketing initiatives, including working with medical professional societies to promote awareness of the benefits of our tests and genetic testing in general, pursuing or supporting scientific studies of our tests and publication of results in medical or scientific journals and making presentations at medical, scientific or industry conferences and trade shows. We may not be successful in implementing these initiatives or other marketing strategies we may develop and pursue. If we are not able to drive sufficient revenue using our sales and marketing strategies to support our planned growth, our business and results of operations would be negatively affected.

Our sales and marketing strategies also include a continued focus on growing our international sales and customer base, which we plan to pursue through our direct sales team, a number of independent contractor sales representatives, and, if opportunities arise, by engaging distributors or establishing other types of arrangements, such as joint ventures or other relationships, to manage or assist with sales, logistics, education or customer support in certain territories. To this end, we have worked with Xi Long USA, Inc., or Xi Long, a large stockholder of our company, to form a joint venture in the second quarter of 2017, which we refer to as FF Gene Biotech, to offer genetic testing to customers in the People's Republic of China, or PRC. Although we believe this joint venture could result in expanded long-term opportunities to address the genetic testing market in Asia, these expectations could turn out to be wrong and we may never realize the benefits we anticipate from this joint venture. While it may become necessary to identify, qualify and engage other commercial partners or distributors with local industry experience and knowledge in order to effectively market and sell our tests outside the United States, we have not established any such relationships to cover any non-U.S. territories except for this joint venture in the PRC. As a result, we may not be successful in finding, attracting and retaining qualified distributors or other commercial partners or we may not be able to enter into arrangements covering desired territories on favorable terms. In addition, sales practices utilized by distributors or other commercial partners that are locally acceptable may not comply with sales practices or standards required under U.S. laws that apply to us, which could subject us to additional compliance risks. If our sales and marketing efforts outside the United States are not successful, we may not achieve significant acceptance for our tests in international markets, which could materially and adversely impact our business operations.

We will need to invest in and expand our infrastructure and hire additional skilled personnel in order to support our desired growth, and our failure to effectively manage any future growth could jeopardize our business.

To increase the volume of tests we offer and deliver, we must invest in our infrastructure, including our testing capacity and information systems, enterprise software systems, customer service, billing and collections systems and processes and internal quality assurance programs. We will also need to invest in our workforce by hiring additional skilled personnel, including biostatisticians, geneticists, software engineers, laboratory directors and specialists, sales and marketing experts and other scientific, technical and managerial personnel to market, process, interpret and validate the quality of results of our genetic tests and otherwise manage our operations. For example, before we deliver a report for any of our genetic tests, the results summarized in the report must be reviewed and approved by a licensed and qualified laboratory director. We currently have only four such laboratory directors with all of the required licenses, including Dr. Han Lin Gao. We may need to hire more licensed laboratory directors in the future to further scale our business. If we fail to hire additional qualified personnel when needed or otherwise develop our infrastructure sufficiently in advance of demand or if we fail to generate demand commensurate with our level of investment in our infrastructure, our business, prospects, financial condition and results of operations could be adversely affected. Additionally, although we do not presently have plans to acquire new or expand our existing laboratory space, we may need to do so in the future if our test volume increases, and any need to obtain an additional facility or replace our existing facility with a larger one could involve significant costs and challenges.

The time and resources required to implement new systems, to add and train new skilled personnel and to expand or acquire new laboratory space as needed are uncertain. Any future growth we may experience could create a strain on our organizational, administrative and operational infrastructure, including laboratory operations, quality control, customer service, sales and marketing and management. We may not be able to maintain the quality of or expected turnaround times for our tests or satisfy customer demand if and when it grows. Our ability to effectively manage any growth we experience will also require us to continue to improve our laboratory and other operational, financial and management systems and controls and our reporting processes and procedures, which may involve significant time and costs and which we may not be able to do successfully.

Our ability to achieve or sustain profitability depends on our collection of payment for the tests we deliver, which we may not be able to do successfully.

Since starting our genetic testing business, we have historically been focused primarily on providing our tests to hospitals, medical institutions and other laboratories. Our current customer base is principally comprised of hospitals, medical institutions and other laboratories. These customers typically pay for the cost of our tests using funds reimbursed in connection with a patient's diagnosis related group, or DRG. However, our ability to collect payment for the tests we deliver to our hospital and medical institution customers, as well as to other types of customers, is subject to a number of risks, many of which are not within our control. These risks include the potential for default or bankruptcy by the party responsible for payment and other risks associated with payment collection generally. Further, healthcare policy changes that influence the way healthcare is financed or other changes in the market that impact payment rates by institutional or non-institutional customers could affect our collection rates. For example, because reimbursement under a DRG is typically provided at a fixed amount intended to cover all services provided to the patient, the cost of our tests may be viewed to limit the profitability of the billing institution. If we are unable to convince hospitals, medical institutions and other laboratories of the value and benefit provided by our tests, or if the amount reimbursed under these DRG codes is decreased, these customers may slow, or stop altogether, their purchases of our tests. Moreover, our ability to collect payment for our tests in a timely manner or at all may decline to the extent we expand our business into new customer groups, including individual physicians and other practitioners, from which collection rates are often significantly lower than hospitals, medical institutions and other laboratories and which involve substantial additional risks that are discussed in these risk factors below. Any inability to maintain our past payment collection levels could cause our revenue and ability to achieve profitability to decline.

If third-party payors do not provide coverage and adequate reimbursement for our tests, our potential for growth could be limited.

Coverage and reimbursement by third-party payors, including managed care organizations, private health insurers and government healthcare programs, such as Medicare and Medicaid, for the types of genetic tests we perform can be limited and uncertain. Although our existing customer base consists primarily of hospitals, medical institutions and other laboratories, from which we typically receive direct payment for ordered tests, we believe our potential for future growth is dependent on our ability to attract new customer groups, including individual physicians and other practitioners. These practitioners may not order our tests unless third-party payors cover and provide adequate reimbursement for a substantial portion of the price of the tests. If we are not able to obtain coverage and an acceptable level of reimbursement for our tests from third-party payors, there would typically be a greater co-insurance or co-payment requirement from the patient for whom the test is ordered or the patient may be forced to pay the entire cost of the test out-of-pocket, which could dissuade practitioners from ordering our tests and, if ordered, could result in a delay in or decreased likelihood of collecting payment, whether from patients or from third-party payors. We believe our ability to increase the number of tests we sell and our revenue will depend in part on our ability to achieve broad coverage and reimbursement for our tests from third-party payors.

Coverage and reimbursement by a third-party payor may depend on a number of factors, including a payor's determination that a test is appropriate, medically necessary and cost-effective. Each payor makes its own decision as to whether to establish a policy or enter into a contract to cover our tests and the amount it will reimburse for each test, and any determination by a payor regarding coverage and amount of reimbursement for our tests would likely be made on an indication-by-indication basis. Even if a test has been approved for reimbursement, for any particular indication or in any particular jurisdiction, there is no guarantee this test will remain approved for reimbursement or that any similar or additional tests will be approved for reimbursement in the future. Moreover, there can be no assurance that any new tests we launch will be reimbursed or reimbursed at rates comparable to the rates of any previously reimbursed tests. In addition, the coding procedure used by all third-party payors with respect to establishing payment rates for various procedures, including our tests, is complex, does not currently adapt well to the genetic tests we perform and may not enable coverage and adequate reimbursement rates for our tests. If physicians fail to provide appropriate codes for desired tests, we may not be reimbursed our tests. Additionally, if we are not able to obtain sufficient clinical information in support of our tests, third-party payors could designate our tests as experimental or investigational and decline to cover and reimburse our tests because of this designation. As a result of these factors, obtaining approvals from third-party payors to cover our tests and establishing adequate reimbursement levels is an unpredictable, challenging, time-consuming and costly process, and we may never be successful.

To date, we have contracted directly with national health insurance companies to become an in-network provider and enrolled as a supplier in the Medicare program and some state Medicaid programs, and we have also received payment for our tests from other third-party payors as an out-of-network provider. Although becoming an in-network provider or enrolling as a supplier means that we have agreed with these payors to provide certain of our tests at negotiated rates, it does not obligate any physicians or other practitioners to order our tests or guarantee that we will receive reimbursement for our tests from these or any other payors at adequate levels. As a result, these payor relationships, any other similar relationships we may establish in the future, or any additional payments we may receive from other payors as an out-of-network provider, may not amount to acceptable levels of reimbursement for our tests or meaningful or any increases in our physician customer base or the number of billable tests we sell to physicians. We expect to focus on increasing coverage and reimbursement for our current tests and any future tests we may develop, but we cannot predict whether, under what circumstances, or at what payment levels payors will cover and reimburse for our tests. Further, even if we are successful, we believe it could take several years to achieve coverage and adequate contracted reimbursement with third-party payors. If we fail to establish and maintain broad coverage and reimbursement for our tests, our ability to maintain or grow our test volume, customer base, collectability rates and revenue levels could be limited and our future prospects and our business could suffer.

Failure to comply with government laws and regulations related to submission of claims for our services could result in significant monetary damages and penalties and exclusion from the Medicare and Medicaid programs and corresponding foreign reimbursement programs.

We are subject to laws and regulations governing the submission of claims for payment for our services, such as those relating to: coverage of our services under Medicare, Medicaid and other state, federal and foreign health care programs; the amounts that we may bill for our services; and the party to which we must submit claims. Our failure to comply with applicable laws and regulations could result in our inability to receive payment for our services or in attempts by state and federal healthcare programs, such as Medicare and Medicaid, to recover payments already made. Submission of claims in violation of these laws and regulations can result in recoupment of payments already received, substantial civil monetary penalties, and exclusion from state and federal health care programs, and can subject us to liability under the federal False Claims Act and similar laws. The failure to report and return an overpayment to the Medicare or Medicaid program within 60 days of identifying its existence can give rise to liability under the False Claims Act. Further, a government agency could attempt to hold us liable for causing the improper submission of claims by another entity for services that we performed if we were found to have knowingly participated in the arrangement at issue.

We may not be successful in developing and marketing new tests, which could negatively impact our performance and prospects.

We believe our future success will depend in part on our ability to continue to expand our test offering and develop and sell new tests. We may not be successful in launching or marketing any new tests we may develop, including our recently launched Picture Genetics offering, and, even if we are successful, the demand for our other tests could decrease or may not continue to increase at historical rates due to sales of the new tests. Our pipeline of new tests is in various stages of development and will be time-consuming and costly to fully develop and introduce, as development and marketing of new tests requires us to conduct research and development activities regarding the new tests and to further scale our laboratory processes and infrastructure to be able to analyze increasing amounts of more diverse data. Further, we may be unable to discover or develop and launch new tests for a variety of reasons, including failure of any proposed test to perform as expected, lack of validation or reference data for the test or failure to demonstrate the utility of the test. Further, any new test we are able to discover and develop may not be launched in a timely manner, meet applicable regulatory standards, successfully compete with other technologies and available tests, avoid infringing the proprietary rights of others, achieve coverage and adequate reimbursement from third-party payors, be capable of performance at commercial levels and at reasonable costs, be successfully marketed or achieve sufficient market acceptance for us to recoup our time and capital investment in the development of the test. Any failure to successfully develop, market and sell new tests could negatively impact our ability to attract and retain customers and our revenue and prospects.

We are exposed to additional business, regulatory, political, operational, financial and economic risks related to our international operations.

Our existing customer base includes international customers from a variety of geographic markets. In addition, we have established FF Gene Biotech to offer genetic testing to customers in the PRC. As part of our strategy, we aim to increase our volume of direct sales to international customers in a variety of markets by conducting targeted marketing outreach activities and, if opportunities arise, engaging distributors or establishing other types of arrangements, such as joint ventures or other relationships. However, we may never be successful in achieving these objectives, and even if we are successful, these strategies may not result in meaningful or any increases in our customer base, test volumes or revenue.

Doing business internationally involves a number of risks, including, among others:

- compliance with the laws and regulations of multiple jurisdictions, which may be conflicting or subject to increasing stringency or other changes, including privacy regulations, tax laws, employment laws, healthcare regulatory requirements and other related approvals, including permitting and licensing requirements;
- logistics associated with the shipment of blood or other tissue specimens, including infrastructure conditions, transportation delays and the impact of U.S. and local laws and regulations, such as export and import restrictions, tariffs or other charges and other trade barriers, all of which involve increased related to the trade policies of the current administration, which may threaten existing and proposed trade agreements and impose more restrictive U.S. export-import regulations that impact our business;
- limits on our ability to penetrate international markets, including legal and regulatory requirements that would force us to conduct our tests locally by building additional laboratories or engaging in joint ventures or other relationships in order to offer our tests in certain countries, which relationships could involve significant time and resources to establish, deny us control over certain aspects of the foreign operations or reduce the economic value to us of these operations;
- failure by us, any joint ventures or other arrangements we may establish or any distributors or other commercial partners we may engage to obtain any regulatory approvals required to market, sell and use our tests in various countries;
- challenges predicting the market for genetic testing generally and tailoring our test menu to meet varying customer expectations in different countries and territories;
- difficulties gaining market share in territories in which we do not have a strong physical presence or brand awareness;
- complexities and difficulties obtaining protection for and enforcing our intellectual property rights;
- difficulties in staffing and managing foreign operations;
- complexities associated with managing multiple payor coverage and reimbursement regimes, government payors or patient self-pay systems;
- financial risks, such as longer payment cycles, difficulty collecting accounts receivable and the impact of local and regional financial conditions on demand and payment for our tests;
- exposure to foreign currency exchange rate fluctuations, including increased risk with respect to the Canadian dollar after we recently started billing certain of our Canadian hospital customers in their local currency and with respect to the renminbi, or RMB, related to revenue received under our agreements with FF Gene Biotech;
- risks relating to conversion and repatriation of certain foreign currencies, particularly the RMB, which is subject to legal procedures and restrictions on currency conversion and movement outside the PRC and which could impact our ability to receive the anticipated financial benefits of our FF Gene Biotech joint venture;
- natural disasters, political and economic instability, including wars, terrorism and political unrest, outbreak of disease (e.g. novel coronavirus epidemic in China), boycotts and other business restrictions; and
- regulatory and compliance risks related to applicable anti-bribery laws, including requirements to maintain accurate information and control over activities that may fall within the purview of these laws.

Any of these factors could significantly harm our existing relationships with international customers or derail our international expansion plans, which would cause our revenue and results of operations to suffer.

In addition, we are exposed to a number of additional risks and challenges related to our efforts to access customers in the PRC with the formation of FF Gene Biotech. These risks include, among others, difficulties predicting the market for genetic testing in Asia; competitive factors in this market, including challenges securing market share; local differences in customer demands and preferences and regulatory requirements; our lack of control over FF Gene Biotech due to our non-majority ownership interest; and many of the other risks of doing business internationally that are discussed above. Further, we could experience declines in our direct sales to, and revenue from, customers in Asia if any of these customers choose to order genetic tests from FF Gene Biotech instead of from us. As a result of these risks, although we believe FF Gene Biotech could result in expanded long-term opportunities to address the genetic testing market in Asia, this belief could turn out to be wrong and we may never realize these or any other benefits we anticipate from this joint venture. Moreover, FF Gene Biotech or any other joint venture we may seek to establish may never produce sufficient revenue to us to recover our capital and other investments in the joint venture, and we could become subject to liabilities based on our involvement in the joint venture's operations. The materialization of any of these risks related to FF Gene Biotech could materially harm our performance and prospects.

If we are sued for product or professional liability, we could face substantial liabilities that exceed our resources.

Our business depends on our ability to provide reliable and accurate test results that incorporate rapidly evolving information about the role of genes and gene variants in disease and clinically relevant outcomes associated with these variants. 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, substantial judgment is required in order to interpret the results of each test we perform and produce a report summarizing these results. Errors, such as failures to detect genomic variants with high accuracy, or mistakes, such as failures to completely and correctly identify the significance of gene variants, could subject us to product liability or professional liability claims. Any such claim against us could result in substantial damages and be costly and time-consuming to defend. Although we maintain liability insurance, including for errors and omissions, our insurance may not 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. Additionally, any liability claim brought against us, with or without merit, could increase our insurance rates or prevent us from securing adequate insurance coverage in the future. Moreover, any liability lawsuit could damage our reputation or force us to suspend sales of our tests. The occurrence of any of these events could have a material adverse effect on our business, reputation and results of operations.

If our sole laboratory facility becomes inoperable, if we are forced to vacate the facility or if we are unable to obtain additional laboratory space as and when needed, we would be unable to perform our tests and our business would be harmed.

We perform all of our tests at a single laboratory in Temple City, California. Our laboratory facility could be damaged or rendered inoperable by natural or man-made disasters, including earthquakes, floods, fires and power outages, which could render it difficult or impossible for us to perform our tests for some period of time. The inability to perform our tests or the backlog that could develop if our laboratory becomes inoperable for even a short time could result in the loss of customers or harm to our reputation. Although we maintain insurance for damage to our property and 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.

Further, if we need to move to a different facility or obtain additional laboratory space, we may have difficulty locating suitable space in a timely manner, on reasonable terms or at all, and even if acceptable space was available, it would be challenging, time-consuming and expensive to obtain or transfer the licensure and accreditation required for a commercial laboratory like ours and the equipment we use to perform our tests. These challenges could be amplified if we or our joint ventures or other commercial partners seek to procure and maintain laboratory space outside the United States as we pursue international expansion. If we are unable to obtain or are delayed in obtaining new laboratory space as needed, we may not be able to provide our existing tests or develop and launch new tests, which could result in harm to our business, reputation, financial condition and results of operations.

We rely on a limited number of suppliers and, in some cases, a sole supplier, for certain of our laboratory substances, equipment and other materials, and any delays or difficulties securing these materials could disrupt our laboratory operations and materially harm our business.

We rely on a limited number of suppliers for certain of our laboratory substances, including reagents, as well as for the sequencers and various other equipment and materials we use in our laboratory operations. In particular, we rely on Illumina, Inc. as the sole supplier of the next generation sequencers and associated reagents we use to perform our genetic tests and as the sole provider of maintenance and repair services for these sequencers. We do not have long-term agreements with any of our suppliers and, as a result, they could cease supplying these materials and equipment to us at any time due to an inability to reach agreement with us on supply terms, disruptions in their operations, a determination to pursue other activities or lines of business or for other reasons, or they could fail to provide us with sufficient quantities of materials that meet our specifications. Transitioning to a new supplier or locating a temporary substitute, if any are available, would be time-consuming and expensive, could result in interruptions in or otherwise affect the performance specifications of our laboratory operations or could require that we revalidate our tests. In addition, the use of equipment or materials provided by a replacement supplier could require us to alter our laboratory operations and procedures. Moreover, we believe there are currently only a few manufacturers that are capable of supplying and servicing some of the equipment and other materials necessary for our laboratory operations, including sequencers and various associated reagents. As a result, replacement equipment and materials that meet our quality control and performance requirements may not be available on reasonable terms, in a timely manner or at all. If we encounter delays or difficulties securing, reconfiguring or revalidating the equipment, reagents and other materials we require for our tests, our operations could be materially disrupted and our business, financial condition, results of operations and reputation could be adversely affected.

Billing and collections processing for our tests is complex and time-consuming, and any delay in transmitting and collecting claims could have an adverse effect on our revenue.

Billing for our tests is complex, time-consuming and expensive. Depending on the billing arrangement and applicable law, we bill various different parties for our tests, including customers directly in the case of our hospital and medical institution customers, as well as Medicare, Medicaid, insurance companies and patients, all of which may have different billing requirements. We may face increased risk in our collection efforts due to the complexities of these billing requirements, including long collection cycles and lower collection rates, which could adversely affect our business, results of operations and financial condition.

Several factors make this billing process complex, including:

- differences between the list price for our tests and the reimbursement rates of payors;
- compliance with complex federal and state regulations related to billing government healthcare programs, including Medicare and Medicaid;
- disputes among payors as to which party is responsible for payment;
- differences in coverage among payors and the effect of patient co-payments or co-insurance;
- differences in information and billing requirements among payors;
- incorrect or missing billing information; and
- the resources required to manage the billing and claims appeals process.

We have developed internal systems and procedures to handle these billing and collections functions, but we will need to make significant efforts and expend substantial resources to further develop our systems and procedures to handle these aspects of our business, which could become increasingly important as we focus on increasing test volumes from non-hospital and medical institution customer groups and establishing coverage and reimbursement policies with third-party payors. As a result, these billing complexities, along with the related uncertainty in obtaining payment for our tests, could negatively affect our revenue and cash flow, our ability to achieve or sustain profitability and the consistency and comparability of our results of operations. In addition, if claims for our tests are not submitted to payors on a timely basis, or if we are required to switch to a different provider to handle our processing and collections functions, our revenue and our business could be adversely affected.

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. Government 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 cause patients to refuse to use, or physicians to be reluctant to order, genetic tests such as ours, even if permissible. These and other ethical, legal and social concerns may limit market acceptance and adoption of our tests or reduce the potential markets for our tests, any of which could have an adverse effect on our business, financial condition and results of operations.

Actual or attempted security breaches, loss of data or other disruptions could compromise sensitive information related to our business or to patients or prevent us from accessing critical information, any of which could expose us to liability and adversely affect our business and our reputation.

In the ordinary course of our business, we generate, collect and store sensitive data, including protected health information, or PHI, personally identifiable information, intellectual property and proprietary and other business-critical information, such as research and development data, commercial data and other business and financial information. We manage and maintain the data we generate, collect and store utilizing a combination of on-site systems and managed data center systems. We also communicate sensitive patient data when we deliver reports summarizing test results to our customers, which we deliver via our online encrypted web portal, encrypted email or fax or overnight courier. We face a number of risks related to protecting this information, including loss of access, unauthorized modification or inappropriate disclosure.

The secure processing, storage, maintenance and transmission of this information are vital to our operations and business strategy, and we devote significant resources to protecting the confidentiality and integrity of this information. Although we have implemented security measures and other controls designed to protect sensitive information from unauthorized access, use or disclosure, our information technology and infrastructure could fail, be inadequate or vulnerable to attacks by hackers or viruses or be breached due to employee error, malfeasance or other disruptions. A breach or interruption could compromise our information systems and the information we store could be accessed by unauthorized parties, manipulated, publicly disclosed, lost or stolen. Any such unauthorized access, manipulation, disclosure or other loss of information could result in legal claims or proceedings and could result in liability or penalties under federal, state or foreign laws that protect the privacy of personal information, discussed below under "—We are subject to broad legal requirements regarding the information we test and analyze, and any failure to comply with these requirements could result in harsh penalties, damage our reputation and materially harm our business." Additionally, unauthorized access, manipulation, loss or dissemination could significantly damage our reputation and disrupt our operations, including our ability to perform our tests, analyze and provide test results, bill customers or other payors, process claims for reimbursement, provide customer service, conduct research and development activities, collect, process, and prepare company financial information, conduct education and outreach activities and manage the administrative aspects of our operations, as described further below under "—We depend on our information technology systems, and any failure of these systems, due to hardware or software malfunctions, delays in operation, failures to implement new or enhanced systems or cybersecurity breaches, could harm our business." The occurrence of any of these risks could materially adversely affect our business.

The loss of any member of our senior management team could adversely affect our business.

Our success depends in large part on the skills, experience and performance of our executive management team and others in key leadership positions, especially Ming Hsieh, our founder, Chief Executive Officer and Chairman of our board of directors, and Dr. Han Lin Gao, our Chief Scientific Officer and Laboratory Director. The continued efforts of these persons will be critical to us as we continue to develop our technologies and test processes and focus on growing our business. If we lose one or more key executives, we could experience difficulties maintaining our operations, including the ability to deliver reports to customers after review and approval by a licensed and qualified laboratory director, competing effectively, advancing our technologies, developing new tests and implementing our business strategies. All of our executives and employees, including Mr. Hsieh and Dr. Gao, are at-will, which means 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 other employees. In addition, we do not have long-term retention agreements in place with any of our executives or key employees.

We rely on highly skilled personnel in a broad array of disciplines, and if we are unable to hire, retain or motivate these individuals, we may not be able to maintain the quality of our tests or grow our business.

Our business, including our research and development programs, laboratory operations and administrative functions, largely depends on our continued ability to identify, hire, train, motivate and retain highly skilled personnel for all areas of our organization, including biostatisticians, geneticists, software engineers, laboratory directors and specialists, sales and marketing experts and other scientific, technical and managerial personnel. Competition in our industry for qualified executives and other employees is intense, and we may not be able to attract or retain the qualified personnel we need to execute our business plans due to high levels of competition for these personnel among our competitors, other life science businesses, universities and public and private research institutions. In addition, our compensation arrangements may not 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 expand our business and support our clinical laboratory operations and our sales and marketing and research and development efforts, which would negatively affect our prospects for future growth and success.

Any inability to obtain additional capital when needed and on acceptable terms may limit our ability to execute our business plans.

We expect our capital expenditures and operating expenses to increase over the next several years as we seek to expand our infrastructure, sales and marketing and other commercial operations and research and development activities. We may seek to raise additional capital through securities offerings, credit facilities or other debt financings, asset sales or collaborations or licensing arrangements. Additional funding may not be available to us when needed, on acceptable terms or at all. If we raise funds by issuing equity securities, our existing stockholders could experience substantial dilution. Additionally, any preferred stock we issue could provide for rights, preferences or privileges senior to those of our common stock, and our issuance of any additional equity securities, or the possibility of such an issuance, could cause the market price of our common stock to decline. The terms of any debt securities we issue or borrowings we incur, if available, could impose significant restrictions on our operations, such as limitations on our ability to incur additional debt or issue additional equity or other restrictions that could adversely affect our ability to conduct our business, and would result in increased fixed payment obligations. If we seek to sell assets or enter into collaborations or licensing arrangements to raise capital, we may be required to accept unfavorable terms or relinquish or license to a third party our rights to important or

valuable technologies or tests we may otherwise seek to develop ourselves. Moreover, we may incur substantial costs in pursuing future capital, including investment banking, legal and accounting fees, printing and distribution expenses and other similar costs. If we are not able to secure funding if and when needed and on reasonable terms, we may be forced to delay, reduce the scope of or eliminate one or more sales and marketing initiatives, research and development programs or other growth plans or strategies. In addition, we may be forced to work with a partner on one or more aspects of our tests or market development programs or initiatives, which could lower the economic value to us of these tests, programs or initiatives. Any such outcome could significantly harm our business, performance and prospects.

Our ability to use net operating losses to offset future taxable income may be subject to limitation.

On December 22, 2017, President Trump signed into law the Tax Cuts and Jobs Act, or the 2017 Tax Act, that significantly reforms the Internal Revenue Code of 1986, as amended. The 2017 Tax Act, among other things, includes changes to U.S. federal tax rates, imposes significant additional limitations on the deductibility of interest and net operating loss carryforwards, or NOLs, allows for the expensing of capital expenditures, and puts into effect the migration from a "worldwide" system of taxation to a territorial system. Many of these changes became effective beginning in 2018, without any transition periods or grandfathering for existing transactions. The legislation is unclear in many respects and could be subject to potential amendments and technical corrections, as well as interpretations and implementing regulations by the U.S. Treasury Department and the Internal Revenue Service, any of which could lessen or increase certain impacts of the legislation. In addition, it is unclear how these U.S. federal income tax changes will affect state and local taxation, which often uses federal taxable income as a starting point for computing state and local tax liabilities.

According to the 2017 Tax Act, our federal NOLs generated in tax years beginning after December 31, 2017 may be carried forward indefinitely, but the deductibility of such federal NOLs is limited. Our NOL carryforwards are also subject to review and possible adjustment by the Internal Revenue Service and state tax authorities.

We may acquire businesses or assets, form joint ventures, make investments in other companies or technologies or establish other strategic relationships, any of which could harm our operating results, dilute our stockholders' ownership or cause us to incur debt or significant expense.

As part of our business strategy, we may pursue acquisitions of complementary businesses or assets, investments in other companies, technology licensing arrangements, joint ventures or other strategic relationships. As an organization, we have limited experience with respect to acquisitions, investments or the formation of strategic relationships or joint ventures. If we make acquisitions in the future, we may not be able to successfully integrate the acquired businesses or technologies into our existing operations, we could assume unknown or contingent liabilities and we could be forced to record significant write-offs or incur debt as a result of the acquisitions, any of which could harm our operating results. Further, integration of an acquired business or technology could involve significant difficulties, and could require management and capital resources that otherwise would be available for ongoing development of our existing business or pursuit of other opportunities. If we pursue relationships with pharmaceutical companies or other strategic relationships, our ability to establish and maintain these relationships could be challenging due to several factors, including competition with other genetic testing companies and internal and external constraints placed on pharmaceutical and other organizations that limit the number and type of relationships they can establish with companies like ours. Moreover, we may not be able to identify or complete any acquisition, investment, technology license, joint venture or other strategic relationship in a timely manner, on a cost-effective basis or at all, and we may not realize the anticipated benefits of any such transaction sufficiently to recoup our costs.

To finance any acquisitions, investments, joint ventures or other strategic relationships, we may seek to raise additional funds through securities offerings, credit facilities, asset sales or collaborations or licensing arrangements. Each of these methods of fundraising is subject to a variety of risks, including those discussed above under "—Any inability to obtain additional capital when needed and on acceptable terms may limit our ability to execute our business plans." Further, additional funds from capital-raising transactions may not be available when needed, on acceptable terms or at all. Any inability to fund any acquisitions, investments or strategic relationships we pursue could cause us to forfeit opportunities we believe are promising or valuable, which could harm our prospects.

We depend on our information technology systems and any failure of these systems, due to hardware or software malfunctions, delays in operation, failures to implement new or enhanced systems or cybersecurity breaches, could harm our business.

We depend on information technology and telecommunications systems for significant elements of our operations, such as our laboratory information management systems, including test validation, specimen tracking and quality control; our bioinformatics analytical software systems; our reference library of information relating to genetic variants and their role in disease; personal information storage, maintenance and transmission; our customer-facing web-based software and customer service functions; our report production systems; our billing and reimbursement procedures; our scientific and medical data analysis and other research and development activities and programs; and our general and administrative activities, including disclosure controls, internal control over

financial reporting and other public reporting functions. In addition, our third-party service providers depend on technology and telecommunications systems in order to provide contracted services for us. We expect we will need to continue to expand and strengthen a number of enterprise software systems that affect a broad range of business processes and functions, particularly if and as our operations grow, including, for example, systems handling human resources, financial and other disclosure controls and reporting, customer relationship management, regulatory compliance, security controls and other infrastructure functions.

Information technology and telecommunications systems are vulnerable to disruption and damage from a variety of sources, including power outages and other telecommunications or network failures, natural disasters, the outbreak of war or acts of terrorism. Moreover, despite network security and back-up measures, our servers and other electronic systems are potentially vulnerable to cybersecurity breaches, such as physical or electronic break-ins, computer viruses and similar disruptive events. Despite the precautionary measures we have taken to detect and prevent or solve problems that could affect our information technology and telecommunications systems, there may be significant downtime or failures of these systems or those used by our third-party service providers. Any such downtime or failure could prevent us from conducting tests, preparing and providing reports to customers, billing payors, responding to customer inquiries, conducting research and development activities, maintaining our financial and disclosure controls and other reporting functions and managing the administrative aspects of our business. Moreover, any such downtime or failure could force us to transfer data collection operations to an alternate provider of server-hosting services, which could involve significant costs and result in further delays in our ability to conduct tests, deliver reports to our customers and otherwise manage our operations. Further, although we carry property and business interruption insurance, the coverage may not be adequate to compensate for all losses that may occur in the event of system downtime or failure. Any such disruption or loss of information technology or telecommunications systems on which critical aspects of our operations depend could have a material adverse effect on our business and our reputation.

Additionally, if and as our business grows, we will need to continually improve and expand the scope of our technology systems in order to maintain their adequacy for the scale of our operations. Any failure to make such improvements or any significant delay in the planned implementation of new or enhanced systems could render our systems obsolete or inadequate, in which case our service to our customers and our other business activities could suffer and we could be more vulnerable to electronic breaches from outside sources.

We rely on commercial courier delivery services to transport specimens to our laboratory facility in a timely and cost-efficient manner, and if these delivery services are disrupted, our business would be harmed.

Our business depends on our ability to quickly and reliably deliver test results to our customers. We typically receive specimens from customers within days of shipment, for analysis at our Temple City, California laboratory. Disruptions in delivery service, whether due to labor disruptions, bad weather, natural disasters, terrorist acts or threats or for other reasons, could adversely affect specimen integrity and our ability to process specimens in a timely manner and otherwise service our customers, and ultimately our reputation and our business. In addition, if we are unable to continue to obtain expedited delivery services on commercially reasonable terms, our operating results may be adversely affected.

If we are unable to maintain effective internal control over financial reporting, investors could lose confidence in the accuracy and completeness of our reported financial information and the market price of our common stock could decline.

We are required to maintain internal control over financial reporting and report any material weaknesses in these 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 annually provide a management report on these internal controls. Although we have implemented systems, processes and controls and performed this evaluation as of the end of 2018, we will need to maintain and enhance them if and as we grow and, we may need to hire additional personnel and devote more resources to our financial reporting function in order to do so.

If we identify one or more material weaknesses during the process of annually evaluating our internal controls, we may not detect errors on a timely basis and our financial statements may be materially misstated. In addition, in that event, our management would be unable to conclude that our internal control over financial reporting is effective. Further, when we are no longer an emerging growth company or smaller reporting company, as described in the risk factors 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. When that occurs, our independent registered public accounting firm may conclude that there are material weaknesses in our internal controls or the level at which our internal controls are documented, designed, implemented or reviewed even if our management concludes that our internal control over financial reporting is effective.

If we or our auditors were to conclude that our internal control over financial reporting was not effective because one or more material weaknesses had been identified or if internal control deficiencies result in the restatement of our financial results, investors could lose confidence in the accuracy and completeness of our financial disclosures and the price of our common stock could decline.

Our disclosure controls and procedures may not prevent or detect all errors or acts of fraud.

We are subject to the periodic reporting and other requirements of the Exchange Act. We have implemented disclosure controls and procedures designed to provide reasonable assurance that information we must disclose in reports we file or submit under the Exchange Act is accumulated and communicated to management and recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC. However, any disclosure controls and procedures, no matter how well-conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. These inherent limitations include the realities that judgments in decision-making can be faulty and that breakdowns can occur because of simple errors or mistakes. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by an unauthorized override of the controls. As a result, because of these inherent limitations in our control system, misstatements or omissions due to error or fraud may occur and may not be detected, which could result in failures to file required reports in a timely manner and filing reports containing incorrect information. Any of these outcomes could result in SEC enforcement actions, monetary fines or other penalties, damage to our reputation and harm to our financial condition and stock price.

We may elect to comply with reduced public company reporting requirements available to us because we are an emerging growth company and a smaller reporting company, which could make our common stock less attractive to investors.

We are an emerging growth company, as defined in the Jumpstart Our Business Startups Act of 2012, as amended, or JOBS Act, and we will remain an emerging growth company until December 31, 2021, unless, before that date, our gross revenue exceeds $1.07 billion in any fiscal year, we issue more than $1.0 billion of non-convertible debt in any three-year period or the market value of our common stock held by non-affiliates exceeds $700 million as of the last business day of the second fiscal quarter of any fiscal year. In addition, beginning in 2018, we are a smaller reporting company, as defined in applicable SEC rules, and we will remain a smaller reporting company until the market value of our common stock held by non-affiliates, or public float, equals or exceeds $250 million. When and if our public float exceeds $250 million, we may still qualify to report as a smaller reporting company provided our public float is less than $700 million and our annual revenues are less than $100 million for the year preceding the date of determination. As an emerging growth company, we are eligible for exemptions from certain reporting requirements applicable to other public companies, including an exemption from the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act, reduced financial statement and other financial disclosure requirements in registration statements and periodic reports we file, reduced disclosure obligations regarding executive compensation and, so long as we remain an emerging growth company, exemption from the requirements to hold non-binding advisory votes on executive compensation and obtain stockholder approval of any golden parachute payments not previously approved. We have relied on many of these exemptions periodic reports to date, and investors may find our common stock less attractive if we choose to continue to rely on these exemptions, in which case there may be a less active trading market for our common stock and our stock price may be more volatile.

Under the Securities Act of 1933, as amended, or Securities Act, emerging growth companies can elect to delay adoption of new or revised accounting standards until those standards apply to private companies. We have irrevocably elected not to avail ourselves of this exemption and, as a result, we are subject to the same new or revised accounting standards at the same time as other public companies that are not emerging growth companies.

Regulatory Risks

Any changes in laws, regulations or the enforcement discretion of the FDA with respect to the marketing of diagnostic products, or violations of laws or regulations by us, could adversely affect our business, prospects, results of operations or financial condition.

The laws and regulations governing the marketing of diagnostic products are evolving, extremely complex and in many instances, there are no significant regulatory or judicial interpretations of these laws and regulations. Pursuant to its authority under the federal Food, Drug, and Cosmetic Act, or FDC Act, the FDA has jurisdiction over medical devices, including in vitro diagnostics and, therefore, potentially our clinical laboratory tests. Among other things, pursuant to the FDC Act and its implementing regulations, the FDA regulates the research, testing, manufacturing, safety, labeling, storage, recordkeeping, premarket clearance or approval, marketing and promotion, and sales and distribution of medical devices in the United States to ensure that medical products distributed domestically are safe and effective for their intended uses. In addition, the FDA regulates the import and export of medical devices.

Although the FDA has statutory authority to assure that medical devices and in vitro diagnostics, including potentially our tests, are safe and effective for their intended uses, the FDA has historically exercised its enforcement discretion and not enforced applicable provisions of the FDC Act and regulations with respect to laboratory developed tests, or LDTs, which are a particular type of medical device. We believe our tests are LDTs. As a result, we believe our tests are not currently subject to the FDA’s enforcement of its medical device regulations and the applicable FDC Act provisions.

Even though we commercialize our tests as LDTs, our tests may in the future become subject to more onerous regulation by the FDA. For example, the FDA may disagree with our assessment that our tests fall within the definition of an LDT and seek to regulate our tests as medical devices. Moreover, the FDA issued draft guidance and a 2017 Discussion Paper to allow for further public discussion about an appropriate LDT oversight approach and to give congressional committees the opportunity to develop a legislative solution. The FDA also solicited public input and published two final guidance documents in April 2018 relating to FDA oversight of NGS-based tests. These two guidance documents describe the FDA's thinking and recommendations regarding test developer's use of FDA-recognized standards to support analytical validity, and public human genetic variant databases to support clinical validity, of these tests. In December 2018, members of Congress released a discussion draft of a possible bill to regulate in vitro clinical tests including LDTs, which incorporated suggestions from the FDA and other industry stakeholders. The new bill is called the Verifying Accurate, Leading-edge IVCT Development (VALID) Act and would codify into law the term "in vitro clinical test" (IVCT), a new medical product category separate from medical devices and that includes products currently regulated as IVDs as well as LDTs. One especially notable feature in the discussion draft of the VALID Act is a precertification program that would enable a IVCT developer to be certified by FDA (or potentially by an FDA-accredited body) as having sufficient skill at developing IVCTs as to not require premarket review for each individual test developed and for which marketing is sought. This program would significantly streamline IVCT review but likely would take years to establish following congressional enactment of the VALID Act, the timing of which is subject to the often-unpredictable political process. Moreover, to date the VALID Act has not been formally introduced in Congress and, even if passed by Congress, it would need to be signed by the President in order to become law. Until the FDA finalizes its regulatory position regarding LDTs, or federal legislation is passed concerning regulation of LDTs, it is unknown how the FDA may regulate our tests in the future and what testing and data may be required to support any required clearance or approval as an medical device or an IVCT.

If the FDA begins to enforce its medical device requirements for LDTs or if the FDA disagrees with our assessment that our tests are LDTs, we could for the first time be subject to enforcement of a variety of regulatory requirements, including registration and listing, medical device reporting and quality control, and we could be required to obtain premarket clearance or approval for our existing tests and any new tests we may develop, which may force us to cease marketing our tests until we obtain the required clearance or approval. The premarket review process can be lengthy, expensive, time-consuming and unpredictable. Further, obtaining pre-market clearance may involve, among other things, successfully completing clinical trials. Clinical trials require significant time and cash resources and are subject to a high degree of risk, including risks of experiencing delays, failing to complete the trial or obtaining unexpected or negative results. If we are required to obtain premarket clearance or approval and/or conduct premarket clinical trials, our development costs could significantly increase, our introduction of any new tests we may develop may be delayed and sales of our existing tests could be interrupted or stopped. Any of these outcomes could reduce our revenue or increase our costs and materially adversely affect our business, prospects, results of operations or financial condition. Moreover, any cleared or approved labeling claims may not be consistent with our current claims or adequate to support continued adoption of and reimbursement for our tests. For instance, if we are required by the FDA to label our tests as investigational, or if labeling claims the FDA allows us to make are limited, order levels may decline and reimbursement may be adversely affected. As a result, we could experience significantly increased development costs and a delay in generating additional revenue from our existing tests or from tests we may develop.

In addition, while we qualify all materials used in our products in accordance with the regulations and guidelines of the Clinical Laboratory Improvement Amendments of 1988, or CLIA, the FDA could promulgate regulations or guidance documents impacting our ability to purchase materials necessary for the performance of our tests. If any of the reagents we obtain from suppliers and use in our tests are affected by future regulatory actions, our business could be adversely affected, including by increasing the cost of testing or delaying, limiting or prohibiting the purchase of reagents necessary to perform testing with our products.

Failure to comply with any applicable FDA requirements could 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.

If we fail to comply with applicable federal, state, local 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 establishes quality standards for all laboratory testing and is intended to ensure the accuracy, reliability and timeliness of patient results. CLIA requires that we hold a certificate specific to the laboratory examinations we perform and that we comply with various standards with respect to personnel qualifications, facility administration, proficiency testing, quality control, quality assurance and inspections. CLIA certification is required in order for us to be eligible to bill federal and state health care programs, as well as many private third-party payors, for our tests. We have obtained CLIA certification to conduct our tests at our laboratory in Temple City, California. To renew this certification, we are subject to survey and inspection every two years and we may be subject to additional unannounced inspections.

In addition to CLIA requirements, we elect to participate in the accreditation program of the College of American Pathologists, or CAP. The Centers for Medicare & Medicaid Services, or CMS, has deemed CAP standards to be equally or more stringent than CLIA regulations and has approved CAP as a recognized accrediting organization. Inspection by CAP is performed in lieu of inspection by CMS for CAP-accredited laboratories. Because we are accredited by the CAP Laboratory Accreditation Program, we are deemed to also comply with CLIA. While not required to operate a CLIA-certified laboratory, many private payors 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. Failure to maintain CAP accreditation could have a material adverse effect on the sales of our tests and the results of our operations.

We are also required to maintain a license to conduct testing in the State of California. California laws establish standards for day-to-day operation of our clinical reference laboratory in Temple City, including with respect to the training and skills required of personnel, quality control and proficiency testing requirements. In addition, because we receive test specimens originating from New York, we have obtained a state laboratory permit for our Temple City laboratory from the New York Department of Health, or DOH. The New York state laboratory laws, regulations and rules are equal to or more stringent than the CLIA regulations and establish standards for the operation of a clinical laboratory and performance of test services, including education and experience requirements for laboratory directors and personnel; physical requirements of a laboratory facility; equipment validations; and quality management practices. The laboratory director must maintain a Certificate of Qualification issued by New York's DOH in permitted categories. We are subject to on-site routine and complaint-driven inspections under both California and New York state laboratory laws and regulations. If we are found to be out of compliance with either California or New York requirements, the CA Department of Public Health or New York's DOH may suspend, restrict or revoke our license or laboratory permit, respectively (and, with respect to California, may exclude persons or entities from owning, operating or directing a laboratory for two years following such license revocation), assess civil monetary penalties, or impose specific corrective action plans, among other sanctions. Any such actions could materially and adversely affect our business by prohibiting or limiting our ability to offer testing.

Moreover, certain other states require us to maintain out-of-state laboratory licenses or obtain approval on a test-specific basis to perform testing on specimens from these states. Additional states could adopt similar licensure requirements in the future, which could require us to modify, delay or discontinue our operations in such jurisdictions. We are also subject to regulation in foreign jurisdictions, which we expect will increase as we seek to expand international utilization of our tests or if jurisdictions in which we pursue operations adopt new or modified licensure requirements. Foreign licensure requirements could require review and modification of our tests in order to offer them in certain jurisdictions or could impose other limitations, such as restrictions on the transport of human blood or other tissue necessary for us to perform our tests that may limit our ability to make our tests available outside the United States. Additionally, 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 could result in a range of enforcement actions, including license suspension, limitation or revocation, directed plan of correction, onsite monitoring, civil monetary penalties, civil injunctive suits, criminal sanctions and exclusion from the Medicare and Medicaid programs, 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 or any other required local, state or foreign license or accreditation, could have a material adverse effect on our business, financial condition and results of operations. In such case, even if we were able to bring our laboratory back into compliance, we could incur significant expenses and lose revenue while doing so.

We are subject to broad legal requirements regarding the information we test and analyze, and any failure to comply with these requirements could result in harsh penalties, damage our reputation and materially harm our business.

Our business is subject to federal and state laws that protect the privacy and security of personal health information, including the federal Health Insurance Portability and Accountability Act of 1986, or HIPAA, the federal Health Information Technology for Economic and Clinical Health Act, or HITECH, and similar state laws, as well as numerous other federal, state and foreign laws, including consumer protection laws and regulations, that govern the collection, dissemination, use, access to, confidentiality and security of patient health information. In addition, new laws and regulations that further protect the privacy and security of medical records or medical information are regularly considered by federal and state governments. Further, with the recent increase in publicity regarding data breaches resulting in improper dissemination of consumer information, federal and state governments have passed or are considering laws regulating the actions that a business must take if it experiences a data breach, such as prompt disclosure to affected customers. The Federal Trade Commission and states' Attorneys General have also brought enforcement actions and prosecuted some data breach cases as unfair and/or deceptive acts or practices under the Federal Trade Commission Act and comparable state laws. In addition to data breach notification laws, some states have enacted statutes and rules requiring businesses to reasonably protect certain types of personal information they hold or to otherwise comply with certain specified data security requirements for personal information. We intend to continue to comprehensively protect all personal information and to comply with all applicable laws regarding the protection of such information.

Any failure to implement appropriate security measures to protect the confidentiality and integrity of personal information or any breach or other failure of these systems resulting in the unauthorized access, manipulation, disclosure or loss of this information could result in our noncompliance with these laws. Penalties for failure to comply with a requirement of HIPAA and HITECH vary significantly depending on the failure and could include civil monetary or criminal penalties.

The European Union formally adopted the General Data Protection Regulation ("GDPR") in 2016, which applies to all European Union member states from May 25, 2018 and replaced the European Data Protection Directive. The GDPR also includes new operational requirements for companies that receive or process personal data of European residents, as well as significant penalties for non-compliance. The regulation introduces stringent new data protection requirements in the European Union and substantial fines for breaches of the data protection rules. It has increased our responsibility and liability in relation to personal data that we process and we may be required to put in place additional mechanisms ensuring compliance with the new European data protection rules. The GDPR is a complex law and the regulatory guidance is still evolving, including with respect to how the GDPR should be applied in the context of clinical studies. Furthermore, many of the countries within the European Union are still in the process of drafting supplementary data protection legislation in key fields where the GDPR allows for national variation, including the fields of clinical study and other health-related information. These variations in the law may raise our costs of compliance and result in greater legal risks.

In addition, various states, such as California (where our clinical laboratory is located) and Massachusetts, have implemented similar privacy laws and regulations, such as the California Confidentiality of Medical Information Act, that impose restrictive requirements regulating the use and disclosure of health information and other personally identifiable information. In addition to fines and penalties imposed upon violators, some of these state laws also afford private rights of action to individuals who believe their personal information has been misused. California's patient privacy laws, for example, provide for penalties of up to $250,000 and permit injured parties to sue for damages. In addition to the California Confidentiality of Medical Information Act, California also recently enacted the California Consumer Privacy Act of 2018, or CCPA, which became effective on January 1, 2020. The CCPA has been characterized as the first "GDPR-like" privacy statute to be enacted in the United States because it mirrors a number of the key provisions of the EU General Data Protection Regulation. The CCPA establishes a new privacy framework for covered businesses in the State of California, by creating an expanded definition of personal information, establishing new data privacy rights for consumers imposing special rules on the collection of consumer data from minors, and creating a new and potentially severe statutory damages framework for violations of the CCPA and for businesses that fail to implement reasonable security procedures and practices to prevent data breaches.

The interplay of federal and state laws may be subject to varying interpretations by courts and government agencies, creating complex compliance issues for us and potentially exposing us to additional expense, adverse publicity and liability. Further, as regulatory focus on privacy issues continues to increase and laws and regulations concerning the protection of personal information expand and become more complex, these potential risks to our business could intensify. Additionally, the interpretation, application and interplay of consumer and health-related data protection laws in the United States, Europe and elsewhere are often uncertain, contradictory and in flux. As a result, it is possible that laws may be interpreted and applied in a manner that is inconsistent with our current practices. Moreover, these laws and their interpretations are constantly evolving and they may become more stringent over time. Complying with these laws or any new laws or interpretations of their application could involve significant time and substantial costs or require us to change our business practices and compliance procedures in a manner adverse to our business. We may not be able to obtain or maintain compliance with the diverse privacy and security requirements in all of the jurisdictions in which we currently or plan to do business, and failure to comply with any of these requirements could result in civil or criminal penalties, harm our reputation and materially adversely affect our business.

We conduct business in a heavily regulated industry. Complying with the numerous statutes and regulations pertaining to our business is expensive and time-consuming, and any failure by us, our consultants or commercial partners to comply could result in substantial penalties.

Our industry and our operations are heavily regulated by various federal, state, local and foreign laws and regulations, and the regulatory environment in which we operate could change significantly and adversely in the future. These laws and regulations currently include, among others:

- the FDA's enforcement discretion policy with respect to LDTs;
- CLIA's and CAP's regulation of our laboratory activities;
- federal and state laws and standards affecting reimbursement by government payors, including certain coding requirements to obtain reimbursement and certain changes to the payment mechanism for clinical laboratory services resulting from the Protecting Access to Medicare Act of 2014, or PAMA;

- HIPAA and HITECH, which establish comprehensive federal standards with respect to the privacy and security of PHI, and requirements for the use of certain standardized electronic transactions with respect to transmission of such information, as well as similar laws protecting other types of personal information;
- state laws governing the maintenance of personally identifiable information of state residents, including medical information, and which impose varying breach notification requirements, some of which allow private rights of action by individuals for violations and also impose penalties for such violations;
- the federal Anti-Kickback Statute, which generally prohibits knowingly and willfully offering, paying, soliciting or receiving remuneration, directly or indirectly, in return for or to induce a person to refer to an individual any good, facility, item or service that is reimbursable under a federal health care program;
- the federal Stark Law, which generally prohibits a physician from making a referral for certain designated health services covered by the Medicare program, including laboratory and pathology services, if the physician or an immediate family member has a financial relationship with the entity providing the designated health services;
- the federal false claims laws, which generally 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 generally prohibits, among other things, the offering or transfer of remuneration to a Medicare or Medicaid beneficiary if it is likely to influence the beneficiary's selection of a particular provider, practitioner or supplier of services reimbursable by Medicare or Medicaid;
- the Affordable Care Act, which, among other things, establishes a requirement for providers and suppliers to report and return any overpayments received from the Medicare and Medicaid programs;
- 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, some of which may extend to services reimbursable by any third-party payor, including private payors;
- the federal Physician Sunshine Payment Act and various state laws on reporting relationships with health care providers and customers, which could be determined to apply to our LDTs;
- the prohibition on reassignment of Medicare claims;
- state laws that prohibit other specified healthcare practices, such as billing physicians for tests that they order, waiving coinsurance, copayments, deductibles and other amounts owed by patients, business corporations practicing medicine or employing or engaging physicians to practice medicine and billing a state Medicaid program at a price that is higher than what is charged to one or more other payors;
- the federal Foreign Corrupt Practices Act, or FCPA, and applicable foreign anti-bribery laws;
- federal, state and local regulations relating to the handling and disposal of regulated medical waste, hazardous waste and biohazardous waste and workplace safety for healthcare employees;
- laws and regulations relating to health and safety, labor and employment, public reporting, taxation and other areas applicable to businesses generally, all of which are subject to change, including, for example, the significant changes to the taxation of business entities were enacted in December 2017; and
- similar foreign laws and regulations that apply to us in the countries in which we operate or may operate in the future.

The genetic testing industry is currently under a high degree of government scrutiny. The Office of Inspector General for the Department of Health and Human Services and a variety of State Attorneys General have issued fraud alerts regarding a variety of cancer genetic testing fraud schemes, and the Department of Justice has announced indictments in such fraud schemes involving a variety of individuals and entities, including genetic testing and other laboratories, physicians who order genetic testing for a large volume of patients without treating them, and third parties who arranged for the genetic testing by approaching patients through telemarketing calls, booths at public events, health fairs, and door-to-door visits. These individuals then shared the proceeds received from Medicare, TRICARE, and other third-party payors. This increased regulatory scrutiny could decrease demand for our testing services or increase our costs of regulatory compliance, either of which could have a material adverse effect on our business.

Any future growth of our business, including, in particular, growth of our international business and continued reliance on consultants, commercial partners and other third parties, may increase the potential for violating these laws. In some cases, our risk of violating these or other laws and regulations is further increased because of the lack of their complete interpretation by applicable regulatory authorities or courts, and their provisions are thus open to a variety of interpretations. Our recently launched Picture Genetics line of at-home genetic test offerings are patient-initiated screening tests, which may receive greater scrutiny from regulatory authorities than our traditional testing services that are offered directly to health care providers.

We have adopted policies and procedures designed to comply with these laws and regulations and, in the ordinary course of our business, we conduct internal reviews of our compliance with these laws. Our compliance is also subject to review by applicable government agencies. It is not always possible to identify and deter misconduct by employees, distributors, consultants and commercial partners, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from government investigations or other actions or lawsuits stemming from a failure to comply with applicable laws or regulations. Additionally, we are subject to the risk that a person or government could allege such fraud or other misconduct, even if none occurred. 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, divert our management's attention from the operation of our business and harm our reputation. If our operations, including the conduct of our employees, consultants and commercial partners, are found to be in violation of any of these laws and regulations, we may be subject to applicable penalties 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 these consequences could seriously harm our business and our financial results.

Healthcare policy changes, including recently enacted and proposed new legislation reforming the U.S. healthcare system, could cause significant harm to our business, operations and financial condition.

The Affordable Care Act made a number of substantial changes to the way healthcare is financed both by governmental and private payors. The Affordable Care Act also introduced mechanisms to reduce the per capita rate of growth in Medicare spending if expenditures exceed certain targets. Any such reductions could affect reimbursement payments for our tests. The Affordable Care Act also contains a number of other provisions, including provisions governing enrollment in federal and state healthcare programs, reimbursement matters and fraud and abuse, which we expect will impact our industry and our operations in ways that we cannot currently predict.

In April 2014, Congress passed PAMA, which included substantial changes to the way in which clinical laboratory services will be paid under Medicare. Under PAMA, certain clinical laboratories are required to periodically report to CMS private payor payment rates and volumes for their tests. Laboratories that fail to report the required payment information may be subject to substantial civil monetary penalties. Further, effective January 1, 2018 under PAMA, Medicare reimbursement for diagnostic tests will be based on the weighted-median of the payments made by private payors for these tests, rendering private payor payment levels even more significant. As a result, future Medicare payments may fluctuate more often and become subject to the willingness of private payors to recognize the value of diagnostic tests generally and any given test individually. The impact of this new payment system on rates for our tests, including any current or future tests we may develop, is uncertain.

We cannot predict whether or when these or other recently enacted healthcare initiatives will be implemented at the federal or state level or how any such legislation or regulation may affect us. For instance, the payment reductions imposed by the Affordable Care Act and the changes to reimbursement amounts paid by Medicare for tests such as ours based on the procedure set forth in PAMA, could limit the prices we will be able to charge or the amount of available reimbursement for our tests, which would reduce our revenue. Additionally, these healthcare policy changes could be amended or additional healthcare initiatives could be implemented in the future. For instance, there is uncertainty regarding the continued effect of the Affordable Care Act in its current form and in light of the policies of the current administration and members of Congress, which have threatened to repeal, replace or change the Affordable Care Act. President Trump has signed two Executive Orders and other directives designed to delay the implementation of certain provisions of the Affordable Care Act or otherwise circumvent some of the requirements for health insurance mandated by the Affordable Care Act. Concurrently, although Congress has not passed comprehensive repeal legislation, at least two bills affecting the implementation of certain taxes under the Affordable Care Act have been signed into law. For example, the Tax Cuts and Jobs Act of 2017 repealed the tax-based shared responsibility payment imposed by the Affordable Care Act on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate." In December 2019, the Fifth Circuit Court of Appeals upheld a district court's finding that the individual mandate in the Affordable Care Act is unconstitutional following removal of the penalty provision from the law. However, the Fifth Circuit reversed and remanded the case to the district court to determine if other reforms enacted as part of the Affordable Care Act but not specifically related to the individual mandate or health insurance could be severed from the rest of the Affordable Care Act so as not to have the law declared invalid in its entirety. It is unclear how this decision, subsequent appeals including potentially to the U.S. Supreme Court, and other efforts to repeal and replace the Affordable Care Act will affect the implementation of that law and our business.

Further, the impact on our business of the expansion of the federal and state governments' role in the U.S. healthcare industry generally, including the social, governmental and other pressures to reduce healthcare costs while expanding individual benefits, is uncertain. Any future changes or initiatives could have a materially adverse effect on our business, financial condition, results of operations and cash flows.

Changes in laws and regulations, or in their application, may adversely affect our business, financial condition and results of operations.

The clinical laboratory testing industry is highly regulated, and failure to comply with applicable regulatory, supervisory, accreditation, registration or licensing requirements may adversely affect our business, financial condition and results of operations. In particular, the laws and regulations governing the marketing and research of clinical diagnostic testing are extremely complex, and in many instances there are no clear regulatory or judicial interpretations of these laws and regulations, increasing the risk that we may be found to be in violation of these laws.

Furthermore, the genetic testing industry as a whole is a growing industry and regulatory agencies such as the United States Department of Health and Human Services, or HHS, or the FDA may apply heightened scrutiny to new developments in the field, or the U.S. Congress may do so. Since 2017, Congress has been working on legislation to create an LDT and IVD regulatory framework that would be separate and distinct from the existing medical device regulatory framework. In August 2018, the FDA recommended changes to draft legislation that had been released by Congress in 2017. The agency's comments addressed the need for a requirement that new tests undergo FDA review to demonstrate analytical and clinical validity and suggested changes to the draft language as it relates to premarket approval, provisional approval, and a precertification program for diagnostics. FDA's recommendations, if included in enacted law, would give the FDA authority to revoke approval, request raw data, and take corrective action against test developers. In December 2018, legislators released a discussion draft of a bill that incorporated many of FDA's suggestions. The new bill is called the Verifying Accurate, Leading-edge IVCT Development (VALID) Act and would codify into law the term "in vitro clinical test" (IVCT), a new medical product category separate from medical devices and that includes products currently regulated as IVDs as well as LDTs. It is unclear whether the VALID Act would be passed by Congress in its current form or signed into law by the President.

In addition, there has been a recent trend of increased U.S. federal and state regulation, scrutiny and enforcement relating to payments made to referral sources, which are governed by laws and regulations including the Stark law, the federal Anti-Kickback Statute, the federal False Claims Act, as well as state equivalents of such laws. For example, the Eliminating Kickbacks in Recovery Act of 2018, or EKRA, was passed in October 2018 as part of the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (referred to as the SUPPORT Act). Similar to the federal Anti-Kickback Statute, EKRA imposes criminal penalties for knowing or willful payment or offer, or solicitation or receipt, of any remuneration, whether directly or indirectly, overtly or covertly, in cash or in kind, in exchange for the referral or inducement of laboratory testing (among other health care services) unless a specific exception applies. However, unlike the federal Anti-Kickback Statute, EKRA is not limited to services covered by federal or state health care programs but applies more broadly to services covered by "health care benefit programs," including commercial insurers. Additionally, because EKRA's exceptions are not identical to the federal Anti-Kickback Statute's safe harbors, compliance with a federal Anti-Kickback Statute safe harbor does not guarantee protection under EKRA. As currently drafted, EKRA potentially expands the universe of arrangements that could be subject to government enforcement under federal fraud and abuse laws. Because EKRA is a new law, there is no agency guidance or court precedent to indicate how and to what extent it will be applied and enforced. We cannot assure you that our relationships with physicians, sales representatives, hospitals, customers, or any other party will not be subject to scrutiny or will survive regulatory challenge under such laws. If imposed for any reason, sanctions under the EKRA could have a negative effect on our business.

If the hazardous materials we use in our operations cause contamination or injury, we could be liable for resulting damages.

Our operations require the use of regulated medical waste, hazardous waste and biohazardous waste, including chemicals, biological agents and compounds and blood and other tissue specimens. We are subject on an ongoing basis to federal, state and local laws and regulations governing the use, storage, handling and disposal of these hazardous materials and other specified waste products. Although we typically use licensed or otherwise qualified outside vendors to dispose of this waste, applicable laws and regulations could hold us liable for damages and fines if our, or others', business operations or other actions result in contamination to the environment or personal injury due to exposure to hazardous materials. We cannot eliminate the risk of contamination or injury, and any liability imposed on us for any resulting damages or injury could exceed our resources or any applicable insurance coverage. The cost to secure such insurance coverage and to comply with these laws and regulations could become more significant in the future, and any failure to comply could result in substantial costs and other business and reputational consequences, any of which could negatively affect our operating results.

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

Our international operations are subject to various anti-bribery laws, including the FCPA and similar anti-bribery laws in the non-U.S. jurisdictions in which we operate. The FCPA prohibits companies and their intermediaries from offering, making, or authorizing improper payments to non-U.S. or foreign officials for the purpose of obtaining or retaining business or securing any other improper advantage. These laws are complex and far-reaching in nature, and we may be required in the future to alter one or more of our practices to be in compliance with these laws or any changes to these laws or their interpretation.

We currently engage in significant business outside the United States, and we plan to increase our international operations in the future. These operations could involve dealings with governments, foreign officials and state-owned entities, such as government hospitals, outside the United States. In addition, we may engage distributors, other commercial partners or third-party intermediaries, such as representatives or contractors, or establish joint ventures or other arrangements to manage or assist with promotion and sale of our tests abroad and obtaining necessary permits, licenses and other regulatory approvals. Any such third parties could be deemed to be our agents and we could be held responsible for any corrupt or other illegal activities of our employees or these third parties, even if we do not explicitly authorize or have actual knowledge of such activities. We have instituted policies, procedures, and internal controls reasonably designed to promote compliance with the FCPA and other anti-corruption laws and we exercise a high degree of vigilance in maintaining, implementing and enforcing these policies and controls. However, these policies and controls could be circumvented or ignored and they cannot guarantee compliance with these laws and regulations. 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 harm our reputation. Additionally, other U.S. companies in the medical device and pharmaceutical fields have faced substantial fines and criminal penalties in the recent past for violating the FCPA, and we could also incur these types of penalties, including criminal and civil penalties, disgorgement, and other remedial measures, if we violate the FCPA or other applicable anti-bribery laws. Any of these outcomes could result in a material adverse effect on our business, prospects, financial condition, or results of operations.

Our services present the potential for embezzlement, identity theft or other similar illegal behavior by our employees, consultants, service providers or commercial partners.

Our operations involve the use and disclosure of personal and business information that could be used to impersonate third parties or otherwise gain access to their data or funds. If any of our employees, consultants, service providers or commercial partners takes, converts or misuses these funds or data, we could be liable for any resulting damages, which could harm our financial condition and damage our business reputation.

We could be adversely affected by alleged violations of the Federal Trade Commission Act or other truth-in-advertising and consumer protection laws.

Our advertising for laboratory services and tests is subject to federal truth-in-advertising laws enforced by the Federal Trade Commission (“FTC”), as well as comparable state consumer protection laws. Under the Federal Trade Commission Act (“FTC Act”), the FTC is empowered, among other things, to (a) prevent unfair methods of competition and unfair or deceptive acts or practices in or affecting commerce; (b) seek monetary redress and other relief for conduct injurious to consumers; and (c) gather and compile information and conduct investigations relating to the organization, business, practices, and management of entities engaged in commerce. The FTC has very broad enforcement authority, and failure to abide by the substantive requirements of the FTC Act and other consumer protection laws can result in administrative or judicial penalties, including civil penalties, injunctions affecting the manner in which we would be able to market services or products in the future, or criminal prosecution. In conjunction with the recent launch of our Picture Genetics line of at-home genetic test offerings that are initiated consumers, we plan to increase our advertising activities that would be subject to these federal and state truth-in-advertising laws. Any actual or perceived non-compliance with those laws could lead to an investigation by the FTC or a comparable state agency, or could lead to allegations of misleading advertising by private plaintiffs. Any such action against us would disrupt our business operations, cause damage to our reputation, and result in a material adverse effects on our business.

Intellectual Property Risks

We currently own no patents or patent applications related to our technology platform and rely on trade secret protection, non-disclosure agreements and invention assignment agreements to protect our proprietary information, which may not be effective.

We currently rely on trade secret protection, non-disclosure agreements and invention assignment agreements with our employees, consultants and third-parties to protect our confidential and proprietary information. Although our competitors have utilized and are expected to continue to utilize technologies and methods similar to ours and have aggregated and are expected to continue to aggregate libraries of genetic information similar to ours, we believe our success will depend in part on our ability to develop proprietary methods and libraries and to defend any advantages afforded to us by these methods and libraries relative to our competitors. If we do not protect our intellectual property and other confidential information adequately, competitors may be able to use our proprietary technologies and information and thereby erode any competitive advantages they provide us.

We will be able to protect our proprietary rights from unauthorized use by third parties only to the extent these rights are effectively maintained as confidential. We expect to rely primarily on trade secret and contractual protections for our confidential and proprietary information and we have taken security measures we believe are appropriate to protect this information. These measures, however, may not provide adequate protection for our trade secrets, know-how or other confidential information. We seek to protect our proprietary information by, among other things, entering into confidentiality agreements with employees, consultants and other third parties. These confidentiality agreements may not sufficiently safeguard our trade secrets and other confidential information and may not provide adequate remedies in the event of unauthorized use or disclosure of this information. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret or other proprietary information could be difficult, expensive and time-consuming and the outcome could be unpredictable. In addition, trade secrets or other confidential information could otherwise become known or be independently developed by others in a manner that could prevent legal recourse by us. If any of our trade secrets or other confidential or proprietary information were disclosed or misappropriated or if any such information was independently developed by a competitor, our competitive position could be harmed and our business could suffer.

Litigation or other proceedings or third-party claims of intellectual property infringement or misappropriation could require us to spend significant time and money and prevent us from selling our tests.

We believe our ability to succeed will depend in part on our avoidance of infringement of patents and other proprietary rights owned by third parties, including the intellectual property rights of competitors. There are numerous third-party-owned U.S. and foreign patents, pending patent applications and other intellectual property rights that cover technologies relevant to genetic testing. We may be unaware of patents or other intellectual property rights that a third-party might assert are infringed by our business, and there may be pending patent applications that, if issued, could be asserted against us. As a result, our existing or future operations may be alleged or found to infringe existing or future patents or other intellectual property rights of others. Moreover, as we continue to sell our existing tests and if we launch new tests and enter new markets, competitors may claim that our tests infringe or misappropriate their intellectual property rights as part of strategies designed to impede our existing operations or our entry into new markets.

If a patent infringement or misappropriation of intellectual property lawsuit was brought against us, we could be forced to discontinue or delay our development or sales of any tests or other activities that are the subject of the lawsuit while it is pending, even if it is not ultimately successful. In the event of a successful claim of infringement against us, we could be forced to pay substantial damages, including treble damages and attorneys' fees if we were found to have willfully infringed patents; obtain one or more licenses, which may not be available when needed, on commercially reasonable terms or at all; pay royalties, which may be substantial; or redesign any infringing tests or other activities, which may be impossible or require substantial time and expense. In addition, third parties making claims against us for infringement or misappropriation of their patents or other intellectual property rights could seek and obtain injunctive or other equitable relief, which, if granted, could prohibit us from performing our tests. Further, defense against these claims, regardless of their merit or success, could cause us to incur substantial expenses, be a substantial diversion to our management and other employee resources and significantly harm our reputation. Any of these outcomes could delay our introduction of new tests, significantly increase our costs or prevent us from conducting certain of our essential activities, which could materially adversely affect our ability to operate and grow our business.

Developments in patent law could have a negative impact on our business.

From time to time, the U.S. Supreme Court, other federal courts, the U.S. Congress or the U.S. Patent and Trademark Office, or USPTO, may change the standards of patentability, and any such changes could have a negative impact on our business.

Three cases involving diagnostic method claims and "gene patents" have been decided by the Supreme Court in recent years. In March 2012, the Supreme Court issued a decision in *Mayo Collaborative v. Prometheus Laboratories*, or Prometheus, a case involving patent claims directed to optimizing the amount of drug administered to a specific patient, holding that the applicable patents' claims failed to incorporate sufficient inventive content above and beyond mere underlying natural correlations to allow the claimed processes to qualify as patent-eligible processes that apply natural laws. In June 2013, the Supreme Court decided *Association for Molecular Pathology v. Myriad Genetics*, or Myriad, a case challenging the validity of patent claims relating to the breast cancer susceptibility genes BRCA1 and BRCA2, holding that isolated genomic DNA that exists in nature, such as the DNA constituting the BRCA1 and BRCA2 genes, is not patentable subject matter, but that cDNA, which is an artificial construct created from RNA transcripts of genes, may be patent eligible. In June 2014, the Supreme Court decided *Alice Corporation Pty. Ltd. v. CLS Bank International*, or Alice, which affirmed the Prometheus and Myriad decisions and provided additional interpretation.

If we make efforts to seek patent protection for our technologies and tests, these efforts may be negatively impacted by the Prometheus, Myriad and Alice decisions, rulings in other cases or guidance or procedures issued by the USPTO. However, we cannot fully predict the impact of the Prometheus, Myriad and Alice decisions on the ability of genetic testing, biopharmaceutical or other companies to obtain or enforce patents relating to DNA, genes or genomic-related discoveries in the future, as the contours of when claims reciting laws of nature, natural phenomena or abstract ideas may meet patent eligibility requirements are not clear and may take years to develop via interpretation at the USPTO and in the courts. There are many previously issued patents claiming nucleic acids and diagnostic methods based on natural correlations that issued before these recent Supreme Court decisions and, although many of these patents may be invalid under the standards set forth in these decisions, they are presumed valid and enforceable until they are successfully challenged, and third parties holding these patents could allege that we infringe or request that we obtain a license under the patents. Whether based on patents issued before or after these Supreme Court decisions, we could be forced to defend against claims of patent infringement or obtain license rights, if available, under these patents. In particular, although the Supreme Court has held in Myriad that isolated genomic DNA is not patent-eligible subject matter, third parties could allege that our activities infringe other classes of gene-related patent claims. There are numerous risks associated with any patent infringement claim that may be brought against us, as discussed above under "—Litigation or other proceedings or third-party claims of intellectual property infringement or misappropriation could require us to spend significant time and money and prevent us from selling our tests."

In addition, the Leahy-Smith America Invents Act, or America Invents Act, which was signed into law in 2011, includes a number of significant changes to U.S. patent law. These changes include a transition from a "first-to-invent" system to a "first-to-file" system, changes to the way issued patents are challenged and changes to the way patent applications are disputed during the examination process. These changes may favor larger and more established companies that have greater resources to devote to patent application filing and prosecution. The USPTO has developed new regulations and procedures to govern the full implementation of the America Invents Act, but the impact of the America Invents Act on the cost of prosecuting any patent applications we may file, our ability to obtain patents based on our discoveries if we pursue them and our ability to enforce or defend any patents that may issue remains uncertain.

These and other substantive changes to U.S. patent law could affect our susceptibility to patent infringement claims and our ability to obtain any patents we may pursue and, if obtained, to enforce or defend them, any of which could have a material adverse effect on our business.

We may not be able to enforce our intellectual property rights outside the United States.

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 the United States. These challenges can be caused by the absence of rules and methods for the establishment and enforcement of intellectual property rights in certain jurisdictions. In addition, the legal systems of some countries, particularly developing countries, do not favor the enforcement of certain intellectual property protection, especially relating to healthcare. These aspects of many foreign legal systems could make it difficult for us to prevent or stop the misappropriation of our intellectual property rights in these jurisdictions. Moreover, changes in the law and legal decisions by courts in foreign countries could affect our ability to obtain adequate protection for our technologies and enforce our intellectual property rights. As a result, our efforts to protect and enforce our intellectual property rights outside the United States may prove inadequate, in which case our ability to remain competitive and grow our business and revenue could be materially harmed.

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 and biometric solution, genetic testing, diagnostic or other healthcare companies, including our competitors or potential competitors. Further, we may become subject to ownership disputes in the future arising from, for example, conflicting obligations of consultants or others who are involved in developing our and other parties' technologies and intellectual property rights. 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 rights, including trade secrets or other proprietary information, of a former employer or other third-party. Litigation may be necessary to defend against these claims, should they arise. If we fail in defending against any such claims, we could be subject to monetary damages and the loss of valuable intellectual property rights or personnel. Even if we are successful in defending against any such claims, litigation could result in substantial costs, distract management and other employees and damage our reputation.

Common Stock Risks

An active, liquid trading market for our common stock may not be sustained, which could make it difficult for stockholders to sell their shares of our common stock.

An active trading market for our common stock may not be sustained. Further, Mr. Hsieh, our founder, Chief Executive Officer and Chairman of our board of directors, beneficially owns just over one third of our outstanding voting equity. As a result, fewer shares are actively traded in the public market, which reduces the liquidity of our common stock. The lack of an active trading market could impair our stockholders' ability to sell their shares at the desired time or at a price considered reasonable. Further, an inactive trading market may impair our ability to raise capital by selling shares of our common stock in the future, and may impair our ability to enter into strategic relationships or acquire companies or technologies using shares of our common stock as consideration.

Our common stock is listed on the Nasdaq Global Market under the symbol "FLGT." If we fail to satisfy the continued listing standards of Nasdaq, however, we could be de-listed, which would negatively impact the price and liquidity of our common stock.

The price of our common stock may be volatile and you could lose all or part of your investment.

The trading price of our common stock has experienced, and may continue to experience, wide fluctuations and significant volatility. This volatility may be exacerbated by the relatively small and illiquid market for our common stock. Other factors that may contribute to this volatility include, among others:

- actual or anticipated fluctuations in our operating results;
- competition from existing tests or new tests that may emerge, particularly if competitive factors in our industry, including prices for genetic testing, become more acute;
- failures to meet or exceed financial estimates and projections of the investment community or guidance we have provided to the public;
- issuance of new or updated research or reports by securities analysts or changed recommendations for our common stock;
- announcements by us or our competitors of significant acquisitions, investments, strategic relationships, joint ventures, collaborations or capital commitments;
- the timing and amount of our investments in our business and the market's perception of these investments and their impact on our prospects;
- actual or anticipated changes in laws or regulations applicable to our business or our tests;
- additions or departures of key management or other personnel;
- changes in coverage and reimbursement by current or potential payors;
- inability to obtain additional funding as and when needed on reasonable terms;
- disputes or other developments with respect to our or others' intellectual property rights;
- product liability claims or other litigation;
- sales of our common stock by us or our stockholders;
- general economic, political, industry and market conditions, including factors not directly related to our operating performance or the operating performance of our competitors, such as increased uncertainty in the U.S. regulatory environment for healthcare, trade and tax-related matters;
- events that affect, or have the potential to affect, general economic conditions, including but not limited to political unrest, global trade wars, natural disasters, act of war, terrorism, or disease outbreaks (such as the recent outbreak of COVID-19, or the novel coronavirus);
- and the other risk factors discussed in this report.

In addition, the stock market in general, and the market for the stock of companies in the life sciences and technology industries in particular, has experienced extreme price and volume fluctuations in recent years that have at times been unrelated or disproportionate to the operating performance of specific companies. These broad market and industry factors may negatively 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 the company. This type of litigation, if instituted against us, could result in substantial costs and a diversion of our management's attention and resources.

Our principal stockholders and management own a significant percentage of our capital stock and are able to exert significant control over matters subject to stockholder approval.

Our executive officers, directors, beneficial owners of 5% or more of our outstanding voting equity and their respective affiliates collectively beneficially own the substantial majority of our outstanding voting equity, and of this, Mr. Hsieh, our founder, Chief Executive Officer and Chairman of our board of directors, by himself beneficially owns just over one third of our outstanding voting equity. As a result, these stockholders have the ability to control matters submitted to our stockholders for approval, including elections of directors, amendments to our organizational documents or approval of any merger, sale of assets or other major corporate transaction. This concentration of ownership may prevent or discourage unsolicited acquisition proposals or offers to acquire our common stock that some of our stockholders feel are in their best interests, as the interests of these stockholders may not coincide with the interests of our other stockholders and they may act in a manner that advances their best interests and not necessarily those of all of our stockholders. Further, this concentration of ownership could adversely affect the prevailing market price for our common stock.

Sales of a substantial number of shares of our common stock in the public market, or the perception that such sales could occur, could cause the price of our common stock to fall.

Sales of a substantial number of shares of our common stock in the public market could occur at any time. Any such sales, or the perception in the market that sales are pending or could occur, could reduce the market price of our common stock. All of the outstanding shares of our common stock are freely tradable without restriction in the public market, subject to certain volume and manner of sale limitations applicable to shares held by our affiliates, as that term is defined in the Securities Act. In addition, subject to similar limitations and any other applicable legal and contractual limitations, all of the shares of our common stock subject to outstanding equity-based awards or reserved for issuance pursuant to such awards we may grant in the future are registered under the Securities Act or are otherwise eligible under applicable securities laws for free trading in the public market upon their issuance. Moreover, Xi Long, a large stockholder of our company, has the right, subject to certain conditions, to include its shares in registration statements we may file for ourselves or other stockholders and to require us to file registration statements covering its shares.

Future issuances of our common stock or rights to purchase our common stock, including pursuant to our equity incentive plan, could result in additional dilution to the percentage ownership of our stockholders and could cause the price of our common stock to fall.

To raise capital or for other strategic purposes, we may sell common stock, convertible securities or other equity securities in one or more transactions at prices and in a manner we determine from time to time. In particular and in August 2019, we entered into an Equity Distribution Agreement with Piper Jaffray & Co. as sales agent (“Piper”), pursuant to which we may, from time to time, sell through Piper shares of our common stock with an aggregate purchase price of up to $30.0 million. During the year ended December 31, 2019, we sold an aggregate of 104,390 shares of our common stock pursuant to the Equity Distribution Agreement at a weighted-average selling price of $9.37 per share. We also may issue common stock or grant other equity awards for compensatory purposes under our equity incentive plan. If we issue common stock, convertible securities or other equity securities, including shares pursuant to the Equity Distribution Agreement or equity awards under our equity incentive plan, our then-existing stockholders could be materially diluted by such issuances and, if we otherwise issue preferred stock, new investors could gain rights, preferences and privileges senior to the holders of our common stock, any of which could cause the price of our common stock to decline.

We do not intend to pay dividends on our common stock, so any returns will be limited to the value of our common stock.

We currently anticipate that we will retain any future earnings to finance the continued development, operation and expansion of our business. As a result, we do not anticipate declaring or paying any cash dividends or other distributions in the foreseeable future. Further, if we were to enter into a credit facility or issue debt securities or preferred stock in the future, we may become contractually restricted from paying dividends. If we do not pay dividends, our common stock may be less valuable because stockholders must rely on sales of their common stock after price appreciation, which may never occur, to realize any gains on their investment.

If securities or industry analysts do not publish research or reports about our business or if they issue an adverse or misleading opinion regarding our common stock, our stock price and trading volume could decline.

The trading market for our common stock is influenced by the research and reports that industry or securities analysts publish about us or our business. If one or more of these analysts ceases coverage of us or fails to publish reports on us regularly, we could lose visibility in the financial markets, which could cause the price and trading volume of our common stock to decline. Further, if any of these analysts issues an adverse or misleading opinion regarding us, our business model, our industry or our stock performance or if our operating results fail to meet analyst expectations, the price of our common stock could also decline.

Provisions in our charter documents and Delaware law could discourage, delay or prevent a change in control of our company or changes in our management and depress the market price of our common stock.

Our certificate of incorporation and bylaws contain provisions that could depress the market price of our common stock by acting to discourage, delay or prevent a change in control of our company or changes in our management that our stockholders may deem advantageous. These provisions, among other things:

- authorize our board of directors to issue, without further action by our stockholders, up to 1,000,000 shares of undesignated or "blank check" preferred stock;
- prohibit stockholder action by written consent, thus requiring all stockholder actions to be taken at a duly noticed and held meeting of our stockholders;
- specify that special meetings of our stockholders can be called only by our board of directors, the Chairman of our board of directors or our President, thereby eliminating the ability of our stockholders to call special meetings;
- permit only our board of directors to establish the number of directors and fill vacancies on the board of directors, except as may be required by law;
- permit our board of directors to amend our bylaws, subject to the power of our stockholders to repeal any such amendment;
- do not permit cumulative voting on the election of directors; and
- establish advance notice requirements for stockholders to propose nominees for election as directors or matters to be acted upon at annual meetings of stockholders.

In addition, we are subject to Section 203 of the Delaware General Corporation Law, or DGCL, which imposes certain restrictions on mergers, business combinations and other transactions between us and holders of 15% or more of our common stock. Section 203 may have the effect of discouraging, delaying or preventing a change in control of our company.

Holders of our common stock could be adversely affected if we issue preferred stock.

Pursuant to our certificate of incorporation, our board of directors is authorized to issue up to 1,000,000 shares of preferred stock without any action by our stockholders. Our board of directors also has the power, without stockholder approval, to set the terms of any series of preferred stock that may be issued, among others, including voting rights, dividend rights and preferences over our common stock with respect to dividends or in the event of a dissolution, liquidation or winding up. If we issue preferred stock in the future that has preferences over our common stock with respect to payment of dividends or upon a liquidation, dissolution or winding up, or if we issue preferred stock that is convertible into our common stock at greater than a one-to-one ratio, the voting and other rights of the holders of our common stock and the market price of our common stock could be adversely affected.

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 judicial forum they consider favorable 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 to our stockholders;
- any action asserting a claim against us arising pursuant to any provision of the DGCL, our certificate of incorporation or our bylaws; and
- 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 is deemed to have notice of and consented to this provision of our certificate of incorporation. This choice-of-forum provision may limit a stockholder's ability to bring a claim in a judicial forum it finds favorable for disputes with us or our directors, officers or other employees, which may discourage these lawsuits. Alternatively, if a court were to find this provision 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 these matters in other jurisdictions, which could adversely affect our business, financial condition or results of operations.

Item 1B. Unresolved Staff Comments.

Not applicable.

Item 2. Properties.

Our corporate headquarters and laboratory operations are located in Temple City, California, where we lease and occupy approximately 12,000 square feet of office and laboratory space under leases that will expire in January 2021. The Company has options to renew some of these leases for three years. We use these facilities for all of our laboratory testing and management activities and certain research and development, administrative and other functions. We also lease approximately 2,200 square feet of office space near Atlanta, Georgia under a lease that will expire in November 2022 and approximately 11,600 square feet of office space in El Monte, California under a lease that will expire in August 2023, where we conduct certain research and development, customer service, report generation and other administrative activities, although no laboratory activities occur at either of these facilities. We believe our existing facilities are adequate for our current and expected near-term needs and additional space would be available on commercially reasonable terms if required.

Item 3. Legal Proceedings.

From time to time, we may be involved in legal proceedings arising in the ordinary course of our business. We are not presently a party, and our properties are not presently subject, to any legal proceedings that, in the opinion of management, would have a material effect on our business. Regardless of outcome, litigation can have an adverse impact on us due to defense and settlement costs, diversion of management resources, negative publicity and reputational harm, among other factors.

Item 4. Mine Safety Disclosures.

Not applicable.

PART II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities.

Market Information

On September 29, 2016, our common stock was listed for trading on the Nasdaq Global Market under the symbol "FLGT." There was no public market for our common stock prior to September 29, 2016.

Holders of Common Stock

As of March 1, 2020, there were 5 holders of record of our common stock, plus an indeterminate number of additional stockholders whose shares of our common stock are held on their behalf by brokerage firms or other agents.

Dividend Policy

We currently anticipate that we will retain any future earnings to finance the continued development, operation and expansion of our business. As a result, we do not anticipate declaring or paying any cash dividends or other distributions in the foreseeable future. Any determination to pay dividends would be at the discretion of our board of directors and would depend on our results of operation, financial condition and other factors that our board of directors, in its discretion, considers relevant**.**

Use of Proceeds from Registered Securities

On October 4, 2016, we completed the initial public offering of our common stock, or the IPO, pursuant to an Underwriting Agreement with Credit Suisse Securities (USA) LLC and Piper Jaffray & Co., as the representatives of the several underwriters, in which we issued and sold an aggregate of 4,830,000 shares of common stock (including 630,000 shares issued and sold on October 7, 2016 pursuant to the underwriters' exercise in full of their option to purchase additional shares) at a public offering price of $9.00 per share. We received net proceeds of approximately $36.0 million, after deducting underwriting discounts and commissions and offering expenses paid or payable by us of approximately $4.4 million. The shares issued and sold in the IPO were registered under the Securities Act on a registration statement on Form S-1 (File No. 333-213469), as amended, and the final prospectus dated September 28, 2016 included in such registration statement, or the Prospectus.

To date, we have used $7.1 million of the net proceeds from the IPO, of which, $3.1 million was used for contributions to our joint venture, FF Gene Biotech in partial satisfaction of our contribution obligations under the joint venture cooperation agreement, and $4.0 million was used to fund the Company's operation. All other net proceeds from the IPO are invested in investment-grade, interest-bearing securities, such as money market accounts, certificates of deposit, commercial paper and guaranteed obligations of the U.S. government. There has been no material change in the planned use of proceeds from the IPO from that described in the Prospectus.

On August 30 2019, we entered into an Equity Distribution Agreement with Piper Jaffray & Co. as sales agent, pursuant to which we may, from time to time, sell through Piper shares of our common stock with an aggregate purchase price of up to $30.0 million. During the year ended December 31, 2019, the Company sold an aggregate of 104,390 shares of its common stock pursuant to the Equity Distribution Agreement at a weighted-average selling price of $12.14 per share, which resulted in $979,000 of net proceeds to the Company. The shares issued and sold in the at-the-market offering were sold pursuant to a shelf registration statement registered under the Securities Act on a registration statement on Form S-3 (File No. 333-233227), as amended, and a prospectus supplement and accompanying base prospectus filed with the Securities and Exchange Commission on August 30, 2019.

In addition, on November 13, 2019 we entered into a Purchase Agreement with Piper Jaffray & Co. as representative of the several underwriters, pursuant to which we sold 2,673,750 shares of our common stock at a price of $10.51875 per share, with a public offering price of $11.25 per share. We received net proceeds of approximately $27.6 million, after deducting underwriting discounts and commissions and offering expenses paid or payable by us of approximately $2.4 million. The shares issued and sold in the underwritten offering were sold pursuant to a shelf registration statement registered under the Securities Act on a registration statement on Form S-3 (File No. 333-233227), as amended, and a prospectus supplement and accompanying base prospectus filed with the Securities and Exchange Commission on November 13, 2019.

Item 6. Selected Financial Data.

Not applicable.

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations.

The following discussion and analysis of our financial condition and results of operations should be read together with our consolidated financial statements and related notes included in this report.

Forward-Looking Statements

The following discussion and analysis contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. Forward-looking statements are statements other than historical facts and relate to future events or circumstances or our future performance, and they are based on our current assumptions, expectations and beliefs concerning future developments and their potential effect on our business. The forward-looking statements in this discussion and analysis include statements about, among other things, our future financial and operating performance, our future cash flows and liquidity and our growth strategies, as well as anticipated trends in our business and industry. These forward-looking statements are subject to a number of risks and uncertainties, including, among others, those described under "Item 1A. Risk Factors" Part I of this report. Moreover, we operate in a competitive and rapidly evolving industry and new risks emerge from time to time. It is not possible for us to predict all of the risks we may face, nor can we assess the impact of all factors on our business or the extent to which any factor or combination of factors could cause actual results to differ from our expectations. In light of these risks and uncertainties, the forward-looking events and circumstances described in this discussion and analysis may not occur, and actual results could differ materially and adversely from those described in or implied by any forward-looking statements we make. Although we have based our forward-looking statements on assumptions and expectations we believe are reasonable, we cannot guarantee future results, levels of activity, performance or achievements or other future events. As a result, forward-looking statements should not be relied on or viewed as predictions of future events, and this discussion and analysis should be read with the understanding that actual future results, levels of activity, performance and achievements may be materially different than our current expectations. The forward-looking statements in this discussion and analysis speak only as of the date of this report, and except as required by law, we undertake no obligation to update publicly any forward-looking statements for any reason after the date of this report to conform these statements to actual results or to changes in our expectations.

Overview

We are a growing technology company with an initial focus on offering comprehensive genetic testing to provide physicians with clinically actionable diagnostic information they can use to improve the quality of patient care. We have developed a proprietary technology platform that allows us to offer a broad and flexible test menu and continually expand and improve our proprietary genetic reference library, while maintaining accessible pricing, high accuracy and competitive turnaround times. We believe our test menu offers more genes for testing than our competitors in today's market, which enables us to provide expansive options for test customization and clinically actionable results.

Our existing customer base consists primarily of hospitals, medical institutions and other laboratories, which are typically frequent and high-volume users of genetic tests and which often pay us directly for our tests. In addition, in 2019 we launched our first patient-initiated offering, Picture Genetics, but as of yet Picture Genetics does not represent a substantial percentage of the amount of tests we delivered. We believe our relationships with these customers provide a meaningful opportunity for further growth, as we seek to deepen these relationships and drive increased ordering. We also believe our offering could be attractive to other types of customers, including individual physicians and other practitioners, research institutions and other organizations, and we are building relationships in these new customer markets. Although we have devoted fewer overall resources to sales and marketing efforts than many of our competitors, we made material investments in our sales and marketing team and strategies, the global reach of our business and other aspects of our operations.

We offer tests at competitive prices, averaging approximately $555 per billable test delivered in 2019, and at a lower cost to us than many of our competitors, averaging approximately $241 per billable test delivered in 2019. Our volume has grown rapidly since our commercial launch, with 58,573 billable tests delivered in 2019, 22,298 billable tests delivered in 2018, and an aggregate of over 117,774 billable tests delivered to approximately 1,100 customers from inception through December 31, 2019. We have experienced compound quarterly growth of 17.1% in the number of billable tests delivered in our last eight completed fiscal quarters. We recorded revenue and loss from operations of $32.5 million and $411,000, respectively, in 2019, compared to revenue and loss from operations of $21.4 million and $5.6 million, respectively, in 2018. We achieved profitability in the first three months of 2017, and in the second and the third quarter of 2019, but we have recorded losses in all other periods since our inception.

2018 Developments

Partnered with Columbia University Irving Medical Center on Expanded Carrier Screening

The Company and the Precision Genomics Laboratory, or PGL, in collaboration with the Department of Obstetrics and Gynecology, at Columbia University Irving Medical Center, or CUIMC, entered into a license and commercialization agreement to make on site performed, expanded carrier screening available to Columbia patients. This unique collaboration will leverage both parties' expertise in laboratory management, bioinformatics, clinical genetics and next-generation sequencing to deliver an expanded carrier screening test with many advantages over other currently available tests.

The PGL is jointly operated by the Institute for Genomic Medicine, or IGM, and the Department of Pathology and Cell Biology and is designed to enhance patient care through genomic diagnostics, research, and education at CUIMC.

Carrier screening is a genetic test used to identify whether individuals and carrier couples are at risk for passing genetic disorders to their children. These genetic disorders may result in physical disabilities, cognitive impairment, and other severe health problems in newborn babies. Traditionally, carrier screening tests targeted couples of certain ethnic groups that have historically been at higher risk for specific genetic disorders. This approach has presented difficulties for patients who are multiracial, adopted, or are unsure of their ethnic backgrounds. To address this challenge, expanded carrier screening, or ECS, was developed to test for mutations that cause hundreds of different genetic disorders regardless of a patient's ethnicity. Professional medical associations like the American College of Obstetricians and Gynecologists, or ACOG, and the American College of Medical Genetics and Genomics, or ACMG, have published guidelines on ECS and its importance in reproductive care.

2019 Developments

Partnered with Parkinson's Foundation on Launch of Genetic Testing Initiative for People with Parkinson's Disease

In 2019, the Company partnered with the Parkinson's Foundation on a new genetic testing initiative for individuals living with Parkinson's Disease. The nation-wide initiative, called PD GENEration: Mapping the Future of Parkinson's Disease, provides genetic testing for clinically relevant Parkinson's-related genes for eligible individuals. The initiative is offered through the Parkinson's Foundation Centers of Excellence network and Parkinson Study Group sites, and it leverages the next generation genetic testing technology of the Company. As part of the collaboration agreement, the Company is compensated for processing, sequencing, and storing each DNA sample for patients participating in the initiative. Also supporting this initiative are Indiana University School of Medicine, providing genetic counseling for tested individuals; University of Florida CTSI Data Coordinating Center, assisting with secure data storage; and University of Rochester's Clinical Trials Coordination Center. In collaboration with these partners, the Company has leveraged the flexibility of its broad testing catalog to select and develop a targeted list of seven genes relevant to Parkinson's patients and clinicians: GBA, LRRK2, SNCA, PRKN, PARK7, VPS35, and PINK1. The Company analyzes and generates clinical reports for these target genes, and the findings are made available to the treating physicians and future researchers.

Genetic testing can help determine whether an individual's genetic makeup indicates a potential genetic cause for Parkinson's disease. This knowledge can assist patients and physicians in better understanding each case and can help to identify whether a patient qualifies for enrollment in certain clinical trials. Participants will also be able to better understand their genetic test results through free genetic counseling provided by Indiana University and on-site clinicians. Raw data accumulated through the initiative will be captured for future research by scientists to develop improved treatments and precision medicine options for Parkinson's Disease.

Launched Picture Genetics, a Patient-Initiated Genetic Testing Offering

In 2019, the Company launched its first patient-initiated genetic testing offering, a new line of at-home screening tests that combines the Company's advanced NGS solutions with actionable results and genetic counseling options for patients. Patients order test kits online, complete a sample collection at home and return the kits for processing and analysis by the Company. Patients receive results that have been reviewed by an independent external physician, as well as genetic counseling support to help them better understand their screening results. The Company has partnered with PWNHealth, an independent provider network, for physician review and genetic counseling. Picture Genetics offers three distinct at-home test options: Picture Parenting, Picture Newborn, and Picture Wellness. Picture Parenting is a carrier screening test that gives prospective parents better insight into their status as carriers of variants in 30 different genes which could affect their children. Picture Newborn and Picture Wellness offer insight into health risks based on genetic markers. All three tests are completed at home without the need for a doctor visit or insurance.

Expanded Reproductive Testing Options Including Preimplantation Genetic Testing (PGT)

In 2019, the Company expanded the reproductive testing options, including Preimplantation Genetic Testing (PGT). PGT (often called PGS, or preimplantation genetic screening), is appropriate for anyone undergoing IVF treatment, especially helpful for women who is over 35, who have previously experienced miscarriages, who want to reduce the likelihood of having multiples, couples experiencing infertility (male or female), and who have experienced IVF failure. By purposefully selecting chromosomally normal embryos for implantation, it will expand the prospects of a successful IVF treatment and a healthy pregnancy.

Factors Affecting Our Performance

Market and Industry Trends

Genetic testing has experienced significant growth in recent years. If this growth trend continues, we believe genetic testing could become a more accepted part of standard medical care and the knowledge of a person's unique genetic makeup could begin to play a more important role in the practice of medicine. The advent of next generation sequencing, or NGS, technology, a relatively new genetic testing technique that enables millions of DNA fragments to be sequenced in parallel, has dramatically lowered the cost and improved the quality of genetic testing, contributing to increased adoption generally and increased volumes for our tests.

The growth of genetic testing in recent years has caused increased competition in our industry. This increased competition, as well as cost-saving initiatives on the part of government entities and other third-party payors, has resulted in downward pressure on the price for genetic analysis and interpretation, which could intensify in future periods if adoption of genetic testing becomes more widespread. We have reduced the prices for certain of our tests in recent periods to maintain our competitive position, and increased downward pricing pressure could harm our revenue and margins and our ability to achieve and sustain profitability. The impact of this pricing pressure has been and may continue to be intensified if we continue to incur increased expenses in order to meet customer demands and make investments in our business.

While adoption of genetic testing has increased in recent years, we believe widespread utilization has been tempered because of certain challenges and barriers to adoption that exist in today's market. Among these industry challenges are that genetic testing can be prohibitively expensive, only a limited number of genetic tests are currently reimbursable, certain genetic conditions cannot be diagnosed due to the limited scope of some genetic analysis, genetic testing can be an inefficient process and the interpretation of genetic results can be cumbersome and time-consuming. We have approached these competitive and operational industry challenges by building and continually advancing a multi-faceted technology platform that we believe will facilitate our ability to address many of these challenges.

Number and Mix of Billable Tests Delivered

Our performance is closely correlated with the number of tests for which we bill our customers, which we refer to as billable tests. The number of billable tests we deliver in any period depends on a number of factors, including the other factors affecting our performance described in this discussion and analysis. We believe the number of billable tests that we deliver is an important indicator of the performance of our business.

In addition, we offer our tests at different price points, and we incur different amounts and types of costs, depending on the nature and level of complexity and customization of the test and the specific terms we have negotiated for the tests, which can vary from customer to customer. As a result, the mix of billable tests delivered in any period, and the customers that order these tests, impacts our financial results for the period.

Mix of Customers

Through December 31, 2019, we have sold our tests to approximately 1,100 total customers. We consider each single billing and paying unit to be an individual customer, even though a unit may represent multiple physicians and healthcare providers ordering tests. The composition and concentration of our customer base can fluctuate from period to period, and in certain prior periods, a small number of customers has accounted for a significant portion of our revenue. Generally, we do not have long-term purchase agreements with any of our customers, including these key customers, and, as result, any or all of them could decide at any time to increase, accelerate, decrease, delay or discontinue their orders from us. Although we believe some of these fluctuations in customer demand may be attributable in part to the nature of our business, in which our customers can experience significant volatility in their genetic testing demand from period to period in the ordinary course of their operations, these demand fluctuations, particularly for our key customers, can have a significant impact on our period-to-period performance regardless of their cause.

Our existing customer base consists primarily of hospitals and medical institutions, which are typically frequent and high-volume users of genetic tests. Additionally, collection of billings from these institutional customers is generally more attainable than from other types of customers in today's reimbursement environment, as approximately 87% of our test billings that were generated and due in 2019 were paid during that period. As a result, we believe our ability to maintain, strengthen and build this customer base could have a meaningful impact on our potential for growth.

We are also making efforts to diversify our customer market, including building relationships with research and other institutional customers, as well as national clinical laboratories, regional medical networks and various other organizations to facilitate access to physicians, practitioners and other new customer groups, including certain U.S. military and other government agencies. In addition, in 2019 we also launched our first patient-initiated testing product, Picture Genetics, and we hope to gain share in the patient-initiated testing market. We are also pursuing relationships with payors, including Medicare, some state Medicaid programs and commercial payors, in an effort to obtain coverage and reimbursement for our tests to make them accessible to more individual physicians. Subject to limited exceptions, none of these relationships obligate any party to order our tests at any agreed volume or frequency or at all, and as a result, these relationships may not lead to meaningful or any increases in our customer base, the number of billable tests we deliver or our revenue. However, we believe our ability to establish these relationships with new customer groups is critical to the growth of our business.

Ability to Maintain Our Broad and Flexible Test Menu

We believe the large number of genes we incorporate into our test menu provides a meaningful competitive advantage. We believe the breadth of genes in our portfolio allows us to provide more comprehensive genetic information and improves our variant detection rate, which can increase the clinical actionability of the data we produce. The breadth of genes in our portfolio also allows us to offer hundreds of pre-established, multi-gene panels that focus on specified genetic conditions, including our *Focus* and *Comprehensive* oncology panels and *Beacon* carrier screening panels and somatic cancer panels. In addition, all of our panel tests can be adjusted up or down to include more or fewer genes, or customers can design their own panels to their exact specifications, resulting in a flexible and customizable test menu. We believe our ability to continue to offer more genes and more ordering flexibility than our competitors could be a key contributor to the long-term growth of our business.

Ability to Maintain Low Internal Costs

We have developed various proprietary technologies that improve our laboratory efficiency and reduce the costs we incur to perform our tests, including our proprietary gene probes, data algorithms, adaptive learning software and genetic reference library. This technology platform enables us to perform each test and deliver its results at a lower cost to us than many of our competitors, and this low cost per billable test allows us to maintain affordable and competitive pricing for our customers, which we believe encourages repeat ordering from existing customers and attracts new customers. We believe this low internal cost is a key factor in our ability to grow our business and obtain margins on our sales that allow us to drive toward sustained profitability.

We calculate our cost per billable test by dividing the number of billable tests delivered in any given period by our cost of revenue in the same period. Investments in our operational capabilities could increase our cost of revenue, but these investments could also, on a near-term and/or long-term basis, increase our operating efficiencies and lead to cost of revenue decreases. As a result, the amount, timing, nature and success of these investments, as well as other influences on our cost of revenue from period to period, can impact the amount of our cost per billable test. Moreover, changes in our other operating expenses, due to investments in these aspects of our business or other factors, are not taken into account in the calculation of this measure but impact our overall results, which can limit the utility of cost per billable test as an overall cost measurement tool.

Ability to Obtain Reimbursement

In today's market, third-party payors generally restrict the reimbursement of genetic testing to only a narrow subset of genetic tests and certain patients who meet specific criteria. The lack of widespread favorable reimbursement policies has presented a challenge for genetic testing companies in building sustainable business models. As part of our business plan for future growth, we intend to pursue coverage and reimbursement from third-party payors at a level adequate for us to achieve profitability with this payor group. However, we cannot predict whether, under what circumstances, or at what payment levels payors will cover and reimburse for our tests, and even if we are successful, we believe it could take several years to achieve coverage and adequate contracted reimbursement with third-party payors. To date, we have contracted directly with national health insurance companies to become an in-network provider and enrolled as a supplier with the Medicare program and some state Medicaid programs, which means that we have agreed with these payors to provide certain of our tests at negotiated rates. Although this does not guarantee that we will receive reimbursement for our tests from these or any other payors at adequate levels, we believe our low cost per billable test could enhance our ability to compete effectively in the third-party payor market and our flexibility in establishing relationships with additional third-party payors in the future. Our level of success in obtaining and maintaining adequate coverage and reimbursement from third-party payors for our testing services will, we believe, be a key factor in the rate and level of growth of our business over the long term.

Impact of Certain Recent Accounting Pronouncements

The majority of our revenue is generated from hospitals, medical institutions and research institutions, with a lesser amount from reimbursement by third-party payors, including managed care organizations, private health insurers and government healthcare programs, such as Medicare and Medicaid. In 2017, 2016 and all other historical periods, we recognized revenue based on a revenue recognition standard that requires the satisfaction of specified criteria, including when the amount of revenue becomes fixed or determinable and when collectability of revenue is reasonably assured, in order to recognize the revenue. Under this standard, if all of the required criteria were not satisfied before payment was received, then we recognized revenue on a cash basis, which means that revenue is recognized only when we receive a cash payment from a customer for the genetic tests it has ordered. As a result, for revenue received from hospitals and medical institutions, in general, we have recognized revenue upon our delivery to a customer of genetic test results from an ordered test, because all criteria to recognize this revenue have been satisfied at that time. For revenue received from third-party payors, in general, we have recognized revenue on a cash basis due to the inability to satisfy the criteria described above before receipt of payment.

Beginning on January 1, 2018, we recognized revenue pursuant to a comprehensive new revenue recognition standard based on several recent accounting pronouncements. Under the new standard, which is designed to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services, we expect to recognize revenue from all customers on an accrual basis, which means that revenue will be recognized at the time of delivery to customers of genetic test results from an ordered test based on our expectation of receiving a cash payment for such tests. In general, the new revenue recognition standard will result in our recognition of revenue from hospitals and medical institutions at a similar time as we recognized revenue from these customers under the prior standard, and will result in our recognition of revenue from third-party payors earlier than we recognized revenue from these customers under the prior standard.

Upon adopting the new standard on January 1, 2018, we recorded an adjustment of $327,000 to beginning accumulated deficit and accounts receivable to reflect genetic tests previously delivered to third-party payors for which revenue was not recognized as of such date.

Foreign Currency Exchange Rate Fluctuations

Much of our business to date has been from non-U.S. customers, and we may record increasing revenue levels from non-U.S. sources as we focus on growing our international customer base. These revenue sources expose us to fluctuations in our results associated with changes in foreign currency exchange rates depending on the value of the U.S. dollar compared to the foreign currencies in which we record revenue. During all periods covered by this report, we consider the estimated effect on our revenue of foreign currency exchange rate fluctuations to be immaterial; however, the impact of foreign currency exchange rate fluctuations may increase in future periods as we pursue continued international expansion. For instance, all of our revenue-producing transactions have historically been denominated in U.S. dollars, but we started billing certain of our Canadian hospital customers in their local currency in the second quarter of 2017, and we may expand this practice in the future to other customers in Canada or other international markets. Additionally, all payments we receive from FF Gene Biotech, including royalty revenue under the license agreement and our share of any earnings of the joint venture, are paid to us in RMB and then converted by us to U.S. dollars, and we expect these payments to increase in the future. These or other changes in the currencies in which we receive payments and record revenue could result in an increased impact in future periods of foreign currency translations and exchange rate fluctuations.

Business Risks and Uncertainties

Our business and prospects are exposed to numerous risks and uncertainties. For more information, see “Item 1A. Risk Factors” in this report.

Financial Overview

Revenue

We generate revenue from sales of our genetic tests. We recognize revenue upon delivery of a report to the ordering physician or other customer based on the established billing rate, less contractual and other adjustments, to arrive at the amount we expect to collect. We generally bill directly to a hospital, medical or research institution customer, or to a patient, a third-party payor or a combination of a patient and a third-party payor.

Cost of Revenue

Cost of revenue reflects the aggregate costs incurred in delivering test results, including sequencing as a service tests, and consists of: personnel costs, including salaries, employee benefit costs, bonuses and equity-based compensation expenses; costs of laboratory supplies; depreciation of laboratory equipment; amortization of leasehold improvements; and allocated overhead expenses, including rent and utilities. Costs associated with performing tests are recorded as tests are processed. We expect cost of revenue to generally increase as we increase the number of billable tests we deliver.

Operating Expenses

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

Research and Development Expenses

Research and development expenses represent costs incurred to develop our technology and future tests. These costs consist of personnel costs, laboratory supplies, consulting costs and allocated overhead expenses, including rent and utilities. We expense all research and development costs in the periods in which they are incurred. We expect our research and development expenses will continue to increase in absolute dollars as we expect to continue to invest in research and development activities.

Selling and Marketing Expenses

Selling and marketing expenses consist of personnel costs, customer service expenses, direct marketing expenses, educational and promotional expenses, market research and analysis and allocated overhead expenses, including rent and utilities. We expense all selling and marketing costs as incurred. We expect our selling and marketing expenses will continue to increase in absolute dollars, primarily driven by our increased investment in sales and marketing in recent periods, including developing and expanding our sales team, creating and implementing new sales and marketing strategies and increasing the overall scope of our marketing efforts.

General and Administrative Expenses

General and administrative expenses include executive, finance, accounting, legal and human resources functions. These expenses consist of personnel costs, audit and legal expenses, consulting costs and allocated overhead expenses, including rent and utilities. We expense all general and administrative costs as incurred. We expect our general and administrative expenses will continue to increase in absolute dollars as we seek to continue to scale our operations. We also expect to continue to incur increased general and administrative expenses as a result of operating as a public company, including expenses related to compliance with the rules and regulations of the Securities and Exchange Commission, or the SEC, and the Nasdaq Stock Market, additional insurance expenses, investor relations activities and other administrative and professional services.

Provision for (Benefit from) Income Taxes

Provision for income taxes consists of U.S. federal and state income taxes. We record a valuation allowance when it is more likely than not that some portion or all of a deferred tax asset will not be realized. In making such a determination, we consider all the available positive and negative evidence, including future reversals of existing taxable temporary differences, projected future taxable income, and ongoing prudent and feasible tax planning strategies, to assess the amount of the valuation allowance. When we determine to establish or reduce the valuation allowance against the deferred tax assets, our provision for income taxes will increase or decrease, respectively, in the period in which the determination is made.

The factors that most significantly impact our effective tax rate include the levels of certain deductions, including those related to equity-based compensation, a full valuation allowance, the effect of state income taxes, return to provision adjustments, and foreign tax rate differential. We expect these factors will continue to cause our consolidated effective tax rate to differ significantly from the U.S. federal income tax rate in future periods.

Results of Operations

The table below summarizes the results of our continuing operations for each of the periods presented. Historical results are not indicative of the results to be expected in the current period or any future period.

	Year Ended December 31,		$	%
	2019	2018	Change	Change
Statement of Operations Data:	(dollars in thousands, except Other Operating Data)			
Revenue	$ 32,528	$ 21,351	$ 11,177	52%
Cost of revenue	14,107	10,697	3,410	32%
Gross profit	18,421	10,654	7,767	73%
Operating expenses:				
Research and development	6,537	5,534	1,003	18%
Selling and marketing	5,898	4,652	1,246	27%
General and administrative	6,414	5,538	876	16%
Total operating expenses	18,849	15,724	3,125	20%
Operating loss	(428)	(5,070)	4,642	(92)%
Interest and other income, net	837	434	403	93%
Income (loss) before income taxes and equity loss in investee	409	(4,636)	5,045	(109)%
Provision for income taxes	43	36	7	19%
Income (loss) before equity loss in investee	366	(4,672)	5,038	(108)%
Equity loss in investee	(777)	(935)	158	(17)%
Net loss	$ (411)	$ (5,607)	$ 5,196	(93)%
Other Operating Data:				
Billable tests delivered(1)	58,573	22,298	36,275	163%
Average price per billable test delivered(2)	$ 555	$ 958	$ (403)	(42)%
Cost per billable test delivered(3)	$ 241	$ 480	$ (239)	(50)%

(1) We determine the number of billable tests delivered in a period by counting the number of tests which are delivered to our customers and for which we bill our customers and recognize some amount of revenue in the period.

(2) We calculate the average price per billable test delivered by dividing the amount of revenue we recognized from the billable tests delivered in a period by the number of billable tests delivered in the same period.

(3) We calculate cost per billable test delivered by dividing our cost of revenue in a period by the number of billable tests delivered in the same period.

Revenue

Revenue increased $11.2 million, or 52%, from $21.4 million in 2018 to $32.5 million in 2019. The increase in revenue between periods was primarily due to an increased number of billable tests delivered, offset by a substantial decline in the average selling price per test.

The average price of the billable tests we delivered decreased $403, or 42%, from $958 in 2018 to $555 in 2019. We believe this decrease was due to (i) lower price-points for the mix of tests we delivered in 2019, (ii) the mix of customers ordering tests in this period, which may order tests at different rates depending on the arrangements we have negotiated with them, and for which we may recognize different amounts of revenue at different times in the delivery and payment process based on the impact of our revenue recognition policy on, and differing collectability rates among, various customer groups, and (iii) our reduction of prices for certain of our tests due to general price degradation for genetic tests and other competitive factors during 2019.

Revenue from non-U.S. sources decreased $1.3 million, or 14%, from $8.8 million in 2018 to $7.5 million in 2019. The decrease in revenue from non-U.S. sources between periods was primarily due to decreased sales to customers in Canada, which decreased by $1.7 million, partially offset by an increase of $481,000 in revenue from sales to customers in other countries. The decrease in sales to customers in Canada was primarily attributable to decreased sales to a few customers that contributed a significant portion of our revenue in 2018 but ordered significantly fewer tests and generated significantly less revenue to us in 2019.

Aggregating customers that are under common control or are affiliates, one customer contributed 28% of our revenue in 2019, and one customer contributed 13%, respectively, in 2018.

Cost of Revenue

Cost of revenue increased $3.4 million, or 32%, from $10.7 million in 2018 to $14.1 million in 2019. The increase was primarily due to increases of $2.5 million in reagent and supply expenses related to increased billable tests delivered, $752,000 in personnel costs and $153,000 in stock-based compensation expense related to increased headcount.

Cost per billable test delivered decreased $239, or 50% from $480 in 2018 to $241 in 2019 as the increase in the number of billable tests we delivered was greater than the increase in our cost of revenue due to economies of scale related to the increased number of billable tests for the period. The greater increase in the number of billable tests we delivered was primarily attributable to new customers. Our cost per billable test decreased in part due to our efforts to leverage our technology, such as engineered chemistry and competitive analytics powered by artificial intelligence and machine learning, for the increased number of billable tests during 2019.

Our gross profit increased $7.8 million, or 73%, from $10.7 million in 2018 to $18.4 million in 2019. The increase in gross profit was primarily due to an increase in revenue between periods that exceeded the increase in cost of revenue over the same period. Our gross profit as a percentage of revenue, or gross margin, increased from 49.9% to 56.6% between periods due in part to the increase in revenue and decreases in our cost per billable test and cost of revenue described above.

Research and Development

Research and development expenses increased $1.0 million, or 18%, from $5.5 million in 2018 to $6.5 million in 2019. The increase was primarily due to increases of $879,000 in personnel costs and $291,000 in stock-based compensation expense related to increased headcount, and $141,000 in depreciation costs related to our increased efforts to maintain our technological advantage and expand our test menu, partially offset by a decrease of $410,000 in reagent and supply expenses related to additional consumables purchased in the prior period.

Selling and Marketing

Selling and marketing expenses increased $1.2 million, or 27%, from $4.7 million in 2018 to $5.9 million in 2019. The increase was primarily due to increases of $585,000 in personnel costs and $385,000 in stock-based compensation expense related to increased commission expense and stock award granted to sales representative, $159,000 in marketing materials cost related to increased billable tests delivered, and $95,000 in consulting and outside labor expense related to the increase of outside labor for customer services in the current period.

General and Administrative

General and administrative expenses increased $876,000, or 16%, from $5.5 million in 2018 to $6.4 million in 2019. The increase was primarily due to increases of $401,000 in legal and professional fees related to case settlement in the current period, $322,000 in merchant service fees related to increased revenue, $190,000 in personnel costs related to increased headcount, and $143,000 in software and licensing related to new billing software, partially offset by a decrease of $125,000 in bad debt expenses related to additional reserve for doubtful accounts in the prior period.

Interest and Other Income, Net

Interest income was $871,000 and $578,000 for 2019 and 2018, respectively. This income mainly related to interest received on various investments in marketable securities.

Other income (expense) was not significant for 2019 or 2018. The primary component of other income (expense) for 2019 and 2018 was foreign currency valuation gains (losses).

Provision for Income Taxes

We recorded income tax of $43,000 and $36,000 for 2019 and 2018, respectively. Our effective income tax rate was 10.5% and 0.7% of loss before income taxes for 2019 and 2018, respectively. The primary factors impacting our effective tax rate for 2019 were the effect of a full valuation allowance, return to provision adjustments, the foreign income tax rate differential, state income taxes, and certain expenses or adjustments related to equity-based compensation. For 2018, the primary factors impacting our effective tax were the effect of a full valuation allowance, state income taxes, changes in foreign tax laws and certain expenses or adjustments related to equity-based compensation.

We have evaluated the realizability of our deferred tax assets and have concluded that it is more likely than not that we may not realize the benefit of the deferred tax assets, primarily as a result of operating losses in recent years and, accordingly, we have provided a full valuation allowance of $2.1 million and $1.4 million at December 31, 2019 and 2018, respectively. As a result, we did not record any federal or state income tax expense or benefit in the statement of operations, other than state minimum taxes. The temporary differences in existence for 2019 and 2018 are primarily from net operating losses, depreciation, research and development credits, equity-based compensation, our foreign joint venture investment, and the lease liability and related right of use asset.

See Note 11, *Income Taxes*, to our consolidated financial statements included in this report for more information regarding our income taxes.

Equity Loss in Investee

Equity loss in investee was $777,000 and $935,000 in 2019 and 2018, respectively, and relates to our 30% ownership interest in FF Gene Biotech.

Liquidity and Capital Resources

Liquidity and Sources of Cash

We had $12.0 million and $6.7 million in cash and cash equivalents as of December 31, 2019 and 2018, respectively, and $58.3 million and $30.7 million in marketable securities, consisting of corporate bonds, as of December 31, 2019 and 2018, respectively.

Since commencing operations in May 2012, our operations have been financed primarily by our founder, Chief Executive Officer and Chairman of our board of directors, Ming Hsieh, and in more recent periods, by cash from our operations and equity financings.

Our primary uses of cash are to fund our operations as we continue to invest in and seek to grow our business. Cash used to fund operating expenses is impacted by the timing of our expense payments, as reflected in the changes in our outstanding accounts payable and accrued expenses. In addition, in April 2017, in connection with the establishment of FF Gene Biotech, we became obligated to contribute to FF Gene Biotech genetic sequencing and other equipment with a total cost of 60,000,000 RMB over a five-year period, previously three-year per original agreement and amended in April 2019. To date, we have purchased and contributed to FF Gene Biotech equipment with an aggregate fair value of $3.1 million pursuant to these contribution obligations, of which $137,000 and $510,000 were contributed in 2019 and 2018, respectively. Depending on the performance of FF Gene Biotech, this joint venture may never produce sufficient revenue to us to recover these capital and other investments and could cause our revenue to decrease if any of our direct customers in Asia choose to order genetic tests from FF Gene Biotech instead of from us, any of which could negatively affect our liquidity and cash flow. In addition, although we have in the past made cash distributions for tax and other purposes to the equity holders of our predecessor, we do not expect to use our cash make these or any other types of distributions or dividends in the foreseeable future.

In August 2019, the Company entered into an Equity Distribution Agreement with Piper Jaffray & Co., as sales agent (“Piper”), pursuant to which the Company may offer and sell, from time to time through Piper, shares of its common stock having an aggregate offering price of up to $30.0 million. Piper is eligible to receive a commission of up to 3% of gross proceeds received by the Company for sales pursuant to the Equity Distribution Agreement. During the year ended December 31, 2019, the Company sold an aggregate of 104,390 shares of its common stock pursuant to the Equity Distribution Agreement at a weighted-average selling price of $12.14 per share, which resulted in $979,000 of net proceeds to the Company. Shares sold under the Equity Distribution Agreement are offered and sold pursuant to the Company’s shelf registration statement on Form S-3 (File No. 333-233227) filed with the SEC on August 12, 2019 and declared effective on August 23, 2019, and a prospectus supplement and accompanying base prospectus filed with the Securities and Exchange Commission on August 30, 2019.

On November 13, 2019 we entered into a Purchase Agreement with Piper Jaffray & Co., as representative of the several underwriters, pursuant to which we sold 2,673,750 shares of our common stock at a price of $10.51875 per share, with a public offering price of $11.25 per share. We received net proceeds of approximately $27.6 million, after deducting underwriting discounts and commissions and offering expenses paid or payable by us of approximately $2.4 million. The shares issued and sold in the underwritten offering were sold pursuant to a shelf registration statement registered under the Securities Act on a registration statement on Form S-3 (File No. 333-233227), as amended, and a prospectus supplement and accompanying base prospectus filed with the Securities and Exchange Commission on November 13, 2019.

We believe our existing cash, along with cash from our operations and proceeds from our equity financings, will be sufficient to meet our anticipated cash requirements for at least the next 12 months. Much of the losses we have incurred were attributable to a variety of non-cash charges, including equity-based compensation expenses. Additionally, if our business grows and we are able to achieve increased efficiencies and economies of scale in line with this growth, we expect that increased revenue levels would increase our ability to rely on cash from our operations to support our business in future periods, even if our expenses also increase as a result of the growth of our business. Based on these factors, we anticipate that cash from our operations will continue to play a meaningful role in our ability to meet our liquidity requirements and pursue our business plans and strategies in the next 12 months and in the longer term.

However, our expectations regarding the cash that may be provided by our operations and our cash needs in future periods could turn out to be wrong, in which case we may require additional financing to support our operations, as we do not presently have any commitments for future capital. For instance, cash provided by our operations has in the past experienced fluctuations from period to period, which we expect may continue in the future. These fluctuations can occur because of a variety of factors, including, among others, the amount and timing of sales of billable tests, the prices we charge for our tests due to changes in product mix, customer mix, general price degradation for genetic tests or other factors, the rate and timing of our billing and collections cycles and the timing and amount of our commitments and other payments. Moreover, even if our liquidity expectations are correct, we may still seek to raise additional capital through securities offerings, credit facilities or other debt financings, asset sales or collaborations or licensing arrangements. Additional funding may not be available to us when needed, on acceptable terms or at all. If we raise funds by issuing equity securities, our existing stockholders could experience substantial dilution. Additionally, any preferred stock we issue could provide for rights, preferences or privileges senior to those of our common stock, and our issuance of any additional equity securities, or the possibility of such an issuance, could cause the market price of our common stock to decline. The terms of any debt securities we issue or borrowings we incur, if available, could impose significant restrictions on our operations, such as limitations on our ability to incur additional debt or issue additional equity or other restrictions that could adversely affect our ability to conduct our business, and would result in increased fixed payment obligations. If we seek to sell assets or enter into collaborations or licensing arrangements to raise capital, we may be required to accept unfavorable terms or relinquish or license to a third party our rights to important or valuable technologies or tests we may otherwise seek to develop ourselves. Moreover, we may incur substantial costs in pursuing future capital, including investment banking, legal and accounting fees, printing and distribution expenses and other similar costs. If we are not able to secure funding if and when needed and on reasonable terms, we may be forced to delay, reduce the scope of or eliminate one or more sales and marketing initiatives, research and development programs or other growth plans or strategies. In addition, we may be forced to work with a partner on one or more aspects of our tests or market development programs or initiatives, which could lower the economic value to us of these tests, programs or initiatives. Any such outcome could significantly harm our business, performance and prospects.

Cash Flows

The following table summarizes cash flows from continuing operations for each of the periods presented:

	Year Ended December 31,	
	2019	2018
	(in thousands)	
Net cash provided by (used in) operations	$ 5,517	$ (675)
Net cash (used in) provided by investing activities	$ (29,046)	$ 950
Net cash provided by financing activities	$ 28,775	$ 15

Operating Activities

Cash provided by operating activities in 2019 was $5.5 million. The difference between net loss and cash provided by operating activities for the period was primarily due to the effect of $3.2 million in equity-based compensation expenses and $2.1 million in the depreciation of assets. Cash provided by operating activities decreased between periods primarily due to the negative effect of a $839,000 increase in accounts receivable mainly due to the timing of collections from customers.

Cash used in operating activities in 2018 was $675,000. The difference between net loss and cash used in operating activities for the period was primarily due to the effect of $2.3 million in equity-based compensation expenses and $2.2 million in the depreciation of assets. Cash used in operating activities decreased between periods primarily due to the negative effect of a $2.0 million increase in accounts receivable mainly due to the timing of collections from customers, partially offset by the positive effect of a $533,000 increase in accrued liabilities mainly related to payroll liabilities and contract liabilities.

Investing Activities

Cash used in investing activities in 2019 was $29.0 million, which primarily related to $52.1 million in purchases of marketable securities, $1.2 million in purchases of fixed assets consisting mainly of medical laboratory equipment, computer hardware and leasehold improvements, and purchased equipment with an aggregate fair value of $137,000 contributed to FF Gene Biotech, partially offset by maturities of $24.4 million of marketable securities.

Cash provided by investing activities in 2018 was $950,000, which primarily related to maturities of $28.0 million of marketable securities, partially offset by $24.2 million in purchases of marketable securities, $2.3 million in purchases of fixed assets consisting mainly of medical laboratory equipment, computer hardware and leasehold improvements, and purchased equipment with an aggregate fair value of $510,000 contributed to FF Gene Biotech.

Financing Activities

Cash provided by financing activities in 2019 was $28.8 million, which primarily represents net proceeds from our at-the-market offering in August 2019 and our underwritten offering in November 2019.

Cash provided by financing activities in 2018 was minimal.

Critical Accounting Policies and Use of Estimates

This discussion and analysis is based on our consolidated financial statements, which have been prepared in accordance with generally accepted accounting principles in the United States of America, or U.S. GAAP. The preparation of consolidated financial statements in accordance with U.S. GAAP requires management to make certain estimates, judgments and assumptions and decisions that affect the reported amounts and related disclosures, including the selection of appropriate accounting principles and the assumptions on which to base accounting estimates. In making these estimates and assumptions and reaching these decisions, we apply judgment based on our understanding and analysis of the relevant circumstances, including historical data and experience available at the date of the consolidated financial statements, as well as various other factors management believes to be reasonable under the circumstances. Actual results could differ from our estimates. We are committed to incorporating accounting principles, assumptions and estimates that promote the representational faithfulness, verifiability, neutrality and transparency of the accounting information included in our consolidated financial statements.

While our significant accounting policies are described in more detail in the notes to the consolidated financial statements included in this report, we believe the accounting policies discussed below used in the preparation of our consolidated financial statements require the most significant estimates, judgments, assumptions and decisions.

Revenue Recognition

We generate revenue from sales of our genetic tests. We currently receive payments from: hospitals and medical institutions with which we have direct-bill relationships; research institutions; individual patients and third-party payors.

We recognize revenue in an amount that reflects the consideration to which we expect to be entitled in exchange for the transfer of promised goods or services to our customers. To determine revenue recognition for contracts with customers, the Company performs the following steps: (1) identifies the contract with the customer, (2) identifies the performance obligations in the contract, (3) determines the transaction price, (4) allocates the transaction price to the performance obligations in the contract, and (5) recognizes revenue when (or as) the entity satisfies a performance obligation.

Our test results are delivered electronically, and as such there are no shipping and handling fees incurred by us or billed to customers. Our sales are typically exempt from state sales taxation due to the nature of the results delivered. As a result, we do not charge customers state sales tax.

Recent Accounting Pronouncements

See Note 2, Summary of Significant Accounting Policies, to our consolidated financial statements included in this report for information about recent accounting pronouncements.

The JOBS Act

We qualify as an “emerging growth company” as defined in the Jumpstart Our Business Startups Act of 2012, as amended, or JOBS Act. As an emerging growth company, we may take advantage of specified reduced disclosure and other requirements that are otherwise applicable to public companies that are not emerging growth companies, including an extended transition period to comply with new or revised accounting standards applicable to public companies. We have chosen to “opt out” of this extended transition period and, as a result, we will comply with new or revised accounting standards as required when they are adopted. This decision to opt out of the extended transition period under the JOBS Act is irrevocable. We will remain an emerging growth company until December 31, 2021, unless our gross revenue exceeds $1.07 billion in any fiscal year before that date, we issue more than $1.0 billion of non-convertible debt in any three-year period before that date or the market value of our common stock held by non-affiliates exceeds $700.0 million as of the last business day of the second fiscal quarter of any fiscal year before that date.

Off-Balance Sheet Arrangements

We did not have during the periods presented, and we do not currently have, any off-balance sheet arrangements, as defined in the rules and regulations of the SEC, that have or are reasonably likely to have a current or future effect on our financial condition, changes in financial condition, revenue or expenses, results of operations, liquidity, capital expenditures or capital resources that is material to investors.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk.

Not applicable.

Item 8. Financial Statements and Supplementary Data.

The information required by this Item 8 immediately follows the signature page to this report and is incorporated herein by reference.

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

None.

Item 9A. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

Disclosure controls and procedures are controls and other procedures of a company that are designed to ensure that information required to be disclosed by the company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company's management, including its principal executive officer and principal financial officer, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure. As required by Rules 13a-15(b) and 15d-15(b) under the Exchange Act, our management, with the participation of our principal executive officer and principal financial officer, conducted an evaluation of the effectiveness of our disclosure controls and procedures as of December 31, 2019. Based on this evaluation, our principal executive officer and principal financial officer concluded that our disclosure controls and procedures were effective as of December 31, 2019.

Management's Annual Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting for our company, as this term is defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act. As required by Rules 13a-15(c) and 15d-15(c) under the Exchange Act, our management, with the participation of our principal executive officer and principal financial officer, conducted an evaluation of the effectiveness of our internal control over financial reporting as of December 31, 2019, based on the criteria set forth in the Internal Control—Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on this evaluation, our management concluded that our internal control over financial reporting was effective as of December 31, 2019.

This report does not include an attestation report of our independent registered public accounting firm regarding our internal control over financial reporting, in accordance with applicable SEC rules that permit us to provide only management's report in this report.

Changes in Internal Control over Financial Reporting

There has been no change in our internal control over financial reporting during the quarter ended December 31, 2019, that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Inherent Limitations on Disclosure Controls and Procedures and Internal Control over Financial Reporting

Management recognizes that any controls and procedures, no matter how well-designed and operated, can provide only reasonable assurance of achieving their objectives, and management necessarily applies its judgment in evaluating the benefits of possible controls and procedures relative to their costs. Because of these inherent limitations, our disclosure and internal controls may not prevent or detect all instances of fraud, misstatements or other control issues. In addition, projections of any evaluation of the effectiveness of disclosure or internal controls to future periods are subject to risks, including, among others, that controls may become inadequate because of changes in conditions or that the degree of compliance with policies or procedures may deteriorate.

Item 9B. Other Information.

None.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

The information required by this item is incorporated by reference to the definitive proxy statement for our 2020 annual meeting of stockholders or an amendment to this report, in either case to be filed with the SEC within 120 days after the end of our fiscal year ended December 31, 2019.

Item 11. Executive Compensation.

The information required by this item is incorporated by reference to the definitive proxy statement for our 2020 annual meeting of stockholders or an amendment to this report, in either case to be filed with the SEC within 120 days after the end of our fiscal year ended December 31, 2019.

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 definitive proxy statement for our 2020 annual meeting of stockholders or an amendment to this report, in either case to be filed with the SEC within 120 days after the end of our fiscal year ended December 31, 2019.

Item 13. Certain Relationships and Related Transactions, and Director Independence.

The information required by this item is incorporated by reference to the definitive proxy statement for our 2020 annual meeting of stockholders or an amendment to this report, in either case to be filed with the SEC within 120 days after the end of our fiscal year ended December 31, 2019.

Item 14. Principal Accounting Fees and Services.

The information required by this item is incorporated by reference to the definitive proxy statement for our 2020 annual meeting of stockholders or an amendment to this report, in either case to be filed with the SEC within 120 days after the end of our fiscal year ended December 31, 2019.

PART IV

Item 15. Exhibits, Financial Statement Schedules.

(a)(1) Consolidated Financial Statements.

The following financial statements are included immediately following the signature page hereof and are filed as part of this report:

Report of Independent Registered Public Accounting Firm	F-2
Consolidated Balance Sheets as of December 31, 2019 and 2018	F-3
Consolidated Statements of Operations for the Years Ended December 31, 2019 and 2018	F-4
Consolidated Statements of Comprehensive Loss for the Years Ended December 31, 2019 and 2018	F-5
Consolidated Statements of Stockholders' Equity for the Years Ended December 2019 and 2018	F-6
Consolidated Statements of Cash Flows for the Years Ended December 31, 2019 and 2018	F-7
Notes to Consolidated Financial Statements	F-8

(a)(2) Financial Statement Schedules.

All financial statement schedules have been omitted, as they are not required, not applicable, or the required information is otherwise included.

(a)(3) Exhibits.

The information required by this Item 15(a)(3) is set forth on the Exhibit Index immediately preceding the signature page of this report and is incorporated herein by reference.

Item 16. Form 10-K Summary.

We have elected not to provide summary information.

EXHIBIT INDEX

Exhibit Number	Description	Form	File Number	Incorporated by Reference Exhibit	Filing Date	Filed Herewith
2.1	Agreement and Plan of Merger, dated September 16, 2016, by and among the registrant, Fulgent MergerSub, LLC and Fulgent Therapeutics LLC.	S-1/A	333-213469	2.1	9/19/2016	
3.1	Certificate of Incorporation of the registrant, dated May 13, 2016.	10-Q	001-37894	3.1	8/14/2017	
3.1.1	Certificate of Amendment to Certificate of Incorporation of the registrant, dated August 2, 2016 .	10-Q	001-37894	3.1.1	8/14/2017	
3.1.2	Certificate of Amendment to Certificate of Incorporation of the registrant, dated May 17, 2017.	10-Q	001-37894	3.1.2	8/14/2017	
3.2	Bylaws of the registrant.	S-1/A	333-213469	3.2	9/26/2016	
4.1	Form of Certificate of Common Stock of the registrant .	S-1/A	333-213469	4.1	9/19/2016	
4.2	Investor's Rights Agreement, dated May 17, 2016, by and between Fulgent Therapeutics LLC and Xi Long USA, Inc..	S-1	333-213469	4.2	9/2/2016	
4.3	Description of the registrant's securities.					X
10.1#	Form of Indemnification Agreement between the registrant and each of its officers and directors.	S-1	333-213469	10.1	9/2/2016	
10.2#	Amended and Restated 2015 Equity Incentive Plan of Fulgent Therapeutics LLC.	S-1	333-213469	10.2	9/2/2016	
10.3#	Form of Notice of Option Grant and Option Agreement under the Amended and Restated 2015 Equity Incentive Plan of Fulgent Therapeutics LLC.	S-1	333-213469	10.3	9/2/2016	
10.4#	Form of Notice of Profits Interest Grant and Profits Interest Agreement under the Amended and Restated 2015 Equity Incentive Plan of Fulgent Therapeutics LLC.	S-1	333-213469	10.4	9/2/2016	
10.5#	Form of Notice of Restricted Share Unit Grant and Restricted Share Unit Agreement under the Amended and Restated 2015 Equity Incentive Plan of Fulgent Therapeutics LLC.	S-1	333-213469	10.5	9/2/2016	
10.6#	2016 Omnibus Incentive Plan of the registrant.	S-1/A	333-213469	10.6	9/26/2016	
10.7#	Form of Notice of Stock Option Award and Stock Option Award Agreement under the 2016 Omnibus Incentive Plan of the registrant.	S-1	333-213469	10.7	9/2/2016	
10.8#	Form of Notice of Restricted Stock Unit Award and Restricted Stock Unit Agreement under the 2016 Omnibus Incentive Plan of the registrant.	10-K	001-37894	10.8	3/17/2017	
10.9#	Form of Option Substitution Award under the 2016 Omnibus Incentive Plan of the registrant.	S-1	333-213469	10.9	9/2/2016	

Exhibit Number	Description	Form	File Number	Incorporated by Reference Exhibit	Filing Date	Filed Herewith
10.10#	Form of Notice of Restricted Stock Unit Substitution Award and Restricted Stock Unit Agreement under the 2016 Omnibus Incentive Plan of the registrant Form of Notice of Restricted Stock Unit Substitution Award and Restricted Stock Unit Agreement under the 2016 Omnibus Incentive Plan of the registrant.	S-1	333-213469	10.10	9/2/2016	
10.11#	Employment Agreement, dated May 25, 2016, by and among Fulgent Therapeutics LLC, the registrant and Ming Hsieh.	S-1	333-213469	10.11	9/2/2016	
10.12#	Employment Agreement, dated May 25, 2016, by and among Fulgent Therapeutics LLC, the registrant and Paul Kim.	S-1	333-213469	10.12	9/2/2016	
10.13#	Amended and Restated Employment Agreement, dated May 25, 2016, by and among Fulgent Therapeutics LLC, the registrant and Han Lin Gao.	S-1	333-213469	10.13	9/2/2016	
10.14#	Severance Agreement, dated July 7, 2016, by and among Fulgent Therapeutics LLC, the registrant and Ming Hsieh.	S-1	333-213469	10.14	9/2/2016	
10.15#	Severance Agreement, dated July 7, 2016, by and among Fulgent Therapeutics LLC, the registrant and Paul Kim.	S-1	333-213469	10.15	9/2/2016	
10.16#	Severance Agreement, dated July 7, 2016, by and among Fulgent Therapeutics LLC, the registrant and Han Lin Gao.	S-1	333-213469	10.16	9/2/2016	
10.17	Contribution and Allocation Agreement, dated May 19, 2016, by and among Fulgent Therapeutics LLC, Fulgent Pharma LLC and Ming Hsieh.	S-1	333-213469	10.17	9/2/2016	
10.18	Form of Fourth Amended and Restated Operating Agreement of Fulgent Therapeutics LLC, to be in effect upon completion of the Reorganization.	S-1/A	333-213469	2.1	9/19/2016	
10.19	Commercial Leases, dated April 14, 2015, April 28, 2016, March 24, 2016 and August 1, 2016, by and between E & E Plaza LLC and Fulgent Therapeutics LLC.	S-1	333-213469	10.19	9/2/2016	
10.20	Director Compensation Program of the registrant, effective as of September 28, 2016 and amended November 2, 2017.	10-K	001-37894	10.20	3/20/2018	
10.21§	Cooperation Agreement on the Establishment of Fujian Fujun Gene Biotech Co., Ltd., dated April 25, 2017, by and among Shenzhen Fujin Gene Science & Technology Co., Ltd., Xilong Scientific Co., Ltd. and Fuzhou Jinqiang Investment Partnership (LP).	10-Q	001-37894	10.1	8/14/2017	
10.22§	Supplemental Agreement to Cooperation Agreement, dated April 10, 2019, by and among Fulgent Genetics, Inc., Shenzhen Fujin Gene Technology Co., Ltd., Xilong Science Co., Ltd. and Fuzhou Jinqiang Investment Partnership (Limited).	10-Q	001-37894	10.1	8/12/2019	

Exhibit Number	Description	Form	File Number	Incorporated by Reference Exhibit	Filing Date	Filed Herewith
10.23	Commercial Lease, dated January 31, 2018, by and between E & E Plaza LLC and Fulgent Therapeutics LLC.	10-K	001-37894	10.23	3/22/2019	
10.24	Commercial Lease, dated April 1, 2018, by and between 4401 Santa Anita Corporation and Fulgent Genetics, Inc.	10-K	001-37894	10.24	3/22/2019	
10.25	Equity Distribution Agreement, dated August 30, 2019, by and between Fulgent Genetics, Inc. and Piper Jaffray & Co.	8-K	001-37894	1.1	8/30/2019	
10.26	Purchase Agreement, dated as of November 13, 2019, by and between Fulgent Genetics, Inc. and Piper Jaffray & Co.	8-K	001-37894	1.1	11/14/2019	
21.1	Subsidiaries of the registrant.	10-K	001-37894	21.1	3/22/2019	
23.1	Consent of Deloitte & Touche LLP, independent registered public accounting firm, relating to the financial statements of the registrant.					X
24.1	Power of Attorney (included on the signature page hereto)					X
31.1	Certification of Principal Executive Officer pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.					X
31.2	Certification of Principal Financial Officer pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.					X
32.1*	Certification of Principal Executive Officer and Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.					X
101.INS	XBRL Instance Document					X
101.SCH	XBRL Taxonomy Extension Schema Document					X
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document					X
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document					X
101.LAB	XBRL Taxonomy Extension Label Linkbase Document					X
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document					X

* This certification is being furnished solely to accompany this report pursuant to 18 U.S.C. 1350, and are not being filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and is not to be incorporated by reference into any filing of the registrant, whether made before or after the date hereof, regardless of any general incorporation by reference language in such filing.

Management contract or compensatory plan, contract or arrangement.

§ Confidential treatment has been granted with respect to portions of this exhibit pursuant to Rule 24b-2 under the Exchange Act, and these confidential portions have been redacted from the version of this agreement that is incorporated by reference in this report. A complete copy of this exhibit, including the redacted portions, has been separately furnished to the SEC.

SIGNATURES

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

FULGENT GENETICS, INC.

Date: March 12, 2020

By: /s/ Ming Hsieh
Ming Hsieh
President, Chief Executive Officer

POWER OF ATTORNEY

IN WITNESS WHEREOF, each person whose signature appears below constitutes and appoints Ming Hsieh and Paul Kim as his true and lawful agent, proxy and attorney-in-fact, each acting alone, with full power of substitution and resubstitution, for him and in his name, place and stead, in any and all capacities, to (i) act on and sign any amendments to this report, with exhibits thereto and other documents in connection therewith, (ii) act on and sign such certificates, instruments, agreements and other documents as may be necessary or appropriate in connection therewith, and in each case file the same with the SEC, hereby approving, ratifying and confirming all that such agent, proxy and attorney-in-fact or any of his substitutes may lawfully do or cause to be done by virtue thereof.

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

Name and Signature	Title	Date
/s/ Ming Hsieh Ming Hsieh	President, Chief Executive Officer and Chairman of the Board (principal executive officer)	March 12, 2020
/s/ Paul Kim Paul Kim	Chief Financial Officer (principal financial and accounting officer)	March 12, 2020
/s/John Bolger John Bolger	Director	March 12, 2020
/s/ James J. Mulay (Mulé) James J. Mulay (Mulé)	Director	March 12, 2020
/s/ Yun Yen Yun Yen	Director	March 12, 2020
/s/ Linda Marsh Linda Marsh	Director	March 12, 2020

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

Report of Independent Registered Public Accounting Firm	F-2
Consolidated Balance Sheets as of December 31, 2019 and 2018	F-3
Consolidated Statements of Operations for the Years Ended December 31, 2019 and 2018	F-4
Consolidated Statements of Comprehensive Loss for the Years Ended December 31, 2019 and 2018	F-5
Consolidated Statements of Stockholders' Equity for the Years Ended December 31, 2019 and 2018	F-6
Consolidated Statements of Cash Flows for the Years Ended December 31, 2019 and 2018	F-7
Notes to Consolidated Financial Statements	F-8

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the stockholders and the Board of Directors of Fulgent Genetics, Inc.:

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Fulgent Genetics, Inc. and subsidiaries (the "Company") as of December 31, 2019 and 2018, the related consolidated statements of operations, comprehensive loss, stockholders' equity, and cash flows, for the years ended December 31, 2019 and 2018, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2019 and 2018, and the results of its operations and its cash flows for the years ended December 31, 2019 and 2018, in conformity with accounting principles generally accepted in the United States of America.

Adoption of New Accounting Standard

As discussed in Note 9 to the financial statements, the Company changed its method of accounting for leases in 2019 due to the adoption of Accounting Standards Update No. 2016-02, Leases (Topic 842), 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/ DELOITTE & TOUCHE LLP
Los Angeles, California

March 12, 2020

We have served as the Company's auditor since 2016.

FULGENT GENETICS, INC.
Consolidated Balance Sheets
(in thousands, except par value data)

	December 31, 2019	December 31, 2018
Assets		
Current assets		
Cash and cash equivalents	$ 11,965	$ 6,736
Marketable securities	16,304	24,298
Trade accounts receivable, net of allowance for doubtful accounts of $751 and $590, as of December 31, 2019 and 2018, respectively	6,555	5,948
Other current assets	2,255	2,561
Total current assets	37,079	39,543
Marketable securities, long-term	41,947	6,386
Equity method investments	872	1,512
Fixed assets, net	5,974	6,446
Operating lease right-of-use asset	2,633	—
Other long-term assets	251	17
Total assets	$ 88,756	$ 53,904
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable	$ 1,581	$ 1,313
Accrued liabilities	1,333	1,259
Income tax payable	24	—
Contract liabilities	365	166
Operating lease liabilities, short-term	420	—
Total current liabilities	3,723	2,738
Operating lease liabilities, long-term	2,256	—
Other long-term liabilities	—	14
Total liabilities	5,979	2,752
Commitments and contingencies (Note 8)		
Stockholders' equity		
Common stock, $0.0001 par value per share, 50,000 shares authorized, 21,483 and 18,172 shares issued and outstanding at December 31, 2019 and 2018, respectively	2	2
Preferred stock, $0.0001 par value per share, 1,000 shares authorized, no shares issued or outstanding at December 31, 2019 and 2018	—	—
Additional paid-in capital	146,058	114,203
Accumulated other comprehensive income (loss)	146	(35)
Accumulated deficit	(63,429)	(63,018)
Total stockholders' equity	82,777	51,152
Total liabilities and stockholders' equity	$ 88,756	$ 53,904

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

FULGENT GENETICS, INC.
Consolidated Statements of Operations
(in thousands, except per share data)

	Year Ended December 31,	
	2019	**2018**
Revenue	$ 32,528	$ 21,351
Cost of revenue	14,107	10,697
Gross profit	18,421	10,654
Operating expenses:		
Research and development	6,537	5,534
Selling and marketing	5,898	4,652
General and administrative	6,414	5,538
Total operating expenses	18,849	15,724
Operating loss	(428)	(5,070)
Interest and other income, net	837	434
Income (loss) before income taxes and equity loss in investee	409	(4,636)
Provision for income taxes	43	36
Income (loss) before equity loss in investee	366	(4,672)
Equity loss in investee	(777)	(935)
Net loss	$ (411)	$ (5,607)
Net loss per common share:		
Basic	$ (0.02)	$ (0.31)
Diluted	$ (0.02)	$ (0.31)
Weighted-average common shares:		
Basic	18,709	17,978
Diluted	18,709	17,978

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

FULGENT GENETICS, INC.
Consolidated Statements of Comprehensive Loss
(in thousands)

	Year Ended December 31,	
	2019	**2018**
Net loss	$ (411)	$ (5,607)
Other comprehensive income (loss)		
Foreign currency translation loss	(17)	(44)
Net unrealized gain on marketable securities, net of tax	198	53
Comprehensive loss	$ (230)	$ (5,598)

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

FULGENT GENETICS, INC.
Consolidated Statements of Stockholders' Equity
(in thousands)

	Stockholders' Equity					
	Shares	Amount	Additional Paid-In Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Equity
Balance at December 31, 2017	**17,847**	**$ 2**	**$ 111,884**	**$ (44)**	**$ (57,664)**	**$ 54,178**
Equity-based compensation	—	—	2,304	—	—	2,304
Exercise of common stock options	40	—	15	—	—	15
Restricted stock awards	285	—	—	—	—	—
Cumulative effect of accounting change	—	—	—	—	327	327
Cumulative tax effect of accounting change	—	—	—	—	(74)	(74)
Other comprehensive gain, net	—	—	—	9	—	9
Net income (loss)	—	—	—	—	(5,607)	(5,607)
Balance at December 31, 2018	**18,172**	**2**	**114,203**	**(35)**	**(63,018)**	**51,152**
Equity-based compensation	—	—	3,209	—	—	3,209
Exercise of common stock options	100	—	38	—	—	38
Restricted stock awards	434	—	—	—	—	—
Issuance of common stock at an average of $9.37 per share, net	104	—	979	—	—	979
Issuance of common stock at an average of $10.34 per share, net	2,674	—	27,650	—	—	27,650
Repurchases of capital stock	(1)	—	(21)	—	—	(21)
Other comprehensive gain, net	—	—	—	181	—	181
Net income (loss)	—	—	—	—	(411)	(411)
Balance at December 31, 2019	**21,483**	**$ 2**	**$ 146,058**	**$ 146**	**$ (63,429)**	**$ 82,777**

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

FULGENT GENETICS, INC.
Consolidated Statements of Cash Flows
(in thousands)

	Year Ended December 31,	
	2019	**2018**
Cash flow from operating activities:		
Net loss	$ (411)	$ (5,607)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities:		
Equity-based compensation	3,209	2,304
Depreciation	2,107	2,163
Noncash lease expense	413	—
Loss on disposal of fixed asset	11	88
Amortization of premium of marketable securities	106	297
Provision for bad debt	189	309
Deferred taxes	(21)	36
Equity loss in investee	777	935
Other	52	44
Changes in operating assets and liabilities:		
Accounts receivable	(839)	(1,970)
Other current and long-term assets	374	91
Accounts payable	(329)	102
Accrued liabilities and other current liabilities	264	533
Income tax payable	24	—
Operating lease liabilities	(409)	—
Net cash provided by (used in) operations	5,517	(675)
Cash flow from investing activities:		
Purchases of fixed assets	(1,182)	(2,322)
Purchase of marketable securities	(52,077)	(24,187)
Maturities of marketable securities	24,350	27,969
Purchase of equipment contributed to Equity Method Investee	(137)	(510)
Net cash (used in) provided by investing activities	(29,046)	950
Cash flow from financing activities:		
Proceeds from public offerings of common stock, net of issuance costs	28,758	—
Proceeds from exercise of stock options	38	15
Repurchases of capital stock	(21)	—
Net cash provided by financing activities	28,775	15
Effect of exchange rate changes on cash and cash equivalents	(17)	(44)
Net increase in cash and cash equivalents	5,229	246
Cash and cash equivalents at beginning of period	6,736	6,490
Cash and cash equivalents at end of period	$ 11,965	$ 6,736
Supplemental disclosures of cash flow information:		
Income taxes paid	$ 20	$ 1
Supplemental disclosures of non-cash investing and financing activities:		
Purchases of fixed assets in accounts payable	$ 557	$ 85
Operating lease right-of-use assets obtained in exchange for lease liabilities	$ 110	$ —
Public offerings costs included in accounts payable	$ 129	$ —

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

Note 1. Overview and Basis of Presentation

The accompanying consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America ("U.S. GAAP"). These financial statements include the assets, liabilities, revenues and expenses of all wholly-owned subsidiaries and entities in which the Company has a controlling financial interest or is deemed to be the primary beneficiary. In determining whether the Company is the primary beneficiary of an entity, the Company applies a qualitative approach that determines whether it has both (1) the power to direct the economically significant activities of the entity and (2) the obligation to absorb losses of, or the right to receive benefits from, the entity that could potentially be significant to that entity. The Company uses the equity method to account for its investments in entities that it does not control, but in which it has the ability to exercise significant influence over operating and financial policies. All significant intercompany accounts and transactions are eliminated from the accompanying consolidated financial statements.

Nature of the Business

Fulgent Genetics, Inc., together with its subsidiaries (collectively referred to as the "Company," unless otherwise noted or the context otherwise requires), is a growing technology company with an initial focus on offering comprehensive genetic testing to provide physicians with clinically actionable diagnostic information they can use to improve the quality of patient care (the "Diagnostics business"). In 2019, the Company launched its first patient-initiated product, Picture Genetics, a new line of at-home screening tests combines the Company's advanced NGS solutions with actionable results and genetic counseling options for individuals. The Company has developed a proprietary technology platform that allows it to offer a broad and flexible test menu and continually expand and improve its proprietary genetic reference library. The Company's test menu currently includes single-gene tests and pre-established, multi-gene, disease-specific panels that collectively test for many genetic conditions, including various cancers, cardiovascular diseases, neurological disorders and pediatric conditions. The Company's existing customer base consists primarily of hospitals and medical institutions, which are typically frequent and high-volume users of genetic tests and which often pay the Company directly for its tests.

Note 2. Summary of Significant Accounting Policies

Use of Estimates

The preparation of consolidated financial statements in conformity with U.S. GAAP requires management to make certain estimates, judgments, assumptions and decisions that affect the reported amounts and related disclosures, including the selection of appropriate accounting policies and the assumptions on which to base accounting estimates. In making these estimates and assumptions and reaching these decisions, the Company applies judgment based on its understanding and analysis of the relevant circumstances, including historical data and experience available at the date of the accompanying consolidated financial statements, as well as various other factors management believes to be reasonable under the circumstances. Actual results could differ from these estimates.

On an on-going basis, management evaluates its estimates, primarily those related to: (i) revenue recognition criteria, (ii) accounts receivable and allowances for doubtful accounts, (iii) the useful lives of fixed assets, (iv) estimates of tax liabilities and (v) the valuation of equity-based awards.

Principles of Consolidation

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

Cash and Cash Equivalents

The Company considers all highly liquid investments with original maturities of three months or less at the date of purchase to be cash equivalents. Cash and cash equivalents include cash held in banks and money market accounts. Cash equivalents are stated at fair value.

Accounts Receivable and Allowance for Doubtful Accounts

Accounts receivable are stated at the amount the Company expects to collect. The Company performs credit evaluations of its customers and generally does not require collateral. The Company establishes an allowance for doubtful accounts based upon factors surrounding the credit risk of specific customers, historical trends and other information that assists in management's evaluation. The Company writes off accounts receivable following a review by management and a determination that the receivable is uncollectible.

A roll-forward of the activity in the Company's allowance for doubtful accounts is as follows:

	December 31,	
	2019	2018
	(in thousands)	
Allowance for doubtful accounts at beginning of year	$ 590	$ 287
Bad debt expense	189	309
Deductions	(28)	(6)
Allowance for doubtful accounts at end of year	$ 751	$ 590

Marketable Securities

All marketable securities, which consist of debt securities, United States Treasury and U.S. government agency securities, have been classified as "available for sale" and are carried at fair value. Unrealized gains and losses, net of any related tax effects, are excluded from earnings and are included in other comprehensive loss and reported as a separate component of stockholders' equity until realized. Realized gains and losses and declines in value judged to be other than temporary, if any, on marketable securities are included in other income (expense), net. The cost of any marketable securities sold is based on the specific-identification method. The amortized cost of marketable securities is adjusted for amortization of premiums and accretion of discounts to maturity. Interest on marketable securities is included in interest income. In accordance with the Company's investment policy, management invests to diversify credit risk and only invests in securities with high credit quality, including U.S. government securities.

The Company regularly evaluates whether declines in the fair value of its investments below their cost are other than temporary. The evaluation includes consideration of the cause of the impairment, including the creditworthiness of the security issuers, the number of securities in an unrealized loss position, the severity and duration of the unrealized losses, whether the Company has the intent to sell the securities, and whether it is more likely than not that the Company will be required to sell the securities before the recovery of their amortized cost basis. If the Company determines that the decline in fair value of an investment is below its accounting basis and this decline is other than temporary, the Company would reduce the carrying value of the security it holds and record a loss for the amount of such decline. The Company has not recorded any realized losses or declines in value judged to be other than temporary on its investments.

Fair Value of Financial Instruments

The Company's financial instruments consist principally of cash and cash equivalents, marketable securities, accounts receivable and accounts payable. The carrying amounts of certain of these financial instruments, including cash and cash equivalents, accounts receivable and accounts payable, approximate fair value due to their short maturities. Fair value of marketable securities is disclosed in Note 4, Fair Value Measurements, to the accompanying consolidated financial statements.

Concentrations of Credit Risk, Customers and Suppliers

Financial instruments that potentially subject the Company to significant concentrations of credit risk consist primarily of cash, accounts receivable and marketable securities, which consist of debt securities, and cash equivalents. As of December 31, 2019, substantially all of the Company's cash and cash equivalents were deposited in accounts at financial institutions, and amounts may exceed federally insured limits. Management believes that the Company is not exposed to significant credit risk due to the financial strength of the depository institutions in which its cash and cash equivalents are held.

In certain periods, a small number of customers has accounted for a significant portion of the Company's revenue. Aggregating customers that are under common control or are affiliates, one customer comprised 28% of total revenue in the year ended December 31, 2019, and one customer comprised 13% of total revenue in the year ended December 31, 2018. No customer comprised at least 10% of total accounts receivable as of December 31, 2019. One customer comprised 18% of total accounts receivable as of December 31, 2018.

Revenue from the U.S. government was less than 10% of total revenue in each of the years ended December 31, 2019 and 2018.

The Company relies on a limited number of suppliers for certain laboratory substances used in the chemical reactions incorporated into its processes, referred to as reagents, as well as for the sequencers and various other equipment and materials it uses in its laboratory operations. In particular, the Company relies on a sole supplier for the next generation sequencers and associated reagents it uses to perform its genetic tests and as the sole provider of maintenance and repair services for these sequencers. The Company's laboratory operations would be interrupted if it encounters delays or difficulties securing these reagents, sequencers, other equipment or materials or maintenance and repair services, which could occur for a variety of reasons, including if the Company needs a replacement or temporary substitute for any of its limited or sole suppliers and is not able to locate and make arrangements with an acceptable replacement or temporary substitute. The Company believes there are currently only a few other manufacturers that are capable of supplying and servicing some of the equipment and other materials necessary for its laboratory operations, including sequencers and various associated reagents.

Equity Method Investments

The Company uses the equity method to account for investments in entities that it does not control, but in which it has the ability to exercise significant influence over operating and financial policies. The Company's proportionate share of the net income or loss of these companies is included in consolidated net earnings. Judgments regarding the level of influence over each equity method investment include consideration of key factors such as the Company's ownership interest, representation on the board of directors or other management body and participation in policy-making decisions.

The Company evaluates its equity method investments for impairment whenever events or changes in circumstances indicate that a decline in value has occurred that is other than temporary. Evidence considered in this evaluation includes, but would not necessarily be limited to, the financial condition and near-term prospects of the investee, recent operating trends and forecasted performance of the investee, market conditions in the geographic area or industry in which the investee operates and the Company's strategic plans for holding the investment in relation to the period of time expected for an anticipated recovery of its carrying value. If the investments is determined to have a decline in value deemed to be other than temporary it is written down to estimated fair value.

Leases

The Company determines if an arrangement is a lease at inception. Operating leases are included as operating lease right-of-use ("ROU") assets, operating lease liabilities, short-term, and operating lease liabilities, long-term, on the Company's Consolidated Balance Sheets.

ROU lease assets represent the Company's right to use an underlying asset for the lease term and lease liabilities represent the Company's obligation to make lease payments arising from the lease. Operating ROU lease assets and liabilities are recognized at the commencement date based on the present value of lease payments over the lease term, including options to extend the lease when it is reasonably certain that the Company will exercise that option. The Company uses its incremental borrowing rate based on the information available at the commencement date in determining the present value of lease payments since its leases do not provide an implicit rate. The ROU lease asset includes any base rent payments made and excludes lease incentives and variable operating expenses. Lease expense for lease payments is recognized on a straight-line basis over the lease term.

Fixed Assets

Fixed assets are recorded at cost, net of accumulated depreciation and amortization. Depreciation is recorded using the straight-line method over the estimated useful lives of the assets, which is generally between three and five years. Leasehold improvements are capitalized and amortized over the shorter of their expected lives or the applicable lease term, including renewal options, if available. Major replacements and improvements are capitalized, while general repairs and maintenance are expensed as incurred.

Software for Internal Use

The Company capitalizes certain costs incurred to purchase computer software for internal use. These costs include purchased software packages for Company use. Capitalized computer software costs are amortized over the estimated useful life of the computer software, which is generally three years. Internally developed software costs are capitalized after management has committed to funding the project, it is probable that the project will be completed and the software will be used for its intended function. Costs that do not meet that criteria and costs incurred on projects in the preliminary and post-implementation phases are expensed as incurred.

Impairment of Long-Lived Assets

The Company evaluates the carrying amount of its long-lived assets whenever events or changes in circumstances indicate that the assets may not be recoverable. An impairment loss would be recognized when estimated future cash flows expected to result from the use of an asset and its eventual disposition is less than the carrying amount of the asset. To date, there have been no such impairment losses.

Reporting Segment and Geographic Information

Reporting segments are identified as components of an enterprise about which separate discrete financial information is available for evaluation by the chief operating decision-maker in making decisions regarding resource allocation and assessing performance. The Company's chief operating decision maker is its Chief Executive Officer. The Company views its operations and manages its business in one reporting segment.

Revenue Recognition

The Company generates revenue from sales of its genetic tests. The Company currently receives payments from: hospitals and medical institutions with which it has direct-bill relationships; research institutions; individual patients and third-party payors.

The Company's test results are delivered electronically, and as such there are no shipping and handling fees incurred by it or billed to customers. The Company's sales are typically exempt from state sales taxation due to the nature of the results delivered. As a result, the Company currently does not charge customers state sales tax and continues to assess.

Effective January 1, 2018, the Company began recognizing revenue in accordance with FASB ASC Topic 606, *Revenue from Contracts with Customers* ("ASC 606"). The Company adopted ASC 606 utilizing the modified retrospective method, meaning the cumulative effect of applying the standard was recognized to opening retained earnings as of January 1, 2018. To reflect the impact of the adoption, the Company recorded an adjustment of $327,000 to beginning accumulated deficit and accounts receivable and an adjustment of ($74,000) to beginning accumulated deficit and deferred taxes. Under ASC 606, the Company recognizes revenue in an amount that reflects the consideration to which it expects to be entitled in exchange for the transfer of promised goods or services to customers. To determine revenue recognition for contracts with customers that are within the scope of ASC 606, the Company performs the following steps: (1) identifies the contract with the customer, (2) identifies the performance obligations in the contract, (3) determines the transaction price, (4) allocates the transaction price to the performance obligations in the contract, and (5) recognizes revenue when (or as) the entity satisfies a performance obligation.

Performance Obligations

Genetic Testing Services

Clinical – Institutional and Patient Direct Pay

The Company's clinical institutional contracts included within genetic testing services typically have a single performance obligation to deliver genetic testing services to the ordering facility or patient. Some arrangements involve the delivery of genetic testing services to research institutions, which we refer to as "sequencing as a service." In arrangements with hospitals, patients who pay directly, medical or research institutions, the transaction price is stated within the contract and is therefore fixed consideration. For most of the Company's clinical volume, we identified the hospital, patients, medical or research institutions as the customer in Step 1 of the model and have determined a contract exists with those customers in Step 1. As these contracts typically have a single performance obligation, no allocation of the transaction price is required in Step 4 of the model. Control over genetic testing services is transferred to the Company's ordering facility at a point in time. Specifically, we determined the customer obtains control of the promised service upon delivery of test results.

Clinical – Insurance

The Company's clinical insurance contracts included within genetic testing services typically have a single performance obligation to deliver genetic testing services to the ordering facility or patient. For most of the Company's clinical insurance volume, we identified the patient as the customer in Step 1 of the model and have determined a contract exists with the patient in Step 1. In arrangements with insurance patients, the transaction price is stated within the contract, however, we accept payments from third-party payors that are less than the contractually stated price and is therefore variable consideration. In developing the estimate of variable consideration, we utilize the expected value method under a portfolio approach. The Company's estimate requires significant judgment and is developed using historical reimbursement data from payors and patients, as well as known current reimbursement trends not reflected in the historical data. As these contracts typically have a single performance obligation, no allocation of the transaction price is required in Step 4 of the model. Control over genetic testing services is transferred to the Company's ordering physicians at a point in time. Specifically, we determined the customer obtains control of the promised service upon delivery of the test results.

Certain incremental costs pertaining to both clinical insurance and institutional, such as commissions, are incurred in obtaining clinical contracts. Historically contract costs have not been significant to the financial statements. We have elected to utilize the practical expedient to expense incremental costs of obtaining a contract that meet the capitalization criteria, as the amortization period of any contract acquisition asset would be one year or less due to the short-term nature of the customer life.

Significant Judgments and Contract Estimates

Genetic Testing Services

Accounting for clinical insurance contracts includes estimation of the transaction price, defined as the amount we expect to be entitled to receive in exchange for providing the services under the contract. Due to the Company's out-of-network status with the majority of payors, estimation of the transaction price represents variable consideration. In order to estimate variable consideration, we utilize a portfolio approach in which payors with similar reimbursement experience are grouped into portfolios. The Company's estimates of variable consideration are based primarily on historical reimbursement data. Certain assumptions will also be adjusted based on known and anticipated factors not reflected in the historical reimbursement data. We monitor these accrual estimates at each reporting period based on actual cash collections in order to assess whether a revision to the estimate is required. Both the initial accrual estimate and any subsequent revision to the estimate contain uncertainty and require the use of judgment in the estimation of the transaction price and application of the constraint for variable consideration. If actual results in the future vary from the Company's estimates, the Company will adjust these estimates, which would affect revenue and earnings in the period such variances become known.

Contract Liabilities

Payments received in advance of services rendered are recorded as contract liabilities and are subsequently recognized as revenue in the period in which the applicable revenue recognition criteria, as described above, are met.

Overhead Expenses

The Company allocates overhead expenses, such as rent and utilities, to cost of revenue and operating expense categories based on headcount. As a result, an overhead expense allocation is reflected in cost of revenue and each operating expense category.

Cost of Revenue

Cost of revenue reflects the aggregate costs incurred in delivering test results and consists of: personnel costs, including salaries, employee benefit costs, bonuses and equity-based compensation expenses; costs of laboratory supplies; depreciation of laboratory equipment; amortization of leasehold improvements and allocated overhead. Costs associated with performing tests are recorded as tests are processed.

Research and Development Expenses

Research and development expenses represent costs incurred to develop the Company's technology and future tests. These costs consist of: personnel costs, including salaries, employee benefit costs, bonuses and equity-based compensation expenses; laboratory supplies; consulting costs and allocated overhead. The Company expenses all research and development costs in the periods in which they are incurred.

Selling and Marketing Expenses

Selling and marketing expenses consist of: personnel costs, including salaries, employee benefit costs, bonuses and equity-based compensation expenses; customer service expenses; direct marketing expenses; educational and promotional expenses; market research and analysis and allocated overhead. The Company expenses all selling and marketing costs as incurred.

General and Administrative Expenses

General and administrative expenses include executive, finance and accounting, legal and human resources functions. These expenses consist of: personnel costs, including salaries, employee benefit costs, bonuses and equity-based compensation expenses; audit and legal expenses; consulting costs and allocated overhead. The Company expenses all general and administrative expenses as incurred.

Income Taxes

Income taxes are accounted for under the asset and liability method. The Company provides for federal, state and foreign income taxes currently payable, as well as for taxes deferred due to timing differences between reporting income and expenses for financial statement purposes versus tax purposes. Deferred tax assets and liabilities are recognized for the future tax consequences attributable to temporary differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases. Deferred tax assets and liabilities are measured using enacted income tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect of a change in income tax rates is recognized as income or expense in the period that includes the enactment date.

The Company recognizes the effect of income tax positions only if those positions are more likely than not to be sustained. Recognized income tax positions are measured at the largest amount with a greater than 50% likelihood of being realized. Changes in recognition or measurement are reflected in the period in which the change in judgment occurs. For income tax positions where it is not more likely than not that a tax benefit will be sustained, the Company does not recognize a tax benefit in its consolidated financial statements. The Company records interest and penalties related to uncertain tax positions, if applicable, as a component of income tax expense.

Equity-Based Compensation

The Company grants various types of equity-based awards to its employees, consultants and non-employee directors. Equity-based compensation costs are reflected in the accompanying statements of operations based upon each award recipient's role with the Company. The Company primarily grants to its employees restricted stock unit (RSU) awards that generally vest over a specified period of time upon the satisfaction of service-based conditions. The Company measures compensation expense for equity-based awards granted to employees based on the fair value of the award on the grant date of the award. Compensation expense for employee RSU awards with a service-based vesting condition is recognized ratably over the vesting period of the award.

Foreign Currency Translation and Foreign Currency Transactions

The Company translates the assets and liabilities of its non-U.S. dollar functional currency subsidiaries into U.S. dollars using exchange rates in effect at the end of each period. Expenses for these subsidiaries are translated using average rates in effect during the period. Gains and losses from these translations are recognized in foreign currency translation included in other comprehensive income (loss) as a component in the accompanying Consolidated Statements of Stockholders' Equity. The Company's subsidiaries that use the U.S. dollar as their functional currency remeasure monetary assets and liabilities at exchange rates in effect at the end of each period, and inventories, property and nonmonetary assets and liabilities at historical rates. Gains and losses resulting from the remeasurements are included in interest and other income, net in the accompanying Consolidated Statements of Operations. Gains and losses from these remeasurements were not significant in the year ended December 31, 2019.

Comprehensive Loss

Comprehensive loss is comprised of net loss and other comprehensive income or loss. Other comprehensive income or loss consists of unrealized gain or loss on marketable securities and foreign currency translation adjustments from its subsidiaries not using the U.S. dollar as their functional currency. The Company did not have reclassifications from other comprehensive income or loss to net loss during the year ended December 31, 2019.

Basic and Diluted Net Loss per Share

Basic net loss per common share is computed by dividing the net loss attributable to common stockholders by the weighted-average number of common shares outstanding during the period. Diluted net loss per common share is computed by dividing the net loss attributable to common stockholders by the weighted-average number of common shares and dilutive common share equivalents outstanding during the period. Because the Company has reported a net loss attributable to common stockholders for all periods presented, diluted net loss per common share is the same as basic net loss per common share for these periods.

Emerging Growth Company

Pursuant to the Jumpstart Our Business Startups Act of 2012 (the "JOBS Act"), a company constituting an "emerging growth company" is, among other things, entitled to rely upon certain reduced reporting requirements. The Company is an emerging growth company, but has irrevocably elected not to take advantage of the extended transition period afforded by the JOBS Act for the implementation of new or revised accounting standards. As a result, the Company will comply with new or revised accounting standards on the relevant dates on which adoption of such standards is required for public companies that are not emerging growth companies.

Disaggregation of Revenue

The Company classifies its customers into three payor types, Clinical Institutional, Patients who pay directly or Clinical Insurance, as we believe this best depicts how the nature, amount, timing, and uncertainty of the Company's revenue and cash flows are affected by economic factors. The following table summarizes revenue from contracts with customers by payor type for the years ended December 31, 2019 and 2018.

	Year Ended December 31,	
	2019	2018
	(in thousands)	
Genetic Testing Services by payor		
Institutional	$ 31,284	$ 19,980
Patient	539	547
Insurance	705	824
Total Revenue	$ 32,528	$ 21,351

There was no material variable consideration recognized in the current period that relates to performance obligations that were completed in the prior period.

Contract Balances

Receivables from contracts with customers - As of December 31, 2019 and 2018, receivables from contracts with customers were approximately $6.6 and $5.9 million, respectively, and are included within Trade accounts receivable on the Consolidated Balance Sheets.

Contracts assets and liabilities - As of December 31, 2019 and 2018, contract assets from contracts with customers were $150,000, associated with contract execution and included in other current assets in the accompanying Consolidated Balance Sheets. Contract liabilities are recorded when the Company receives payment prior to completing its obligation to transfer goods or services to a customer. The Company had $365,000 and $166,000 of contract liabilities as of December 31, 2019 and 2018, respectively. Revenues of $59,000 and $16,000 for the years ended December 31, 2019 and 2018, respectively, related to contract liabilities at the beginning of the respective periods were recognized.

Reclassifications

Certain reclassifications have been made to the consolidated financial statements of the prior year in order to conform to the current year presentation. These reclassifications had no impact on shareholder's equity or net income for the year ended December 31, 2018. In the Consolidated Balance Sheet for the year ended December 31, 2018, the financial statement line item Contract liabilities was reclassified from Accrued Liabilities.

Transaction Price Allocated to Future Performance Obligations

ASC 606 requires that the Company disclose the aggregate amount of transaction price that is allocated to performance obligations that have not yet been satisfied as December 31, 2019. ASC 606 provides certain practical expedients that limit the requirement to disclose the aggregate amount of transaction price allocated to unsatisfied performance obligations.

The Company applied the practical expedient to not disclose the amount of transaction price allocated to unsatisfied performance obligations when the performance obligation is part of a contract that has an original expected duration of one year or less. The Company does not have material future obligations associated with Genetic Testing Services that extend beyond one year.

Recent Accounting Pronouncements

We evaluate all Accounting Standards Updates (ASUs) issued by the Financial Accounting Standards Board (FASB) for consideration of their applicability. ASUs not included in the Company's disclosures 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 or disclosures.

ASU No. 2016-01

In January 2016, the FASB issued *ASU No. 2016-01, Financial Instruments Overall (Subtopic 825-10): Recognition and Measurement of Financial Assets and Financial Liabilities*, which addresses certain aspects of recognition, measurement,

presentation, and disclosure of financial instruments, including a provision that requires equity investments (except for investments accounted for under the equity method of accounting) to be measured at fair value, with changes in fair value recognized in current earnings. The ASU was effective for the Company in the first quarter of 2018. The adoption of this update did not have a material impact on the Company's consolidated financial statements or disclosures.

ASU No. 2016-02

In February 2016, the FASB issued *ASU No. 2016-02, Leases (Topic 842), which supersedes ASC 840, Leases*. The FASB has issued subsequent amendments to improve and clarify the implementation guidance of Topic 842. The new standard requires an entity to recognize leases on the balance sheet and to disclose key information about the entity's leasing arrangements. The Company adopted this standard as of January 1, 2019 using the modified retrospective transition approach, including certain practical expedients, for all leases existing as of January 1, 2019, the effective and initial application date. Prior period financial statements were not recast under the new guidance. The Company elected to apply practical expedients, to not separate non-lease components from lease components, and to not reassess lease classification, treatment of initial direct costs, or whether an existing or expired contract contains a lease. The Company also elected to use the short-term exemption for all class assets. The adoption of the new standard resulted in recognition of operating lease liabilities of approximately $3.0 million with corresponding right-of-use assets of approximately the same amount. There was no impact to retained earnings upon adoption. This standard had a material impact on the Consolidated Balance Sheets and did not have a material impact on the Company's Consolidated Statements of Operations and Consolidated Statements of Cash Flows.

See Note 9, Leases, for further information.

ASU No. 2016-13

In June 2016, the FASB issued *ASU No. 2016-13, Financial Instruments-Credit Losses: Measurement of Credit Losses on Financial Instruments*. ASU No. 2016-13 replaces the incurred loss impairment methodology in current U.S. GAAP with a methodology that reflects expected credit losses. The update is intended to provide financial statement users with more decision-useful information about the expected credit losses on financial instruments and other commitments to extend credit held by a reporting entity at each reporting date. Entities will apply the standard's provisions as a cumulative-effect adjustment to retained earnings as of the beginning of the first reporting period in which the guidance is effective. The standard will be effective for annual reporting periods beginning after December 15, 2019, including interim periods within those reporting periods. The Company does not expect the adoption of the new guidance under the standard to materially affect its financial position or results of operations.

ASU No. 2017-08

In March 2017, the FASB issued *ASU No. 2017-08, Receivables–Nonrefundable Fees and Other Costs (Subtopic 310-20).* Under the ASU, entities must amortize to the earliest call date the premium on certain purchased callable debt securities. The ASU does not require any accounting change for debt securities held at a discount. The guidance calls for a modified retrospective transition approach under which a cumulative-effect adjustment will be made to retained earnings as of the beginning of the first reporting period in which the guidance is adopted. The ASU is effective for public business entities for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2018. The adoption of this update did not have a material impact on the Company's consolidated financial statements or disclosures.

ASU No. 2018-02

In February 2018, the FASB issued *ASU No. 2018-02, Income Statement–Reporting Comprehensive Income (Topic 220): Reclassification of Certain Tax Effects from Accumulated Other Comprehensive Income*, which allows a reclassification from accumulated other comprehensive income to retained earnings for stranded tax effects resulting from the Tax Cuts and Jobs Act enacted by the U.S. federal government on December 22, 2017 (the "2017 Tax Act"). Consequently, the amendments eliminate the stranded tax effects resulting from the 2017 Tax Act and will improve the usefulness of information reported to financial statement users. The amendments in this ASU are effective for all entities for fiscal years beginning after December 15, 2018, and interim periods within those fiscal years. The adoption of this update did not have a material impact on the Company's consolidated financial statements or disclosures.

ASU No. 2018-15

In August 2018, the FASB issued *ASU No. 2018-15, Intangibles-Goodwill and Other-Internal-Use Software (Subtopic 350-40): Customer's Accounting for Implementation Costs Incurred in a Cloud Computing Arrangement That Is a Service Contract*, which provides new guidance on the accounting for implementation, set-up, and other upfront costs incurred in a hosted cloud computing arrangement. Under the new guidance, entities will apply the same criteria for capitalizing implementation costs as they would for an

internal-use software license arrangement. This guidance is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2019. This ASU can be adopted prospectively to eligible costs incurred on or after the date of adoption or retrospectively. The Company does not expect the adoption of the new guidance under the standard to materially affect its financial position or results of operations.

ASU No. 2019-12

In December 2019, the FASB issued *ASU No. 2019-12, Simplifying the Accounting for Income Taxes (Topic 740)*, which is intended to reduce the complexity of accounting standards while maintaining or enhancing the helpfulness of information provided to financial statement users. The amendment in this update simplifies the accounting for income taxes by removing some exceptions including the incremental approach for intraperiod tax allocation, the requirement to recognize a deferred tax liability for equity method investments, the ability not to recognize a deferred tax liability for a foreign subsidiary, and the general methodology for calculating income taxes in an interim period. Other changes include requiring entities to recognize franchise tax that is partially based on income as an income-based tax and account for any incremental amount incurred as a non-income-based tax, evaluate tax basis step-up in goodwill obtained in a transaction that is not a business combination, and reflect the effect of an enacted change in tax laws or rates in the annual effective tax rate computation in the interim period that includes the enactment date, making minor codification improvements for income taxes related to employee stock ownership plans and investments in qualified affordable housing projects accounted for using the equity method, and specifying that an entity is not required to allocate the consolidated current and deferred tax expense to a legal entity that is not subject to tax in its separate financial statements. This amendment is effective for public business entities beginning after December 15, 2020 with early adoption permitted. The Company has decided not to early adopt the amendments. The Company is currently evaluating the amendment and has not yet determined the impact on its consolidated financial statements.

Note 3. Marketable Securities

The Company's marketable securities consisted of the following:

	December 31, 2019			
	Amortized Cost Basis	Unrealized Gains	Unrealized Losses	Aggregate Fair Value
	(in thousands)			
Marketable securities:				
Short-term				
Money market accounts	$ 4,700	$ —	$ —	$ 4,700
Corporate debt securities	17,962	43	(2)	18,003
Less: Cash equivalents	(6,399)	—	—	(6,399)
Total short-term marketable securities	16,263	43	(2)	16,304
Corporate debt securities	41,861	116	(30)	41,947
Total long-term marketable securities	41,861	116	(30)	41,947
Total marketable securities	$ 58,124	$ 159	$ (32)	$ 58,251

	December 31, 2018			
	Amortized Cost Basis	Unrealized Gains	Unrealized Losses	Aggregate Fair Value
	(in thousands)			
Marketable securities:				
Short-term				
Money market accounts	$ 2,692	$ —	$ —	$ 2,692
United States Treasury	990	—	—	990
U.S. government agency securities	790	—	—	790
Corporate debt securities	22,613	1	(96)	22,518
Less: Cash equivalents	(2,692)	—	—	(2,692)
Total short-term marketable securities	24,393	1	(96)	24,298
Corporate debt securities	6,383	11	(8)	6,386
Total long-term marketable securities	6,383	11	(8)	6,386
Total marketable securities	$ 30,776	$ 12	$ (104)	$ 30,684

Management determined that the gross unrealized losses of $32,000 on the Company's marketable securities as of December 31, 2019 were temporary in nature. Gross unrealized losses on the Company's marketable securities were $104,000 as of December 31, 2018. The Company currently does not intend to sell these securities prior to maturity and does not consider these investments to be other-than-temporarily impaired as of December 31, 2019.

Note 4. Fair Value Measurements

The authoritative guidance on fair value measurements establishes a framework with respect to measuring assets and liabilities at fair value on a recurring basis and non-recurring basis. Under the framework, fair value is defined as the exit price, or the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants, as of the measurement date. The framework also establishes a three-tier hierarchy for inputs used in measuring fair value that maximizes the use of observable inputs and minimizes the use of unobservable inputs by requiring that the most observable inputs be used when available. Observable inputs are inputs market participants would use in valuing the asset or liability and are developed based on market data obtained from sources independent of the Company. Unobservable inputs are inputs that reflect the Company's assumptions about the factors market participants would use in valuing the asset or liability and are developed based on the best information available in the circumstances. The hierarchy consists of the following three levels:

Level 1:	Inputs are quoted prices (unadjusted) in active markets for identical assets or liabilities that the reporting entity can access at the measurement date.
Level 2:	Inputs are inputs other than quoted prices included within Level 1 that are observable for the asset or liability, either directly or indirectly.
Level 3:	Inputs are unobservable inputs for the asset or liability.

The following tables present information about the Company's financial assets measured at fair value on a recurring basis, based on the three-tier fair value hierarchy:

	December 31, 2019			
	Total	Level 1	Level 2	Level 3
	(in thousands)			
Marketable securities and cash equivalents:				
Corporate debt securities	$ 59,950	$ —	$ 59,950	$ —
Money market accounts	4,700	4,700	—	—
Total marketable securities and cash equivalents	$ 64,650	$ 4,700	$ 59,950	$ —

	December 31, 2018			
	Total	Level 1	Level 2	Level 3
	(in thousands)			
Marketable securities and cash equivalents:				
Corporate debt securities	$ 28,904	$ —	$ 28,904	$ —
United States Treasury	990	—	990	—
U.S. government agency securities	790	—	790	—
Money market accounts	2,692	2,692	—	—
Total marketable securities and cash equivalents	$ 33,376	$ 2,692	$ 30,684	$ —

The Company's Level 1 assets include money market instruments and are valued based upon observable market prices. Level 2 assets consist of United States Treasury, U.S. government agency securities, and corporate debt securities. Level 2 securities are valued based upon observable inputs that include reported trades, broker/dealer quotes, bids and offers. As of December 31, 2019 and 2018, the Company had no investments that were measured using unobservable (Level 3) inputs.

There were no transfers between fair value measurement levels during the years ended December 31, 2019 and 2018.

Gross unrealized gains or losses for cash equivalents and marketable securities as of December 31, 2019 were not material. As of December 31, 2019, unrealized losses for securities in an unrealized loss position for more than 12 months were zero. During the years ended December 31, 2019 and 2018, the Company did not recognize other-than-temporary impairment losses related to its marketable securities.

Note 5. Fixed Assets

Major classes of fixed assets consisted of the following:

	Useful Lives	December 31, 2019	December 31, 2018
		(in thousands)	
Computer hardware	3 Years	$ 1,705	$ 1,579
Computer software	3 Years	541	495
Medical lab equipment	5 Years	10,493	8,136
Furniture and fixtures	5 Years	235	233
Leasehold improvements	Shorter of lease term or estimated useful life	876	802
Assets not yet placed in service		114	1,087
Total		13,964	12,332
Less: Accumulated depreciation		(7,990)	(5,886)
Property and equipment, net		$ 5,974	$ 6,446

Depreciation expense on fixed assets totaled $2.1 million and $2.2 million for the years ended December 31, 2019 and 2018, respectively.

Note 6. Other Current Assets

Other current assets consisted of the following:

	December 31, 2019	December 31, 2018
	(in thousands)	
Reagents	$ 277	$ 314
Contract assets	150	150
Prepaid expenses	1,288	556
Prepaid income taxes	46	1,251
Marketable securities interest receivable	478	220
Other receivable	16	70
Total	$ 2,255	$ 2,561

Reagents are used for DNA sequencing applications in the Company's DNA sequencing equipment.

Note 7. Reporting Segment and Geographic Information

The Company views its operations and manages its business in one reporting segment. Long-lived assets were primarily located in the United States as of December 31, 2019 with an insignificant amount located in Canada. All long-lived assets were located in the United States as of December 31, 2018. Revenue by region for the years ended December 31, 2019 and 2018 were as follows:

	Year Ended December 31, 2019	Year Ended December 31, 2018
	(in thousands)	
Revenue:		
United States	$ 25,014	$ 12,579
Foreign:		
Canada	2,245	3,984
Other Countries	5,269	4,788
Total	$ 32,528	$ 21,351

Note 8. Commitments and Contingencies

Operating Leases

See Note 9, Leases, for further information.

Gene Biotech

See Note 15 for a description of the Company's commitments related to its joint venture, FF Gene Biotech (as defined in Note 15).

Purchase Obligations

As of December 31, 2019, the Company had non-cancelable purchase obligations of $2.9 million for reagents and other supplies, of which, $1.5 million is payable within twelve months, and $1.4 million is payable within the next twenty-four months.

Contingencies

From time to time, the Company may be subject to legal proceedings and claims arising in the ordinary course of business. Management does not believe that the outcome of any of these matters will have a material effect on the Company's consolidated financial position, results of operations or cash flows.

Note 9. Leases

The Company has various non-cancelable operating leases with varying terms through August 2023 primarily for office space. The Company has options to renew some of these leases for three years after their expiration. The Company considers these options, which may be elected at the Company's sole discretion, in determining the lease term on a lease-by-lease basis. The Company does not have any finance leases or leases with variable lease payments.

The determination of whether an arrangement contains a lease is made at inception by evaluating whether the arrangement conveys the right to use an identified asset and whether the Company obtains substantially all of the economic benefits from and has the ability to direct the use of the asset.

The Company's headquarters is located in Temple City, California, which is comprised of various corporate offices and a laboratory certified under the Clinical Laboratory Improvement Amendments of 1988 ("CLIA"), accredited by the College of American Pathologists ("CAP") and licensed by the State of California Department of Public Health. Additional offices are located in El Monte, California and Atlanta, Georgia and are used for certain research and development, customer service, report generation and other administrative functions.

Rent expense, including sublease consideration, was approximately $548,000 and $418,000 for the years ended December 31, 2019 and 2018, respectively.

The Company adopted new accounting standard *ASC 842, Leases*, on January 1, 2019. Upon adoption, the Company recorded ROU assets of $3.0 million and short-term and long-term lease liabilities of $384,000 and $2.6 million, respectively. The difference between the ROU asset and liability is due to the existing balance of deferred rent at the date of adoption. There was no impact to retained earnings upon adoption. The Company terminated the lease in Georgia on August 31, 2019 and entered into a new lease on September 1, 2019. Upon entering the new lease, the Company recorded ROU assets of $110,000 and short term and long-term lease liabilities of $23,000 and $87,000, respectively.

As the Company's leases do not provide an implicit rate, the Company uses its incremental borrowing rate based on information available at the commencement date in determining the discount rate used to calculate present value lease payment. The Company determined its incremental borrowing rate based on inquiries with its bank. The Company's lease agreements do not contain any residual value guarantees, material restrictive covenants, bargain purchase options or asset retirement obligations. Lease expense for the Company's operating leases is recognized on a straight-line basis over the lease term. The Company's leases do not contain variable lease payments. The Company does not have any short-term leases and thus has excluded short-term costs from the table below. Other than the new lease in Georgia, the Company did not enter into any new leases during the year ended December 31, 2019.

The following was operating lease expense:

	Year Ended December 31, 2019
	(in thousands)
Operating lease cost	$ 587

Supplemental cash flow information related to leases was the following:

	Year Ended December 31, 2019
	(in thousands)
Cash paid for amounts included in the measurement of lease liabilities	$ 535
Noncash lease expense	$ 413
Right-of-assets obtained in exchange for new operating lease liabilities	$ 110

Supplemental information related to leases was the following:

	December 31, 2019
Weighted average remaining lease term - operating leases	5.6 years
Weighted average discount rate - operating leases	6.25%

The following is a maturity analysis of operating lease liabilities using undiscounted cash flows on an annual basis with renewal periods included:

	Operating Leases
	(in thousands)
Year Ending December 31,	
2020	$ 575
2021	591
2022	597
2023	567
2024	330
Thereafter	532
Total lease payments	3,192
Less imputed interest	(516)
Total	$ 2,676

Supplemental Information for Comparative Periods

As of December 31, 2018, prior to the adoption of Topic 842, future minimum payments under non-cancelable operating leases are as follows:

	Operating Leases
	(in thousands)
Year Ending December 31,	
2019	$ 560
2020	559
2021	550
2022	558
2023	567
Thereafter	862
Total minimum payments	$ 3,656

Note 10. Equity-Based Compensation

The Company has included equity-based compensation expense as part of cost of revenue and operating expenses in the accompanying Consolidated Statements of Operations as follows:

	Year Ended December 31,	
	2019	2018
	(in thousands)	
Cost of revenue	$ 676	$ 523
Research and development	1,024	732
Selling and marketing	845	460
General and administrative	664	589
Total	$ 3,209	$ 2,304

Award Activity

Option Awards

The following table summarizes activity for options to acquire shares of the Company's common stock in the years ended December 31, 2019 and 2018:

	Number of Shares Subject to Options (in thousands)	Weighted-Average Exercise Price	Weighted-Average Grant Date Fair Value	Weighted-Average Remaining Contractual Life (in years)	Aggregate Intrinsic Value (in thousands) (1)
Balance at December 31, 2017	465	$ 0.84		8.0	$ 1,785
Granted	10	$ 3.93	$ 2.92		
Exercised	(40)	$ 0.38	$ 5.80		
Canceled	(18)	$ 8.19	$ 8.47		
Balance at December 31, 2018	417	$ 0.64		7.1	$ 1,116
Granted	30	$ 6.98	$ 4.58		
Exercised	(100)	$ 0.38	$ 5.36		
Canceled	(6)	$ 0.38	$ 7.10		
Balance at December 31, 2019	341	$ 1.27		6.4	$ 3,960
Exercisable as of December 31, 2019	284	$ 0.64		6.0	$ 3,482

(1) Aggregate intrinsic value is calculated as the difference between (i) the exercise price of options that, as of the applicable date, have an exercise price in excess of the fair value of the Company's common stock, and (ii) the fair value of the Company's common stock as of the applicable date.

The total fair value of options that vested during the years ended December 31, 2019 and 2018 was $549,000 and $645,000, respectively. As of December 31, 2019, the remaining unrecognized compensation expense related to all outstanding option awards was $146,000 and is expected to be recognized over a weighted-average period of 0.5 year.

RSU Awards

RSUs are awards that entitle the holder to receive shares of the Company's common stock upon satisfaction of vesting conditions. Each RSU represents the contingent right to receive one share of the Company's common stock upon vesting and settlement.

The following table summarizes activity for RSUs relating to shares of the Company's common stock in the years ended December 31, 2019 and 2018:

	Number of Shares (in thousands)	Weighted-Average Grant Date Fair Value
Balance at December 31, 2017	937	$ 7.39
Granted	554	$ 4.39
Vested and settled	(285)	$ 7.78
Forfeited	(120)	$ 5.77
Balance at December 31, 2018	1,086	$ 5.94
Granted	982	$ 7.00
Vested and settled	(434)	$ 6.39
Forfeited	(123)	$ 5.38
Balance at December 31, 2019	1,511	$ 6.54

The RSU awards granted in the years ended December 31, 2019 and 2018 will result in aggregate equity-based compensation expense of $6.9 million and $2.4 million, respectively, in each case to be recognized over four years from the grant date of each award granted in the period. As of December 31, 2019, the remaining unrecognized compensation expense related to all outstanding RSU awards was $8.7 million and is expected to be recognized over a weighted-average period of 2.9 years. As of December 31, 2018, the remaining unrecognized compensation expense related to all outstanding RSU awards was $5.6 million and is expected to be recognized over a weighted-average period of 2.9 years.

Fair Value Assumptions for Option Awards

The Company uses the Black-Scholes option-pricing model to measure the fair value of option awards. The Black-Scholes option-pricing model requires the input of various assumptions, each of which is subjective and requires significant judgment. These assumptions include the following:

- *Expected Term.* The expected term represents the period that the Company's equity-based awards are expected to be outstanding. The Company determines the expected term assumption based on the vesting terms, exercise terms and contractual terms of the options.
- *Risk-Free Interest Rate.* The Company determines the risk-free interest rate by using the equivalent to the expected term based on the U.S. Treasury yield curve in effect as of the date of grant.
- *Dividend Yield.* The assumed dividend yield is based on the Company's expectation that it will not pay dividends in the foreseeable future, which is consistent with its history of not paying dividends.
- *Expected Volatility.* The Company calculates expected volatility based on historical volatility data of its stock that is publicly traded.
- *Forfeiture Rate.* The Company accounts for forfeitures as they occur.

Awards to Employees

The table below sets forth the weighted-average assumptions used in the Black-Scholes option-pricing model to estimate the fair value of options to acquire shares of the Company's common stock granted to employees during the year ended December 31, 2019 and 2018.

	Year Ended December 31,	
	2019	**2018**
Expected term (in years)	6.1	6.1
Risk-free interest rates	1.8%	2.8%
Dividend yield	—	—
Expected volatility	73.6%	87.4%

Determination of Fair Value on Grant Dates

The fair value of the shares of the Company's common stock underlying option and RSU awards is determined by the Company's board of directors or the compensation committee thereof based on the closing sales price of the Company's common stock on the date of grant as reported by the Nasdaq Global Market.

Note 11. Income Taxes

Provision for income taxes consists of U.S. federal and state income taxes. A deferred tax liability is recognized for all taxable temporary differences, and a deferred tax asset is recognized for all deductible temporary differences, operating losses and tax credit carryforwards. 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.

As of December 31, 2019 and 2018 the Company has incurred net taxable losses, and accordingly, a current provision for income taxes has only been recorded for nominal federal and state taxes. This amount differs from the amount computed by applying the U.S. federal income tax rate of 21.0% to pretax loss due primarily to the provision of a valuation allowance to the extent of the Company's net deferred tax asset.

The following table summarizes income (loss) before income taxes and equity loss in investee:

	Year Ended December 31,	
	2019	2018
	(in thousands)	
U.S. income (loss) before income taxes and equity loss in investee	$ 679	$ (4,602)
Foreign income (loss) before income taxes and equity loss in investee	(270)	(34)
Income (loss) before income taxes and equity loss in investee	$ 409	$ (4,636)

Income tax expense (benefit) consisted of the following:

	Year Ended December 31,	
	2019	2018
	(in thousands)	
Current:		
Federal	$ 5	$ —
State	38	—
Total Current	43	—
Deferred:		
Federal	(249)	(987)
State	(280)	(308)
Change in valuation allowance	529	1,331
Total Deferred	—	36
Total income tax expense (benefit)	$ 43	$ 36

Reconciliation of the difference between the federal statutory income tax rate and the effective income tax rate is as follows:

	Year Ended December 31,	
	2019	2018
Tax provision at federal statutory rate	21.00%	21.00%
State taxes	-46.76%	4.37%
Foreign tax rate differential	13.83%	—
Stock based compensation	-53.53%	-4.08%
Return to provision	-57.11%	2.31%
Meals and entertainment	3.87%	-0.13%
Other	0.01%	-0.22%
Change in valuation allowance	129.22%	-23.90%
Tax provision	10.53%	-0.65%

The following table summarizes the elements of the deferred tax assets (liabilities):

	Year Ended December 31,	
	2019	2018
	(in thousands)	
Deferred tax assets		
Accrued vacation and other accrued expenses	$ 97	$ 118
Provision for bad debts	180	136
Net operating losses	445	699
Stock based compensation	609	579
Unrealized loss on investments	—	21
State income taxes	8	9
Foreign	545	343
Credits	680	261
Lease liability	643	—
Gross deferred tax assets	3,207	2,166
Less: Valuation allowance	(2,125)	(1,448)
Net deferred tax assets	1,082	718
Deferred tax liabilities		
Depreciation	419	644
Right of use asset	633	—
Other	30	74
Total deferred tax liabilities	1,082	718
Net deferred tax assets (liabilities)	$ —	$ —

As of December 31, 2019, the Company has estimated federal and state net operating loss (“NOL”) carryforwards of $1.6 million and $1.9 million for federal and state income tax purposes, respectively. The Company’s federal NOL of $1.6 million does not expire. The Company’s state NOLs are scheduled to expire from 2022 through 2039. Past ownership changes and other equity transactions may have triggered Section 382 and 383 provisions of the Internal Revenue Code, resulting in certain annual limitations on the utilization of existing federal and state net operating losses and credits. Such provisions may limit the potential future tax benefit to be realized by the Company from its accumulated net operating losses and credits.

FASB ASC 740 requires that deferred income tax assets be reduced by a valuation allowance if it is more likely than not that some or all of the deferred income tax assets will not be realized. The Company has evaluated the realizability of its deferred tax assets and has concluded that it is more likely than not that the Company may not realize the benefit of its deferred tax assets, primarily as a result of operating losses in recent years and, accordingly, has provided a full valuation allowance of $2.1 million and $1.4 million at December 31, 2019 and 2018, respectively. The increase in the valuation allowance of $677,000 for the year ended December 31, 2019 was primarily due to net operating losses, depreciation, research and development credits, equity-based compensation, our foreign joint venture investment, and the lease liability and related right of use asset.

During 2019 and 2018 the Company recorded a deferred tax asset related to its equity method investment in FF Gene Biotech. When realized, the asset will generate a capital loss which may only be used to offset capital gain income. The Company does not currently have any capital gain income and has therefore recorded a full valuation allowance against this asset.

Uncertain Tax Positions

The Company is subject to income taxation by the United States government and certain states in which the Company's activities give rise to an income tax filing requirement. The Company does not have income tax filing requirements in any foreign jurisdiction. As of December 31, 2019, there were no pending tax audits in any jurisdiction. The tax returns are subject to statutes of limitations that vary by jurisdiction. At December 31, 2019, the Company remains subject to income tax examinations in the U.S. and various states for tax years 2016 through 2019.

The Company had no accrual for interest or penalties at December 31, 2019 or 2018, and has not recognized interest or penalties during the years ended December 31, 2019 and 2018.

While the Company believes it has adequately provided for all tax positions, amounts asserted by taxing authorities could differ from the Company's accrued positions. Accordingly, additional provisions on federal, state and foreign tax-related matters could be recorded in future periods as revised estimates are settled or otherwise resolved.

Note 12. Loss per Share

The following is a reconciliation of the basic and diluted loss per share computations:

	Year Ended December 31,	
	2019	2018
	(in thousands, except per share data)	
Net loss	$ (411)	$ (5,607)
Weighted-average common shares - outstanding, basic	18,709	17,978
Weighted-average common shares - outstanding, diluted	18,709	17,978
Net loss per common share, basic	$ (0.02)	$ (0.31)
Net loss per common share, diluted	$ (0.02)	$ (0.31)

The following securities have been excluded from the calculation of diluted loss per share for all periods presented because their effect would have been anti-dilutive:

	Year Ended December 31,	
	2019	2018
	(in thousands)	
Options	36	413
RSUs	161	857

The anti-dilutive shares described above were calculated using the treasury stock method. During the years ended December 31, 2019 and 2018, the Company had outstanding options and RSUs that were excluded from the weighted-average share calculation for continuing operations due to the Company’s net loss positions.

Note 13. Retirement Plans

The Company offers a 401(k) retirement savings plan (the “401(k) Plan”) for its employees, including its executive officers, who satisfy certain eligibility requirements. The Internal Revenue Code of 1986, as amended, allows eligible employees to defer a portion of their compensation, within prescribed limits, on a pre-tax basis through contributions to the 401(k) Plan. The Company matches contributions to the 401(k) Plan based on the amount of salary deferral contributions the participant makes to the 401(k) Plan. The Company will match up to 3% of an employee’s compensation that the employee contributes to his or her 401(k) Plan account. Total Company matching contributions to the 401(k) Plan were $237,000 and $176,000 in the years ended December 31, 2019 and 2018, respectively.

Note 14. Related Party

Dr. Yun Yen, who is a member of the Company’s Board of Directors and a stockholder, serves as the President and Chairman of the Board for the Sino-American Cancer Foundation (the “Foundation”) and served as the President for the Taipei Medical University (the “University”), from August 1, 2011 through July 31, 2016 and currently serves as a Chair Professor for the University.

From time to time, the Company performs research testing services, on an arms-length basis, for the Foundation. The Company recognized an insignificant amount and zero during the years ended December 31, 2019 and 2018, respectively, as consideration for such services. Additionally, the Company subleases certain of its headquarters facilities to the Foundation. The Company recognized $16,000 and $33,000 in the years ended December 31, 2019 and 2018, respectively, as consideration for such sublease. As of December 31, 2019 and 2018, an insignificant amount and zero, respectively, was owed to the Company by the Foundation in connection with these relationships.

From time to time, the Company performs genetic sequencing services, on an arms-length basis, for the University. The Company recognized $53,000 and $66,000 in the years ended December 31, 2019 and 2018, respectively, as consideration for such services. As of December 31, 2019 and 2018, $39,000 and $51,000, respectively, was owed to the Company by the University in connection with this relationship.

As more fully described in Note 15, in April 2017, the Company, through an affiliated company formed for the purpose of the relationship, entered into a cooperation agreement (the "JV Agreement") with Xilong Scientific Co., Ltd. ("Xilong Scientific") and Fuzhou Jinqiang Investment Partnership (LP) ("FJIP") to form a joint venture under the laws of the PRC called Fujian Fujun Gene Biotech Co., Ltd. ("FF Gene Biotech"). Xilong Scientific is an affiliate of Xi Long, which, as of December 31, 2019, owned 9% of the outstanding shares of the Company's common stock, and FJIP is owned by key management of FF Gene Biotech, including Dr. Han Lin Gao, the Chief Scientific Officer and a large stockholder of the Company and the owner of approximately 25% of FJIP.

Fulgent Pharma utilizes space in the facility at which the Company's laboratory and corporate headquarters are located. Since the completion of the Pharma Split-Off, Fulgent Pharma reimburses the Company, on an arms-length basis, for the portion of the rent the Company pays that is attributable to the space used by Fulgent Pharma, which amounts are not significant. As of December 31, 2019 and 2018, $26,000 and $22,000, respectively, was owed to the Company by Fulgent Pharma as a result of this arrangement, which is recorded in Other receivable in Other current assets in the accompanying Consolidated Balance Sheets.

Note 15. Equity Method Investments

In April 2017, the Company, through an affiliated company formed for the purpose of the relationship, entered into the JV Agreement with Xilong Scientific and FJIP to form FF Gene Biotech, a joint venture formed under the laws of the PRC to offer genetic testing services to customers in the PRC. Pursuant to the terms of the JV Agreement, the Company has agreed to contribute to FF Gene Biotech genetic sequencing and other equipment with a total cost of 60,000,000 renminbi ("RMB") over a five-year period for a 30% ownership interest in FF Gene Biotech, previously three-year per original agreement and amended in April 2019. Xilong Scientific has agreed to contribute to FF Gene Biotech 102,000,000 RMB over a five-year period for a 51% ownership interest in the FF Gene Biotech, previously three-year per original agreement and amended in April 2019. FJIP has agreed to contribute to FF Gene Biotech 19,000,000 RMB over a ten-year period for a 19% ownership interest in FF Gene Biotech, previously five-year per original agreement and amended in April 2019. The Company's maximum exposure to fund losses of FF Gene Biotech as a result of its minority ownership of this entity is equal to its contribution obligation under the JV Agreement as described above. As of December 31, 2019, 39,300,000 RMB (or approximately $5.6 million U.S. dollars) remained to be contributed to FF Gene Biotech by the Company under the terms of the JV Agreement, and the Company has purchased and contributed equipment with an aggregate fair value of $3.1 million pursuant to its contribution commitment under the JV Agreement, of which, $137,000 and $510,000 were contributed in the year ended December 31, 2019 and 2018, respectively. The Company accounted for this contribution in accordance with ASC 845, Nonmonetary Transactions, and recorded an investment based on the fair value of the contributed equipment, which is the same as carryover basis.

The Company concluded FF Gene Biotech is a variable interest entity as FF Gene Biotech lacks sufficient capital to operate independently. The Company concluded that it alone does not have the power to direct the most significant activities of FF Gene Biotech and therefore is not the primary beneficiary of the entity. Judgment regarding the level of influence over FF Gene Biotech includes consideration of key factors such as the Company's ownership interest, representation on the board of directors or other management body and participation in policy-making decisions.

The Company accounts for its 30% interest in FF Gene Biotech using the equity method of accounting. The Company recorded its proportionate share of the losses of FF Gene Biotech for the year ended December 31, 2019 and 2018 in the accompanying Consolidated Statements of Operations, and recorded its contribution during the period, net of its proportionate share in the accumulated losses of FF Gene Biotech, in the accompanying Consolidated Balance Sheet as of December 31, 2019 and 2018.

The Company entered into a license agreement with FF Gene Biotech, pursuant to which it granted FF Gene Biotech a license to use certain of the Company's clinical molecular diagnostic gene detection technology and related software and proprietary reference library of genetic information, along with any improvements on this technology the Company may develop during the term of the license agreement. Under the license agreement, FF Gene Biotech paid to the Company, on a quarterly basis, certain royalties based on the revenues of FF Gene Biotech. The license agreement expired on December 31, 2018. The Company earned an insignificant amount of royalties under the license agreement for the year ended December 31, 2018. In 2019, FF Gene Biotech provided curation services, on an arms-length basis, for the Company, the cost of such services was insignificant for the year ended December 31, 2019.

The financial information of the subsidiary is consolidated in the summarized financial information for FF Gene Biotech disclosed below.

Equity method investments as of December 31, 2019 and 2018 consisted of the following:

	December 31,			
	2019		2018	
	Carrying Value	Ownership Percentage	Carrying Value	Ownership Percentage
	(in thousands)		(in thousands)	
FF Gene Biotech	$ 872	30%	$ 1,512	30%
Total equity method investments	$ 872	30%	$ 1,512	30%

Summary Financial Information

Summary financial information for FF Gene Biotech is as follows:

	December 31,	
	2019	2018
Consolidated Balance Sheet Data:	(in thousands)	
Current assets	$ 3,007	$ 1,916
Non-current assets	$ 4,457	$ 4,068
Current liabilities	$ 3,748	$ 2,415
Non-current liabilities	$ 889	$ —
Minority interest	$ (426)	$ —
Stockholders' equity	$ 3,253	$ 3,569

	Year Ended December 31,	
	2019	2018
Consolidated Statement of Operations Data:	(in thousands)	
Net sales	$ 4,055	$ 1,254
Gross profit	$ 1,354	$ 67
Net loss	$ (3,009)	$ (3,101)
Share of loss from investments accounted for using the equity method	$ (777)	$ (935)

Note 16. Equity Distribution Agreement

In August 2019, the Company entered into an Equity Distribution Agreement with Piper Jaffray & Co., as sales agent (“Piper”), pursuant to which the Company may offer and sell, from time to time through Piper, shares of its common stock having an aggregate offering price of up to $30.0 million. Piper is eligible to receive a commission of up to 3% of gross proceeds received by the Company for sales pursuant to the Equity Distribution Agreement. During the year ended December 31, 2019, the Company sold an aggregate of 104,390 shares of its common stock pursuant to the Equity Distribution Agreement at a weighted-average selling price of $12.14 per share, which resulted in $979,000 of net proceeds to the Company. Shares sold under the Equity Distribution Agreement are offered and sold pursuant to the Company’s shelf registration statement on Form S-3 (File No. 333-233227) filed with the SEC on August 12, 2019 and declared effective on August 23, 2019, and a prospectus supplement and accompanying base prospectus filed with the Securities and Exchange Commission on August 30, 2019.

Note 17. Underwriting Agreement

On November 13, 2019 we entered into a Purchase Agreement with Piper Jaffray & Co. as representative of the several underwriters, pursuant to which we sold 2,673,750 shares of our common stock at a price of $10.51875 per share, with a public offering price of $11.25 per share. We received net proceeds of approximately $27.6 million, after deducting underwriting discounts and commissions and offering expenses paid or payable by us of approximately $2.4 million. The shares issued and sold in the underwritten offering were sold pursuant to a shelf registration statement registered under the Securities Act on a registration statement on Form S-3 (File No. 333-233227), as amended, and a prospectus supplement and accompanying base prospectus filed with the Securities and Exchange Commission on November 13, 2019.

Note 18. Selected Quarterly Financial Data (Unaudited)

The tables below set forth the Company's quarterly Consolidated Statements of Operations data for the eight quarters ended December 31, 2019. In the opinion of management, this quarterly data has been prepared on the same basis as the accompanying consolidated financial statements and includes all adjustments, consisting of normal recurring adjustments, necessary for a fair presentation of the results of operations for the periods presented. See Item 7. "Management's Discussion and Analysis of Financial Condition and Results of Operations," in the report in which these consolidated financial statements are included for descriptions of the effects of any extraordinary, unusual or infrequently occurring items recognized in any of the periods covered by this data. The results for any one quarter are not indicative of the results to be expected in the current period or any future period.

	Three Months Ended							
	Dec. 31, 2019	Sept. 30, 2019	June 30, 2019	Mar. 31, 2019	Dec. 31, 2018	Sept. 30, 2018	June 30, 2018	Mar. 31, 2018
	(dollars in thousands, except per share data)							
Statement of Operations Data:								
Revenue	$ 8,387	$ 10,347	$ 8,424	$ 5,370	$ 5,673	$ 5,625	$ 5,400	$ 4,653
Cost of revenue	3,634	3,885	3,620	2,968	2,769	2,612	2,544	2,772
Gross profit	4,753	6,462	4,804	2,402	2,904	3,013	2,856	1,881
Operating expenses:								
Research and development	1,795	1,744	1,574	1,424	1,426	1,438	1,212	1,458
Selling and marketing	1,635	1,687	1,304	1,272	1,128	1,115	1,279	1,130
General and administrative	1,732	1,522	1,631	1,529	1,379	1,306	1,366	1,487
Total operating expenses	5,162	4,953	4,509	4,225	3,933	3,859	3,857	4,075
Operating income (loss)	(409)	1,509	295	(1,823)	(1,029)	(846)	(1,001)	(2,194)
Interest and other income, net	249	189	192	207	98	143	98	95
Income (loss) before income taxes and equity loss in investee	(160)	1,698	487	(1,616)	(931)	(703)	(903)	(2,099)
Provision for (benefit from) income taxes	(38)	61	7	13	888	(318)	(100)	(434)
Income (loss) before equity loss in investee	(122)	1,637	480	(1,629)	(1,819)	(385)	(803)	(1,665)
Equity loss in investee	(174)	(175)	(149)	(279)	(234)	(210)	(246)	(245)
Net income (loss)	$ (296)	$ 1,462	$ 331	$ (1,908)	$ (2,053)	$ (595)	$ (1,049)	$ (1,910)
Net income (loss) per common share:								
Basic	$ (0.01)	$ 0.08	$ 0.02	$ (0.10)	$ (0.11)	$ (0.03)	$ (0.06)	$ (0.11)
Diluted	$ (0.01)	$ 0.08	$ 0.02	$ (0.10)	$ (0.11)	$ (0.03)	$ (0.06)	$ (0.11)

DESCRIPTION OF FULGENT GENETICS, INC.'S SECURITIES REGISTERED PURSUANT TO SECTION 12 OF THE SECURITIES EXCHANGE ACT OF 1934

As of December 31, 2019, Fulgent Genetics, Inc. had one class of securities registered under Section 12 of the Securities Exchange Act of 1934, as amended, or the Exchange Act: common stock, $0.0001 par value per share, or Common Stock.

Unless the context otherwise requires, all references to "we" or "us" in this Exhibit 4.3 refer to Fulgent Genetics, Inc.

DESCRIPTION OF CAPITAL STOCK

The following summary description of our capital stock is based on the provisions of our Certificate of Incorporation, as amended, or the Certificate, as well as our Bylaws, and the applicable provisions of the Delaware General Corporation Law, or the DGCL. The following description is only a summary and it may not contain all the information that is important to you. This information is qualified entirely by reference to the applicable provisions of our Certificate and Bylaws, which are exhibits to this report, and the DGCL.

As of the date of this report, our certificate of incorporation authorizes us to issue 50,000,000 shares of common stock, par value $0.0001 per share, and 1,000,000 shares of preferred stock, par value $0.0001 per share. As of December 31, 2019, [•] shares of common stock were outstanding, and no shares of preferred stock were outstanding.

Common Stock

The holders of our common stock are entitled to one vote for each share held on all matters submitted to a vote of our stockholders. The holders of our common stock do not have any cumulative voting rights. Because of this absence of cumulative voting, the holders of a majority of the shares of common stock entitled to vote in any election of directors have the power to elect all of the directors standing for election, if they should so choose. Holders of our common stock are entitled to receive ratably any dividends that may be declared by our board of directors from time to time out of funds legally available for that purpose, subject to any preferential dividend rights of any outstanding preferred stock. Our common stock has no preemptive rights, conversion rights or other subscription rights or redemption or sinking fund provisions. In the event of our liquidation, dissolution or winding up, holders of our common stock will be entitled to share ratably in all assets remaining after payment of all debts and other liabilities and any liquidation preference of any outstanding preferred stock. All of the outstanding shares of our common stock, as well as any shares of common stock issuable upon the conversion of any securities convertible into our common stock, are (or will be upon issuance) fully paid and non-assessable.

Blank Check Preferred Stock

Our board of directors is authorized, subject to the limitations imposed by Delaware law, to issue up to 1,000,000 shares of preferred stock, par value $0.0001 per share, in one or more series, without stockholder approval. Our board of directors may fix the rights, preferences, privileges and restrictions of our authorized shares of preferred stock in one or more series and authorize their issuance without the approval of our stockholders. These rights, preferences, privileges and restrictions could include dividend rights, conversion rights, voting rights, terms of redemption, liquidation preferences, sinking fund terms and the number of shares constituting any series or the designation of such series, any or all of which may be greater than the rights of our common stock. The issuance of our preferred stock could adversely affect the voting power of holders of our common stock and the likelihood that such holders will receive dividend payments and payments upon liquidation. In addition, the issuance of preferred stock could have the effect of delaying, deferring or preventing a change of control of our company or other corporate action. As of the date of the filing of this report, no shares of preferred stock will be outstanding.

Antitakeover Provisions

Certain provisions of Delaware law, our Certificate and/or our Bylaws may have the effect of delaying, deferring or discouraging another person from acquiring control of our company, as described below.

Section 203 of the DGCL

We are subject to Section 203 of the DGCL, which prohibits a Delaware corporation from engaging in any business combination with any interested stockholder for a period of three years after the date that such stockholder became an interested stockholder, with the following exceptions:

- before such date, the board of directors of the corporation approved either the business combination or the transaction that resulted in the stockholder becoming an interested stockholder;
- upon completion of the transaction that resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction began, excluding for purposes of determining the voting stock outstanding (but not the outstanding voting stock owned by the interested stockholder) those shares owned by (i) persons who are directors and also officers and (ii) employee stock plans in which employee participants do not have the right to determine confidentially whether shares held subject to the plan will be tendered in a tender or exchange offer; or
- on or after such date, the business combination is approved by the board of directors and authorized at an annual or special meeting of the stockholders, and not by written consent, by the affirmative vote of at least 66 2/3% of the outstanding voting stock that is not owned by the interested stockholder

In general, Section 203 defines a "business combination" to include the following:

- any merger or consolidation involving the corporation and the interested stockholder;
- any sale, transfer, pledge or other disposition of 10% or more of the assets of the corporation involving the interested stockholder;
- subject to certain exceptions, any transaction that results in the issuance or transfer by the corporation of any stock of the corporation to the interested stockholder
- any transaction involving the corporation that has the effect of increasing the proportionate share of the stock or any class or series of the corporation beneficially owned by the interested stockholder; or
- the receipt by the interested stockholder of the benefit of any loans, advances, guarantees, pledges or other financial benefits by or through the corporation.

In general, Section 203 defines an "interested stockholder" as an entity or person who, together with the person's affiliates and associates, beneficially owns, or within three years prior to the time of determination of interested stockholder status did own, 15% or more of the outstanding voting stock of the corporation.

Certificate of Incorporation and Bylaws

Our Certificate and Bylaws include a number of provisions that may discourage or delay attempts to take over our company or effect change to our management. These provisions are intended to enhance the likelihood of continued stability in the composition of our board of directors and its policies and to discourage coercive takeover practices and inadequate takeover bids. These provisions are also designed to reduce our vulnerability to hostile takeovers and to discourage certain tactics that may be used in proxy fights. We believe the benefits of these provisions, including increased protection of our potential ability to negotiate with the proponent of an unfriendly or unsolicited proposal to acquire or restructure our company, outweigh the disadvantages of discouraging takeover proposals.

No Cumulative Voting Rights

Because our Certificate does not provide for cumulative voting rights, stockholders holding a majority of our outstanding voting power will be able to elect all of our directors.

Removal of Directors; Number of Directors; Vacancies

Our Bylaws provide that directors may be removed by our stockholders upon the vote of a majority of our outstanding common stock, voting together as a single class, and subject to any rights of holders of any series of preferred stock that we may issue in the future, and that any such removal may be made with or without cause. Further, subject to any rights of holders of any series of preferred stock that we may issue in the future, the authorized number of directors may be changed only by the board of directors. Vacancies and newly created directorships on the board of directors may, except as otherwise required by law or determined by the board of directors, only be filled by a majority vote of the directors then serving on the board of directors, even though less than a quorum. These provisions will make it difficult for stockholders to remove directors and will prevent a stockholder from increasing the size of our board of directors and gaining control of our board of directors by filling the resulting vacancies with its own nominees.

Stockholder Actions; Special Meetings of Stockholders

Our Certificate and Bylaws provide that all stockholder actions must be effected at a duly called meeting of stockholders, thereby eliminating the right of stockholders to act by written consent without a meeting. Our Bylaws also provide that special meetings of stockholders may only be called by the Chairman of our board of directors, our President or our board of directors.

Advance Notice Requirements for Stockholder Proposals and Director Nominations

Our Bylaws provide advance notice procedures that must be followed by stockholders seeking to bring business before an annual meeting of our stockholders or to nominate candidates for election as directors at any meeting of our stockholders, which will require any such notice to be delivered to us at a specified time and in a specified form and contain certain specified information. These provisions may preclude our stockholders from bringing matters before our meetings of stockholders or from making nominations for directors at our meetings of stockholders if they do not comply with these requirements.

Issuance of Undesignated Preferred Stock

The existence of authorized but unissued shares of preferred stock enables our board of directors to render more difficult or to discourage an attempt to obtain control of our company by means of a merger, tender offer, proxy contest or otherwise.

Limitations on Liability and Indemnification Matters

Our Certificate contains provisions that limit the liability of our directors for monetary damages to the fullest extent permitted by the DGCL. Consequently, our directors will not be personally liable to us or our stockholders for monetary damages for any breach of fiduciary duties as directors, except liability for:

- any breach of the director's duty of loyalty to us or our stockholders;
- any act or omission not in good faith or that involves intentional misconduct or a knowing violation of law;
- unlawful payments of dividends or unlawful stock repurchases or redemptions as provided in Section 174 of the DGCL; or
- any transaction from which the director derived an improper personal benefit.

Additionally, our Certificate and Bylaws require us to indemnify our directors and officers to the maximum extent permitted by the DGCL and allow us to indemnify other employees and agents as set forth in the DGCL. These documents further provide that we shall pay expenses (including attorneys' fees) incurred by an director or officer in defending any civil, criminal, administrative or investigative action, suit or proceeding for which such director or officer may be entitled to indemnification in advance of the final disposition of such action, suit or proceeding, upon receipt of an undertaking by or on behalf of such director or officer to repay such amount if it shall ultimately be determined that he or she is not entitled to be indemnified by us.

We have entered separate indemnification agreements with each of our directors which provide these individuals with indemnification in addition to the indemnification provided for in our certificate of incorporation and bylaws. These agreements, among other things, require us to indemnify our directors and officers for certain expenses, including attorneys' fees, judgments, penalties, fines and settlement amounts actually and reasonably incurred by such director and officer in any action or proceeding arising out of his or her service to us or any of our subsidiaries or any other company or enterprise to which the individual provides services at our request. Subject to certain limitations, these indemnification agreements also require us to advance expenses incurred by our directors and officers for the defense of any action for which indemnification is required or permitted.

The limitation of liability and indemnification provisions in our Certificate, Bylaws and indemnification agreements may discourage stockholders from bringing a lawsuit against our directors and officers for breach of their fiduciary duty. They may also reduce the likelihood of derivative litigation against our directors and officers, even though an action, if successful, might benefit us and other stockholders. Further, a stockholder's investment may be adversely affected to the extent that we pay the costs of settlement and damage awards against directors and officers as required by these indemnification provisions.

Transfer Agent and Registrar

The transfer agent and registrar for our common stock is Computershare Trust Company, N.A. The transfer agent's address is 250 Royall Street, Canton, Massachusetts 02021 and its telephone number is 1(800) 662-7232.

Listing on the Nasdaq Global Market

Our common stock is listed on the Nasdaq Global Market under the symbol "FLGT."

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in Registration Statement No. 333-233227 on Form S-3 and No. 333-213912 on Form S-8 of our report dated March 12, 2020, relating to the financial statements of Fulgent Genetics, Inc., appearing in this Annual Report on Form 10-K for the year ended December 31, 2019.

/s/ DELOITTE & TOUCHE LLP

Los Angeles, California
March 12, 2020

Exhibit 31.1

CERTIFICATION PURSUANT TO
RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Ming Hsieh, certify that:

1. I have reviewed this Annual Report on Form 10-K for the fiscal year ended December 31, 2019 of Fulgent Genetics, Inc.;

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: March 12, 2020

By: /s/ Ming Hsieh
Ming Hsieh
President, Chief Executive Officer
(principal executive officer)

Exhibit 31.2

CERTIFICATION PURSUANT TO
RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Paul Kim, certify that:

1. I have reviewed this Annual Report on Form 10-K for the fiscal year ended December 31, 2019 of Fulgent Genetics, Inc.;

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: March 12, 2020

By: /s/ Paul Kim
Paul Kim
Chief Financial Officer
(principal financial and accounting officer)

Exhibit 32.1

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 on Form 10-K for the fiscal year ended December 31, 2019 of Fulgent Genetics, Inc. (the "Company"), as filed with the Securities and Exchange Commission on the date hereof (the "Report"), each of the undersigned hereby certifies in his capacity as the specified officer of the Company, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that, to the best of his 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 result of operations of the Company.

Date: March 12, 2020

By: /s/ Ming Hsieh
Ming Hsieh
President, Chief Executive Officer
(principal executive officer)

Date: March 12, 2020

By: /s/ Paul Kim
Paul Kim
Chief Financial Officer
(principal financial and accounting officer)

This certification accompanies the Report to which it relates and shall not be deemed filed with the Securities and Exchange Commission or incorporated by reference into any filing of the Company under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Report), irrespective of any general incorporation language contained in such filing.