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, 2021

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 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	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value $0.0001 per share	FLGT	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 has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☒

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, 2021 (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 $1.6 billion. 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 5% 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 February 15, 2022, there were 30,252,511 outstanding shares of the registrant's common stock.

DOCUMENTS INCORPORATED BY REFERENCE

Certain portions of the registrant's definitive proxy statement for its 2022 annual meeting of stockholders are incorporated by reference in Part III of this report.

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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 expectations regarding the impact of the COVID-19 pandemic on our business, including the duration of the demand for our COVID-19 testing services;
- our operating performance, including our ability to achieve equal or higher levels of revenue, stabilize the historical fluctuations in our performance and maintain or grow profitability;
- the rate and degree of market acceptance and adoption of our genetic and clinical tests and genetic testing and clinical testing generally and other anticipated trends in our industry;
- our ability to remain competitive, particularly if the testing markets continue 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 the genetic testing 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 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 laboratory facilities and our ability to adapt in the event any of our facilities are damaged or rendered inoperable;
- the impact on our business of our investments in building and restructuring our sales and marketing strategies and teams and our plans for future sales and marketing efforts;
- the impact of the investments we have made in increasing our testing capacity to meet the demand for COVID-19 testing;
- 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 Item 1A. “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.

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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.

Fulgent Genetics, Inc., together with its subsidiaries and an affiliated professional corporation with which the Company has a management services arrangement, are collectively referred to in this Annual Report on Form 10-K as the “Company,” “Fulgent,” “we,” “us,” and “our.”

PART I

Item 1. Business.

Overview

We are a technology company offering large-scale COVID-19 testing services, molecular diagnostic testing services and comprehensive genetic testing designed to provide physicians and patients with clinically actionable diagnostic information to improve the quality of patient care. A cornerstone of our business is our ability to provide expansive options and flexibility for all clients' unique testing needs. To this end, we have developed a proprietary technology platform allowing us to offer a broad and flexible test menu and to continually expand and improve our proprietary genetic variant 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 have experienced rapid volume growth since our commercial launch in 2013, with approximately 10.0 million billable tests delivered in 2021, compared to 4.4 million billable tests delivered in 2020, and an aggregate of approximately 14.5 million billable tests delivered to over 1,800 customers from inception through December 31, 2021.

Mission

Our mission is to offer and develop flexible and affordable genetic testing services designed to improve patient care and quality of life. Founded in 2011, Fulgent began with two simple ideas; flexibility and affordability. Today, we strive to provide the most effective and wide-ranging genetic testing menu on the market.

Our Genetic Tests, Molecular Diagnostics and COVID-19 Tests

Our Genetic Tests

Our offerings consist 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 patient or provider may select a single-gene test of any of the genes in our portfolio or they 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 436 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. Our test offerings also include 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. 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.

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 20,096 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 providers and patients 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 of 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.

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. 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 contributed to the growth in the global market for genetic testing 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.

Our COVID-19 Testing Services

Since March 2020, we have also offered several tests for the detection of SARS-CoV-2, the virus that causes the novel coronavirus disease, or COVID-19, including NGS and reverse transcription polymerase chain reaction-based tests, or RT-PCR-based tests. We have received an Emergency Use Authorization, or EUA, from the U.S. Food and Drug Administration, or the FDA, that authorizes the use of our RT-PCR-based tests for the detection of SARS-CoV-2 using upper respiratory specimens (nasal, nasopharyngeal, and oropharyngeal swabs) and in conjunction with at-home specimen collection kits that are offered as a service through Picture Genetics. Our at-home testing service for COVID-19 and RT-PCR-based test are authorized for emergency use by the FDA only for the detection of nucleic acid from SARS-CoV-2, not for any other viruses or pathogens. We are currently accepting patient samples directly to our Biosafety Level 2, or BSL-2, certified laboratories where we have the capacity to accept and process thousands of samples per day with a typical turn-around time of 24-48 hours from the time a sample is received and accepted. To date, we have processed orders for our COVID-19 tests from a variety of customers, including governmental bodies, payors, municipalities, and large corporations. In 2020 and 2021, we established and operated COVID-19 testing sites for certain municipalities. We also offer at-home COVID-19 testing services through our Picture Genetics platform.

Currently available diagnostic tests for the detection of SARS-CoV-2 are based on a variety of technologies and formats, including conventional antigen-based tests for detecting viral proteins and nucleic acid amplification tests which include RT-PCR-based tests. While antigen-based diagnostic tests are relatively inexpensive and can be used at the point of care, antigen-based diagnostic tests for the detection of SARS-CoV-2 have been observed to be less sensitive than genetic and RT-PCR-based tests. U.S. Centers for Disease Control, or CDC, guidelines indicate that the "gold standard" for clinical diagnostic detection of SARS-CoV-2 is nucleic acid amplification which includes RT-PCR-based tests. We believe our ability to provide COVID-19 NGS and RT-PCR-based diagnostic testing services with expedited turn-around times makes us competitive in this new market.

Our Molecular Diagnostic Testing Services

In August 2021, we acquired Cytometry Specialists, Inc., or CSI, to expand our presence and capabilities in somatic molecular diagnostics and cancer testing. We plan to leverage our established technology platform, NGS expertise, lab operations, and sales infrastructure in conjunction with CSI's extensive cancer testing menu to establish a differentiated foothold in oncologic testing in the United States. Through our acquisition of CSI, we have added the following types of testing services to our test menu:

- Flow Cytometry – a sophisticated cell analysis technique providing diagnosis, prognosis, and monitoring of malignancies with a relatively small sample size. It provides the ability to identify emerging abnormalities and perform rare event analysis of patient-specific aberrant immunophenotypes, or cells expressing abnormal proteins unique to a specific patient.
- Fluorescence In-Situ Hybridization, or FISH – a laboratory technique for detecting and locating a specific DNA sequence on a chromosome, FISH probe panels and individual probes are able to precisely isolate and identify genetic alterations in solid tumor and hematological neoplasms, or abnormal cells located in the blood and blood forming tissues, such as bone marrow and lymphatic tissue. FISH cancer testing is a diagnostic tool that can detect and confirm chromosome abnormalities such as deletions, duplications, translocations and other numerical or structural aberrations to diagnose and help predict the best therapeutic approach for cancer patients.
- Immunohistochemistry, or IHC – an imaging technique used to visualize antigens in cells. IHC antibodies and histochemical stains are used to detect the presence, relative quantity, and localization of specific proteins to aid in determining differentiation in abnormal cells with similar structures. In addition to other applications, IHC is used to provide prognostic or therapeutic information.

- Cytogenetics – analyzes the entire chromosome set for numerical and structural abnormalities such as chromosome additions, deletions and translocations. Identification of each abnormality may aid diagnosis and treatment decisions for cancer patients.
- Molecular Testing – includes both hematopoietic and solid tumor molecular assays for qualitative and quantitative analysis. Advanced single gene testing, targeted profile molecular assays, and broad-spectrum tumor testing yield clinically actionable data for precise diagnosis and appropriate therapy selection.

New Offerings in 2021

New test offerings in 2021 included a COVID-19 Neutralizing antibody test, a Respiratory Pathogen Panel, that detects viral and bacterial infections of the upper and lower respiratory tracts, including COVID-19, HelioLiver, a revolutionary multi-analyte blood test for early liver cancer detection, and PD Aware, a Picture Genetics product that provides easy at-home sampling to assess genetic risk for Parkinson's disease.

Our Technology Platform

Our tests and testing services are provided using our integrated technology platform featuring the following proprietary tools and processes:

Proprietary Gene Probes

We have developed technologies to design and formulate our own proprietary gene probes, which, when combined with our proprietary genetic reference library of genetic variants 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 variant 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 a variant database from certain of our non-COVID genetic tests into our expansive genetic reference library of genetic variants, 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 increased 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 Customers

Historically, we 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. In addition, we believe hospitals and medical institutions are early adopters of NGS technology and could influence broader clinical acceptance of genetic testing. Beginning in March 2020, we also began processing orders for our COVID-19 tests from a variety of customers, including governmental bodies, municipalities, and large corporations. Since inception, we have sold our tests to over 1,800 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, one of our customers, the County of Los Angeles, contributed 26% of our total revenue in 2021, and two of our customers contributed 28% and 10% of our total revenue in 2020, respectively.

We currently classify our customers by their payor types: (i) Insurance, including claims covered by the Health Resources & Services Administration, or HRSA, COVID-19 Uninsured Program for uninsured individuals, (ii) Institutional, including hospitals, medical institutions, other laboratories, governmental bodies, payors, municipalities and large corporations or (iii) Patients who pay directly. Typically, we bill our Institutional customers for our tests and they are responsible for paying us directly and billing their patients separately or obtaining reimbursement from third-party payors. In some cases, Institutional customers receive a per-visit or per-admission payment that includes our testing, which means that separate reimbursement is not available. 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 and government health care programs, including Medicare and Medicaid, require us to identify the test for which we are seeking reimbursement using the 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.

We are making efforts to diversify our customer market, including building relationships with research institutions and other similar institutional customers, national clinical laboratories, governmental bodies, municipalities and large corporations in need of regular COVID-19 testing for large populations 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 third-party payors, some state Medicaid programs and commercial insurers, in an effort to obtain coverage and reimbursement for our genetic tests to make them accessible to more individual physicians.

Sales and Marketing

Our sales and marketing force currently consists of two internal teams of sales and marketing professionals, 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 to generate interest in our tests, which we believe demonstrates the value of our offering. In recent years, 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.

This strategy is designed to expand our brand awareness, grow our customer base and further penetrate existing relationships. We aim to achieve these objectives by providing education about the benefits and full scale of our offerings, both to the medical community in general and to our targeted 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 and as opportunities arise, by engaging distributors or establishing other types of arrangements, such as joint ventures, 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, such as Late-Breaking Positive Performance Data of HelioLiver™ for Early Liver Cancer Detection Data from the ENCORE study that was presented at The Liver Meeting® 2021, hosted by the American Association for the Study of Liver Diseases; and pursuing or supporting scientific studies of our tests and publication of results in medical or scientific journals. 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, we launched more tests including PD Aware that determines genetic risk for Parkinson's and Pharmacogenetics testing, the use of genetic data to guide drug therapy decisions, or PGx testing, through our Picture Genetics platform, 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 team also explores strategic collaboration opportunities with various research and medical institutions. New partnerships formed in 2021 include partnering with governmental bodies, municipalities, and large corporations for providing COVID-19 services to citizens, employees, and students.

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, collection kits, 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. In addition, we rely on a limited number of suppliers for COVID-19 test collection kits. Our laboratory operations would be interrupted if we encounter delays or difficulties securing these reagents, collection kits, 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 and other COVID-19 diagnostic test providers. Principal competitors include companies such as Quest Diagnostics Incorporated; Laboratory Corporation of America Holdings; Abbott Laboratories; Perkin Elmer, Inc.; Natera, Inc.; Invitae Corporation; GeneDx, a subsidiary of OPKO Health, Inc.; Myriad Genetics, Inc.; Sema4 Genomics; Ambry Genetics, a subsidiary of Konica Minolta Inc.; Baylor Genetics; and 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. This team conducts 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.

Joint Venture

In May 2021, we entered into a restructuring agreement with Xilong Scientific Co., Ltd., or Xilong Scientific, and Fuzhou Jinqiang Investment Partnership (LP), or FJIP, to form a joint venture under the laws of the People's Republic of China, or PRC, resulting in the Company indirectly acquiring a controlling financial interest in Fujian Fujun Gene Biotech Co., Ltd., or FF Gene Biotech. FF Gene Biotech was founded to bring our NGS capabilities to the Chinese genetic testing market through entities separate from our U.S. operations, and FF Gene Biotech is pursuing this objective separate from our business elsewhere.

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. The Clinical Laboratory Improvement Amendments of 1988, or CLIA, establishes quality standards for all laboratory testing to ensure the accuracy, reliability and timeliness of patient test results. Our laboratories located in California, Texas, Georgia and Florida are CLIA-certified and are accredited by the College of American Pathologists, or CAP, a CMS-approved accrediting organization.

CLIA requires that we hold a certificate applicable to the categories of testing that 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 obtain a certificate from the Centers for Medicare & Medicaid Services, or 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. We have CLIA certifications for our laboratories located in Temple City, California, Houston, Texas, Alpharetta, Georgia, and Jupiter, Florida. Each CLIA certification is valid for two years from the date of issuance. If either laboratory is found to be out of compliance with CLIA requirements, 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 Temple City, California laboratory is required to maintain a state license issued by the California Department of Public Health, or CA DPH. 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 CA DPH may suspend, restrict or revoke our license to operate our clinical 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. The other three states in which our laboratories are located do not require a state license.

Additionally, several states require the licensure of out-of-state laboratories that accept specimens from those states. For example, our Houston, Texas laboratory holds the required out-of-state license to perform testing on specimens from California, and our Temple City, California laboratory holds the required out-of-state laboratory licenses to perform testing on specimens from Maryland, New York, Rhode Island and Pennsylvania. For laboratories accepting samples from New York, the director of those laboratories must also maintain a Certificate of Qualification issued by New York's Department of Health, or DOH, in permitted categories. The New York state laboratory laws and regulations are more stringent than CLIA. Among other things, the DOH requires approval on a test-specific basis before testing can be performed on specimens from New York. Our Houston, Texas laboratory does not have a permit issued by the New York DOH, but it received temporary exemption from New York to perform COVID-19 tests on specimens from New York.

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. For example, in 2017, the FDA published a Discussion Paper on Laboratory Developed Tests to further public discussion about an appropriate LDT oversight approach and to give congressional committees the opportunity to develop a legislative solution to the competing interests of ensuring the public health and promoting innovation in the clinical testing industry. However, on August 19, 2020, the United States Department of Health and Human Services, or HHS, published a policy announcement that FDA must go through the formal notice-and-comment rulemaking process before requiring premarket review of LDTs rather than making such changes through guidance documents, compliance manuals, or other informal policy statements. HHS's policy statement did not affect proposed legislation for the regulation of LDTs, which is discussed below. In November 2021, the Biden Administration withdrew that HHS policy announcement and ostensibly restored FDA's regulatory oversight of LDTs.

In December 2018, members of Congress released a discussion draft of a possible bill to regulate in vitro clinical tests including LDTs, and provided opportunities for additional stakeholders to also provide input on the proposed reform legislation. On March 5, 2020, U.S. Representatives Diana DeGette (D-CO) and Dr. Larry Bucshon (R-IN) formally introduced the long-awaited legislation, called the Verifying Accurate, Leading-edge IVCT Development, or VALID Act. An identical version of the bill was introduced concurrently in the Senate, demonstrating both bicameral and bipartisan support for the effort to overhaul how the FDA reviews and approves diagnostic tests going forward. The VALID Act would codify into law the term "in vitro clinical test", or IVCT, to create a new medical product category separate from medical devices that includes products currently regulated as IVDs as well as LDTs. The VALID Act would also create a new system for labs and hospitals to use to submit their tests electronically to the FDA for approval, which is aimed at reducing the amount of time it takes for the agency to approve such tests, and establish a new program to expedite the development of diagnostic tests that can be used to address a current unmet need for patients. A substantively unchanged version of the VALID Act was re-introduced in both houses of Congress on June 24, 2021.

It is unclear whether the VALID Act would be passed by Congress in its current form or signed into law by the President. Until the FDA finalizes its position on regulation of LDTs through formal notice-and-comment rulemaking, or the VALID Act or other federal legislation is passed reforming the government's regulation of LDTs, or alternatively, 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. Any new legislation or formal FDA regulations 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, whether as a result of new legislative authority or following formal notice-and-comment rulemaking, 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.

Additionally, the FDA previously 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 delays.

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. 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 not directly subject to FDA's device requirements 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, or the 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, or CPT, codes, which are published by the American Medical Association, or 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 one or more 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, taking into consideration 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 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's CLFS. 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 private payor payment rates and volumes for clinical diagnostic laboratory tests (CDLTs) to CMS every three years (or annually for advanced diagnostic laboratory test, or ADLT). We do not believe that any of our tests meet the current definition of ADLTs. We therefore must report private payor rates for our tests every three years. Laboratories that fail to report the required payment information may be subject to substantial civil monetary penalties.

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, 2010, 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, President Trump signed the Further Consolidated Appropriations Act, which included the Laboratory Access for Beneficiaries Act, or LAB Act. The LAB Act delayed by one year the reporting of payment data under PAMA for CDLTs that are not ADLTs until the first quarter of 2021. The Coronavirus Aid, Relief, and Economic Security Act, or the CARES Act, which was signed into law on March 27, 2020, delayed the reporting period by an additional year, until the first quarter of 2022. Then, on December 10, 2021, Congress passed the Protecting Medicare and American Farmers from Sequester Cuts Act, which included a provision that further delayed the next PAMA reporting period for CDLTs that are not ADLTs to January 1, 2023 through March 31, 2023. New CLFS rates for CDLTs will be established based on that data beginning in 2024, subject to phase-in limits. As a result, Medicare payment rates determined by data reported in 2017 will continue through December 31, 2023.

In addition, under PAMA, as amended, the payment reduction cap will be 15% per test per year in each of the years 2023 through 2025.

Privacy and Security Laws and Patient Information Access

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 ("HIPAA 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. As a clinical laboratory, we are acting as a covered entity and are subject to HIPAA and HITECH. 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 have 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 privacy or data security.

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 $1.8 million per violation of the same requirement per calendar year (as of November 2021, subject to annual inflation adjustments). A single breach incident can violate multiple requirements, resulting in potential penalties in excess of approximately $1.8 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.

In addition to our clinical laboratory services, we provide management and technology services to certain companies, institutions, and agencies that are covered entities and have entered into business associate agreements with these entities as business associates. In addition to being directly responsible for compliance with applicable HITECH Act requirements and HIPAA regulations as a business associate, we have contractually agreed to comply with HIPAA, HITECH, and HIPAA Regulations and in some instances have agreed to indemnify our covered entity clients if we breach our obligations with respect to these laws and regulations and/or in the event of a reportable breach of protected health information.

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, or CMIA, 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 CMIA, 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. Although the CCPA does not directly apply to medical information covered by HIPAA or CMIA, certain other personal information that our business may collect and use does not fall under the CCPA exception. On November 3, 2020, California voters passed the California Privacy Rights Act, or CPRA, which expands the CCPA. The CPRA will be fully effective in January of 2023 and, among other things, establishes the California Privacy Protection Agency, or CPPA, a new regulatory authority charged with administering and enforcing the CRPA and privacy rights in California. The CPPA will have the power to levy fines and bring other enforcement actions. The CPRA could impact our operations or that of our collaborators and business partners and impose new regulatory requirements and increase costs of compliance. Other states are considering expanded privacy legislation similar to the GDPR and CPRA, with Virginia and Colorado enacting their own consumer privacy laws in 2021 similar to CCPA and CPRA. Both the Virginia and Colorado laws take full effect in 2023. There are also several federal privacy proposals under consideration in Congress and other states have already introduced privacy legislation for consideration in 2022.

Many states 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 FTC 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.

Information Blocking Rules

The National Coordinator for Health Information Technology ("ONC") coordinates the ongoing development of standards to enable interoperable health information technology infrastructure nationwide in the healthcare sector. In May 2020, ONC released the final Information Blocking Rule to implement the interoperability and patient access provisions of the 21st Century Cures Act. We will need to continually engage in ongoing reviews of all potential practices that could be considered likely to interfere with access, exchange or use of electronic health information, as those practices are prohibited by the Information Blocking Rule unless one of the exceptions outlined in the Information Blocking Rule applies. Among other things, the Information Blocking Rule requires us to provide patients with on-demand access to laboratory test results. These requirements can be inconsistent with our obligations under state law and/or medical or ethical standards. It is currently unclear how the ONC will approach delays in providing patient access in these situations. Health care providers including laboratories will be subject to civil monetary penalties for violations of the Information Blocking Rule once the penalty regulations are finalized; the proposed rule allows for up to $1 million in penalties per violation.

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 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 continues to evolve in guidance from the main regulatory authority, the European Data Protection Board, 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 and are enforced by individual country data protection authorities, which have power to enforce privacy regulations. Various data protection authorities have issued fines in the millions of euros for violations of privacy laws.

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 differently, 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 regardless of payor type.

In addition, in October 2018, the Eliminating Kickbacks in Recovery Act of 2018, or EKRA, was enacted as part of the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities 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 are inconsistent with the federal Anti-Kickback Statute and regulations. 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.

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, providers and suppliers must report and return any overpayments received from 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 June 19, 2020, whose associated violations occurred after November 2, 2015, the civil penalty amount ranges between $11,665 and $23,331 per claim; as of December 13, 2021, the amounts increased to $11,803 and $23,607 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 $174,172 (which reflects the annual adjustment for inflation effective as of November 15, 2021) 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 $26,125 per service (which reflects the annual inflation adjustment effective as of November 15, 2021), 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 VALID Act or other legislation renders our tests regulated by FDA or if FDA engages in notice-and-comment rulemaking to exercise authority over LDTs or otherwise 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, or ACA, was enacted in the United States. The ACA made a number of substantial changes to the way healthcare is financed both by governmental and private payors. Although the ACA included a medical device tax, the tax never went into effect and was fully repealed by Congress with enactment of the 2019 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 ACA, and as a result, certain sections of the ACA have not been fully implemented or were effectively repealed. However, following several years of litigation in the federal courts, in June 2021, the United States Supreme Court, or the Supreme Court, upheld the ACA when it dismissed a legal challenge to the Act's constitutionality. Further legislative and regulatory changes under the ACA remain possible, although the new Democrat-led presidential administration has been taking steps to strengthen the ACA and the 117th Congress is not expected to have the same interest in repealing the law, in part due to the healthcare economic impacts of the ongoing COVID-19 pandemic on many subsets of the U.S. population. Future changes or additions to the ACA, the Medicare and Medicaid programs, such as changes allowing the federal government to directly negotiate drug prices, and changes stemming from other health care reform measures, especially with regard to health care access, financing or other legislation in individual states, could have a material adverse effect on the health care industry in the U.S. The uncertainty around the future of the ACA, and in particular the impact to reimbursement levels and the number of insured individuals, may lead to delay in the purchasing decisions of our customers.

In addition to the ACA, there will likely continue to be proposals by legislators at both the federal and state levels, regulators and private third-party payors to reduce costs while expanding individual healthcare benefits.

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.

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 and Human Capital Resources

We believe growing and retaining a strong team is crucial to our success. As of February 1, 2022, we had 645 full-time employees, engaged in bioinformatics, genetics, COVID-19 and molecular testing, software engineering, laboratory management, sales and marketing and corporate and administrative activities. Consistent with our core belief in the values of diversity and inclusion, as of February 1, 2022, underrepresented minorities (which include women, Asian and Hispanic) made up 50% or more of each major level of our organization, including our board of directors, senior management and rank and file staff. To encourage the professional and personal development of every Fulgent employee, we offer certain reimbursement for qualified educational expenses and successful completion of undergraduate, graduate, post-graduate, professional training, and licensure courses from accredited colleges, universities and professional organizations. We also provide mandatory training courses on a variety of topics, including discrimination, anti-corruption and anti-bribery through third party providers. As we navigate the COVID-19 pandemic and to help limit exposure to COVID-19, we have acted to protect employees in business-critical functions who cannot work from home, including those in research and development, quality, accessioning, curation, distribution, and sales. Personal protective equipment, increased sanitation, social distancing guidance, and facility updates (one-way hallways, cafeteria partitions and extra sinks) are provided to protect our employees. 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 Therapeutics LLC, which was initially formed in June 2011. On September 30, 2016, Fulgent Therapeutics 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 Therapeutics LLC immediately prior to the Reorganization became all of our stockholders immediately following the Reorganization.

Our initial operations focused on Fulgent Therapeutics 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 Therapeutics 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 Therapeutics LLC separated the Pharma Business from the genetic testing business we are currently pursuing. 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.

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.

Summary 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, together with the other risk factors set forth in this Item 1A, all other information included in this report, and the other reports and documents filed by us with the SEC. The risk factors described below are a summary of the principal risk factors associated with an investment in us.

Business and Strategy Risks

- Our results of operations may fluctuate significantly from period to period and can be difficult to predict.
- The expansion of our COVID-19 testing business has resulted in a substantial change in our business that presents important challenges to our ability to manage our rapidly expanding business, and there can be no assurance that our recent growth due to demand for our COVID-19 tests, or that any revenue growth we may experience will continue.
- 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.
- We have a history of losses, and we may not be able to achieve or sustain profitability.
- 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.
- 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.
- 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 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.
- 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.
- 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.

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.
- 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 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.
- Changes in laws and regulations, or in their application, may adversely affect our business, financial condition and results of operations.
- Marketing of our COVID-19 tests under the EUA from the FDA is subject to certain limitations and we are required to maintain compliance with the terms of the EUA, among other things, and the continuance of our EUA is subject to government discretion.

Intellectual Property Risks

- We primarily rely on trade secret protection, non-disclosure agreements and invention assignment agreements to protect our proprietary information, which may not be effective.

- 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.

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

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, global health crises and pandemics which may generate demand for our tests, such as the ongoing pandemic related to COVID-19 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. Our results have been, and may in the future be, impacted by events that may not recur regularly, in the same amounts or at all in the future. In 2020, we developed and began offering a series of COVID-19 tests. The pricing and margins from these tests continue to evolve. We experienced substantial revenue growth in recent years due primarily to the sales of, and growing demand, for these COVID-19 tests. While we believe there will be a continued demand for our COVID-19 tests in the near term, the future outcome and circumstances of the COVID-19 pandemic continue to rapidly evolve and remain uncertain. There can be no assurance our COVID-19-related growth or other growth we may experience will continue. This recent growth and other 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. 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. Moreover, our limited operating history may make it difficult to determine if fluctuations in our performance reflect seasonality, pandemic-related demand or other trends or if these fluctuations are the result of other factors or events.

The expansion of our COVID-19 testing business has resulted in substantial changes and growth in our business. 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 growth or future growth could jeopardize our business.

In March 2020 we commercially launched several COVID-19 tests for the detection of SARS-CoV-2, the virus that causes COVID-19, including NGS and RT-PCR-based tests. We are currently accepting patient samples directly to our Biosafety Level 2, certified laboratories in Temple City, California and Houston, Texas where we have the capacity to accept and process thousands of samples per day with a typical turn-around time of 24-48 hours from the time the sample is received and accepted. To date, we have processed orders for our COVID-19 tests from a variety of sources, including governmental bodies, municipalities, and large corporations. Due to the significant demand for COVID-19 testing services, our business has expanded rapidly since March 2020. This expansion has necessitated a very significant increase in our total headcount, and the volume of tests we perform on a daily basis has increased by approximately 14,800% since March 2020. To meet the demand for COVID-19 testing, we have increased the number of shifts at our main laboratory in Temple City, California and established the laboratory in Houston, Texas. The continued success of this business will depend upon circumstances related to the ongoing COVID-19 pandemic and our ability to rapidly deliver accurate results, and any failure, or perceived failure, in meeting these objectives could cause our COVID-19 testing business to decline rapidly.

To continue to increase the volume of tests we offer and deliver, we must make substantial additional investments in our infrastructure, including our testing capacity, laboratory capacity, 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.

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 growth or 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. 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. If we fail to manage these activities effectively, our business, prospects, financial condition and results of operations could be adversely affected.

We have previously and may again in the future 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 or dilute our stockholders' ownership.

As part of our business strategy, we have previously and may again in the future pursue acquisitions of complementary businesses or assets (such as our recent acquisition of CSI) investments in other companies (such as our recent investment in Helio Health) 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 pursue relationships with strategic partners or other strategic relationships, our ability to establish and maintain these relationships could be challenging due to several factors. Factors include competition with other 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 acquisition, investment or joint venture as needed 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. To the extent these financing transactions call for the issuance of shares of our capital stock, our existing stockholder would experience dilution in their relative ownership of shares of our capital stock. 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 have a history of losses, and we may not be able to achieve or sustain profitability. We anticipate that profits resulting from our COVID-19 testing will eventually decrease as and if the prevalence of COVID-19 eventually decreases.

We have a history of losses. Although we achieved profitability for the years ended December 31, 2020 and 2021, we may not be able to maintain profitability in future periods. Further, our revenue levels may not grow at historical rates or at all, and we may not be able to achieve additional profitability or sustain profitability. We may incur additional losses in the future. While we experienced significant profitability in connection with the launch of our COVID-19 tests, we anticipate that demands for these tests will eventually decrease as and if the prevalence of COVID-19 eventually decreases. In addition, there are a number of competitive entrants to the COVID-19 testing market since we first launched our COVID-19 testing services in March 2020, and these competitors may cause price declines or reduced market share for us. There can be no assurance that our increased investments in our COVID-19 testing capacity and capabilities will result in desirable returns, and our profits or operating results may decline as a result of decreased demand for these tests. Any future losses may have an adverse effect on our stockholders' equity and working capital, which could negatively impact our operations and your investment in the Company. Any failure to sustain or grow our revenue levels and to 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.

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 unable to enhance our tests more quickly and more effectively 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 unable 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. When customers who, to our knowledge, are under common control or otherwise affiliated with each other are aggregated, one customer, the County of Los Angeles, contributed 26% of our total revenue during the year ended December 31, 2021, respectively. 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. We believe some of these fluctuations in customer demand may be attributable, in part, to the nature of our business. Our traditional genetic testing customers can experience significant volatility in their genetic testing demand from period to period in the ordinary course of their operations and demand for our COVID-19 tests may vary widely depending on circumstances surrounding the pandemic, including the emergence or reemergence of viral variants such as the Delta variant and the Omicron variant. 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 to receive payment 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 unable 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, by expanding sales of our COVID-19 tests to additional governmental bodies, municipalities and large corporations in need of regular testing for large populations and by further establishing our presence in the cancer and molecular diagnostic testing markets. 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, governmental bodies, municipalities and large corporations in need of regular COVID-19 testing for large populations and various other organizations to facilitate access to physicians, practitioners and other new customer groups, including certain U.S. government agencies. These efforts could fail. Even if we successfully develop relationships with new customers in these or any other new customers groups, these relationships may not lead to improve our ability to achieve or sustain profitability. 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, most of these relationships do not 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.

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 NGS genetic tests and our COVID-19 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 FDA, or other applicable government agencies; and
- our competitors could introduce new tests that cover more genes or that provide more accurate, reliable or rapid 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 rely on a single source provider to market and sell our COVID-19 testing services and any interruptions of operations of this provider could significantly delay or have a material adverse effect on our business.

We rely on PWN Health to provide physician services in order to market and sell COVID testing services through our direct-to-consumer product, Picture Genetics. If PWN is unable or ceases providing these services for any reason, we may be required to seek FDA approval to amend our EUA to permit us to use another physician service provider for these testing services. Until an alternative provider is identified and this FDA approval is obtained, we may be required to suspend the sale and marketing of our COVID-19 testing services through our Picture Genetics platform. It is unclear how long this FDA approval process may take and we may be unable to find an alternative provider for these services. Our business, prospects and results of operations may be materially harmed if we are required to suspend the provision of COVID-19 testing services through our Picture Genetics platform for this or any other reason.

We may incur cost overruns as a result of fixed price contracts which could limit profits or otherwise adversely affect our business results of operations and financial condition.

In particular, certain of our government contracts are multi-award, indefinite-delivery and indefinite-quantity, or IDIQ, task order-based contracts, which generally provide for fixed price schedules for products and services, have no pre-set delivery schedules, have very low minimum purchase requirements, are typically competed among multiple awardees and force us to carry the burden of any cost overruns. Due to their nature, fixed-priced contracts inherently have more risk than cost reimbursable contracts. If we are unable to control costs or if our initial cost estimates are incorrect, we can lose money on these contracts. In addition, some of our contracts may have provisions relating to cost controls and audit rights, and if we fail to meet the terms specified in those contracts, we may not realize their full benefits. Low earnings caused by cost overruns and cost controls would have a negative impact on our results of operations. Since the price competition to win both IDIQ and fixed-priced contracts is intense and costs of further contract performance cannot be predicted with certainty, there can be no assurance as to the profits, if any, that the Company will realize over the term of these contracts.

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

With the development of NGS, the clinical genetic testing market has become increasingly competitive, and as the COVID-19 pandemic continues, competitive COVID-19 tests have entered and may continue to enter the market. This competition may intensify in the future. We face competition from a variety of sources, including, among others, an increasing number of companies seeking to develop and commercialize, or who have developed and commercialized, COVID-19 tests, dozens of companies focused on molecular genetic and cancer testing services, such as specialty and reference laboratories that offer traditional single-gene and multi-gene tests, and 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 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, individual physicians and other practitioners, governmental bodies, municipalities and corporations may also seek to perform testing, including rapid COVID-19 testing, at their own facilities rather than use our services and some consumers may increasingly rely on rapid COVID-19 tests. In this regard, access to these on site or point-of-care testing solutions and the 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 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 our testing services and 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, 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. Further, companies or governments that effectively control access to 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 depends 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, 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 markets. We 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 unable 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 worked with Xi Long USA, Inc. to form a

joint venture in the second quarter of 2017 which was restructured in 2021, in an effort to bring our NGS capabilities to the Chinese genetic testing market through entities separate from our U.S. operations. Although this joint venture has enabled us to have an operational presence on the ground in China to capitalize on the large and growing genetic testing opportunity in the country and 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. 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 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.

Our ability to achieve or sustain profitability also 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 focused primarily on providing our tests to hospitals, medical institutions and other laboratories, our traditional genetic testing customer base. Our customer base for our COVID-19 tests is principally comprised of governmental bodies, municipalities, and large corporations who pay us directly or through third-party payors. In March 2020, the Coronavirus Aid, Relief, and Economic Security Act, or CARES Act, was enacted, providing for reimbursement to healthcare providers for COVID-19 tests provided to uninsured individuals, subject to continued available funding. Should reimbursement under the CARES Act for COVID-19 testing cease to be available for any reason, our ability to collect payment would be adversely affected. 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 also affect our collection rates. If we are unable to convince hospitals, medical institutions and other laboratories of the value and benefit provided by our tests, 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 from our healthcare provider customers may decline to the extent we expand our business into new healthcare provider 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. Our collection risks also include the potential for default or bankruptcy by the party responsible for payment and other risks associated with payment collection generally. Any inability to maintain our past payment collection levels could cause our revenue and ability to achieve profitability to decline and adversely affect our business, prospects and financial condition.

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, municipalities, governmental bodies, large corporations and other laboratories from which we typically receive direct payment for ordered tests, including our COVID-19 tests, we believe our potential for future growth is dependent on our ability to attract new customer groups, including individual physicians and other practitioners. Our healthcare provider customers, including laboratories 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, deductible 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 to our healthcare provider customers and any corresponding revenue will depend in part on our ability to achieve and maintain 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 at all or 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 diagnosis codes for tests that they order, we

may not be reimbursed for 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 a provider in 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 or provider means that we have agreed with these payors to provide certain of our tests at negotiated or set fee schedule 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 customer base or the number of billable tests we sell. 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 us 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 health care 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 offerings and develop and sell new tests and on our ability to expand our presence in new and existing markets, including our presence in the molecular diagnostic and cancer testing markets. We may not be successful in launching or marketing any new tests we may develop or in expanding into any new or existing markets, and, even if we are successful, the demand for our tests could decrease or may not continue to increase at historical rates due to resulting sales of any new tests. Development of new tests is time-consuming and costly, 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. 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, 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. 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 additional 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 risk 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 have or may establish or by any distributors or other commercial partners we have engaged or 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 trade 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, conversions of currencies and the risk of repatriation of certain foreign currencies;
- natural disasters, political and economic instability, including wars, terrorism and political unrest, outbreak of disease (e.g. the COVID-19 pandemic), 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 joint venture in China. 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; and many of the other risks of doing business internationally that are discussed above. Although we believe this joint venture 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 FF Gene Biotech. Moreover, any 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 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, including tests 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. 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 laboratory facilities become inoperable, if we are forced to vacate a 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 our tests at our CLIA-certified laboratories in Temple City, California, Houston, Texas, Alpharetta, Georgia, and Jupiter, Florida. Our laboratories and the equipment we use to perform our tests would be costly to replace and could require substantial lead time to replace and qualify for use. Additionally, any other laboratory facilities or equipment we may use could be damaged or rendered inoperable by natural disasters (which may be exacerbated by the effects of climate change) or man-made disasters 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 a 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 relocate from one laboratory facility to another laboratory facility or obtain additional laboratory space, we may have difficulty locating suitable space in a timely manner, on reasonable terms or at all. 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 used 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 face risks related to the impact of the COVID-19 pandemic and the related protective public health measures.

Despite our recent revenue growth and recent demand for our COVID-19 tests, our business could be materially and adversely affected by the effects of the global pandemic of COVID-19 and the related protective public health measures. Our business depends upon the continuous testing services that we provide at our laboratory facilities, and our business faces the same risks as are currently prevalent in most of the United States, including the risks that employees could contract COVID-19, which could result in a disruption in our ability to continue to provide testing services. Although we take what we believe are reasonable precautions to prevent the spread of COVID-19 within our facilities and among our employees, we cannot provide assurance that we will not suffer from exposure to the SARS-CoV-2 virus that would require a temporary closure of our laboratory facilities, which would materially adversely affect our operations and financial results. Other adverse effects of the pandemic on our business could include disruptions or restrictions on our employees' ability to travel, as well as temporary closures of the facilities of our suppliers, third party service providers or customers, which could impact our test volume and results of operations.

We rely on a limited number of suppliers and, in some cases, a sole supplier, for certain 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 laboratory substances, including reagents, as well as for the sequencers and various other equipment and materials used in our laboratory operations. In particular, we rely on Illumina, Inc. as the sole supplier of the next generation sequencers and associated reagents used 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 most 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 they could fail to provide us with sufficient quantities of materials that meet our specifications, among other reasons. These suppliers may also be affected by, natural disasters such as extreme weather events, fires or flooding (which may be exacerbated as a result of climate change), and the ongoing COVID-19 pandemic and its related effects on the global supply chain. 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 certain 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 required for our tests, including as a result of the COVID-19 pandemic, 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 may bill various different parties for our tests. This includes billing customers directly, as in the case of our hospital and other medical institution customers, as well as billing through 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:

- contractual restrictions in our customer contracts that may limit our ability to utilize certain third-party billing service providers;
- 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. In addition, California has enacted the Genetic Information Privacy Act that imposes privacy requirements on direct-to-consumer genetic testing companies that could change the discussion among patients and physicians related to genetic testing as a whole, and potentially reduce consumer interest in such testing more broadly.

Our reputation and business could be damaged by negative publicity.

We may be subject to negative publicly. Reputational risk, including as a result of negative publicity, is inherent in our business. Negative publicity can result from actual or alleged conduct in a number of areas, including legal and regulatory compliance, corporate governance, litigation, inadequate protection of health information, illegal or unauthorized acts taken by third parties that supply products or services to us and the conduct of our employees or agents. In particular, COVID-19 has been a politically controversial topic and our provision of COVID-19 testing and services may cause third parties to malign our reputation for political reasons. Negative publicity can damage our reputation and business even if these statements about us are untrue. Damage to our reputation could adversely impact our ability to attract new and to maintain existing customers, employees and business relationships.

This damage and these circumstances may have a material adverse effect on our financial condition, prospects 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 is 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 skill, 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, Paul Kim, our Chief Financial Officer, Dr. Han Lin Gao, our Chief Scientific Officer and Laboratory Director, and Jian Xie, our Chief Operating Officer. 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 our ability to compete effectively, advance our technologies, develop new tests and implement our business strategies. All of our executives and employees, including Messrs. Hsieh, Kim and Xie, and Dr. Gao, are at-will, meaning either we or the executive may terminate his employment at any time. We do not carry key person 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 depend 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, and our liquidity needs could be materially affected by market fluctuations and general economic conditions.

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. As of December 31, 2021, we had cash, cash equivalents and marketable securities of approximately $935.5 million. We maintain our cash, cash equivalents and marketable securities with high quality, accredited financial institutions. However, some of these accounts exceed federally insured limits, and, while we believe the Company is not exposed to significant credit risk due to the financial strength of these depository institutions or investments, the failure or collapse of one or more of these depository institutions or default on these investments could materially adversely affect our ability to recover these assets and/or materially harm our financial condition. We may seek to fund future cash needs 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. For example, the COVID-19 pandemic initially caused extreme disruption and volatility in the global capital markets. High volatility in capital markets may reduce our ability to access capital and/or adversely affect the stability of the depository institutions maintaining our assets.

If we raise additional 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 unable 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.

U.S. federal income tax reform could adversely affect us.

New legislation or regulation which could affect our tax burden could be enacted by a governmental authority. We cannot predict the timing or extent of such tax-related developments which could have a negative impact on our financial results.

Additionally, we use our best judgment in attempting to quantify and reserve for our tax obligations. However, a challenge by a taxing authority, our ability to utilize tax benefits such as carryforwards or tax credits, or a deviation from other tax-related assumptions may cause actual our actual tax obligations to exceed previous reserve estimates.

We may not be successful in our efforts to integrate any acquired businesses and technologies, and this may adversely affect our business and results of operations. We may incur unexpected liabilities as a result of our acquisitions.

Our ability to integrate any organizations or technology that we may acquire, including our recent acquisition of CSI, is subject to a number of risks including the following:

- failure to integrate successfully the personnel, information systems, technology and operations of the acquired business;
- failure to maximize the potential financial and strategic benefits of the acquisition;
- failure to realize the expected synergies of the acquired business;
- possible impairment of relationships with employees and clients as a result of any integration of new businesses and management personnel;
- impairment of goodwill;
- increased demand on human resources and operating systems, procedures and controls; and
- reductions in future operating results as a result of the amortization of intangible assets.

Acquisitions are also accompanied by the risk that obligations and liabilities of an acquired business may not be adequately reflected in the historical financial statements of that business and the risk that historical financial statements may be based on assumptions, which are incorrect or inconsistent with our assumptions or approach to accounting policies. The acquisition and integration of businesses may not be managed effectively and any failure to manage the integration process could lead to disruptions in the overall activities of the Company, a loss of clients and revenue and increased expenses. 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. We may also acquire contingent liabilities in connection with the acquisitions of business, which maybe material. Any estimates we might make regarding any acquired contingent liabilities and the likelihood that these liabilities will materialize could differ materially from the liabilities actually incurred. These circumstances could materially harm our business, results of operations and prospects.

We depend on our information technology systems and any failure of these systems, due to hardware or software malfunctions, delays in operation, and/or 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, and the outbreak of war or acts of terrorism. Breaches resulting in the compromise, disruption, degradation, manipulation, loss, theft, destruction, or unauthorized disclosure of sensitive information can occur in a variety of ways, including but not limited to, negligent or wrongful conduct by employees or former employees or others with permitted access to our information technology systems and information, or wrongful conduct by hackers, competitors, or certain governments. Our third-party vendors and business partners face similar risks. 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, ransomware attacks, phishing schemes, 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 our systems or those used by our third-party service providers. These events could lead to the unauthorized access, disclosure, and unauthorized use of confidential information, including protected health information. Cyber-attacks come in many forms, including the deployment of harmful malware or ransomware, exploitation of vulnerabilities, phishing and other use of social engineering, and other means to compromise the confidentiality, integrity, and availability of our IT systems and confidential information. The techniques used by criminal elements to attack computer systems are sophisticated, change frequently and may originate from less regulated or remote areas of the world. As a result, we may not be able to address these techniques proactively or implement adequate preventative measures. There can be no assurance that we will promptly detect and/or intercept any such disruption or security breach, if at all. 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, business interruption and cyber liability 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.

If our computer systems are compromised, we could be subject to fines, damages, reputational harm, litigation and enforcement actions, and we could lose trade secrets, the occurrence of which could harm our business, in addition to possibly requiring substantial expenditures of resources to remedy. For example, any such event that leads to unauthorized access, use or disclosure of personal information, including personal information regarding our patients or employees, could harm our reputation, require us to comply with federal and/or state breach notification laws and foreign law equivalents, and otherwise subject us to liability under laws and regulations that protect the privacy and security of personal information. In addition, a cybersecurity breach could adversely affect our reputation and could result in other negative consequences, including disruption of our internal operations, increased cyber security protection costs, lost revenues or litigation. Despite precautionary measures to prevent unanticipated problems that could affect our information systems, sustained or repeated system failures that interrupt our ability to generate and maintain data could adversely affect our ability to operate our business.

We rely on commercial courier delivery services to transport specimens to our laboratory facilities 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, or in some cases overnight, for analysis at our laboratory facilities. Disruptions in delivery service, whether due to labor disruptions, bad weather or natural disasters (including severe weather, fires or other natural events which may be exacerbated by climate change), pandemics or epidemics, 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 2021, we will need to maintain and enhance these controls if and as we grow. Moreover, we may need to hire additional personnel and devote more resources to our financial reporting function in order to do so.

If one or more material weaknesses is identified during the process of evaluating our internal controls or if we do not detect errors on a timely basis, 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. In addition, now that we are no longer an emerging growth company, we are required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. Any failure to develop or maintain effective controls, or any difficulties encountered in their implementation or improvement, could harm our results of operations, cause us to fail to meet our reporting obligations, result in a restatement of our financial statements for prior periods, or adversely affect the results of management evaluations and independent registered public accounting firm audits of our internal control over financial reporting that we are required to include in our periodic reports that will be filed with the SEC. 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

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, have 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 IVDs, 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 IVDs, 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 August 2020, the U.S. Department of Health and Human Services, or HHS, published a policy announcement that the FDA must go through the formal notice-and-comment rulemaking process before requiring pre-market review of LDTs rather than making such changes through guidance documents, compliance manuals, or other informal policy statements. HHS's policy statement did not affect proposed legislation for the regulation of LDTs, which is discussed below. In November 2021, the Biden Administration withdrew that HHS policy announcement and ostensibly restored FDA's regulatory oversight of LDTs.

Separately, members of Congress have been working with stakeholders for several years on a possible bill to reform the regulation of in vitro clinical tests including LDTs. In March 2020, U.S. Representatives Diana DeGette (D-CO) and Dr. Larry Bucshon (R-IN) formally introduced the long-awaited legislation, called the Verifying Accurate, Leading-edge IVCT Development Act, or VALID Act. An identical version of the bill was also introduced in the Senate and is sponsored by U.S. Senators Michael Bennet (D-CO) and Richard Burr (R-NC), demonstrating both bicameral and bipartisan support for the effort to overhaul how the FDA reviews and approves diagnostic tests going forward. The VALID Act would codify into law the term "in vitro clinical test" to create a new medical product category separate from medical devices that includes products currently regulated as IVDs, as well as LDTs. The VALID Act would also create a new system for labs and hospitals to use to submit their tests electronically to the FDA for approval, which is aimed at reducing the amount of time it takes for the agency to approve such tests, and establish a new program to expedite the development of diagnostic tests that can be used to address a current unmet need for patients. A substantively unchanged version of the VALID Act was re-introduced in both houses of Congress on June 24, 2021.

It is unclear whether the VALID Act would be passed by Congress in its current form or signed into law by President Biden. Until the FDA promulgates binding regulations through notice-and-comment rulemaking regarding LDTs, or the VALID Act or other legislation is passed reforming the federal government's 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.

If the FDA creates a new regulation 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 premarket 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 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 categories of laboratory testing that 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 laboratories in Temple City, California, Houston, Texas, Alpharetta, Georgia and Jupiter, Florida.

In addition to CLIA requirements, we elect to have our laboratories accredited by 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 CAP, we are deemed to also comply with CLIA. 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 State Department of Health, or DOH. The New York state laboratory laws and regulations are equal to or more stringent than CLIA. In addition, 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 information, including the HIPAA, 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 FTC 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.

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 GDPR in 2016, which applies to all European Union member states from May 25, 2018 and replaced the European Data Protection Directive. The GDPR introduced stringent new data protection and operational requirements in the European Union for companies that receive or process personal data of European residents, as well as 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 are required to maintain additional mechanisms ensuring compliance with the GDPR. 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 and the collection, processing, and storage of sensitive personal data, including genetic information and testing. 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. On July 16, 2020, the highest Court of Justice of the European Union or the CJEU, issued a landmark opinion in the case *Maximilian Schrems vs. Facebook* (Case C-311/18), or *Schrems II.* This decision calls into question certain data transfer mechanisms as between the European Union member states and the U.S. The CJEU is the highest court in Europe, and the *Schrems II* decision heightens the burden on data importers to assess U.S. national security laws on their business and future actions of European Union data protection authorities are difficult to predict at this early date. Consequently, there is some risk of any such data transfers from the European Union being halted by one or more European Union member states. Any contractual arrangements requiring the transfer of personal data from the European Union to us in the United States will require greater scrutiny and assessments as required under *Schrems II* and may have an adverse impact on cross-border transfers of personal data or increase costs of compliance.

In addition, many states, such as California (where one of our clinical laboratories is located), 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 patient health information and other personal 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 GDPR. 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 California residents, imposing special rules on the collection of personal 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. On November 3, 2020, California voters passed the California Privacy Rights Act, or CPRA, which expands the CCPA. The CPRA will be fully effective in January of 2023 and, among other things, establishes the California Privacy Protection Agency, or CPPA, a new regulatory authority charged with administering and enforcing the CRPA and privacy rights in California. The CPPA will have the power to levy fines and bring other enforcement actions. The CPRA could impact our operations or that of our collaborators and business partners and impose new regulatory requirements and increase costs of compliance. Other states are considering expanded privacy legislation similar to the GDPR and CPRA, with Virginia and Colorado enacting their own consumer privacy laws similar to CCPA and CPRA. Both the Virginia and Colorado laws take full effect in 2023. There are also several federal privacy proposals under consideration in Congress.

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 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 potentially 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:

- CLIA's and CAP's regulation of our laboratory activities;
- FDA laws and regulations, including but not limited to requirements for offering LDTs;
- 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 Act, which imposes civil penalties, and provides for civil whistleblower or qui tam actions, against individuals or entities for knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money 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 Eliminating Kickbacks in Recovery Act of 2018, or EKRA, which 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) covered by health care benefit programs (including commercial insurers) unless a specific exception applies;
- the Affordable Care Act, or ACA, 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 and other Medicare and Medicaid billing and coverage requirements;
- 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 U.S. 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 states' Attorneys General have issued fraud alerts regarding a variety of cancer genetic testing fraud schemes, and the Department of Justice has announced indictments and guilty pleas in such fraud schemes involving a variety of individuals and entities, including genetic testing and other laboratories, physicians who ordered 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, and these activities allegedly violated the federal Anti-Kickback Statute and other criminal laws. 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 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.

We may be required to modify our business practices, pay fines, incur significant expenses or experience losses due to litigation or governmental investigations.

From time to time and in the ordinary course of our business, we may be subject to litigation or governmental investigation on a variety of matters in the United States or foreign jurisdictions, including, without limitation, regulatory, intellectual property, product liability, antitrust, consumer, false claims, whistleblower, Qui Tam, privacy, anti-kickback, anti-bribery, environmental, commercial, securities and employment litigation and claims and other legal proceedings that may arise from the conduct of our business. Our activities relating to our products and services are subject to extensive regulation in the United States and foreign jurisdictions. Like many companies in our industry, we have in the ordinary course of business received inquiries, subpoenas, civil investigative demand, or CIDs, and other types of information requests from government authorities. We have received a CID issued by the U.S. Department of Justice pursuant to the False Claims Act related to its investigation of allegations of medically unnecessary laboratory testing, improper billing for laboratory testing, and remuneration received or provided in violation of the Anti-Kickback Statute and the Stark Law. This CID requests information and records relating to certain of our customers named in the CID which represent a small portion of our revenues. We are fully cooperating with the U.S. Department of Justice to promptly respond to the requests for information in this CID, and do not presently expect this CID or resulting investigation to have a material adverse impact on our business. However, we cannot predict when the investigation will be resolved, the outcome of the investigation or its potential impact on our business which may ultimately be greater than we expect. In addition, responding to this CID, and any litigation or government investigation generally, diverts the attention of our management team and diverts resources from our core business. As such, the time and attention of our management team in responding to these matters may limit their time available to devote to our business, and we may also incur significant expenses or experience losses in relation to these matters. As a result of these matters, we may also be required to alter the conduct of our operations or pay penalties. Any of these circumstances may adversely affect our business, prospects, reputation and results of operations.

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 ACA made a number of substantial changes to the way healthcare is financed both by governmental and private payors. The ACA 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 ACA 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 are be paid under Medicare Clinical Laboratory Fee Schedule. Under PAMA, certain clinical laboratories are required to periodically report to CMS private payor payment rates and volumes for their tests, and laboratories that fail to report the required payment information may be subject to substantial civil monetary penalties. Medicare reimbursement for clinical laboratory diagnostic tests is based on the weighted-median of the payments made by private payors for these tests, rendering private payor payment levels even more significant than in the past. 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 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 ACA 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, the new Democrat-led presidential administration has been taking steps to strengthen the ACA and, following several years of litigation in the federal courts, in June 2021, the U.S. Supreme Court upheld the ACA when it dismissed a legal challenge to the ACA's constitutionality. Legislation related to precision medicine is also being considered in Congress and, if passed and signed into law, such legislation may affect genetic or genomic testing and related clinical laboratory offerings.

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 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. On March 5, 2020, U.S. Representatives Diana DeGette (D-CO) and Dr. Larry Bucshon (R-IN) formally introduced the VALID Act in the House and an identical version of the bill was introduced in the U.S. Senate by Senators Michael Bennet (D-CO) and Richard Burr (R-NC). The VALID Act would codify into law the term "in vitro clinical test" to create a new medical product category separate from medical devices, and bring all such products within the scope of the FDA's oversight. A substantively unchanged version of the VALID Act was re-introduced in both houses of Congress on June 24, 2021. It is unclear whether the VALID Act would be passed by Congress in its current form or signed into law by President Biden.

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, 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. 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. 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.

Marketing of our COVID-19 tests under the EUA from the FDA is subject to certain limitations and we are required to maintain compliance with the terms of the EUA, among other things, and the continuance of our EUA is subject to government discretion.

Since March 2020, we have commercially launched several molecular tests for the detection of SARS-CoV-2, the virus that causes COVID-19, including NGS and RT-PCR-based tests as well as related antibody testing options. In May 2020, we were granted an EUA for our RT-PCR-based test for the detection of SARS-CoV-2 using upper and lower respiratory specimens (nasal, nasopharyngeal, and oropharyngeal swabs). In June 2020, we received an amendment to the EUA to add our at-home testing solution for COVID-19 through Picture Genetics. Since that time, the FDA has granted authorizations to revise the authorized labeling for the RT-PCR test and to allow for the use of an additional at-home specimen collection kit in conjunction with our test. In addition, the FDA has established additional conditions for emergency authorizations of COVID-19 molecular, antigen, and serology tests to account for emerging mutations of the SARS-CoV-2 virus, which revise our previously issued EUA.

Although there are certain regulatory requirements the FDA has waived for the duration of the EUA, we remain subject to specific conditions of the authorizations. As with other FDA-regulated tests, issues could emerge during the course of the marketing and use of our test under an EUA that could impact our ability to continue the sale and distribution of the authorized test or home collection kit. Factors that may be out of the Company's control, such as the availability of supplies and key personnel, may impact the Company's ability to maintain testing capacity and test result delivery, and its other responses to the COVID-19 pandemic, and may have an adverse impact on the Company's operations. Our EUA remains effective only until the HHS declaration is terminated or revoked, and FDA also may revoke an EUA if it determines the criteria for issuance are no longer met or other circumstances make such revocation appropriate to protect the public health or safety. In December 2021, the FDA issued draft guidance documents describing a phased transition process following the end of public health emergency for diagnostics and other medical devices that were developed to respond to the COVID-19 pandemic and received EUA marketing authorization. It is unclear how those proposed policies could impact our test offerings and business in the future.

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.

If we were deemed to be an investment company under the Investment Company Act of 1940, as amended, applicable restrictions could make it impractical for us to continue our business as currently conducted and could have a material adverse effect on our business, financial condition and results of operations.

Under the Investment Company Act of 1940, or 1940 Act, a company generally will be deemed to be an "investment company" for purposes of the 1940 Act if (1) it is, or holds itself out as being, engaged primarily, or proposes to engage primarily, in the business of investing, reinvesting or trading in securities or (2) it engages, or proposes to engage, in the business of investing, reinvesting, owning, holding or trading in securities and it owns or proposes to acquire investment securities having a value exceeding 40% of the value of its total assets (exclusive of U.S. government securities and cash items) on an unconsolidated basis. We do not believe that we are an "investment company," as such term is defined in either of those sections of the 1940 Act and we intend to conduct our operations so that we will not be deemed an investment company. However, if we were to be deemed an investment company, restrictions imposed by the 1940 Act, including limitations on our capital structure and our ability to transact with affiliates, could make it impractical for us to continue our business as it is currently being conducted and could have a material adverse effect on our business, financial condition and results of operations.

Our joint venture in China is subject to risks and uncertainties relating to the laws and regulations of China and the changes in relations between the United States and China.

Under its current leadership, the government of China has been pursuing economic reform policies, including by encouraging foreign trade and investment. However, there is no assurance that the Chinese government will continue to pursue such policies, that such policies will be successfully implemented, that such policies will not be significantly altered, or that such policies will be beneficial to our partnerships or activities in China. China's system of laws can be unpredictable, especially with respect to foreign investment and foreign trade. The United States government has called for substantial changes to foreign trade policy with China and has raised, and has proposed to further raise in the future, tariffs on several Chinese goods. China has retaliated with increased tariffs on United States goods. Moreover, China's legislature has adopted a national security law to substantially change the way Hong Kong has been governed since the territory was handed over by the United Kingdom to China in 1997. This law increases the power of the central government in Beijing over Hong Kong, limits the civil liberties of residents of Hong Kong and could restrict the ability of businesses in Hong Kong to continue to conduct business or to continue to with business as previously conducted. The U.S. State Department has indicated that the United States no longer considers Hong Kong to have significant autonomy from China. The U.S. State Department has recently enacted sanctions related to China's governing of Hong Kong. Any further changes in United States trade policy could trigger retaliatory actions by affected countries, including China, resulting in trade wars. Any regulatory changes and changes in United States and China relations may have a material adverse effect on our partnerships or activities in China, which could materially harm our business and financial condition.

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 we 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 FTC 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 FTC, as well as comparable state consumer protection laws. Under the 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 launch of our Picture Genetics line of at-home genetic test offerings that are initiated by 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 effect on our business.

Intellectual Property Risks

We primarily 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 our intellectual property and other confidential information 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 on commercially reasonable terms when needed 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 some or all of 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 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 such 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 approximately 26% of our outstanding voting equity as of December 31, 2021. 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, or Nasdaq, 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 or other 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 global pandemic related to COVID-19);
- 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 such company. This type of litigation, if instituted against us, could result in substantial costs, a diversion of our management's attention and resources and could damage our reputation.

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 approximately 41% of our outstanding voting equity as of December 31, 2021, and of this, Mr. Hsieh, our founder, Chief Executive Officer and Chairman of our board of directors, by himself beneficially owns approximately 26% of our outstanding voting equity as of December 31, 2021. 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. The vast majority 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.

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 addition, in November 2020 we entered into an Equity Distribution Agreement, or the November 2020 Equity Distribution Agreement. During the year ended December 31, 2021, we sold an aggregate of 1.1 million shares of our common stock pursuant to the November 2020 Equity Distribution Agreement at a weighted-average net selling price of $64.83 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 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 1.0 million 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 by our stockholders 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 1.0 million 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 and bylaws provide 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 brought on our behalf;
- any direct action brought by a stockholder against us or any of our directors, officers or other employees, alleging a breach of a fiduciary duty;
- any action brought by a stockholder against us or any of our directors, officers or other employees, alleging a violation of the DGCL, our certificate of incorporation or our bylaws; and
- any action brought by a stockholder against us or any of our directors, officers or other employees, asserting a claim against us governed by the internal affairs doctrine.

We refer to the forgoing limitations as the Exclusive Forum Provisions. The Exclusive Forum Provisions do not apply to (i) actions in which the Court of Chancery in the State of Delaware concludes that an indispensable party is not subject to the jurisdiction of the Delaware courts, and (ii) actions in which a federal court has assumed exclusive jurisdiction of a proceeding.

Accordingly, the Exclusive Forum Provisions do not apply to actions brought to enforce a duty or liability created by the Exchange Act or the rules and regulations thereunder, or Exchange Act Claims. Further, the clause in our certificate of incorporation excepting "actions in which a federal court has assumed exclusive jurisdiction of a proceeding" from the Exclusive Forum Provisions is not intended to mean that a federal court must take any actual or affirmative action to assume jurisdiction over an Exchange Act Claim, as Section 27 of the Exchange Act creates exclusive federal jurisdiction over all Exchange Act Claims, regardless of whether a federal court takes any action. The Exclusive Forum Provisions also do not apply to federal and state suits brought to enforce any duty or liability created by the Securities Act or the rules and regulations thereunder, or Securities Act Claims. To the extent applicable or enforceable, the Exclusive Forum Provisions 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, for Securities Act Claims, Exchange Act Claims or claims for which a court were to find these Exclusive Forum Provisions inapplicable or unenforceable for 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 2023. We use these facilities for laboratory testing and management activities and certain research and development, administrative and other functions.

We have CLIA-certified laboratories located in Houston, Texas and Alpharetta, Georgia. In Houston, Texas, we lease and occupy approximately 12,000 square feet under a lease that will expire in November 2023. In Alpharetta, Georgia, we lease and occupy approximately 65,000 square feet under a lease that will expire in March 2028. We use these facilities for laboratory testing and certain administrative and other functions.

We also own a real property located at 4399-4401 Santa Anita Avenue, El Monte, California, which consists of approximately 61,612 total square feet of building situated on 2.6 acres of land. We will build more CLIA-certified laboratories at this location. 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 Nasdaq under the symbol "FLGT." There was no public market for our common stock prior to September 29, 2016.

Holders of Common Stock

As of February 1, 2022, there were 9 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, as the representatives of the several underwriters, in which we issued and sold an aggregate of 4.8 million 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 $28.8 million of the net proceeds from the IPO, of which, $4.5 million was used for contributions to FF Gene Biotech prior to the FF Gene Biotech Acquisition and $24.4 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 the 2019 Equity Distribution Agreement with Piper as sales agent, which was amended on August 4, 2020. During the year ended December 31, 2019, we sold an aggregate of 104,000 shares of our common stock pursuant to the 2019 Equity Distribution Agreement at a weighted-average net selling price of $9.37 per share, which resulted in $979,000 of net proceeds to the Company. During the year ended December 31, 2020, we sold an aggregate of 1.1 million shares of our common stock pursuant to the 2019 Equity Distribution Agreement at a weighted-average net selling price of $38.50 per share, which resulted in $42.7 million of net proceeds to the Company. Shares sold under the Equity Distribution Agreement were offered and sold pursuant to our 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 prospectus supplements and accompanying base prospectus filed with the SEC on August 30, 2019, May 6, 2020 and August 5, 2020. There has been no material change in the planned use of proceeds as described in the prospectus supplements and accompanying base prospectus.

On November 13, 2019, we entered into a purchase agreement with Piper, as representative of the several underwriters, pursuant to which we sold 2.7 million shares of our common stock at a price of $10.52 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 registered under the Securities Act and sold pursuant to our shelf registration statement on Form S-3 (File No. 333-233227), and a prospectus supplement and accompanying base prospectus filed with the SEC on November 13, 2019. There has been no material change in the planned use of proceeds as described in the prospectus supplement and accompanying base prospectus.

On September 25, 2020, we entered into an Equity Distribution Agreement, or the September 2020 Equity Distribution Agreement, with Piper as sales agent, pursuant to which we sold 2.8 million shares of our common stock pursuant to the September 2020 Equity Distribution Agreement at a weighted-average net selling price of $42.90 per share during the year ended December 31, 2020, which resulted in $122.1 million of net proceeds to the Company. Piper may receive a commission of up to 3% of the gross

proceeds received by the Company for sales pursuant to the September 2020 Equity Distribution Agreement. Shares sold under the September 2020 Equity Distribution Agreement were offered and sold pursuant to our registration statement on Form S-3 (File No. 333-239964) filed with the SEC on July 21, 2020, as amended on August 5, 2020, and declared effective on August 12, 2020, and a prospectus supplement and accompanying base prospectus filed with the SEC on September 25, 2020. There has been no material change in the planned use of proceeds as described in the prospectus supplement and accompanying base prospectus.

On November 20, 2020, we entered into the November 2020 Equity Distribution Agreement, with Piper, Oppenheimer & Co. Inc., and BTIG LLC, as sales agents, pursuant to which we may offer and sell, from time to time through Piper, shares of our common stock having an aggregate offering price of up to $175.0 million. Piper may receive a commission of up to 3% of the gross proceeds received by the Company for sales pursuant to the November 2020 Equity Distribution Agreement. During the year ended December 31, 2020, the Company sold an aggregate of 2.0 million shares of our common stock pursuant to the November 2020 Equity Distribution Agreement at a weighted-average net selling price of $48.70 per share, which resulted in $99.1 million of net proceeds to the Company. During the year ended December 31, 2021, we sold approximately 1.1 million shares of our common stock pursuant to the November 2020 Equity Distribution Agreement at a weighted-average net selling price of $64.83 per share, which resulted in $72.0 million of net proceeds to the Company. Shares sold under the November 2020 Equity Distribution Agreement were offered and sold pursuant to the Company's registration statement on Form S-3 (File No. 333-239964) filed with the SEC on July 21, 2020, as amended on August 5, 2020, and declared effective on August 12, 2020, and a prospectus supplement and accompanying base prospectus filed with the SEC on November 20, 2020. There has been no material change in the planned use of proceeds as described in the prospectus supplement and accompanying base prospectus.

Item 6. [Reserved]

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

Forward-Looking Statements

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 and contains forward-looking statements within the meaning of Section 27A of the Securities Act and Section 21E of the Securities Exchange Act. We have omitted discussion of 2019 results where it would be redundant to the discussion previously included in Item 7 of our 2020 Annual Report on Form 10-K. 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" in 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 technology company offering large-scale COVID-19 testing services, molecular diagnostic testing services and comprehensive genetic testing designed to provide physicians and patients with clinically actionable diagnostic information to improve the quality of patient care. A cornerstone of our business is our ability to provide expansive options and flexibility for all clients' unique testing needs. To this end, we have developed a proprietary technology platform allowing us to offer a broad and flexible test menu and to 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 have experienced rapid volume growth since our commercial launch in 2013, with approximately 10.0 million billable tests delivered in 2021, compared to 4.4 million billable tests delivered in 2020, and an aggregate of approximately 14.5 million billable tests delivered to over 1,800 customers from inception through December 31, 2021.

Our technology platform, which integrates sophisticated data comparison and suppression algorithms, adaptive learning software, in comparison to our competitors 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.

We offer tests at competitive prices, averaging approximately $100 per billable test delivered in 2021, and at a low cost to us, averaging approximately $22 per billable test delivered in 2021. Our volume has grown rapidly since our commercial launch in 2013, with approximately 10.0 million billable tests delivered in 2021, 4.4 million billable tests delivered in 2020, and an aggregate of approximately 14.5 million billable tests delivered to over 1,800 customers from inception through December 31, 2021. We have experienced compound quarterly growth of 111.0% in the number of billable tests delivered in our last eight completed fiscal quarters. We recorded revenue and income from operations of $992.6 million and $507.4 million, respectively, in 2021, compared to revenue and income from operations of $421.7 million and $214.3 million, respectively, in 2020. We achieved profitability in the first quarter

of 2017, and in the second and the third quarter of 2019, the second, third and fourth quarters of 2020, and all the quarters of 2021, but we have recorded losses in all other periods since our inception.

2021 Developments

Incremental Investment in Chinese Joint Venture entity, FF Gene Biotech

In May 2021, we entered into a restructuring agreement with Xilong Scientific and FJIP, resulting in the Company indirectly acquiring a controlling financial interest in FF Gene Biotech. FF Gene Biotech was founded as a joint venture to bring our NGS capabilities to the Chinese genetic testing market through entities separate from our U.S. operations, and FF Gene Biotech is pursuing this objective separate from our business elsewhere.

Acquisition of CSI

We completed the acquisition of CSI, a leading cancer testing laboratory, to expand our presence in somatic molecular diagnostics and cancer testing. CSI was founded to provide a client- and patient-focused model of cancer diagnostic testing for pathologists, community hospitals, and their patients. CSI offers approximately 400 unique tests with a focus on oncology and capabilities across flow cytometry, cytogenetic analysis, fluorescence in-situ hybridization, or FISH, immunohistochemistry, and molecular genetics. CSI's philosophy of providing expert diagnostic testing with speed, precision, and care, is highly complementary with our core value proposition of offering a broad menu of actionable diagnostic tests with quality results and rapid turnaround times. CSI is based in Alpharetta, GA and expands our presence in the southeastern United States.

Strategic Partnership with Laboratory for Advanced Medicine, Inc., or Helio Health

We made an investment in and entered into a strategic partnership with Helio Health, an AI-biotechnology company developing blood-based early cancer detection tests, to commercialize Helio Health's blood-based early cancer detection tests. In conjunction with the commercial strategic partnership whereby Helio Health has secured exclusive commercial rights for laboratory develop tests, or LDTs, in the U.S. and Canada. Under this partnership, we and Helio Health commercialized and co-branded HelioLiver, a cell-free DNA (cfDNA) methylation blood test that incorporates protein markers and demographics for the detection of hepatocellular carcinoma (HCC) – or liver cancer.

COVID-19 Considerations

The current COVID-19 pandemic has presented a substantial public health and economic challenge around the world and is affecting our employees, patients, communities and business operations, as well as the U.S. economy and financial markets. We are closely monitoring the impact of COVID-19 on all aspects of our business, including its impact on our customers, suppliers, third-party service providers, and our employees. The full extent to which the COVID-19 pandemic will directly or indirectly impact our business, results of operations and financial condition will depend on future developments that are highly uncertain and cannot be accurately predicted, including new information that may emerge concerning COVID-19 and its variants, the actions taken to contain it or treat it and the economic impact on local, regional, national and international markets and supply chains.

During the year ended December 31, 2021, and for the entirety of the COVID-19 pandemic to such point, we continued to operate as an essential business in response to COVID-19. In years ended December 31, 2020 and December 31, 2021, the COVID-19 pandemic did not have a negative impact on our consolidated operating results. Since the outbreak of the current COVID-19 pandemic there has been strong demand for accurate COVID-19 testing with rapid turn-around times as private businesses, municipalities and healthcare providers began to increasingly rely on diagnostic testing to continue operations and as a tool to aide containment efforts, and as result we have recognized significant revenue growth in connection with sales of our COVID-19 tests. While the duration of the ongoing COVID-19 pandemic and continuing market for COVID-19 diagnostic tests remains subject to a number of uncertainties, including uncertainties regarding the effectiveness of disease containment efforts, speed and effectiveness of global COVID-19 vaccine distributions, newly emerging viral variants, continuing government actions in response to the pandemic and regulatory requirements or preferences that may emerge following the pandemic, a robust market for COVID-19 diagnostic testing persists to present day. However, the responses of the federal, international, state and regional governments to the pandemic, including any shelter in place orders and the allocation of healthcare resources to treating those infected with the virus, previously caused a significant decline in the number of our traditional genetic tests ordered and, if repeated, may again cause the volume of our traditional genetic tests to decline. Even after the COVID-19 outbreak has subsided, we may experience materially adverse impacts on our financial condition and results of operations. Our ability to continue to operate as currently planned, including our ability to continue to offer our COVID-19 tests with accurate results and competitive turn-around times without any significant negative operational impact from the COVID-19 pandemic will depend in part on our, and any of our third-party service providers' and suppliers' ability to protect our respective employees and supply chains. We have endeavored to follow the recommended actions of government and health authorities to protect our employees. We intend to continue to adhere to our employee safety measures to ensure that any

disruptions to our operations remain minimal during the pandemic. However, the uncertainty resulting from the pandemic could result in an unforeseen disruption to our, or our third-party service providers' and suppliers', workforce and supply chain.

The COVID-19 pandemic has not negatively impacted the Company's liquidity position as of December 31, 2021. We have not incurred any material impairments of our assets or a significant change in the fair value of our assets due to the COVID-19 pandemic as of December 31, 2021.

For additional information on risk factors related to the COVID-19 pandemic or other risks that could impact our results, please refer to "Item 1A. Risk Factors" in Part I of this Form 10-K.

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 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.

Launch of COVID-19 Testing Services

We have experienced rapid volume growth since our commercial launch in 2013, especially after the launch of our COVID-19 testing services, with approximately 10.0 million billable tests delivered in 2021, compared to 4.4 million billable tests delivered in 2020, and an aggregate of approximately 14.5 million billable tests delivered to over 1,800 customers from inception through December 31, 2021. Most of the recent growth in our testing volume has resulted from COVID-19 tests that we conduct for certain counties, states and municipalities. The expansion of our COVID-19 testing business has resulted in a substantial change in our business that presents important challenges to our ability to manage our rapidly expanding business, and we anticipate that this business will eventually decrease after the development and widespread deployment of an effective vaccine.

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, 2021, we have sold our tests to over 1,800 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 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.

We currently classify our customers into three payor types: (i) Insurance, including claim reimbursement from HRSA for uninsured individuals, (ii) Institutional, including hospitals, medical institutions, other laboratories, governmental bodies, municipalities and large corporations or (iii) Patients who pay directly. Typically, we bill our Institutional customers for our tests and they are responsible for paying us directly and billing their patients separately or obtaining reimbursement from third-party payors in connection with a patient's diagnosis related group. 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.

We are making efforts to diversify our customer market, including building relationships with research institutions and other similar institutional customers, national clinical laboratories, governmental bodies, municipalities and large corporations in need of regular COVID-19 testing for large populations 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, most of these relationships do not 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 without prior notice. Our efforts to pursue individual consumers under our Picture Genetics platform, new payor or institutional customers, new COVID-19 testing 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.

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.

Foreign Currency Exchange Rate Fluctuations

Some 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.

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 COVID-19 tests and 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.

Cost of Revenue

Cost of revenue reflects the aggregate costs incurred in delivering test results, including "sequencing as a service", and consists of: costs of laboratory supplies, including collection kits, personnel costs, including salaries, employee benefit costs, bonuses and equity-based compensation expenses; 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 SEC, and the Nasdaq Stock Market, additional insurance expenses, investor relations activities and other administrative and professional services.

Provision for 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.

The factors that most significantly impact our effective tax rate include the levels of net earnings and certain deductions, including those related to equity-based compensation, the effect of state income taxes, return to provision adjustments, and foreign tax rate differential. We expect that these factors could 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,		$	%
	2021	2020	Change	Change
Statement of Operations Data:	(dollars and billable tests in thousands, except per billable test data)			
Revenue	$ 992,584	$ 421,712	$ 570,872	135%
Cost of revenue	215,533	89,807	125,726	140%
Gross profit	777,051	331,905	445,146	134%
Operating expenses:				
Research and development	24,219	11,580	12,639	109%
Selling and marketing	24,439	14,952	9,487	63%
General and administrative	50,732	15,215	35,517	233%
Amortization of intangible assets	1,708	—	1,708	*
Total operating expenses	101,098	41,747	59,351	142%
Operating income	675,953	290,158	385,795	133%
Interest and other income, net	1,347	1,526	(179)	(12)%
Income before income taxes, equity loss in investee and gain (loss) on equity-method investments	677,300	291,684	385,616	132%
Provision for income taxes	174,795	72,532	102,263	141%
Income before equity loss in investee and gain (loss) on equity-method investments	502,505	219,152	283,353	129%
Equity loss in investee	—	(488)	488	100%
Gain (loss) on equity-method investments	3,734	(4,354)	8,088	186%
Net income from consolidated operations	506,239	214,310	291,929	136%
Net loss attributable to noncontrolling interests	1,125	—	1,125	*
Net income attributable to Fulgent	$ 507,364	$ 214,310	$ 293,054	137%
Other Operating Data:				
Billable tests delivered(1)	9,962	4,409	5,553	126%
Average price per billable test delivered(2)	$ 100	$ 96	$ 4	4%
Cost per billable test delivered(3)	$ 22	$ 20	$ 2	10%

* Percentage not meaningful.

(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 $570.9 million, or 135%, from $421.7 million in 2020 to $992.6 million in 2021. The increase in revenue between periods was primarily due to an increase in the number of COVID-19 billable tests delivered, as well as a higher average price per billable test.

The average price of the billable tests we delivered increased $4, or 4%, from $96 in 2020 to $100 in 2021. The increase was due to the mix of tests we delivered in 2021 and the mix of customers ordering tests in these periods, who may order tests at different rates depending on the arrangements we have negotiated with them.

Revenue from non-U.S. sources increased $7.2 million, or 113%, from $6.4 million in 2020 to $13.6 million in 2021. The increase in revenue from non-U.S. sources between periods were primarily due to increased sales of our traditional genetic testing services to customers in China through FF Gene Biotech which contributed $6.6 million in total revenue in 2021.

The number of billable tests we delivered in 2021 increased approximately 5.6 million, from 4.4 million in 2020 to 10.0 million. The increases were primarily attributable to the expansion of our test menu, including our COVID-19 tests launched in 2020, and increase in sales to certain of our existing and new customers.

Aggregating customers that are under common control, one customer, the County of Los Angeles, contributed 26% of our revenue in 2021, and two customers, the County of Los Angeles and San Bernardino County, contributed 28% and 10% of our revenue in 2020. respectively.

Cost of Revenue

Cost of revenue increased $125.7 million, or 140%, from $89.8 million in 2020 to $215.5 million in 2021. The increase was primarily due to increases of $43.3 million in reagent and supply expenses related to increased billable tests delivered, $35.9 million in consulting and outside labor expense related to increase of outside labor for production 2021, $18.0 million in personnel costs and equity-based compensation related to increased headcount and the market price of the Company's stock, $11.6 million in shipping and handling costs related to delivery of collection kits for of COVID-19 tests, $6.8 million in software expense related to usage of COVID-19 testing software, $5.8 million in depreciation related to medical lab equipment purchased, and $2.6 million in facilities primarily related to certain modifications made to our mini vans used for our COVID-19 business.

Cost per billable test delivered increased $2, or 10% from $20 in 2020 to $22 in 2021 as the increase in our cost of revenue was greater than in the number of billable tests we delivered primarily due to increased shipping and handling costs for our at-home COVID-19 testing services and increased outside labor related to testing site operations.

Our gross profit increased $445.1 million, or 134%, from $331.9 million in 2020 to $777.1 million in 2021. The increase in gross profit was primarily due to the increase in revenue from our COVID-19 tests that exceeded the increase in cost of revenue described above. Our gross profit as a percentage of revenue, or gross margin, decreased from 78.7% to 78.3% due to the increased cost per billable test delivered for reasons stated above.

Research and Development

Research and development expenses increased $12.6 million, or 109%, from $11.6 million in 2020 to $24.2 million in 2021. The increase was primarily due to increases of $8.8 million in personnel costs and equity-based compensation related to increased headcount and the market price of the Company's stock and $2.0 million in reagent and supply expenses related to increased reagent usage for COVID-19 research.

Selling and Marketing

Selling and marketing expenses increased $9.5 million, or 63%, from $15.0 million in 2020 to $24.4 million in 2021. The increase was primarily due to increases of $8.8 million in personnel costs and equity-based compensation related to increased commission expense and market price of the Company's stock, $2.4 million in consulting and outside labor costs for increased outside labor used, partially offset by a decrease of $2.4 million in marketing supplies and related shipping costs.

General and Administrative

General and administrative expenses increased $35.5 million, or 233%, from $15.2 million in 2020 to $50.7 million in 2021. The increase was primarily due to increases of $13.4 million in personnel costs and equity-based compensation related to increased bonus accrued for executive officers, increased headcount and the market price of the Company's stock, $7.8 million additional provision for credit losses, $3.2 million in software and licensing related to increased number of billings, $2.9 million in consulting and $2.6 million in legal expenses related to business acquisitions and internal control compliance, $1.5 million in accounting expenses related to financial statement and internal control audit and reviews, $1.1 million in facility repair and maintenance, and $1.0 million in business insurance expenses.

Amortization of Intangible Assets

Amortization of intangible assets represents amortization expenses on the intangible assets arose from the business combinations and a patent purchased in 2021.

Interest and Other Income, Net

Interest income, net was $1.3 million and $1.5 million for 2021 and 2020, respectively. This income mainly related to interest received on various investments in marketable securities and holding gain or loss on marketable equity securities.

Other income (expense) was not significant for 2021 or 2020. The primary components of other income (expense) for 2021 and 2020 were rental income net of rental expenses and foreign currency exchange gains (losses).

Provision for Income Taxes

Provision for income taxes were $174.8 million and $72.5 million in 2021 and 2020, respectively. The effective income tax rate was 25.8% and 24.9% of income before income taxes for 2021 and 2020, respectively. The increase in tax expense for 2021 relative to 2020 was primarily attributable to a significant increase in income for the year ended December 31, 2021.

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

Gain (Loss) on Equity-Method Investments

We recognized a gain of $3.7 million in 2021 related to our preexisting equity interest at FF Gene Biotech as a result of remeasuring to fair value our 30% equity interest held before the FF Gene Biotech Acquisition. The fair value of the preexisting equity interest was determined based on the characteristics before consummating the FF Gene Biotech Acquisition and estimated by applying income approach and utilizing the discounted cash flow method.

Impairment loss in equity-method investments was $4.4 million in 2020 related to our 30% ownership interest in FF Gene Biotech and 25% ownership interest in BostonMolecules.

Equity Loss in Investee

Equity loss in investee was $488,000 in 2020 related to our 30% ownership interest in FF Gene Biotech. There was no such loss in 2021.

Net Loss Attributable to Noncontrolling Interest

Net loss attributable to noncontrolling interest represents net loss of FF Gene Biotech attributable to the minority shareholders, Xilong Scientific and FJIP.

Liquidity and Capital Resources

Liquidity and Sources of Cash

We had $935.5 million and $431.9 million in cash, cash equivalents and marketable securities as of December 31, 2021 and 2020, respectively. Our marketable securities primarily consist of equity securities and corporate bonds, municipal bonds, and U.S. government and U.S. agency debt securities as of December 31, 2021 and 2020.

Initially after commencing operations in May 2012, our operations were 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.

On August 30, 2019, we entered into an Equity Distribution Agreement, or the 2019 Equity Distribution Agreement, with Piper, as sales agent, which was subsequently amended on August 4, 2020. Pursuant to the 2019 Equity Distribution Agreement, we offered and sold an aggregate of 104,000 shares of our common stock at a weighted-average net selling price of $9.37 per share, which resulted in $979,000 of net proceeds to the Company during the year ended December 31, 2019, and we sold an aggregate of 1.1 million shares of our common stock at a weighted-average net selling price of $38.50 per share, which resulted in $42.7 million of net proceeds to the Company during the year ended December 31, 2020. Shares sold under the 2019 Equity Distribution Agreement were offered and sold pursuant to the Company's 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 prospectus supplements and accompanying base prospectus filed with the SEC on August 30, 2019, May 6, 2020 and August 5, 2020.

On November 13, 2019, we entered into a purchase agreement with Piper, as representative of the several underwriters, pursuant to which we sold 2.7 million shares of our common stock at a price of $10.52 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 the Company's registration statement on Form S-3 (File No. 333-233227), and a prospectus supplement and accompanying base prospectus filed with the SEC on November 13, 2019.

On September 25, 2020, we entered into the September 2020 Equity Distribution Agreement, with Piper as sales agent, pursuant to which we offered and sold an aggregate of 2.8 million shares of our common stock at a weighted-average net selling price of $42.90 per share, which resulted in $122.1 million of net proceeds to the Company. Shares sold under the September 2020 Equity Distribution Agreement were offered and sold pursuant to the Company's registration statement on Form S-3 (File No. 333-239964) filed with the SEC on July 21, 2020, as amended on August 5, 2020, and declared effective on August 12, 2020, and a prospectus supplement and accompanying base prospectus filed with the SEC on September 25, 2020.

On November 20, 2020, we entered into the November 2020 Equity Distribution Agreement, with Piper, Oppenheimer & Co. Inc., and BTIG LLC, as sales agents, pursuant to which we may offer and sell, from time to time through Piper, shares of our common stock having an aggregate offering price of up to $175.0 million. Piper may receive a commission of up to 3% of the gross proceeds received by the Company for sales pursuant to the November 2020 Equity Distribution Agreement. During the year ended December 31, 2020, the Company sold an aggregate of 2.0 million shares of our common stock pursuant to the November 2020 Equity Distribution Agreement at a weighted-average net selling price of $48.70 per share, which resulted in $99.1 million of net proceeds to the Company. During the year ended December 31, 2021, we sold approximately 1.1 million shares of our common stock pursuant to the November 2020 Equity Distribution Agreement at a weighted-average net selling price of $64.83 per share, which resulted in $72.0 million of net proceeds to the Company. Shares sold under the November 2020 Equity Distribution Agreement were offered and sold pursuant to the Company's registration statement on Form S-3 (File No. 333-239964) filed with the SEC on July 21, 2020, as amended on August 5, 2020, and declared effective on August 12, 2020, and a prospectus supplement and accompanying base prospectus filed with the SEC on November 20, 2020.

We believe our existing cash, cash equivalent, short-term marketable securities, along with cash from 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 in certain prior periods were attributable to a variety of non-cash charges, including equity-based compensation expenses. As a result, in spite of the losses we recorded during these periods, cash provided by continuing operations has been mostly positive since 2015 and has significantly contributed to our ability to meet our liquidity needs, including paying for capital expenditures. Additionally, if our business continues to grow and we are able to achieve increased efficiencies and economies of scale in line with this growth, we expect 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 during 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, factors relating to the ongoing COVID-19 pandemic, 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 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.

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. Additional funding may not be available to us when needed, on acceptable terms or at all. For example, the COVID-19 pandemic caused extreme disruption and volatility in the global capital markets, which could reduce our ability to access capital. 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,	
	2021	2020
	(in thousands)	
Net cash provided by operating activities	$ 538,577	$ 140,628
Net cash used in investing activities	$ (546,548)	$ (326,438)
Net cash provided by financing activities	$ 85,405	$ 261,251

Operating Activities

Cash provided by operating activities in 2021 was $538.6 million. The difference between net income and cash provided by operating activities for the period was primarily due to the effect of $15.9 million in equity-based compensation expenses and $11.0 million in the depreciation and amortization. Cash provided by operating activities decreased between periods primarily due to decreases of $52.5 million in income tax payable due to tax payments made during the current period and $12.2 million in accounts payable partially offset by the negative impact of a decrease of $42.3 million in accounts receivable mainly due to the timing of collections from customers and an increase of $13.1 million in accrued and other liabilities primary due to increased customer deposits and bonus accrual.

Cash provided by operating activities in 2020 was $140.6 million. The difference between net income and cash provided by operating activities for the period was primarily due to the effect of $8.2 million in equity-based compensation expenses, $4.4 million in impairment loss from equity-method investments and $3.0 million in the depreciation of assets. Cash provided by operating activities decreased between periods primarily due to the negative effect of increases of $178.5 million in accounts receivable mainly due to the timing of collections from customers and $21.1 million in other current assets related to purchases of an increased amount of reagents and supplies, partially offset by increases of $53.3 million in income tax payable due to a significant increase in income,

$32.7 million in accrued and other liabilities related to contract liabilities, and $22.6 million in accounts payable mainly due to timing of payments.

Investing Activities

Cash used in investing activities in 2021 was $546.5 million, which primarily related to $710.5 million in purchases of marketable securities, $61.9 million related to business acquisitions, $23.8 million related to purchase of fixed assets consisting mainly medical laboratory equipment and building improvement, and $20.0 million related to purchase of redeemable preferred stock, partially offset by proceeds of $185.7 million related to sales of marketable securities and $83.8 million related to maturities of marketable securities.

Cash used in investing activities in 2020 was $326.4 million, which primarily related to $324.4 million in purchases of marketable securities, $35.1 million in purchases of fixed assets consisting mainly of medical laboratory equipment, real property located in El Monte, California, a 2008 Cessna Citation Sovereign aircraft, computer hardware and building and land improvements, $2.6 million in investment in BostonMolecules and direct costs associates with the investment, and purchase equipment with an aggregate fair value of $1.4 million contributed to FF Gene Biotech, partially offset by maturities of $19.9 million of marketable debt securities and proceeds of $17.1 million from sales of marketable securities.

Financing Activities

Cash provided by financing activities in 2021 was $85.4 million, which primarily related to $89.5 million proceeds from the November 2020 Equity Distribution Agreement, partially offset by $4.2 million in common stock withholding for employee tax obligations.

Cash provided by financing activities in 2020 was $261.3 million, which primarily represents net proceeds from sales of shares of our common stock made pursuant to various equity distribution agreements with Piper and $15.0 million borrowed from a margin loan collateralized by marketable debt securities held by the Company, to purchase real property located in El Monte, California.

Material Cash Requirements and Contractual Obligations as of December 31, 2021

As of December 31, 2021, we have an outstanding balance of $15.1 million in our margin account and $6.1 million in notes payable which is payable on December 31, 2022.

The following summarizes our contractual obligations as of December 31, 2021:

	Payments Due by Period				
	Total	Less than 1 year	1-3 years	3-5 years	More than 5 years
			(in thousands)		
Operating lease obligations (1)	$ 7,782	$ 2,037	$ 2,733	$ 1,932	$ 1,080
Finance lease obligations(2)	1,874	383	759	732	—
Purchase obligations(3)	11,584	11,584	—	—	—
Total contractual obligations	$ 21,240	$ 14,004	$ 3,492	$ 2,664	$ 1,080

(1) Represents non-cancelable operating leases. For further information, refer to Note 9 to the Consolidated Financial Statements.
(2) Represents non-cancelable finance leases. For further information, refer to Note 9 to the Consolidated Financial Statements.
(3) Represents non-cancelable purchase obligations for medical lab equipment, reagents and other supplies, see Note 8 to the Consolidated Financial Statements.

Critical Accounting Policies and Use of Estimates

This discussion and analysis is based on our consolidated financial statements included in this report, which have been prepared in accordance with U.S. Generally Accepted Accounting Principles, 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, including but not limited to valuation of intangible assets and goodwill in recent business combinations and the potential impacts arising from the recent global pandemic related to COVID-19. As the extent and duration of the impacts from

COVID-19 remain unclear, our estimates and assumptions may evolve as conditions change. 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 COVID-19, molecular diagnostic and genetic testing services. We currently receive payments from: insurance, institutional customers, including hospitals, medical institutions, other laboratories, governmental bodies, municipalities and large corporations, and patients who pay directly.

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 primarily delivered electronically. We bill certain customers for shipping and handling fees incurred by us associated with COVID-19 tests, and shipping and handling fees billed to customers are included in revenue, and shipping and handling fees incurred are included in cost of revenue in the accompanying Consolidated Statements of Operations.

While the transaction price is typically stated within the contract, we may accept payments from third-party payors that are less than the contractually stated price and is therefore variable consideration. Accounting for 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 our out-of-network status with the majority of insurance payors for COVID-19 tests, estimation of the transaction price represents variable consideration. We estimate that the variable consideration paid by insurance payors will approximate our self-pay rate for COVID-19 tests that is published on our website, which is the rate established by the Center for Medicare & Medicaid Services, as supported by a historical reimbursement trend analysis.

Valuation of Goodwill and Intangible Assets

The valuation of assets acquired in a business combination and asset impairment reviews require the use of significant estimates and assumptions. The acquisition method of accounting for business combinations requires us to estimate the fair value of assets acquired, liabilities assumed, and any noncontrolling interest in an acquired business to properly allocate purchase price consideration between assets that are depreciated or amortized and goodwill.

Long-lived assets, including property and equipment and intangible assets, excluding goodwill, are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. An impairment loss would be recognized when estimated future cash flows expected from an asset and its eventual disposition is less than the carrying amount.

We evaluate goodwill annually or more frequently if events or changes in circumstances indicate that goodwill may be impaired. In accordance with guidance related to impairment testing, we have the option to first assess qualitative factors to determine whether it is necessary to perform the quantitative goodwill impairment test. If the qualitative assessment option is not elected, or if the qualitative assessment indicates that it is more likely than not that the fair value is less than its carrying amount, a quantitative analysis is then performed. The quantitative analysis, if performed, compares the fair value of the reporting unit with its respective carrying amount, including goodwill. If the fair value of the reporting unit exceeds its carrying amount, including goodwill, goodwill is considered not to be impaired and no additional steps are necessary. If the fair value is less than the carrying amount, including goodwill, then an impairment adjustment must be recorded up to the carrying amount of goodwill.

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.

Off-Balance Sheet Arrangements

We did not have, and do not currently have, any off-balance sheet arrangements during the periods presented, 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, 2021. 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, 2021.

Internal Control over Financial Reporting

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, 2021, that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

In August 2021, we completed the acquisition of CSI. See Note 15 of "Notes to Consolidated Financial Statements" for more information. We are currently integrating CSI into our operations and internal control processes. As we complete this integration, we are analyzing, evaluating, and where necessary, making changes in control and procedures related to the CSI business, which we expect to complete within one year after the date of acquisition. Pursuant to the SEC's guidance that an assessment of a recently acquired business may be omitted from the scope of an assessment in the year of acquisition, the scope of our assessment of the effectiveness of our internal controls over financial reporting at December 31, 2021 excludes CSI to the extent that they are not yet integrated into our internal controls environment.

Management's Annual Report on Internal Control over Financial Reporting.

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as defined in Rule 13a-15(f) of the Exchange Act. Our management conducted an evaluation of the effectiveness of our internal control over financial reporting based on the framework in *Internal Control—Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework). Based on this evaluation, management concluded that our internal control over financial reporting was effective as of December 31, 2021. Management reviewed the results of its assessment with our Audit and Compliance Committee. The effectiveness of our internal control over financial reporting, excluding controls at components, as of December 31, 2021 has been audited by Deloitte & Touche LLP, an independent registered public accounting firm, as stated in its report, which is included in Item 8 of this Annual Report on Form 10-K.

As permitted by the Securities and Exchange Commission, companies are allowed to exclude acquisitions from their assessment of internal control over financial reporting during the first year of an acquisition. In August 2021, we acquired CSI. Pursuant to applicable rules, because we have not yet fully incorporated the internal controls and procedures of the acquired entity into our internal control over financial reporting, management excluded certain elements related to the acquired business from our assessment of the effectiveness of internal control over financial reporting as of December 31, 2021. The excluded elements of the CSI business represented 2% of our revenue and 6% of our total assets as of and for the year ended December 31, 2021.

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.

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

Opinion on Internal Control over Financial Reporting

We have audited the internal control over financial reporting of Fulgent Genetics, Inc. and subsidiaries (the “Company”) as of December 31, 2021, based on criteria established in *Internal Control — Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). In our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2021, based on criteria established in *Internal Control — Integrated Framework (2013)* issued by COSO.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the consolidated financial statements as of and for the year ended December 31, 2021, of the Company and our report dated February 28, 2022, expressed an unqualified opinion on those financial statements.

As described in Management’s Annual Report on Internal Control over Financial Reporting, management excluded from its assessment of internal control over financial reporting certain elements related to Cytometry Specialists, Inc, ("CSI, Inc") which was acquired in August 2021. The excluded elements of CSI, Inc represented 2% of the Company’s revenue and 6% of the Company’s total assets as of and for the year ended December 31, 2021. Accordingly, our audit did not include the internal control over financial reporting for certain elements related to CSI, Inc.

Basis for Opinion

The Company’s management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in Management’s Annual Report on Internal Control over Financial Reporting. Our responsibility is to express an opinion on the Company’s internal control over financial reporting based on our audit. We are a public accounting firm registered with the 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 audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

Definition and Limitations of Internal Control over Financial Reporting

A company’s internal control over financial reporting is a process designed 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. A company’s internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company’s assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

/s/ DELOITTE & TOUCHE LLP

Los Angeles, California

February 28, 2022

Item 9B. Other Information.

None

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections.

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 2022 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, 2021.

Item 11. Executive Compensation.

The information required by this item is incorporated by reference to the definitive proxy statement for our 2022 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, 2021.

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 2022 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, 2021.

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 2022 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, 2021.

Item 14. Principal Accounting Fees and Services.

The information required by this item is incorporated by reference to the definitive proxy statement for our 2022 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, 2021.

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:

(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.

None.

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.	10-K	001-37894	4.3	3/13/2020	
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.	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	
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	

Exhibit Number	Description	Form	File Number	Incorporated by Reference Exhibit	Filing Date	Filed Herewith
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	
10.27	Amendment No. 1 to Equity Distribution Agreement, dated August 4, 2020, by and between Fulgent Genetics, Inc. and Piper Sandler & Co.	8-K	001-37894	1.1	8/5/2020	
10.28	Equity Distribution Agreement, dated as of September 24, 2020, by and between Fulgent Genetics, Inc. and Piper Sandler & Co.	8-K	001-37894	1.1	9/25/2020	
10.29	Equity Distribution Agreement, dated as of November 20, 2020, by and between Fulgent Genetics, Inc. and Piper Sandler & Co., BTIG, LLC, and Oppenheimer & Co. Inc.	8-K	001-37894	1.1	11/20/2020	
10.30	Fulgent Genetics, Inc. Amended and Restated 2016 Omnibus Incentive Plan	8-K	001-37894	10.1	5/21/2018	
10.31	Fulgent Genetics, Inc. Amended and Restated 2016 Omnibus Incentive Plan	8-K	001-37894	10.1	9/18/2020	
10.32^	Agreement for Purchase and Sale of Property, dated July 23, 2020	8-K	001-37894	2.1	10/21/2020	
10.33^	Aircraft Purchase Agreement, dated August 18, 2020, by and between ServiceMaster Acceptance Corporation and the Company	10-Q	001-37894	10.2	11/9/2020	
10.34	Commercial Sublease Agreement, dated July 1st, 2020, between Medscan Laboratories Inc. and Fulgent Genetics, Inc.; Commercial Lease Agreement, dated June 17, 2020, by and between Medscan Laboratories Inc. and Ten-Voss Ltd.	10-K	001-37894	10.34	3/8/2021	
10.35	Commercial Lease Assignment & Assumption, dated January 11, 2021 by and between Ten-Voss Ltd., Medscan Laboratories, Inc. and Fulgent Genetics, Inc.	10-K	001-37894	10.35	3/8/2021	
10.36	Commercial Lease Addendum, dated February 1, 2021, by and between E & E Plaza LLC and Fulgent Genetics, Inc.	10-K	001-37894	10.36	3/8/2021	
10.37#	Employment Agreement, dated March 8, 2021, by and among Fulgent Therapeutics, LLC, Fulgent Genetics, Inc. and Jian Xie.	10-K	001-37894	10.37	3/8/2021	
10.38#	Severance Agreement, dated March 8, 2021, by and among Fulgent Therapeutics LLC, Fulgent Genetics, Inc. and Jian Xie.	10-K	001-37894	10.38	3/8/2021	
10.39#^	Amended and Restated Non-Employee Director Compensation Policy.	10-Q	001-37894	10.1	5/7/2021	
10.40§	Restructuring Agreement of Fujian Fujun Gene Biotech Co., Ltd.	10-Q	001-37894	10.1	8/10/2021	

Exhibit Number	Description	Form	File Number	Incorporated by Reference Exhibit	Filing Date	Filed Herewith
10.41^	Amended and Restated Commercial Lease Agreement, dated May 6, 2016, by and between Store Master Funding IX, LLC and Cytometry Specialists, Inc.					X
21.1	Subsidiaries of the registrant.					X
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	Inline XBRL Instance Document – the instance document does not appear in the Interactive Data File because XBRL tags are embedded within the Inline XBRL document.					X
101.SCH	Inline XBRL Taxonomy Extension Schema Document					X
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document					X
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document					X
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document					X
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document					X
104	Cover Page Interactive Data File (embedded within the Inline XBRL 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.

^ Certain exhibits and schedules have been omitted pursuant to Item 601(a)(5) of Regulation S-K. The Company hereby undertakes to furnish supplementally a copy of any omitted exhibit or schedule upon request by 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: February 28, 2022

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)	February 28, 2022
/s/ Paul Kim Paul Kim	Chief Financial Officer (principal financial and accounting officer)	February 28, 2022
/s/ John Bolger John Bolger	Director	February 28, 2022
/s/ Yun Yen Yun Yen	Director	February 28, 2022
/s/ Linda Marsh Linda Marsh	Director	February 28, 2022

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

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, 2021 and 2020, the related consolidated statements of operations, comprehensive income (loss), stockholders' equity, and cash flows, for each of the three years in the period ended December 31, 2021, 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, 2021 and 2020, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2021, in conformity with accounting principles generally accepted in the United States of America.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the Company's internal control over financial reporting as of December 31, 2021, based on criteria established in *Internal Control — Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated February 28, 2022, expressed an unqualified opinion on the Company's internal control over financial reporting.

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 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. 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.

Critical Audit Matter

The critical audit matter communicated below is a matter arising from the current-period audit of the financial statements that was communicated or required to be communicated to the audit committee and that (1) relates to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective, or complex judgments. The communication of critical audit matters does not alter in any way our opinion on the financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing separate opinions on the critical audit matters or on the accounts or disclosures to which they relate.

Business Combinations—CSI Acquisition — Refer to Notes 2 and 15 to the financial statements

Critical Audit Matter Description

In August 2021, the Company acquired 100% of the outstanding equity of Cytometry Specialists, Inc., or CSI, a multi-site reference laboratory business in the United States. This acquisition was accounted for under the acquisition method of accounting for business combinations. The Company allocated the purchase price to tangible and identified intangible assets acquired and liabilities assumed based on their respective fair values, including a customer relationships intangible asset in the amount of $27.6 million.

We identified the fair value of the customer relationships intangible asset as a critical audit matter because of the significant estimates and assumptions management makes to determine its fair value. This required a high degree of auditor judgment and an increased extent of effort, including the need to involve our fair value specialists, when performing audit procedures to evaluate the reasonableness of management’s forecasts of future cash flows, the selection of the discount rates, and customer attrition rate.

How the Critical Audit Matter Was Addressed in the Audit

Our audit procedures related to the fair value of the customer relationships intangible asset for CSI, included the following, among others:

- We tested the operating effectiveness of controls over the valuation of the customer relationships intangible asset, including management's controls over projected future cash flows, the discount rates, and customer attrition rate.
- We assessed the reasonableness of management's key estimates and assumptions by comparing the estimates and assumptions to historical results, relevant peer companies, and third-party industry reports.
- With the assistance of our fair value specialists, we evaluated the valuation assumptions by:
  - Testing the source information underlying the determination of the valuation assumptions and testing the mathematical accuracy of the calculations.
  - Developing a range of independent estimates for certain assumptions and comparing those to the assumptions selected by management.

/s/ DELOITTE & TOUCHE LLP
Los Angeles, California

February 28, 2022

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

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

	December 31,	
	2021	2020
Assets		
Current assets		
Cash and cash equivalents	$ 164,894	$ 87,426
Marketable securities	285,605	211,941
Trade accounts receivable, net of allowance for credit losses of $11,217 and $1,898 as of December 31, 2021 and 2020, respectively	138,912	183,857
Other current assets	22,549	40,392
Total current assets	611,960	523,616
Marketable securities, long-term	485,047	132,502
Redeemable preferred stock investment	21,965	—
Fixed assets, net	62,287	40,199
Intangible assets, net	35,914	—
Goodwill	50,897	—
Other long-term assets	10,650	4,144
Total assets	$ 1,278,720	$ 700,461
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable	$ 20,494	$ 26,488
Accrued liabilities	17,689	8,446
Income tax payable	787	53,319
Contract liabilities	14,570	26,576
Customer deposit	19,806	185
Investment margin loan	15,137	15,019
Contingent consideration	10,000	—
Notes payable	6,147	—
Other current liabilities	680	82
Total current liabilities	105,310	130,115
Unrecognized tax benefits	725	377
Other long-term liabilities	6,805	582
Total liabilities	112,840	131,074
Commitments and contingencies (Note 8)		
Stockholders' equity		
Common stock, $0.0001 par value per share, 50,000 shares authorized, 30,160 and 28,178 shares issued and outstanding at December 31, 2021 and 2020, respectively	3	3
Preferred stock, $0.0001 par value per share, 1,000 shares authorized, no shares issued or outstanding at December 31, 2021 and 2020	—	—
Additional paid-in capital	501,908	418,065
Accumulated other comprehensive (loss) income	(759)	438
Retained earnings	657,597	150,881
Total Fulgent stockholders' equity	1,158,749	569,387
Noncontrolling interest	7,131	—
Total stockholders' equity	1,165,880	569,387
Total liabilities and stockholders' equity	$ 1,278,720	$ 700,461

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

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

	Year Ended December 31,		
	2021	2020	2019
Revenue	$ 992,584	$ 421,712	$ 32,528
Cost of revenue	215,533	89,807	14,107
Gross profit	777,051	331,905	18,421
Operating expenses:			
Research and development	24,219	11,580	6,537
Selling and marketing	24,439	14,952	5,898
General and administrative	50,732	15,215	6,414
Amortization of intangible assets	1,708	—	—
Total operating expenses	101,098	41,747	18,849
Operating income (loss)	675,953	290,158	(428)
Interest and other income, net	1,347	1,526	837
Income before income taxes, equity loss in investee and gain (loss) on equity-method investments	677,300	291,684	409
Provision for income taxes	174,795	72,532	43
Income before equity loss in investee and gain (loss) on equity-method investments	502,505	219,152	366
Equity loss in investee	—	(488)	(777)
Gain (loss) on equity-method investments	3,734	(4,354)	—
Net income (loss) from consolidated operations	506,239	214,310	(411)
Net loss attributable to noncontrolling interests	1,125	—	—
Net income (loss) attributable to Fulgent	$ 507,364	$ 214,310	$ (411)
Net income (loss) per common share attributable to Fulgent:			
Basic	$ 17.25	$ 9.44	$ (0.02)
Diluted	$ 16.38	$ 8.91	$ (0.02)
Weighted-average common shares:			
Basic	29,408	22,694	18,709
Diluted	30,976	24,056	18,709

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

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

	Year Ended December 31,		
	2021	2020	2019
Net income (loss) from consolidated operations	$ 506,239	$ 214,310	$ (411)
Other comprehensive income (loss):			
Foreign currency translation gain (loss)	456	20	(17)
Net unrealized (loss) gain on available-for-sale debt securities, net of tax	(1,548)	272	198
Comprehensive income (loss) from consolidated operations	505,147	214,602	(230)
Net loss attributable to noncontrolling interest	1,125	—	—
Foreign currency translation gain attributable to noncontrolling interest	(105)	—	—
Comprehensive loss attributable to noncontrolling interest	1,020	—	—
Comprehensive income (loss) attributable to Fulgent	$ 506,167	$ 214,602	$ (230)

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

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

	Fulgent Stockholders' Equity							
	Shares	Amount	Additional Paid-In Capital	Accumulated Other Comprehensive Income (Loss)	Retained Earnings (Accumulated Deficit)	Fulgent Stockholders' Equity	Noncontrolling Interest	Total Equity
Balance at January 1, 2019	18,172	$ 2	$ 114,203	$ (35)	$ (63,018)	$ 51,152	$ —	$ 51,152
Equity-based compensation	—	—	3,209	—	—	3,209	—	3,209
Exercise of common stock options	100	—	38	—	—	38	—	38
Restricted stock awards	434	—	—	—	—	—	—	—
Issuance of common stock at an average of $9.37 per share, net	104	—	979	—	—	979	—	979
Issuance of common stock at an average of $10.34 per share, net	2,674	—	27,650	—	—	27,650	—	27,650
Common stock withholding for employee tax obligations	(1)	—	(21)	—	—	(21)	—	(21)
Other comprehensive gain, net	—	—	—	181	—	181	—	181
Net loss	—	—	—	—	(411)	(411)	—	(411)
Balance at December 31, 2019	21,483	2	146,058	146	(63,429)	82,777	—	82,777
Equity-based compensation	—	—	8,157	—	—	8,157	—	8,157
Exercise of common stock options	56	—	104	—	—	104	—	104
Restricted stock awards	655	—	—	—	—	—	—	—
Issuance of common stock at an average of $38.50 per share, net	1,108	—	42,655	—	—	42,655	—	42,655
Issuance of common stock at an average of $42.90 per share, net	2,846	1	122,102	—	—	122,103	—	122,103
Issuance of common stock at an average of $48.70 per share, net	2,034	—	99,051	—	—	99,051	—	99,051
Common stock withholding for employee tax obligations	(4)	—	(62)	—	—	(62)	—	(62)
Other comprehensive gain, net	—	—	—	292	—	292	—	292
Net income	—	—	—	—	214,310	214,310	—	214,310
Balance at December 31, 2020	28,178	3	418,065	438	150,881	569,387	—	569,387
Equity-based compensation	—	—	15,882	—	—	15,882	—	15,882
Exercise of common stock options	76	—	86	—	—	86	—	86
Restricted stock awards	836	—	—	—	—	—	—	—
Issuance of common stock at an average of $64.83 per share, net	1,111	—	72,030	—	—	72,030	—	72,030
Common stock withholding for employee tax obligations	(41)	—	(4,155)	—	—	(4,155)	—	(4,155)
Cumulative effect of accounting change	—	—	—	—	(887)	(887)	—	(887)
Cumulative tax effect of accounting change	—	—	—	—	239	239	—	239
Noncontrolling interest assumed related to acquisitions	—	—	—	—	—	—	8,151	8,151
Other comprehensive loss, net	—	—	—	(1,197)	—	(1,197)	105	(1,092)
Net income (loss)	—	—	—	—	507,364	507,364	(1,125)	506,239
Balance at December 31, 2021	30,160	$ 3	$ 501,908	$ (759)	$ 657,597	$ 1,158,749	$ 7,131	$ 1,165,880

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,		
	2021	**2020**	**2019**
Cash flow from operating activities:			
Net income (loss) from consolidated operations	$ 506,239	$ 214,310	$ (411)
Adjustments to reconcile net income (loss) to net cash provided by operating activities:			
Equity-based compensation	15,882	8,157	3,209
Depreciation and amortization	11,004	2,962	2,107
Noncash lease expense	1,154	409	413
Loss on disposal of fixed asset	850	672	11
Amortization of premium of marketable securities	7,596	857	106
Provision for credit losses	8,931	1,170	189
Deferred taxes	(8,188)	(1,775)	(21)
Unrecognized tax benefits	348	377	—
Net loss on marketable securities	1,186	90	—
Equity loss in investee	—	488	777
(Gain) loss in equity-method investments	(3,734)	4,354	—
Other	(15)	8	52
Changes in operating assets and liabilities:			
Accounts receivable	42,300	(178,480)	(839)
Other current and long-term assets	7,804	(21,149)	374
Accounts payable	(12,206)	22,617	(329)
Accrued liabilities and other liabilities	13,081	32,655	264
Income tax payable	(52,532)	53,295	24
Operating and finance lease liabilities	(1,123)	(389)	(409)
Net cash provided by operating activities	538,577	140,628	5,517
Cash flow from investing activities:			
Purchases of fixed assets	(23,812)	(35,130)	(1,182)
Purchases of intangible assets	(32)	—	—
Proceeds from sale of fixed assets	63	8	—
Purchase of marketable securities	(710,490)	(324,359)	(52,077)
Purchase of redeemable preferred stock	(20,000)	—	—
Maturities of marketable securities	83,842	19,919	24,350
Proceeds from sale of marketable securities	185,749	17,095	—
Acquisition of businesses, net of cash acquired	(61,868)	—	—
Investment in equity-method investees	—	(3,971)	(137)
Net cash used in investing activities	(546,548)	(326,438)	(29,046)
Cash flow from financing activities:			
Proceeds from public offerings of common stock, net of issuance costs	89,475	246,190	28,758
Proceeds from noncontrolling interest	10	—	—
Proceeds from exercise of stock options	86	104	38
Principal paid for finance lease	(7)	—	—
Common stock withholding for employee tax obligations	(4,155)	(62)	(21)
Repayment of notes payable	(4)	—	—
Borrowing under margin account	—	15,019	—
Net cash provided by financing activities	85,405	261,251	28,775
Effect of exchange rate changes on cash and cash equivalents	34	20	(17)
Net increase in cash and cash equivalents	77,468	75,461	5,229
Cash and cash equivalents at beginning of period	87,426	11,965	6,736
Cash and cash equivalents at end of period	$ 164,894	$ 87,426	$ 11,965
Supplemental disclosures of cash flow information:			
Income taxes paid	$ 237,069	$ 20,612	$ 20
Supplemental disclosures of non-cash investing and financing activities:			
Contingent consideration for business acquisition included in current liabilities	$ 10,000	$ —	$ —
Purchases of fixed assets in accounts payable	$ 1,075	$ 3,402	$ 557
Operating lease right-of-use assets obtained in exchange for lease liabilities	$ 1,797	$ 402	$ 110
Operating lease right-of-use assets reduced due to lease modification or termination	$ 399	$ 1,853	$ —
Public offerings proceeds in other receivable included in other current assets	$ —	$ 17,799	$ —
Finance lease right-of-use assets obtained in exchange for lease liabilities	$ 1,693	$ —	$ —
Public offerings costs included in accounts payable	$ 5	$ 359	$ 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, or U.S. GAAP. These financial statements include the assets, liabilities, revenues and expenses of all 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 (i) the power to direct the economically significant activities of the entity and (ii) 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 and an affiliated professional corporation, or PC, collectively referred to as the Company, unless otherwise noted or the context otherwise requires, is a technology company offering large-scale COVID-19 testing services, molecular diagnostic testing services and comprehensive genetic testing designed to provide physicians with clinically actionable diagnostic information to improve the quality of patient care. The PC was established in November 2021, with which the Company has a management services arrangement, and the PC provides professional pathology and related professional services to its patients. A cornerstone of the Company's business is its ability to provide expansive options and flexibility for all clients' unique testing needs. To this end, the Company has developed a proprietary technology platform allowing it to offer a broad and flexible test menu and to continually expand and improve its proprietary genetic reference library, while maintaining accessible pricing, high accuracy and competitive turnaround times. Combining next generation sequencing, or NGS, with its technology platform, the Company performs 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.

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 and assumptions that affect the reported amounts of assets and liabilities at the date of the financial statements, as well as the reported amounts of revenue and expenses during the reporting periods. These estimates, judgments and assumptions are based on 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, including but not limited to the potential impacts arising from the recent global pandemic related to COVID-19. As the extent and duration of the impacts from COVID-19 remain unclear, the Company's estimates and assumptions may evolve as conditions change. Actual results could differ significantly 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 credit losses, (iii) the useful lives of fixed assets and intangible assets, (iv) estimates of tax liabilities, and (v) valuation of intangible assets and goodwill.

Principles of Consolidation

The accompanying consolidated financial statements include the accounts of the Company and its subsidiaries and PC. 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.

Marketable Securities

All marketable debt securities, which consist of corporate debt securities, municipal bonds, U.S. government and agency debt securities, and Yankee debt securities issued by foreign governments or entities and denominated in U.S. dollars have been classified

as “available-for-sale,” and are carried at fair value. Net unrealized gains and losses, net of any related tax effects, are excluded from earnings and are included in other comprehensive income (loss) and reported as a separate component of stockholders’ equity until realized. Realized gains and losses on marketable debt securities are included in interest and other income, net, in the accompanying Consolidated Statements of Operations. The cost of any marketable debt securities sold is based on the specific-identification method. The amortized cost of marketable debt securities is adjusted for amortization of premiums and accretion of discounts to maturity. Interest on marketable debt securities is included in interest and other income, net. 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’s investments in marketable equity securities are measured at fair value with the related gains and losses, realized and unrealized, recognized in interest and other income, net, in the accompanying Consolidated Statements of Operations. The cost of any marketable equity securities sold is based on the specific-identification method.

For available-for-sale debt securities, in an unrealized loss, the Company determines whether a credit loss exists. The credit loss is estimated by considering available information relevant to the collectability of the security and information about past events, current conditions, and reasonable and supportable forecasts. Any credit loss is recorded as a charge to interest and other income, net, not to exceed the amount of the unrealized loss. If the Company has an intent to sell, or if it is more likely than not that the Company will be required to sell a debt security in an unrealized loss position before recovery of its amortized cost basis, the Company will write down the security to its fair value and record the corresponding charge as a component of interest and other income, net.

Trade Accounts Receivable and Allowance for Credit Losses

The Company adopted Accounting Standards Update, or ASU 2016-13, *Financial Instruments-Credit Losses: Measurement of Credit Losses on Financial Instruments*, using the modified retrospective approach as of January 1, 2021. Trade accounts receivable are stated at the amount the Company expects to collect. The Company maintains an allowance for credit losses for expected uncollectible trade accounts receivable, which is recorded as an offset to trade accounts receivable, and changes in allowance for credit losses are classified as a general and administrative expense in the accompanying Consolidated Statements of Operations. The Company assesses collectability by reviewing trade accounts receivable on a collective basis where similar risk characteristics exist and on an individual basis when it identifies specific customers that have deterioration in credit quality such that they may no longer share similar risk characteristics with the other receivables. In determining the amount of the allowance for credit losses, the Company uses a probability-of-default and loss given default model, which allows the ability to define a point of default and measure credit losses for receivables that have reached the point of default for purposes of calculating the allowance for credit losses. Loss given default represents the likelihood that a receivable that has reached the point of default will not be collected in full. The Company updates its probability-of-default and loss given default factors annually to incorporate the most recent historical data and adjusts the quantitative portion of the reserve through its qualitative reserve overlay. The Company looks at qualitative factors such as general economic conditions in determining expected credit losses.

A roll-forward of the activity in the Company’s allowance for credit losses is as follows:

	December 31,		
	2021	2020	2019
	(in thousands)		
Allowance for credit losses at beginning of year	$ 1,898	$ 751	$ 590
Impact of ASU 2016-13 adoption	887	—	—
Current period provision	8,931	1,170	189
Write-downs	(499)	(23)	(28)
Allowance for credit losses at end of year	$ 11,217	$ 1,898	$ 751

Redeemable Preferred Stock Investment

The redeemable preferred stock investment of $22.0 million as of December 31, 2021 represents the fair value of redeemable preferred stock of Laboratory for Advanced Medicine, Inc., or Helio Health, that the Company purchased in July 2021. The investment is classified as available-for-sale debt securities. The fair value of available-for-sale debt security is included in the Consolidated Statement of Balance Sheets. Unrealized holding gains of $2.0 million are excluded from earnings and reported in other comprehensive income (loss) as of December 31, 2021. Since the Company intends on holding the preferred stock, and preferred stock is not redeemable until July 2027, the investment is recorded as a long-term investment.

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. 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. See Note 5, Fixed Assets, for useful lives for each major class of fixed assets.

Intangible assets

Intangible assets with definite lives are amortized over their estimated useful lives. The Company amortizes intangible assets on a straight-line basis with definite lives generally over periods ranging from five to twelve years. See Note 17, Goodwill and Intangible Assets, for details of intangible assets.

Business Combinations

The Company uses the acquisition method of accounting and allocates the fair value of purchase consideration to the assets acquired and liabilities assumed from an acquiree based on their respective fair values as of the acquisition date. The excess of the fair value of purchase consideration over the fair value of these assets acquired and liabilities assumed is recorded as goodwill. When determining the fair values of assets acquired and liabilities assumed, management makes significant estimates and assumptions, especially with respect to intangible assets. Critical estimates in valuing intangible assets include, but are not limited to, expected future cash flows, which includes consideration of future growth and margins, future changes in technology, expected cost and time to develop in-process research and development, brand awareness and discount rates. Fair value estimates are based on the assumptions that management believes a market participant would use in pricing the asset or liability.

Goodwill

Goodwill is not amortized but is subject to impairment tests on an annual basis or more frequently if indicators of potential impairment exist, and goodwill is written down when it is determined to be impaired. The Company typically performs an annual impairment review in the fourth quarter of each fiscal year unless one had been performed previously within the past 12 months and compares the fair value of the reporting unit in which the goodwill resides to its carrying value.

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.

Reagents and Supplies

The Company maintains reagents and other consumables primarily used in sample collections and testing which are valued at the lower of cost or net realizable value. Cost is determined using actual costs on a first-in, first-out basis. The reagents and other consumables were included in other current assets in the accompanying Consolidated Balance Sheets.

Fair Value of Financial Instruments

The Company's financial instruments consist principally of cash and cash equivalents, marketable securities, trade accounts receivable, redeemable preferred stock investment, accounts payable and investment margin loan. The carrying amounts of certain of these financial instruments, including cash and cash equivalents, accounts receivable, accounts payable, investment margin loan, contingent consideration, and notes payable approximate fair value due to their short maturities. Fair value of marketable securities and redeemable preferred stock investment 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 and cash equivalents, trade accounts receivable and marketable securities, which consist of debt securities and equity securities. As of December 31, 2021, 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 under common control, one customer comprised 26% of total revenue in the year ended December 31, 2021, two customers comprised 28% and 10% of total revenue in the year ended December 31, 2020, and one customer comprised 28% of total revenue in the year ended December 31, 2019. No customer comprised at least 10% of total accounts receivable as of December 31, 2021 and 2020.

The Company relies on a limited number of suppliers for its test collection kits and 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 encountered delays or difficulties securing these test collection kits, 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 collection kits, 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.

The Company's 25% interest in BostonMolecules was accounted for using the equity method, and the carrying value was $0 as of December 31, 2021 and 2020 due to the impairment loss recorded in 2020.

Leases

The Company determines if an arrangement is a lease 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. Operating and finance lease right-of-use assets, or ROU assets, short-term lease liabilities, and long-term lease liabilities are included in other long-term assets, other current liabilities, and other long-term liabilities, respectively, in the accompanying Consolidated Balance Sheets.

Lease ROU 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. Lease ROU 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, including inquiries with its bank, in determining the present value of lease payments since its leases do not provide an implicit rate. Lease ROU assets consist of initial measurement of lease liabilities, any lease payments made to lessor on or before the lease commencement date, minus any lease incentive received, and any initial direct costs incurred by the Company. Operating lease expense for lease payments is recognized on a straight-line basis over the lease term. For finance lease, ROU assets are amortized on a straight-line basis from the commencement date to the earlier of the end of useful life of the ROU assets or the end of the lease term. Amortization of ROU assets and interest on the lease liability for finance leases are included as charges to the accompanying Consolidated Statements of Operations.

Lease ROU assets and liabilities arising from business combinations are recognized and measured at the acquisition dates as if an acquired lease were a new lease at the date of acquisition using the Company's incremental borrowing rate unless the discount rate

is implicit in the lease. The Company elects to not to recognize assets or liabilities as of the acquisition dates for leases that, on the acquisition dates, have a remaining lease term of 12 months or less. The Company also retains the acquirees' classification of the leases if there are no modifications as part of the business combinations.

The Company leases and subleases out space in buildings it owns or leases to third-party tenants or subtenants under noncancelable operating leases. The Company recognizes lease payments as income over the lease terms on a straight-line basis and recognizes variable lease payments as income in the period in which the changes in facts and circumstances on which the variable lease payments are based occur. The net rental income is included in the interest and other income, net, in the accompanying Consolidated Statement of Operations.

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 to five 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.

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 COVID-19, molecular diagnostic and genetic testing services. The Company currently receives payments from primarily three different customer types: insurance, institutional customers, including hospitals, medical institutions, other laboratories, governmental bodies, municipalities and large corporations, and patients who pay directly.

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 its customers. To determine revenue recognition for contracts with customers, the Company performs the following steps described in the Accounting Standards Codification, or ASC 606, *Revenue from Contracts with Customers*: (1) identifies the contract with the customer, or Step 1, (2) identifies the performance obligations in the contract, or Step 2, (3) determines the transaction price, or Step 3, (4) allocates the transaction price to the performance obligations in the contract, or Step 4, and (5) recognizes revenue when (or as) the entity satisfies a performance obligation, or Step 5.

The Company's test results are primarily delivered electronically. The Company bills certain customers for shipping and handling fees incurred by the Company associated with COVID-19 tests, and shipping and handlings fees billed to customers are included in revenue, and shipping and handling fees incurred are included in cost of revenue in the accompanying Consolidated Statements of Operations.

Performance Obligations

Institutional and Patient Direct Pay

The Company's institutional contracts for its testing services typically have a single performance obligation to deliver COVID-19, molecular diagnostic or genetic testing services to the ordering facility or patient. Some arrangements involve the delivery of genetic testing services to research institutions, which the Company refers to as "sequencing as a service." In arrangements with institutions, including hospitals, medical institutions, other laboratories, governmental bodies, municipalities and large corporations, and patients who pay directly, the transaction price is stated within the contract and is therefore fixed consideration. For most of the Company's testing volume, the Company identified the institutions, including hospitals, medical institutions, other laboratories, governmental bodies, municipalities and large corporations, and patients as the customer in Step 1 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. Control over testing services is transferred to the Company's ordering facility at a point in time. Specifically, the Company determined the customer obtains control of the promised service upon delivery of test results.

Insurance

The Company's insurance contracts for testing services typically have a single performance obligation to deliver testing services to the ordering facility or patient. For most of the Company's insurance volume, the Company identified the patient as the customer in Step 1 and determined a contract exists with the patient in Step 1. In arrangements with insurance patients, the transaction price is typically stated within the contract, however, the Company may 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, the Company utilizes the expected value method under a portfolio approach. The Company's estimate requires significant judgment and is developed using known reimbursement rates and historical reimbursement data from payors and patients. As these contracts typically have a single performance obligation, no allocation of the transaction price is required in Step 4. Control over testing services is transferred to the Company's ordering physicians at a point in time. Specifically, the Company determined the customer obtains control of the promised service upon delivery of the test results.

Certain incremental costs pertaining to both insurance and institutional, such as commissions, are incurred in obtaining contracts. Contract costs are capitalized if the Company expects to recover them, and amortization of contract costs is classified in the general and administrative expense in the Consolidated Statements of Operations. Historically contract costs have not been significant to the financial statements.

Significant Judgments and Contract Estimates

Accounting for insurance contracts includes estimation of the transaction price, defined as the amount the Company expects 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 insurance payors for COVID-19 tests, estimation of the transaction price represents variable consideration. The Company estimates that the variable consideration paid by insurance payors will approximate the Company's self-pay rate for COVID-19 tests that is published on its website, which is the rate established by the Center for Medicare & Medicaid Services, as supported by a historical reimbursement trend analysis.

Contract Liabilities

Contract liabilities are recorded when the Company receives payment or bills prior to completing its obligation to transfer goods or services to a customer, and the Company subsequently recognizes contract liabilities as revenue in the period in which the applicable revenue recognition criteria, as described above, are met.

Customer Deposit

Customer deposit in the accompanying Consolidated Balance Sheets consists primarily of payments received from customers in excess of their outstanding trade accounts receivable balances, and the excess payments will be refunded to the customers or offset against future testing receivables.

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 and building 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 Consolidated Statements of Operations based upon each award recipient's role with the Company. The Company primarily grants to its employees restricted stock unit awards, or 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 rates that approximate those in effect during the period. Gains and losses from these translations are recognized in foreign currency translation included in accumulated other comprehensive income (loss) in the accompanying Consolidated Statements of Stockholders' Equity. Gain from these translations were $456,000 in the year ended December 31, 2021. The gain or loss were not significant in the year ended December 31, 2020 or 2019, respectively. The Company and its 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. Losses from these remeasurements were not significant in 2021, 2020 and 2019.

Comprehensive Income (Loss)

Comprehensive income (loss) is comprised of net income (loss) and other comprehensive income (loss). Other comprehensive income (loss) consists of net unrealized gain or loss on available-for-sale debt securities, net of tax, and foreign currency translation adjustments from its subsidiaries not using the U.S. dollar as their functional currency. Reclassifications from other comprehensive income (loss) to net earnings were not significant in 2021 or 2020. The Company did not have reclassifications from other comprehensive income (loss) to net loss in 2019. The tax effects related to net unrealized loss on available-for-sale debt securities were $437,000 in 2021. The tax effects related to net unrealized gain on the available-for-sale debt securities were $147,000 in 2020. The tax effects related to unrealized gain was insignificant in 2019 due to valuation allowance.

Basic and Diluted Net Income or Loss per Share

Basic net income or loss per common share is computed by dividing the net income or loss attributable to common stockholders by the weighted-average number of common shares outstanding during the period. Diluted net income or loss per common share is computed by dividing the net income or loss attributable to common stockholders by the weighted-average number of common shares and dilutive common share equivalents outstanding during the period.

Disaggregation of Revenue

The Company classifies its customers into three payor types: (i) Insurance, including claim reimbursement from HRSA for uninsured individuals, (ii) Institutional, including hospitals, medical institutions, other laboratories, governmental bodies, municipalities and large corporations, or (iii) Patients who pay directly, as the Company believes this best depicts how the nature, amount, timing, and uncertainty of its 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, 2021, 2020 and 2019.

	Year Ended December 31,		
	2021	2020	2019
	(in thousands)		
Testing Services by payor			
Insurance	$ 555,762	$ 257,587	$ 705
Institutional	435,688	163,083	31,284
Patient	1,134	1,042	539
Total Revenue	$ 992,584	$ 421,712	$ 32,528

The insurance revenue category above includes $310.4 million and $155.4 million for the years ended December 31, 2021 and 2020, respectively, for services related to claims covered by the HRSA COVID-19 Uninsured Program.

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

Collection of the Company's net revenues from insurers is normally a function of providing complete and correct billing information within the various filing deadlines. Provided the Company has billed insurers accurately with complete information prior to the established filing deadline, there has historically been little to no credit risk. If there has been a delay in billing, the Company determines if the amounts in question will likely go past the filing deadline, and if so, the Company will reserve accordingly for the billing.

Contract Balances

Receivables from contracts with customers - Receivables from contracts with customers are included within trade accounts receivable on the Consolidated Balance Sheets. Receivable from Insurance and Institutional customers represented 47% and 53%, respectively, as of December 31, 2021 and 40% and 60%, respectively, as of December 31, 2020.

Contracts assets and liabilities - Contract assets from contracts with customers associated with contract execution and certain costs to fulfill a contract are 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. Contract liabilities are included in the Consolidated Balance Sheets. Revenues of $26.4 million, $257,000 and $59,000 for the years ended December 31, 2021, 2020, and 2019, respectively, related to contract liabilities at the beginning of the respective periods were recognized.

Transaction Price Allocated to Future Performance Obligations

ASC 606, *Revenue from Contracts with Customers*, issued by the Financial Accounting Standards Board, or FASB, 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, 2021. 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 COVID 19, molecular diagnostic or genetic testing services that extend beyond one year.

Recent Accounting Pronouncements

The Company evaluates all ASUs issued by 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.

Recently Adopted Accounting Pronouncements

ASU 2016-13

In June 2016, the FASB issued ASU No. 2016-13, *Financial Instruments-Credit Losses: Measurement of Credit Losses on Financial Instruments*, or ASU 2016-13. ASU 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 was effective for annual reporting periods beginning after December 15, 2019, including interim periods within those reporting periods for public business entities that meet the definition of an SEC filer, excluding entities eligible to be smaller reporting companies as defined by the SEC. For all other entities, the amendments in this update are effective for fiscal years beginning after December 15, 2022, including interim periods within those fiscal years. Early application of the amendments is permitted. The Company adopted ASU 2016-13 using the modified retrospective approach as of January 1, 2021. The cumulative effect upon adoption was $887,000 to the retained earnings in the accompanying Consolidated Statements of Stockholders' Equity and trade accounts receivable, net, in the accompanying Consolidated Balance Sheets. The cumulative tax effect was $239,000 to retained earnings in the accompanying Consolidated Statements of Stockholders' Equity and deferred tax assets included in other long-term liabilities in the accompanying Consolidated Balance Sheets. There was no impact related to available-for-sale debt securities.

ASU 2019-12

In December 2019, the FASB issued ASU No. 2019-12, *Simplifying the Accounting for Income Taxes (Topic 740)*, or ASU 2019-12, 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 ASU 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. For public business entities, this amendment is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2020 with early adoption permitted. The Company adopted ASU 2019-12 in the first quarter of 2021, and the adoption had no material impact to the Company's consolidated financial statements.

Note 3. Equity and Debt Securities

The Company's equity and debt securities consisted of the following:

	December 31, 2021			
	Amortized Cost Basis	Unrealized Gains	Unrealized Losses	Aggregate Fair Value
	(in thousands)			
Equity securities:				
Short-term				
Bond funds	$ 99,314	$ —	$ (515)	$ 98,799
Exchange traded funds	35,174	—	(174)	35,000
Total equity securities	134,488	—	(689)	133,799
Available-for-sale debt securities				
Short-term				
Corporate debt securities	92,116	24	(148)	91,992
Money market accounts	77,067	—	—	77,067
U.S. government debt securities	51,318	—	(81)	51,237
Municipal bonds	4,980	—	(12)	4,968
Yankee debt securities	3,615	—	(6)	3,609
Less: Cash equivalents	(77,067)	—	—	(77,067)
Total debt securities due within 1 year	152,029	24	(247)	151,806
After 1 year through 5 years				
Corporate debt securities	242,421	29	(1,913)	240,537
U.S. government debt securities	147,699	7	(786)	146,920
U.S. agency debt securities	70,069	—	(535)	69,534
Municipal bonds	11,920	13	(11)	11,922
Yankee debt securities	8,633	—	(89)	8,544
Total debt securities due after 1 year through 5 years	480,742	49	(3,334)	477,457
After 5 years through 10 years				
Municipal bonds	7,633	—	(43)	7,590
Redeemable preferred stock investment	20,000	1,965	—	21,965
Total debt securities due after 5 years through 10 years	27,633	1,965	(43)	29,555
Total available-for-sale debt securities	660,404	2,038	(3,624)	658,818
Total equity and debt securities	$ 794,892	$ 2,038	$ (4,313)	$ 792,617

	December 31, 2020			
	Amortized Cost Basis	Unrealized Gains	Unrealized Losses	Aggregate Fair Value
	(in thousands)			
Equity securities:				
Short-term				
Bond funds	$ 153,269	$ 67	$ (151)	$ 153,185
Exchange traded funds	17,614	—	(5)	17,609
Total equity securities	170,883	67	(156)	170,794
Available-for-sale debt securities				
Short-term				
Money market accounts	47,461	—	—	47,461
Corporate debt securities	41,061	101	(15)	41,147
Less: Cash equivalents	(47,461)	—	—	(47,461)
Total debt securities due within 1 year	41,061	101	(15)	41,147
After 1 year through 5 years				
Corporate debt securities	124,989	580	(117)	125,452
U.S. agency debt securities	1,000	2	—	1,002
Yankee debt securities	6,054	4	(10)	6,048
Total debt securities due after 1 year through 5 years	132,043	586	(127)	132,502
Total available-for-sale debt securities	173,104	687	(142)	173,649
Total equity and debt securities	$ 343,987	$ 754	$ (298)	$ 344,443

Gross unrealized losses on the Company's equity and debt securities were $4.3 million and $298,000 as of December 31, 2021 and 2020. The Company did not recognize any credit losses for its available-for-sale debt securities in 2021.

The Company's marketable securities of $499.4 million are used as collateral for an outstanding margin account borrowing. See Note 8, Debt, Commitments and Contingencies, for more information on the margin loan.

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 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, 2021			
	Total	Level 1	Level 2	Level 3
	(in thousands)			
Equity securities, debt securities and cash equivalents:				
Corporate debt securities	$ 332,529	$ —	$ 332,529	$ —
U.S. government debt securities	198,157	—	198,157	—
Bond funds	98,799	98,799	—	—
U.S. agency debt securities	69,534	—	69,534	—
Exchange traded funds	35,000	35,000	—	—
Municipal bonds	24,480	—	24,480	—
Yankee debt securities	12,153	—	12,153	—
Redeemable preferred stock investment	21,965	—	—	21,965
Money market accounts	77,067	77,067	—	—
Total equity securities, debt securities and cash equivalents	$ 869,684	$ 210,866	$ 636,853	$ 21,965

	December 31, 2020			
	Total	Level 1	Level 2	Level 3
	(in thousands)			
Equity securities, debt securities and cash equivalents:				
Corporate debt securities	$ 166,599	$ —	$ 166,599	$ —
Bond funds	153,185	153,185	—	—
Exchange traded funds	17,609	17,609	—	—
Yankee debt securities	6,048	—	6,048	—
U.S. agency debt securities	1,002	—	1,002	—
Money market accounts	47,461	47,461	—	—
Total equity securities, debt securities, and cash equivalents	$ 391,904	$ 218,255	$ 173,649	$ —

The Company's Level 1 assets include bond funds, exchange traded funds, and money market instruments and are valued based upon observable market prices. Level 2 assets consist of U.S. government and U.S. agency debt securities, municipal bonds, corporate debt securities and Yankee debt securities. Level 2 securities are valued based upon observable inputs that include reported trades, broker/dealer quotes, bids and offers. As of December 30, 2021, the Company had $22.0 million of redeemable preferred stock of Helio Health that was measured using unobservable (Level 3) inputs. The fair value is based on the most recent valuation as of December 31, 2021 performed by a third-party valuation company utilizing the guideline public company method under market approach and the discounted cash flow method under income approach. The asset approach was not used in determining the fair value of Helio Health as the asset approach is not representative.

There were no transfers between fair value measurement levels in 2021, 2020, and 2019.

Note 5. Fixed Assets

Major classes of fixed assets consisted of the following:

	Useful Lives	December 31, 2021	December 31, 2020
		(in thousands)	
Medical lab equipment	2 to 12 Years	$ 35,930	$ 20,849
Building	39 Years	6,731	6,731
Aircraft	7 Years	6,503	6,503
Computer hardware	1 to 5 Years	5,661	3,699
Leasehold improvements	Shorter of lease term or estimated useful life	4,003	1,580
Building improvements	6 months to 39 Years	3,936	707
Furniture and fixtures	2 to 10 Years	2,255	454
Computer software	3 to 5 Years	1,408	541
Automobile	2 to 7 Years	825	53
Land improvements	5 to 15 Years	403	403
General equipment	3 to 5 Years	44	44
Land		7,500	7,500
Assets not yet placed in service		6,718	2,055
Total		81,917	51,119
Less: Accumulated depreciation		(19,630)	(10,920)
Fixed assets, net		$ 62,287	$ 40,199

Depreciation expense on fixed assets totaled $9.3 million, $3.0 million and $2.1 million for the years ended December 31, 2021, 2020 and 2019, respectively.

Note 6. Other Current Assets

Other current assets consisted of the following:

	December 31, 2021	December 31, 2020
	(in thousands)	
Reagents and supplies	$ 12,206	$ 16,491
Prepaid expenses	4,244	3,682
Marketable securities interest receivable	2,743	1,016
Prepaid income taxes	1,716	14
Other receivable	1,403	17,810
Contract assets	237	1,379
Total	$ 22,549	$ 40,392

Reagents and supplies include reagents and consumables used for COVID-19 testing and genetics testing and collection kits for COVID-19 testing. Other receivable as of December 31, 2020 primarily consists of proceeds to be received from public offerings of the Company’s common stock, which were all collected in 2021.

Note 7. Reporting Segment and Geographic Information

The Company views its operations and manages its business in one reporting segment. All long-lived assets were located in the United States as of December 31, 2021 and 2020 with an insignificant amount located in China and Canada. Revenue by region for the years ended December 31, 2021, 2020 and 2019 were as follows:

	Year Ended December 31,		
	2021	2020	2019
	(in thousands)		
Revenue:			
United States	$ 978,978	$ 415,334	$ 25,014
Foreign	13,606	6,378	7,514
Total	$ 992,584	$ 421,712	$ 32,528

Note 8. Debt, Commitments and Contingencies

Debt

As of December 31, 2021, the Company had an outstanding borrowing of $15.1 million under its margin account with the custodian of the Company's marketable debt security investment account, Pershing Advisor Solutions, LLC, a BNY Mellon Company, or BNY Mellon. The outstanding balance is included in the Consolidated Balance Sheets. Margin account borrowings were used for the purchase of real property located in El Monte, California in 2020. The securities in the brokerage account were used as collateral for the margin loan. The custodian can issue a margin call at any time. The interest rate on the margin loan was the effective federal funds rate, or EFFR, plus a spread, and the EFFR and/or the spread can be changed by BNY Mellon at any time. The interest was 1% at the time of withdrawal of $15.0 million from the margin account, and the interest rate at December 31, 2021 was less than 1%. The related interest expenses in 2021 and 2020 were $117,000 and $20,000, respectively.

Notes payable as of December 31, 2021 consisted of $6.1 million of notes payable to Xilong Scientific, by FF Gene Biotech. The loan is payable on December 31, 2022, and interest rate on the loan is 4.97%. The related interest expenses in 2021 were $177,000.

Operating Leases

See Note 9, Leases, for further information.

Purchase Obligations

As of December 31, 2021, the Company had non-cancelable purchase obligations of $11.6 million, of which, $10.9 million for reagents and other supplies and $732,000 for medical lab equipment are payable within twelve 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.

The Company has received a CID issued by the U.S. Department of Justice pursuant to the False Claims Act related to its investigation of allegations of medically unnecessary laboratory testing, improper billing for laboratory testing, and remuneration received or provided in violation of the Anti-Kickback Statute and the Stark Law. This CID requests information and records relating to certain of the Company's customers named in the CID, which represent a small portion of the Company's revenues. The Company is fully cooperating with the U.S. Department of Justice to promptly respond to the requests for information in this CID, and does not presently expect this CID or resulting investigation to have a material adverse impact. However, the Company cannot predict when the investigation will be resolved, the outcome of the investigation or its potential impact, which may ultimately be greater than the Company currently expects.

The contingent consideration of $10.0 million as of December 31, 2021 was related to the acquisition of CSI (see Note 15, Business Acquisitions), which is included in the Consolidated Balance Sheets.

Note 9. Leases

Lessee

The Company is party as a lessee to various non-cancelable operating leases with varying terms through March 2028 primarily for laboratory and office space and equipment. The Company has options to renew some of these leases after their expirations. On a lease-by-lease basis, the Company considers such options, which may be elected at the Company's sole discretion, in determining the lease term. The Company also has two finance leases for lab equipment through December 2026, one of which was acquired in the acquisition of CSI. The Company retained CSI's classification of its leases. The Company does not have any leases with variable lease payments. The Company's operating lease agreements do not contain any residual value guarantees, material restrictive covenants, bargain purchase options or asset retirement obligations.

The Company's headquarters are located in Temple City, California, which is comprised of various corporate offices and a laboratory certified under the Clinical Laboratory Improvement Amendments of 1988, or CLIA, accredited by the College of American Pathologists, or CAP, and licensed by the State of California Department of Public Health. Other CLIA-certified laboratories are located in Houston, Texas and Alpharetta, Georgia. Additional offices are located in Atlanta, Georgia and are used for certain report generation functions.

In February 2021, the Company extended the lease for its headquarters located in Temple City, California, to January 31, 2023. In March 2021, the Company entered into a new lease for its 12,000 square foot CLIA-certified laboratory in Houston, Texas, which will expire in November 2023.

The operating and finance lease right-of-use asset, short-term lease liabilities, and long-term lease liabilities as of December 31, 2021, and 2020 were as follows:

	December 31,	
	2021	2020
	(in thousands)	
Operating lease ROU asset, net	$ 7,141	$ 828
Operating lease liabilities, short term	$ 1,842	$ 267
Operating lease liabilities, long term	$ 5,344	$ 568
Finance lease ROU asset, net	$ 1,735	$ —
Finance lease liabilities, short term	$ 332	$ —
Finance lease liabilities, long term	$ 1,398	$ —

The following was operating and finance lease expense:

	Year Ended December 31,		
	2021	2020	2019
	(in thousands)		
Operating lease cost	$ 1,262	$ 566	$ 587
Finance lease cost:			
Amortization of ROU assets	7	—	—
Interest on lease liabilities	1	—	—
Short-term lease cost	296	142	—
Total lease cost	$ 1,566	$ 708	$ 587

Supplemental information related to leases was the following:

	December 31, 2021
Weighted average remaining lease term - operating leases	4.96 years
Weighted average discount rate - operating leases	3.15%
Weighted average remaining lease term -finance lease	4.94 years
Weighted average discount rate - finance lease	3.21%

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

	Operating Leases	Financing Leases
	(in thousands)	
Year Ending December 31,		
2022	$ 2,037	$ 383
2023	1,579	383
2024	1,154	376
2025	1,048	366
2026	884	366
Thereafter	1,080	—
Total lease payments	7,782	1,874
Less imputed interest	(596)	(144)
Total	$ 7,186	$ 1,730

Lessor

The Company leases out space in buildings it owns to third-party tenants under noncancelable operating leases and has leased out such space since the Company purchased such buildings in October 2020. The Company also subleases out some space in a lease acquired as part of the acquisition of CSI. As of December 31, 2021, the remaining lease terms left range from 11 months to 44 months including renewal options and may include rent escalation clauses. Lease income primarily represents fixed lease payments from tenants recognized on a straight-line basis over the application lease term. Variable lease income represents tenant payments for real estate taxes, insurance and maintenance.

The lease income was included in interest and other income, net, in the accompanying Consolidated Statements of Operations. Total lease income was as follows:

	Year Ended December 31,		
	2021	2020	2019
	(in thousands)		
Lease income	$ 413	$ 144	$ —
Variable lease income	7	1	—
Total lease income	$ 420	$ 145	$ —

Future fixed lease payments from tenants for all noncancelable operating leases as of December 31, 2021 are as follows:

	Lease Payments from Tenants
	(in thousands)
Year Ending December 31,	
2022	$ 355
2023	264
2024	180
2025	120
Total	$ 919

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,		
	2021	2020	2019
	(in thousands)		
Cost of revenue	$ 3,563	$ 1,452	$ 676
Research and development	6,326	2,693	1,024
Selling and marketing	2,513	2,092	845
General and administrative	3,480	1,920	664
Total	$ 15,882	$ 8,157	$ 3,209

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, 2021, 2020 and 2019:

	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, 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
Granted	10	$ 15.82	$ 11.45		
Exercised	(56)	$ 1.86	$ 5.04		
Canceled	(8)	$ 4.18	$ 4.68		
Balance at December 31, 2020	287	$ 1.59		5.5	$ 14,484
Granted	5	$ 73.64	$ 56.34		
Exercised	(76)	$ 1.13	$ 8.40		
Canceled	—	$ —	$ —		
Balance at December 31, 2021	216	$ 3.42		4.6	$ 20,965
Exercisable as of December 31, 2021	193	$ 0.99		4.2	$ 19,249

(1) Aggregate intrinsic value is calculated as the difference between (i) the exercise price of options and (ii) the market 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, 2021, 2020 and 2019 was $76,000, $223,000 and $549,000, respectively. As of December 31, 2021, the remaining unrecognized compensation expense related to all outstanding option awards was $354,000 and is expected to be recognized over a weighted-average period of 2.9 years. As of December 31, 2020, the remaining unrecognized compensation expense related to all outstanding option awards was $178,000 and is expected to be recognized over a weighted-average period of 3.0 years.

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, 2021, 2020, and 2019:

	Number of Shares (in thousands)	Weighted-Average Grant Date Fair Value
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
Granted	1,389	$ 24.86
Vested and settled	(655)	$ 7.97
Forfeited	(160)	$ 11.17
Balance at December 31, 2020	2,085	$ 17.93
Granted	477	$ 95.33
Vested and settled	(836)	$ 15.43
Forfeited	(107)	$ 37.83
Balance at December 31, 2021	1,619	$ 40.74

The RSU awards granted in the years ended December 31, 2021, 2020 and 2019 will result in aggregate equity-based compensation expense of $45.5 million, $34.5 million and $6.9 million, respectively, to be recognized over the vesting periods from the grant date of each award granted in the period. As of December 31, 2021, the remaining unrecognized compensation expense related to all outstanding RSU awards was $59.1 million and is expected to be recognized over a weighted-average period of 3.1 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 years ended December 31, 2021, 2020 and 2019.

	Year Ended December 31,		
	2021	2020	2019
Expected term (in years)	6.1	6.1	6.1
Risk-free interest rates	1.1%	0.4%	1.8%
Dividend yield	—	—	—
Expected volatility	94.6%	87.5%	73.6%

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.

The following table summarizes income (loss) before income taxes, equity loss in investee and gain (loss) on equity-method investments:

	Year Ended December 31,		
	2021	2020	2019
	(in thousands)		
U.S. income before income taxes, equity loss in investee and gain (loss) on equity-method investments	$ 681,403	$ 291,739	$ 679
Foreign loss before income taxes, equity loss in investee and gain (loss) on equity-method investments	(4,103)	(55)	(270)
Income before income taxes, equity loss in investee and gain (loss) on equity-method investments	$ 677,300	$ 291,684	$ 409

Income tax expense consisted of the following:

	Year Ended December 31,		
	2021	2020	2019
	(in thousands)		
Current:			
Federal	$ 131,907	$ 53,794	$ 5
State	51,076	20,513	38
Total Current	182,983	74,307	43
Deferred:			
Federal	(7,471)	(248)	(249)
State	(717)	(14)	(280)
Foreign	669	—	—
Change in valuation allowance	(669)	(1,513)	529
Total Deferred	(8,188)	(1,775)	—
Total income tax expense	$ 174,795	$ 72,532	$ 43

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

	Year Ended December 31,		
	2021	2020	2019
Tax provision at federal statutory rate	21.00%	21.00%	21.00%
State taxes	5.99%	5.68%	-46.76%
Foreign tax rate differential	0.00%	0.00%	13.83%
Uncertain Tax Positions	0.05%	0.13%	0.00%
Stock based compensation	-1.96%	-0.92%	-53.53%
Return to provision	-0.17%	-0.11%	-57.11%
Other permanent differences	1.09%	0.02%	3.87%
Other	-0.14%	-0.41%	0.01%
Change in valuation allowance	-0.10%	-0.52%	129.22%
Effective tax rate	25.76%	24.87%	10.53%

The following table summarizes the elements of the deferred tax assets (liabilities). Net deferred tax assets are included in other long-term assets in the Consolidated Balance Sheets.

	Year Ended December 31,		
	2021	2020	2019
	(in thousands)		
Deferred tax assets			
Accrued vacation and other accrued expenses	$ 1,486	$ 166	$ 97
Provision for credit losses	2,755	513	180
Net operating losses	199	206	445
Stock based compensation	1,739	1,424	609
State income taxes	10,991	4,306	8
Foreign	1,808	1,220	545
Credits	—	—	680
Lease liability	1,643	226	643
Equity loss in investment	700	700	—
Other	599	89	—
Gross deferred tax assets	21,920	8,850	3,207
Less: Valuation allowance	(2,609)	(2,021)	(2,125)
Net deferred tax assets	19,311	6,829	1,082
Deferred tax liabilities			
Intangible assets	8,083	—	—
Depreciation	7,371	4,830	419
Right of use asset	1,640	224	633
Other	1,458	147	30
Total deferred tax liabilities	18,552	5,201	1,082
Net deferred tax assets	$ 759	$ 1,628	$ —

As of December 31, 2021, the Company has no estimated federal net operating loss, or NOL, carryforwards and estimated state NOL carryforwards of $1.8 million. The Company's state NOLs are scheduled to begin expiring in 2037. The Company also has foreign NOL carryforwards of $13.7 million which are scheduled to expire from 2022 through 2026.

ASC 740-10-30-5 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 certain deferred tax assets. These deferred tax assets consist primarily of equity losses in joint ventures and foreign net operating loss carryforwards; accordingly, a valuation allowance of $2.6 million and $2.0 million has been recorded on these deferred tax assets as of December 31, 2021 and 2020. The increase in the valuation allowance of $588,000 for the years ended December 31, 2021 was primarily due to an increase in foreign deferred tax assets that are more likely than not to expire unrealized.

During 2020 and 2019 the Company recorded a deferred tax asset related to its equity-method investment in FF Gene Biotech. When realized, the excess tax basis would have generated a capital loss which only would have been available to offset capital gain income. As a result, the Company recorded a full valuation allowance against this asset in 2020 and 2021. However, due to an incremental investment in FF Gene Biotech in 2021, the Company now includes the subsidiary in its consolidated balance sheet; it is no longer an equity-method investment. Therefore, the previously recorded deferred tax asset was reversed as part of the related acquisition accounting. During 2020, the Company recorded a deferred tax asset related to the impairment of its investment in BostonMolecules, Inc. When realized, the asset will generate a capital loss which may only be used to offset capital gain income; therefore, the Company has recorded a full valuation allowance against this asset. The net deferred assets are included in other long-term assets in the accompanying Consolidated Balance Sheets.

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 any significant income tax filing requirements in any foreign jurisdiction. As of December 31, 2021, 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, 2021, the Company remains subject to income tax examinations in the U.S. and various states for tax years 2018 through 2021; certain other states remain subject to examination for tax years 2017 through 2021. However, due to the Company's NOL carryforwards in various jurisdictions, tax authorities have the ability to adjust carryforwards related to closed years until the statute expires on the year(s) in which the NOL carryforwards are utilized.

A reconciliation of the Company's gross unrecognized tax benefits is as follows:

	Year Ended December 31,		
	2021	2020	2019
	(in thousands)		
Balance at beginning of year	$ 377	$ —	$ —
Increases to prior positions	—	141	—
Increases for current year positions	333	236	—
Balance at end of year	$ 710	$ 377	$ —

As of December 31, 2021, the Company has $710,000 of gross unrecognized tax benefits, related to research and experimental tax credits. The Company has $710,000 of unrecognized tax benefits as of December 31, 2021, which, if recognized, would affect the annual effective tax rate. The Company has accrued $15,000 and $0 for interest at December 31, 2021 or 2020, respectively, and has recognized interest expense of $15,000 and $0 for the years ended December 31, 2021 and 2020, respectively. Although it is possible that the amount of unrecognized benefits with respect to our uncertain tax positions will increase or decrease in the next twelve months, the Company does not expect material changes.

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. Income (Loss) per Share

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

	Year Ended December 31,		
	2021	2020	2019
	(in thousands, except per share data)		
Net income (loss) attributable to Fulgent	$ 507,364	$ 214,310	$ (411)
Weighted-average common shares - outstanding, basic	29,408	22,694	18,709
Weighted-average common shares - outstanding, diluted	30,976	24,056	18,709
Net income (loss) per common share, basic	$ 17.25	$ 9.44	$ (0.02)
Net income (loss) per common share, diluted	$ 16.38	$ 8.91	$ (0.02)

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,		
	2021	2020	2019
	(in thousands)		
Options	5	10	36
RSUs	182	347	161

The anti-dilutive shares described above were calculated using the treasury stock method.

Note 13. Retirement Plans

The Company offers a 401(k) retirement savings plan, or 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 $697,000,$422,000 and $237,000 in the years ended December 31, 2021, 2020 and 2019, respectively.

Note 14. Related Party

Linda Marsh, who is a member of the Company's board of directors, is currently the Senior Executive Vice President of AHMC Healthcare Inc., or AHMC. The Company performs genetic testing and other testing services, on an arms-length basis, for AHMC, and the Company recognized $3.4 million and $3.1 million in revenue in the years ended December 31, 2021 and 2020, respectively. The Company did not recognize any revenue from AHMC in the year ended December 31, 2019. As of December 31, 2021 and 2020, $556,000 and $1.8 million was owed to the Company by AHMC, respectively, which is included in trade accounts receivable, net, in the accompanying Consolidated Balance Sheets, in connection with this relationship.

The Spouse of the Company's founder, Chief Executive Officer and Chairman of the Company's board of directors, Ming Hsieh, is the owner of JEM Enterprise, or JEM. In the year ended December 31, 2020, the Company purchased $200,000 of office furniture and supplies from JEM. The Company believes $200,000 was a fair market price for the furniture purchased. As of December 31, 2021 and 2020, zero was owed to JEM by the Company in connection with this relationship.

The Chief Executive Officer and Chairman of the Company's board of directors, Ming Hsieh, is the owner of PTJ Associates Inc., or PTJ. PTJ provides flight services to the Company on an arms-length basis. In the years ended December 31, 2021 and 2020, the Company incurred $142,000 and $343,000, respectively, in expenses for flights between California and Texas to transport employees and supplies. The Company did not incur such expense in the year ended December 31, 2019. As of December 31, 2021 and 2020, $0 and $94,000, respectively, was owed to PTJ by the Company, which is included in accounts payable in the accompanying Consolidated Balance Sheets, in connection with this relationship.

The Company and Fulgent Pharma LLC, the Company's former subsidiary, are party to shared services arrangements where research and development and administrative services and office space and equipment are provided between the companies, on an arms-length basis. Ming Hsieh is the Manager and a member of Fulgent Pharma LLC. In the years ended December 31, 2021 and 2020, the research development service rendered by Fulgent Pharma LLC was $330,000 and $427,000, respectively, and costs allocated to Fulgent Pharma, LLC were $27,000 and $52,000, respectively. Costs allocated to Fulgent Pharma LLC were not significant in the year ended December 31, 2019. As of December 31, 2021 and 2020, $679,000 and $409,000, respectively, was owed to Fulgent Pharma LLC by the Company, which is recorded in other receivable in other current assets in the accompanying Consolidated Balance Sheet, in connection with these relationships.

Note 15. Business Combinations

The Company believes that the acquisitions of businesses enhance its existing businesses by either expanding its geographic range and customer base or expanding its existing product lines. The Company incurred $2.8 million in acquisition related costs for the year ended December 31, 2021, respectively, which was included in general and administrative expenses in the accompanying Consolidated Statements of Operations.

FF Gene Biotech

In April 2017, the Company acquired a 30% equity interest in FF Gene Biotech, a newly formed a joint venture with Xilong Scientific and FJIP. The joint venture was formed under the laws of China to offer genetic testing services to customers in China.

In May 2021, we entered into a restructuring agreement with Xilong Scientific and FJIP, resulting in the Company indirectly acquiring a controlling financial interest of 72% in FF Gene Biotech. FF Gene Biotech was founded to bring the Company's next generation sequencing, or NGS, capabilities to the Chinese genetic testing market through entities separate from the Company's U.S. operations, and FF Gene Biotech is pursuing this separate from the Company's business elsewhere. As a result of the acquisition of FF Gene Biotech, or the FF Gene Biotech Acquisition, the Company seeks to be more strategically aligned with its geographic expansion strategy. It also expects to reduce costs through economies of scale.

The Company allocated the purchase price to tangible and identified intangible assets acquired and liabilities assumed based on estimated fair values. As additional information becomes available, such as the finalization of the estimated fair value of tax-related items, the Company may further update the preliminary purchase price allocation during the remainder of the measurement period (up to one year from the FF Gene Biotech Acquisition date). The following table summarizes the consideration paid and the amounts of the assets acquired and liabilities assumed recognized at the FF Gene Biotech Acquisition date, as well as the fair value of the noncontrolling interest at the FF Gene Biotech Acquisition date.

	Amounts (in thousands)
Considerations	
Cash	$ 18,974
Fair value of the Company's 30% equity interest held before the business combination	3,734
	$ 22,708
Recognized amounts of identifiable assets acquired and liabilities assumed	
Financial assets	$ 3,181
Reagents and supplies	1,288
Fixed assets	3,874
Other tangible assets	944
Identifiable intangible assets	6,958
Other current liabilities	(2,585)
Notes payable	(5,893)
Recognized amounts of identifiable assets acquired and liabilities assumed, net	7,767
Noncontrolling interest	(8,141)
Goodwill	23,082
Total	$ 22,708

The fair value of the noncontrolling interest, or NCI, in FF Gene Biotech, a private entity, $8.1 million, was estimated by applying the income approach and market approach. The fair value measurement was based on significant inputs that are not observable in the market and thus represents a fair value categorized within Level 3 of the three-tier fair value hierarchy. The NCI represents a minority interest of 28% in the post-restructuring FF Gene Biotech. Since the NCI is the result of the restructuring, the implied value was utilized to value the NCI based on the 42% effective investment. After determining the implied value, a discount for lack of marketability was applied to the 28% interest representing lack of marketability related to the holding period to monetize the NCI in a future initial public offering, or IPO, or sale, and marketability related to market participant acquisition premiums implied in the value of the $19.0 million purchase price for a 42% interest. The resultant total discount applied was 35%, which is supported both by the put option analyses related to the potential holding period, and a 10% discount owed to a market participant acquisition premium.

The Company recognized a gain of $3.7 million as a result of remeasuring to fair value its 30% equity interest held before the FF Gene Biotech Acquisition. The fair value of the preexisting equity interest was determined based on the characteristics before consummating the FF Gene Biotech Acquisition and estimated by applying income approach and utilized the discounted cash flow method. The Company did not apply the market approach based on its characteristics before consummating the restructuring. The gain on the equity-method investment is included in the Company's Consolidated Statements of Operations for the year ended December 31, 2021.

The goodwill of $23.1 million arising from the FF Gene Biotech Acquisition is attributed to the expected synergies and other benefits that will be potentially generated from the combination of the Company and FF Gene Biotech. The goodwill recognized is not deductible for tax purposes.

The identified intangible assets acquired in the FF Gene Biotech Acquisition consisted of a $5.7 million royalty-free technology with an estimated amortization life of 10 years and $1.2 million customer relationships with an estimated amortization life of 5 years. The value of these assets was based upon the preliminary fair values as of the closing date of the FF Gene Biotech Acquisition.

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 has the power to direct the most significant activities of FF Gene Biotech and therefore is the primary beneficiary of the entity post the FF Gene Biotech Acquisition. 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.

CSI Acquisition

In August 2021, the Company acquired 100% of the outstanding equity of CSI, a multi-site reference laboratory business in the United States. This acquisition of CSI, or the CSI Acquisition, expands the Company's national reference laboratory presence in the United States.

The Company allocated the purchase price to tangible and identified intangible assets acquired and liabilities assumed based on estimated fair values. As additional information becomes available, such as the finalization of the estimated fair value of tax-related items, the Company may further update the preliminary purchase price allocation during the remainder of the measurement period (up to one year from the CSI Acquisition date). The following tables summarizes the consideration paid and the amounts of the assets acquired and liabilities assumed recognized at the CSI Acquisition date:

	Amounts (in thousands)
Considerations	
Cash	$ 43,359
Contingent consideration	10,000
	$ 53,359
Recognized amounts of identifiable assets acquired and liabilities assumed	
Debt-free net working capital	$ 4,270
Fixed assets	6,855
ROU assets - operating	4,988
ROU assets - finance	49
Other assets	160
Identifiable intangible assets	30,540
Deferred tax liability	(9,881)
Operating lease liabilities	(4,988)
Finance lease liabilities	(49)
Other liabilities	(6,069)
Recognized amounts of identifiable assets acquired and liabilities assumed, net	25,875
Goodwill	27,484
Total	$ 53,359

The CSI Acquisition includes a contingent consideration arrangement that requires additional consideration to be paid by the Company based on CSI's achievement of a minimum level of earnings, for the year ending December 31, 2021, as described in the acquisition agreement. The range of undiscounted amounts the Company may be required to pay under the contingent consideration agreement is between zero and $10.0 million. The fair value of the contingent consideration recognized on the CSI Acquisition date of $10.0 million was estimated by applying the income approach using discounted cash flows. Given the short-term nature of the contingent consideration, the most significant assumption is the probability weighted cash flow.

The goodwill of $27.5 million arising from the CSI Acquisition is attributed to the expected synergies, assembled workforce, other benefits that will be potentially generated from the combination and deferred tax. The goodwill recognized is not deductible for tax purposes.

The identified intangible assets acquired in the CSI Acquisition consisted of $27.6 million customer relationships with an estimated amortization life of 12 years, $1.9 million laboratory information system platform with an estimated amortization life of 5 years, and $1.1 million trade name with an estimated amortization life of 10 years.

Prior to the acquisitions, the financial results for FF Gene Biotech and CSI were not significant for pro forma financial information. Post the acquisitions, the financial results for FF Gene Biotech and CSI are included in the Company's consolidated financial statements. Revenue and operating income or loss from both acquisitions since the respective 2021 acquisition dates are included in the accompanying Consolidated Statements of Operations as follows, in thousands:

	Net Sales	Operating Income (Loss)
FF Gene Biotech	$ 6,632	$ (3,894)
CSI	17,390	1,138
Total	$ 24,022	$ (2,756)

Note 16. Equity Distribution Agreements

In August 2019, the Company entered into an Equity Distribution Agreement, or the 2019 Equity Distribution Agreement, with Piper Jaffray & Co., or Piper, as sales agent, which was amended on August 4, 2020. During the year ended December 31, 2019, the Company sold an aggregate of 104,000 shares of its common stock pursuant to the 2019 Equity Distribution Agreement at a weighted-average net selling price of $9.37 per share, which resulted in $979,000 of net proceeds to the Company. During the year ended December 31, 2020, the Company sold an aggregate of 1.1 million shares of its common stock pursuant to the 2019 Equity Distribution Agreement at a weighted-average net selling price of $38.50 per share, which resulted in $42.7 million of net proceeds to the Company. Shares sold under the 2019 Equity Distribution Agreement were 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 prospectus supplements and accompanying base prospectus filed with the SEC on August 30, 2019, May 6, 2020 and August 5, 2020.

In September 2020, the Company entered into an Equity Distribution Agreement, or the September 2020 Equity Distribution Agreement, with Piper as sales agent, pursuant to which the Company sold an aggregate of 2.8 million shares of its common stock at a weighted-average net selling price of $42.90 per share, which resulted in $122.1 million of net proceeds to the Company. Shares sold under the September 2020 Equity Distribution Agreement were offered and sold pursuant to the Company's registration statement on Form S-3 (File No. 333-239964) filed with the SEC on July 21, 2020, as amended on August 5, 2020, and declared effective on August 12, 2020, and a prospectus supplement and accompanying base prospectus filed with the SEC on September 25, 2020.

In November 2020, the Company entered into an Equity Distribution Agreement, or the November 2020 Equity Distribution Agreement, with Piper, Oppenheimer & Co. Inc., and BTIG LLC, as sales agents, 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 $175.0 million. Piper may receive a commission of up to 3% of the gross proceeds received by the Company for sales pursuant to the November 2020 Equity Distribution Agreement. During the year ended December 31, 2020, the Company sold an aggregate of 2.0 million shares of its common stock pursuant to the November 2020 Equity Distribution Agreement at a weighted-average net selling price of $48.70 per share, which resulted in $99.1 million of net proceeds to the Company. During the year ended December 31, 2021, the Company sold an aggregate of 1.1 million shares of its common stock pursuant to the November 2020 Equity Distribution Agreement at a weighted-average net selling price of $64.83 per share, which resulted in $72.0 million of net proceeds to the Company. Shares sold under the November 2020 Equity Distribution Agreement were offered and sold pursuant to the Company's registration statement on Form S-3 (File No. 333-239964) filed with the SEC on July 21, 2020, as amended on August 5, 2020, and declared effective on August 12, 2020, and a prospectus supplement and accompanying base prospectus filed with the SEC on November 20, 2020.

Note 17. Goodwill and Intangible Assets

Summaries of goodwill and intangible assets balances as of December 31, 2021 and 2020 were as follows:

	Weighted-Average Amortization Period	December 31, 2021	December 31, 2020
		(in thousands)	
Goodwill		$ 50,897	$ —
Royalty-free technology	10 Years	$ 5,803	$ —
Less: accumulated amortization		(387)	—
Royalty-free technology, net		5,416	—
Customer relationships	12 Years	28,845	—
Less: accumulated amortization		(1,125)	—
Customer relationships, net		27,720	—
Trade name	10 Years	1,090	—
Less: accumulated amortization		(45)	—
Trade name, net		1,045	—
Laboratory information system platform	5 Years	1,860	—
Less: accumulated amortization		(155)	—
Laboratory information system platform, net		1,705	—
Purchased patent	10 Years	31	—
Less: accumulated amortization		(3)	—
Purchased patent, net		28	—
Total intangible assets, net		$ 35,914	$ —

During the year ended December 31, 2021, the Company recorded $23.1 million of goodwill and $7.0 million of intangible assets attributable to the FF Gene Biotech Acquisition. See Note 15, Business Combinations, to the Company's consolidated financial statements.

During the year ended December 31, 2021, the Company recorded $27.5 million of goodwill and $30.5 million of intangible assets attributable to the CSI Acquisition. See Note 15, Business Combinations, to the Company's consolidated financial statements.

During the year ended December 31, 2021, the Company purchased a 10-year patent of $31,000 for a novel mutation causative gene in Gitelman syndrome and its encoded protein and application.

Based on the carrying value of intangible assets recorded as of December 31, 2021, and assuming no subsequent impairment of the underlying assets, the annual amortization expense for intangible assets is expected to be as follows:

	Amounts
	(in thousands)
2022	$ 3,615
2023	3,615
2024	3,615
2025	3,615
2026	3,292
Thereafter	18,162
Total	$ 35,914

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, 2021. 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, 2021	Sept. 30, 2021	June 30, 2021	Mar. 31, 2021	Dec. 31, 2020	Sept. 30, 2020	June 30, 2020	Mar. 31, 2020
	(dollars in thousands, except per share data)							
Statement of Operations Data:								
Revenue	$ 251,671	$ 227,868	$ 153,616	$ 359,429	$ 294,978	$ 101,716	$ 17,265	$ 7,753
Cost of revenue	62,134	43,466	35,858	74,075	51,772	26,261	7,717	4,057
Gross profit	189,537	184,402	117,758	285,354	243,206	75,455	9,548	3,696
Operating expenses:								
Research and development	7,464	6,021	5,312	5,422	4,576	3,177	1,849	1,978
Selling and marketing	8,200	6,012	5,219	5,008	5,081	5,014	3,260	1,597
General and administrative	22,102	12,299	8,329	8,002	7,640	3,741	1,799	2,035
Amortization of intangible assets	911	797	—	—	—	—	—	—
Total operating expenses	38,677	25,129	18,860	18,432	17,297	11,932	6,908	5,610
Operating income (loss)	150,860	159,273	98,898	266,922	225,909	63,523	2,640	(1,914)
Interest and other (expense) income, net	(35)	496	604	282	589	421	275	241
Income (loss) before income taxes, equity earnings (loss) in investee and gain (loss) on equity-method investments	150,825	159,769	99,502	267,204	226,498	63,944	2,915	(1,673)
Provision for (benefit from) income taxes	47,148	37,545	23,589	66,513	58,571	14,526	(599)	34
Income (loss) before equity earnings (loss) in investee and gain (loss) on equity-method investments	103,677	122,224	75,913	200,691	167,927	49,418	3,514	(1,707)
Equity earnings (loss) in investee	—	—	—	—	143	(189)	(193)	(249)
Gain (loss) on equity-method investments	—	—	3,734	—	(1,763)	(2,591)	—	—
Net income (loss) from consolidated operations	103,677	122,224	79,647	200,691	166,307	46,638	3,321	(1,956)
Net loss attributable to noncontrolling interests	662	298	165	—	—	—	—	—
Net income (loss) attributable to Fulgent	$ 104,339	$ 122,522	$ 79,812	$ 200,691	$ 166,307	$ 46,638	$ 3,321	$ (1,956)
Net income (loss) per common share attributable to Fulgent:								
Basic	$ 3.48	$ 4.13	$ 2.74	$ 6.96	$ 6.55	$ 2.11	$ 0.15	$ (0.09)
Diluted	$ 3.34	$ 3.93	$ 2.59	$ 6.52	$ 6.16	$ 1.98	$ 0.14	$ (0.09)

Note 19. Subsequent Event

In February 2022, the Company entered into a stock purchase agreement with Spatial Genomics, Inc., or Spatial Genomics, a Delaware corporation, to invest up to $40.0 million in Series A Preferred Stock of Spatial Genomics. The strategic investment and partnership will bring Spatial Genomics' sequential fluorescence in situ hybridization technology to the Company's comprehensive genomic testing platform.

Exhibit 10.41

AMENDED AND RESTATEDLEASE

by and between

STORE MASTER FUNDING IX, LLC
as Landlord
and

CYTOMETRY SPECIALISTS, INC.,

as Tenant.

May 6, 2016

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AMENDED AND RESTATED LEASE

THIS AMENDED AND RESTATED LEASE (the "**Lease**") dated as of May 6, 2016 (the "**Effective Date**"), by and between **STORE MASTER FUNDING IX, LLC,** a Delaware limited liabilitycompany ("**Landlord**"), and **CYTOMETRY SPECIALISTS, INC.,** a Georgia corporation ("**Tenant**").

WITNESSETH:

WHEREAS, as of March 17, 2016, Landlord has purchased from Tenant that certain realproperty more particularly described on Exhibit A attached hereto and incorporated by reference herein, all rights, privileges, and appurtenances associated therewith, and all buildings, fixtures (to the extent permanently affixed to such real estate) and other improvements (whether or not affixed to such real estate) now or hereafter located on such parcel or parcels of real estate (such buildings, fixtures and other improvements now or hereafter located on such real estate hereinafter referred to as the "**Property**");

WHEREAS, this Lease amends and restates in its entirety that certain Lease dated March 17, 2016, together with any and all amendments thereto (the "**Original Lease**") by and between Landlord andTenant. The terms of the Original Lease shall remain in force and effect as to the period ending on 11:59 P.M. prior to the Effective Date hereof. The terms contained in this Lease shall apply to and be effective with respect to the period from and after the Effective Date, without novation, replacement or substitutionof the Original Lease, and the leasehold estate of Tenant shall mean the leasehold estate commencing under the Original Lease.

WHEREAS, Tenant desires to lease from Landlord, and Landlord desires to lease to Tenant, the Premises (as defined in Section 1.2) on the terms and conditions set forth in this Lease.

NOW, THEREFORE, in consideration of the Premises and the mutual covenants and agreements contained herein, and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties hereby agree as follows:

ARTICLE I

LEASE OF PREMISES; POSSESSION

Section 1.1. Lease to Tenant. Landlord hereby leases to Tenant, and Tenant hereby leases from Landlord, the Premises described in Section 1.2. below, for the Term provided for in Section 1.3. below, at the Rent provided for in Section 1.4. below, and under the other terms and conditions provided for in this Lease.

Section 1.2. Premises. The "**Premises**" being leased under this Lease consists of the real estate more particularly described on Exhibit A, which is attached to this Lease and incorporated by reference herein, and includes all of the real property owned by Landlord in such location, and all of the Property situated thereon, including all equipment, appliances and other property attached or appurtenant to such real estate. The Premises shall not include furniture, fixtures (to the extent not permanently affixed to the real estate), equipment, appliances and other personal property owned by Tenant or other permitted subtenants or occupants.

Section 1.3. Term. The Term of this Lease shall expire on March 31, 2028, subject to earlier termination as provided herein. Provided Tenant is not in default under this Lease beyond any applicable notice and cure period at the time of the exercise of the option granted herein and at the time of the commencement of the Extended Term (as defined below), Tenant shall have an option to extend the Termof this Lease for four (4) additional five (5) year periods (collectively the "**Extended Terms**" and individually the "**Extended Term**"), commencing immediately upon the expiration of the original Term hereof and

continuing for five (5) years thereafter for each Extended Term. Tenant shall exercise the foregoing option by written notice to Landlord ("**Tenant's Extension Notice**") given no less than nine (9)months prior to the expiration of the original Term or the previous Extended Term. The foregoing option shall terminate if notice is not timely given, time being of the essence with respect thereto. All references to the "**Term**" of this Lease shall, unless the context shall clearly indicate a different meaning, be deemed to constitute a reference to the original Term of this Lease and the Extended Terms, as the same may be exercised as permitted hereunder.

In the event Tenant exercises its option to extend the Term of this Lease, then the Base Rent payable during the Extended Term shall be increased as set forth in Section 4.1.

Section 1.4. Rent. The "**Rent**" payable by the Tenant under this Lease shall consist of the Base Rent provided for in Section 4.1. hereof and the Additional Rent provided for in Section 4.2. hereof.

Section 1.5. Permitted Uses. Tenant may use the Premises for office, laboratory and related purposes (the "**Permitted Uses**"). In the event that Tenant desires to use the Premises for purposes other than Permitted Uses, Tenant shall obtain Landlord's and Landlord's Mortgagee's (as "Landlord's Mortgagee" is hereinafter defined) prior written consent, which consent may not be unreasonably withheld, conditioned or delayed by Landlord or Landlord's Mortgagee.

Section 1.6. Delivery of Possession; Condition of Title. Tenant acknowledges and agrees that its affiliate is the owner or prior owner of the Premises and that Tenant, or affiliates, lessees or sublessees of Tenant have at all times been in possession and occupancy of the Premises and have full and complete knowledge of and responsibility for all current conditions of the Premises, including, without limitation, the physical condition of the Premises and the Property and title to the Premises and the Property. Accordingly, subject to Section 1.1. above, Landlord delivered actual and exclusive possession of the Premises to Tenant on the Commencement Date (as hereafter defined) in an "as is, where is" condition without representation or warranty. Tenant acknowledges that Landlord's title to the Premises is subject to the matters of record as of the Commencement Date, each of which has been examined by and is acceptable to Tenant (the "**Title Matters**"). Furthermore, the Premises are leased to Tenant in an "as is, where is" condition without representation or warranty by Landlord, subject to the existing state of title and any state of facts which an accurate survey or physical inspection might reveal and to all applicable laws now or hereafter in effect. Tenant waives any claim or action against Landlord in respect of the condition of the Premises. LANDLORD MAKES NO WARRANTY OR REPRESENTATION, EXPRESS OR IMPLIED, IN RESPECT OF THE PREMISES OR ANY PART THEREOF, EITHER AS TO ITS FITNESS FOR USE, SUITABILITY, DESIGN OR CONDITION FOR ANY PARTICULAR USE OR PURPOSE OR OTHERWISE, AS TO QUALITY OF THE MATERIAL OR WORKMANSHIP THEREIN, LATENT OR PATENT, IT BEING AGREED THAT ALL SUCH RISKS ARE TO BE BORNE BY TENANT. TENANT ACKNOWLEDGES THAT THE PREMISES HAS BEEN INSPECTED BY TENANT AND IS SATISFACTORY TO IT. LANDLORD HEREBY DISCLAIMS ANY AND ALL EXPRESS OR IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR ANY PARTICULAR PURPOSE RELATIVE TO THE PREMISES OR ANY COMPONENT PART THEREOF. Tenant acknowledges and agrees that no representations or warranties, express or implied, have been made by Landlord, or by any person, firm or agent acting or purporting to act on behalf of Landlord, as to (i) the presence or absence on or in the Premises of any particular materials or substances (including, without limitation, asbestos, hydrocarbons or hazardous or toxic substances), (ii) the condition or repair of the Premises or any portion thereof, (iii) the value, expense of operation or income potential of the Premises, (iv) the accuracy or completeness of any title, survey, structural reports, environmental audits or other information provided to Tenant by any third party contractor relative to the Premises (regardless of whether the same were retained or paid for by Landlord), or (v) any other fact or condition which has or might affect the Premises or the condition, repair, value, expense of operation or income potential thereof. Tenant represents that the officers of Tenant are knowledgeable and experienced in the leasing of properties comparable to the Premises and agrees that Tenant will be relying solely on Tenant's inspections of the Premises in leasing the Premises. THE PROVISIONS OF THIS

PARAGRAPH HAVE BEEN NEGOTIATED AND ARE INTENDED TO BE A COMPLETE EXCLUSION AND NEGATION BY LANDLORD OF, AND LANDLORD DOES HEREBY DISCLAIM, ANY AND ALL WARRANTIES BY LANDLORD, EXPRESS OR IMPLIED, WITH RESPECT TO THE PREMISES OR ANY PORTION THEREOF, WHETHER ARISING PURSUANT TO THE UNIFORM COMMERCIAL CODE OR ANY OTHER LAW NOW OR HEREAFTER IN EFFECT OR OTHERWISE, AND TENANT HEREBY ACKNOWLEDGES AND ACCEPTS SUCH EXCLUSION, NEGATION AND DISCLAIMER.

ARTICLE II

COMMENCEMENT DATE; MORTGAGES

Section 2.1. Commencement Date. The "**Commencement Date**" of this Lease shall be March 17, 2016. Upon the Commencement Date, Tenant shall have the right to occupy the Premises and any part thereof, subject to the terms and conditions of this Lease.

Section 2.2. Right to Mortgage Premises. Landlord and Tenant acknowledge that, subject to Article XV of this Lease, Landlord shall have the right to and may, from time to time, encumber the Premises with a mortgage or deed of trust (a "**Mortgage**") as security for a loan (a "**Loan**") to Landlordor Landlord's affiliates by a lender (which, together with its successors and assigns, and any future provider of Mortgage Debt (as defined herein), is referred to herein as the "**Landlord's Mortgagee**"). Asused herein, the term "**Mortgage Debt**" shall refer to the Loan from the Landlord's Mortgagee and any future loan or financing entered into by the Landlord.

ARTICLE III

USE AND QUIET ENJOYMENT OF PREMISES

Section 3.1. Use of Premises. Tenant shall use the Premises solely for the Permitted Uses. No use shall be made or permitted to be made of the Premises, or acts done, that will cause a cancellation of any insurance policy covering the Premises, or any part thereof.

Section 3.2. Quiet Enjoyment. Landlord agrees that unless an Event of Default (as defined in Section 13.1. hereof) has occurred and is continuing, Tenant shall have quiet and peaceable possession of the Premises throughout the Term, without hindrance by Landlord or any persons claiming under Landlord, subject only to (i) this Lease, (ii) the lien of any Mortgage or other security device serving at any time a similar function upon or affecting the Premises and the Property, (iii) Landlord's right to show the Premises, without material interference with Tenant's use of the Premises, at any time to prospective purchasers and mortgagees of the Premises, and during the last nine (9) months of the Term, to prospective tenants of the Premises; and (iv) the Title Matters.

Section 3.3. Compliance with Applicable Laws. Tenant shall, at its sole cost and expense, comply with all applicable laws, ordinances, rules, regulations, directives and requirements (including those relating to environmental hazardous, toxic or regulated substances or materials whether or not such substances or materials existed on or in the Premises prior to the Commencement Date) relating to the Premises and/or Tenant's activities on or about the Premises, and with all orders of court and all other tribunals and governmental or quasi-governmental departments, agencies and authorities relating to the Premises and/or Tenant's activities on or about the Premises, and with all recorded covenants, conditions and restrictions relating to the Premises (including, but not limited to, the Title Matters) (hereinafter collectively referred to as "**Legal Requirements**").

Section 3.4. Nuisance and Waste Prohibited. Tenant shall keep and maintain the Premises and abutting grounds, sidewalks, roads, parking and landscaped areas in good and neat order and repair and free of nuisance, and shall not commit or suffer to be committed any waste of the Premises.

Section 3.5. Parking. Tenant, Tenant's subtenants, and the employees, invitees, licensees, and agents of Tenant or Tenant's subtenants shall have the exclusive right to use the parking areas of the Premises. Such parking areas shall be under Tenant's sole control, subject to any applicable Legal Requirements.

Section 3.6. Signage. Tenant shall have the right to affix or remove or cause to be affixed or removed to the Premises such signage as Tenant, in its sole discretion, deems appropriate, provided that such signage shall comply with any applicable Legal Requirements.

ARTICLE IV

RENT

Section 4.1. Base Rent. Commencing upon the Commencement Date, Tenant shall pay to Landlord annual "**Base Rent**" in the amount of $697,708.00. If the Term begins on a date other than on the first (1st) day of the month, Base Rent for any such month shall be prorated on a daily basis (at therate of 1/365th of the annual Base Rent) for each day the Term of this Lease is in effect for such month. During the Term (including any Extended Term), on April 1, 2017 and every anniversary thereafter ("**Adjustment Date**"), the annual Base Rent shall be increased by an amount equal to the lesser of (a) 2.0% of the Base Rent in effect immediately prior to the applicable Adjustment Date, or (b) 1.25 multiplied by the product of (i) the percentage change between the Price Index for the month which is two months prior to the Commencement Date or the Price Index used for the immediately preceding Adjustment Date, as applicable, and the Price Index for the month which is two months prior to the applicable Adjustment Date; and (ii) the then current Base Rent (the "**Rental Adjustment**"); *provided, however*, that in no event shall annual Base Rent be reduced as a result of the application of the Rental Adjustment. For purposes hereof, "**Price Index**" shall mean the Consumer Price Index which is designated for the applicable month of determination as the United States City Average for All Urban Consumers, All Items, Not Seasonally Adjusted, with a base period equaling 100 in 1982-1984, as published by the United States Department of Labor's Bureau of Labor Statistics or any successor agency.In the event that the Price Index ceases to be published, its successor index measuring cost of living as published by the same governmental authority which published the Price Index shall be substituted and any necessary reasonable adjustments shall be made by Landlord and Tenant in order to carry out the intent of this Section. In the event there is no successor index measuring cost of living, Landlord shall reasonably select an alternative price index measuring cost of living that will constitute a reasonable substitute for the Price Index.

Section 4.2. Additional Rent. In addition to paying the Base Rent provided for in Section 4.1 hereof, to the extent not paid directly to third party vendors, Tenant shall pay to Landlord "**Additional Rent**" consisting of all operating expenses of any kind or nature with respect to the ownership, operation, management, maintenance and repair of the Premises and the Property.

Section 4.3. Payment of Rent. The Rent shall be paid by Tenant to Landlord by Automated Clearing House Debit initiated by Landlord from an account established by Tenant at a United States bank or other financial institution to such account as Landlord may designate. Upon execution of this Lease, Tenant shall deliver to Landlord a complete Authorization Agreement – Pre-Arranged Payments in the form of Exhibit B attached hereto and incorporated herein by this reference, together with a voided check for account verification, establishing arrangements for payments of the monthly Base Rent. Tenantshall continue to pay all Base Rent by Automated Clearing House Debit unless otherwise directed by Landlord. Tenant shall pay the Base Rent in advance on or before the first (1st) day of each month during the Term hereof. All Additional Rent shall be paid by Tenant when due or if payable to Landlord shall bepayable within twenty (20) days after written demand therefor. All amounts to be paid to Landlord under this Lease shall be paid to Landlord at the address set forth in Section 17.8. hereof or at such other addressas Landlord shall designate in writing from

time to time. Past due Rent payments shall accrue interest at an annual rate equal to the lesser of twelve percent (12%) or the highest rate allowed by applicable law ("**Interest Rate**"). Additionally, if Tenant fails to pay any Rent when due, Tenant shall automatically incur a late fee equal to the greater of $250.00 or two percent (2%) of the amount of the late payment. Notwithstanding the foregoing, no interest shall accrue, and no late fee shall be due, for the first two (2) late payments in any calendar year.

Section 4.4. Net Lease; Rent Absolute. This Lease is and shall be an absolutely net lease, and Landlord is not nor shall it be required to provide any services or do any act or thing with respect to the Premises except as specifically provided herein. All obligations of Tenant under this Lease for the payment of Rent and all other sums payable under the Lease and all obligations of Tenant to perform its obligations under this Lease shall constitute independent obligations of Tenant and shall be paid and performed by Tenant without abatement, deduction, counterclaim, recoupment, suspension, deferment, diminution, deduction, reduction, defense or setoff whatsoever and shall, to the extent not satisfied, survive the termination of this Lease. Except as otherwise expressly provided in this Lease, (i) this Lease shall not terminate, and Tenant shall not have any right to terminate this Lease, during the Term, and (ii) Tenant's obligation to pay the Rent and to perform its obligations is absolute and unconditional and shall survive and not be limited, abated or otherwise affected by any occurrence, event or circumstance whatsoever, including, without limitation, any of the following: expiration or termination of this Lease for whatever reason, any partial or complete destruction from whatever cause; any constructive or actual eviction or dispossession of Tenant from the Premises for failure to pay Rent, or the failure or inability ofthe Tenant to use, occupy or enjoy the same; any foreclosure of any Mortgage Debt or other lien with respect to the Premises for failure to pay Rent; any sale of all or part of the Premises as long as the Lease remains in full force and effect; any bankruptcy or insolvency of Landlord; any action or non-action by Landlord or any other person. Tenant, after receiving advice from its counsel, knowingly, irrevocably, unconditionally and absolutely waives any rights, claims, and defenses that it now has or may have in the future (but for the effect of this Section) under or pursuant to any law, statute, judicial doctrine or regulation relating to its obligation to pay the Rent.

Section 4.5. First Month's Rent. Simultaneously with the execution and delivery of this Leaseby Tenant to Landlord, Tenant shall pay to Landlord an amount equal to the first month's Base Rent. Landlord shall apply the first month's Base Rent to Tenant's Base Rent obligations on the CommencementDate.

Section 4.6. Adjustment of Rent. If this Lease terminates as to any portion of the Premises (i.e., less than the entirety of the Premises) for any reason, including without limitation, Article VIII or Article X of the Lease, during the Term of the Lease, then the Rent for the remaining portion of the Premises shall be adjusted as set forth in this Lease. Rent shall not be adjusted as a result of Tenant entering into one or more Permitted Subleases, and Tenant shall retain all rent, fees and other payments made to Tenant pursuant to such Permitted Subleases.

Section 4.7. Guaranty. On or before the execution of this Lease, Tenant shall cause Ron Ghafary ("**Guarantor**") to execute and deliver to Landlord that certain Amended and Restated Unconditional Guaranty of Payment and Performance dated as of the date hereof given by Guarantor for the benefit of Landlord, as the same may be amended from time to time (the "**Guaranty**").

ARTICLE V

TAXES AND ASSESSMENTS; UTILITIES

Section 5.1. Taxes and Assessments. Tenant shall pay directly to the appropriate governmental entities on or before the due date thereof, all taxes, levies, fees, assessments and other governmental charges of every kind and nature (including, without limitation, real property, ad valorem, personal property, gross

income, franchise, withholding, profits, rent, single business, value added, excise, occupancy, use, impact fees, sales and gross receipts taxes) (collectively, "**Impositions**") levied upon the Premises or personal property located at or used in connection with operating the Premises whether the same shall become due and payable before, or after, and during any tax assessment year or period which is within or partially within, the Term, including all Impositions which may be partially within the Term, including all Impositions which may be assessed, levied or imposed in replacement of, or in addition to, all or any part of same, whether or not measured, calculated by or based upon the Premises or any estate or interest in the Premises or the revenue or income generated by the Premises, regardless of the time at which, or period for which, such Impositions are assessed or charged or the time that such Impositions become a lien against the Premises. Impositions shall not include Landlord's income taxes, excess profit taxes, franchise taxes, or similar taxes on Landlord's business; provided, however, the foregoing exclusion shall not include any rental sales, leasing or similar taxes levied on or with respect to the Rent, or any part thereof, payable under the Lease in lieu of or in addition to general real and/or personal property taxes. Upon receipt of written request by Landlord or Landlord's Mortgagee, Tenant shall provide proof of payment of Impositions.

Section 5.2. Utilities. Tenant shall be responsible for the cost of all Utilities for the Premises, including, without limitation, electricity, gas, water and sewer, telephone and all other communication services. Tenant shall cause all such utility services to the Premises to be metered in its own name or in the name of its subtenants and shall pay or cause to be paid all charges and deposits for such utilities. Tenant shall use utilities only within the capacity of the circuits in the Premises. Landlord shall not be liable for damages resulting from utility interruptions caused by casualty, accident, labor dispute or any other cause, nor shall any interruptions be deemed an actual or constructive or partial eviction or result in any abatement of Rent.

Section 5.3. Other Charges. Tenant shall be responsible for all charges and/or taxes related toany easement or similar agreements, general and special assessments, condominium assessments and fees,levies, fees, vault charges, permits, inspection and license fees affecting the Premises.

ARTICLE VI

COVENANTS OF TENANT CONCERNING MAINTENANCE,INDEMNIFICATION AND OTHER MATTERS

Section 6.1. Maintenance. Tenant shall maintain, and make all repairs, alterations and replacements (including, without limitation, all ordinary, extraordinary, foreseen and unforeseen repairs, alterations and replacements) necessary to operate and maintain the entire Premises in good condition and repair and in compliance with all applicable laws, ordinances, rules and regulations and any recorded covenants, conditions or restrictions relating to the Premises, and shall surrender the Premises when required by this Lease in good condition, reasonable use and wear excepted, with all repairs and maintenance required under this Lease being complete. Notwithstanding anything to the contrary contained herein, Tenant shall make all determinations as to whether capital improvements or replacements are required in order to maintain the Premises in good order and repair, free from actual or constructive waste, in accordance with the standards and requirements set forth in this Lease.

Section 6.2. Alterations. Tenant shall not make any alterations, decorations, additions or improvements (collectively "**Alterations**") of a structural nature in or to the Premises or any Alterationsto the exterior of the Premises without the prior written consent of Landlord in each instance, which consent may be withheld in Landlord's reasonable discretion. The term "**Alterations**" shall not include by way of example and not limitation: (1) painting or wallpapering interior walls of the Premises; (2) hanging pictures and other decorations in a reasonable manner in reasonable locations within the Premises; or (3) installing movable personal property such as oriental carpets, plants and the like. All Alterations to the Premises, or any part

thereof, shall be made in a good and workmanlike manner and in compliance with applicable laws, ordinances, rules, regulations, codes and requirements and any recorded covenants, conditions or restrictions relating to the Premises, or any part thereof. All Alterations which are not movable trade fixtures shall be the property of Landlord and shall remain upon and be surrendered with the Premises. To the extent any Alterations will involve changes to the structure or systems of the Premises, or require a building permit, Tenant shall furnish to Landlord, prior to the commencement of construction, the proposed plans and specifications for Landlord's approval and upon completion of construction, "as-built" plans and specifications for such Alterations. Landlord shall provide Tenant with its objections, in writing, to Tenant's proposed plans and specifications within fifteen (15) business days after receipt from Tenant. Tenant shall submit revised plans and specifications until such time as Landlord has approved Tenant's proposed plans and specifications for such Alterations. If Landlord fails to object, in writing, to Tenant's proposed plans and specifications within fifteen (15) business days after receipt from Tenant, Landlord shall be deemed to have approved such proposed plans and specifications. Notwithstanding the foregoing, Tenant shall have the right, but not the obligation, to remove all Alterations from the Premises at the end of the Term; provided, however, should Tenant remove any such Alterations from the Premises, Tenant shall repair any and all damage to the Premises caused by such removal.

Section 6.3. Landlord's Non-liability; Indemnification of Landlord. Landlord shall not be liable for any loss, damage or injury of any kind or character to any person or property, arising from any use of the Premises, or any part thereof, or caused by any defect in any improvements located on the Premises, or any part thereof, or in any equipment or other facility therein, or caused by or arising from any act or omission of Tenant, or of any subtenants, agents, employees, contractors, subcontractors, licensees, or invitees of Tenant, or arising out of any work or Alterations performed by Tenant or any subtenant, or by or from any accident on the Premises, or any part thereof, or any fire or other casualty thereon, or occasioned by the failure of Tenant to maintain the Premises, or any part thereof, in safe condition, or arising from any other cause whatsoever. Tenant, as a material part of the consideration of this Lease, hereby waives on its behalf all claims and demands against Landlord for any such loss, damage or injury of Tenant, and hereby agrees to indemnify and hold Landlord entirely free and harmless from all liability for any such loss, damage or injury of Tenant, and hereby agrees to indemnify and hold Landlord entirely free and harmless from all liability for any such loss, damage or injury of all other persons, and from all costs and expenses arising therefrom (including reasonable attorneys' fees and expenses). Tenant agrees to pay, and to protect, indemnify, and save harmless Landlord from and against any and all liabilities, losses, damages, costs, expenses (including reasonable attorneys' fees and expenses), causes of action, suits, claims, demands, or judgments of any nature whatsoever arising from

(i) any injury to or the death of, any person, or damage to property, in, on or about the Premises, or any part thereof, or upon adjoining public sidewalks, streets, or ways, or in any manner growing out of or connected with the use, nonuse, condition, or occupation of the Premises, or any part thereof, or resulting from the condition thereof or of adjoining public sidewalks, streets or ways, except to the extent caused by any negligent act or omission by Landlord; (ii) violation by Tenant of any agreement or condition of this Lease; (iii) violation by Tenant of any contract or agreement to which Tenant is a party or of any restriction, statute, law, ordinance, or regulation, in each case affecting the Premises, or any part thereof, or the ownership, occupancy or use thereof; and (iv) (1) the presence of any "Hazardous Material" (as defined below) on or under, or the escape, seepage, leakage, spillage, discharge, emission, discharging or release of any Hazardous Material from, the Premises or any part thereof, (2) any liens against the Premises, or any part thereof, permitted or imposed by any Environmental Laws (as defined below), or any actual or asserted liability or obligations of Landlord or any of its affiliates or subsidiaries under any Environmental Laws, and (3) any actual or asserted liability or obligations of Tenant or any of its affiliates or subsidiaries under any Environmental Laws. Tenant hereby acknowledges and agrees that Tenant, or affiliates of Tenant, were the prior owners of the Premises. Tenant further agrees that the terms and conditions of this Section 6.3. shall

apply to any and all matters notwithstanding that such matters may have occurred or arisen prior to the date of this Lease or during the term of this Lease. Landlord, as used in this Section 6.3 shall include any beneficiary of any trust or any agent, employee, or representative of Landlord or any trustee and the Landlord's Mortgagee and their shareholders, directors, officers, employees, agents, representatives, members and partners. Any indemnification under this Section 6.3. shall constitute Additional Rent payable within twenty (20) days of demand and shall survivethe termination or expiration of this Lease, including without limitation, the termination or rejection ofthis Lease in bankruptcy.

For purposes of this Lease, the following terms shall have the following respective meanings:

(i) "**Hazardous Material**" means any hazardous substance or any pollutant or contaminant defined as such in (or for purposes of) the Comprehensive Environmental Response, Compensation, and Liability Act, any so-called "Superfund" or "Superlien" law, The Toxic Substances Control Act, or any other federal, state or local statute, law, ordinance, code, rule, regulation, order or decree, now or hereafter in force, regulating, relating to or imposing liability or standards of conduct concerning any hazardous, toxic or dangerous waste, substance or material; asbestos or any substance or compound containing asbestos; polychlorinated biphenyls or any substance or compound containing any polychlorinated biphenyl; petroleum and petroleum products; pesticides; and any other hazardous, toxic or dangerous waste, substance or material.

(ii) "**Environmental Laws**" means the Comprehensive EnvironmentalResponse, Compensation, and Liability Act, any so-called "Superfund" or "Superlien" law, the Toxic Substances Control Act, or any other federal, state or local statute, law, ordinance, code, rule, regulation,order or decree, now or hereafter in force, regulating, relating to, or imposing liability or standards of conduct concerning any Hazardous Material.

Section 6.4. No Liens. Tenant shall not create or suffer to be created or to remain, directly or indirectly, and will discharge or promptly cause to be discharged, any lien, charge or encumbrance on, or pledge of, all or any part of the Premises (each an "**Encumbrance**"), including, without limitation, any mechanic's, materialmen's, contractor's or subcontractor's liens arising from or any claim for damage growing out of any Alterations, construction, repair, restoration, replacement or improvement related to the Premises. If Tenant fails to remove or bond over any such Encumbrance within twenty (20) days afterwritten notice thereof from Landlord, Landlord may, but shall not be obligated to, discharge the same either by paying the amount claimed to be due or otherwise, without any investigation or contest of the validity thereof, and any amounts expended by Landlord in so doing, including costs, expenses and reasonable attorneys' fees, shall constitute Additional Rent payable within twenty (20) days of demand and shall survive the termination of this Lease.

ARTICLE VII

RIGHT TO CONTEST

Landlord shall have the right to contest all Impositions at Landlord’s sole cost and expense. Landlord shall give notice to Tenant of Landlord’s contest to any Impositions. Landlord agrees that each such contest shall be promptly prosecuted to its final conclusion, except to the extent deemed commercially unreasonable by Landlord, in Landlord’s sole discretion. Landlord shall give notice to Tenant of any increases in Impositions. In the event Landlord elects not to contest any Impositions, then Tenant shall have the right to contest such Impositions upon written notice to Landlord. Landlord and Tenant agree that each such contest shall be promptly prosecuted to a final conclusion. If necessary in theprosecution of any such contest by Landlord or Tenant, the non-prosecuting party shall join as a party to such contest, and the prosecuting party shall pay, and save the non-prosecuting party, or the non-prosecuting party’s mortgagee, if any, harmless

against, any and all losses, judgments, decrease and costs (including reasonable attorneys' fees and expenses) in connection with any such contest and shall,promptly after the final settlement, compromise, or determination of such contest, fully pay and dischargethe amounts that shall be levied, assessed, charged or imposed or be determined to be payable therein orin connection therewith, and perform all acts, the performance of which shall be ordered or decreed as a result thereof. No such contest by Tenant shall subject Landlord to the risk of any civil or criminal liability.

ARTICLE VIII

DAMAGE OR DESTRUCTION BY FIRE OR OTHER CASUALTY

If, during the Term, the Premises, or the Property comprising part of the Premises, is partially or totally damaged or destroyed by fire or other casualty, Tenant shall, at its sole cost and expense, repair and restore the Premises and/or the Property, as applicable, as speedily as possible, to the value, character and condition existing prior to such damage or destruction in accordance with the provisions of this Lease applicable to maintenance and repair, alterations and restoration, regardless of whether Tenant receives sufficient insurance proceeds, subject to the provisions below. Where insurance proceeds are available, Tenant shall not be obligated to begin to repair and restore the Property until such time as such insurance proceeds have been made available to Tenant; provided, however, that Tenant shall take reasonable steps to ensure that the affected Property is secure and does not pose unreasonable risk of harm to adjoining property and/or persons. Upon the written request of Tenant (accompanied by evidence reasonably

satisfactory to Landlord that such amount has been paid or is due and payable and is properly part of such costs), Landlord shall promptly make available in installments, an amount up to but not exceeding the amount of any insurance proceeds received by Landlord with respect to such casualty. Landlord shall use commercially reasonable efforts in good faith to cause insurance proceeds to be made available to Tenant by Landlord or Landlord's Mortgagee for purposes of such repair and restoration. Provided that Landlordhas received evidence reasonably satisfactory to Landlord that the Premises and Property have been restored and repaired to at least the value, character and condition existing prior to such damage or destruction, then Tenant shall be entitled to keep any portion of the insurance proceeds which may be in excess of the cost of restoration. Tenant shall bear all additional costs of such restoration in excess of the insurance proceeds. There shall be no abatement or reduction of any Rent under this Lease due to any such damage, destruction or repair or restoration and Tenant shall have no right to terminate this Lease. Notwithstanding anything to the contrary contained herein, if the Property comprising the Premises is totally destroyed by fire or other casualty, or, as to a material portion of the Property, is partially destroyed by fire or other casualty and the time to restore the Property is reasonably estimated to take longer than one hundred eighty (180) days, and fewer than two (2) years remain in the Term at the time ofthe casualty, then Tenant shall have the right to cancel and terminate this Lease upon written notice to Landlord, provided within 60 days of the date of the casualty, in which case Landlord shall be entitled to such insurance proceeds. Upon Tenant's notice to Landlord of Tenant's election to terminate this Lease, the Lease shall automatically terminate, and the Term hereof shall come to an end with the same forceand effect as if the Term of the Lease, by the terms and provisions hereof, were to expire on such date.

ARTICLE IX

INSURANCE AND WAIVER OF SUBROGATION

Section 9.1. Property Insurance. Tenant shall, at Tenant's cost and expense, insure the Premises against loss or damage normally covered under commercial property insurance policies (including rent loss and/or business interruption) and otherwise with such coverages, deductibles (not to exceed $25,000.00), sub-

limits, and exclusions as are typical for owners of real estate similar to the Premises from time to time and/or as are required by applicable law. Such insurance shall be for the full insurable value (actual replacement value without deduction for physical deterioration) of the Premises, shall name Landlord as an additional insured, Landlord's Mortgagee as first mortgagee/secured party, and Tenant, Landlord and Landlord's Mortgagee as loss payees, and shall provide that the insurer shall endeavor to provide at least thirty (30) days' prior written notice of cancelation or change of the insurance policy to Landlord, Tenant and the Landlord's Mortgagee. Tenant shall, from time to time and upon the written request of Landlord or the Landlord's Mortgagee, furnish the requesting party with certificates of insurance demonstrating that such insurance is in full force and effect. Landlord shall use commercially reasonable efforts in good faith to cause Landlord's Mortgagee to make insurance proceeds available to Tenant for purposes of such repair and restoration of the Premises (and the Property comprising part of the Premises), as provided in Article VIII above.

Section 9.2. Liability and Other Insurance. Tenant shall, at Tenant's cost and expense, obtain and keep in force a policy or policies of commercial general liability insurance covering the Premises and any losses or claims arising in whole or in part from the use of the Premises, naming Landlord and Landlord's Mortgagee as additional insureds, which as of the Commencement Date shall be with minimum single limit of coverage for any one occurrence of not less than $1,000,000 with an aggregate of not less than $2,000,000 and an excess liability policy of not less than $5,000,000 on a per location basis. Tenant's liability insurance shall provide that it is primary coverage and not excess over or contributory with any other insurance coverage (including any other insurance maintained by Landlord or Tenant). All such insurance shall provide that the insurer shall endeavor to provide at least thirty (30) days' prior written notice of cancelation or change of the insurance policy to Landlord, Tenant and the Landlord's Mortgagee. Tenant shall from time to time upon the written request of the Landlord (or Landlord's Mortgagee) furnish to the requesting party certificates of insurance demonstrating that all such insurance is in full force and effect. Tenant shall not maintain deductibles in excess of Twenty-Five Thousand and No/100 Dollars ($25,000.00) without Landlord's prior consent, which shall not be unreasonably withheld, conditioned or delayed.

Section 9.3. Additional Insurance. Tenant shall, at Tenant's cost and expense, obtain and keep in force a policy or policies of the following insurance covering the Premises:

(i) If the Premises, or any part thereof, is located within a one hundred (100) year flood plain area designated by Federal Emergency Management Agency, federal flood and excess flood, in such amounts as may be customary for comparable properties in the area and if available from insurance companies authorized to do business in the state in which the Premises are located at rates which are economically practicable in relation to the risks covered.

(ii) If Tenant shall engage or cause to be engaged any contractor to perform work any Alterations in, on or about the Premises, the estimated cost of which will exceed $250,000.00, Tenant shall require such contractor to carry and maintain, at no expense to Landlord, commercial general liability insurance, builder's risk insurance, including but not limited to contractor's liability coverage, completed operations coverage, broad form property damage endorsement, workers compensation, and contractor's protection liability coverage in such amounts and with such deductibles and such companies as are customary for the Alterations to be performed. Upon Landlord or Landlord's Mortgagee's written request, Tenant shall provide evidence of that such insurance is in full force and effect.

(iii) Rental loss insurance in an amount equal to at least twelve (12) months' Base Rent. Landlord shall be named additional insured on such policy.

(iv) Comprehensive Boiler and Machinery or Equipment Breakdown Insurance against loss or damage from explosion of any steam or pressure boilers or similar apparatus, if any, and other building equipment including HVAC units located in or about the Premises and in an amount equal to the lesser of 25% of the 100% replacement cost of the Premises or $5,000,000.00.

(v) Automobile liability insurance, including owned, non-owned and hired car liability insurance for combined limits of liability of $5,000,000.00 per occurrence. The limits of liability can be provided in a combination of an automobile liability policy and an umbrella liability policy.

(vi) Workers' compensation and Employers Liability insurance with statutorily mandated limits covering all persons employed by Tenant on the Premises in connection with any work done on or about the Premises for which claims for death or bodily injury could be asserted against Landlord, Tenant or the Premises.

Section 9.4. Waiver of Subrogation. Any insurance maintained by either Landlord or Tenant shall provide that, to the extent permitted by law, the insurer waives all rights of subrogation against the Landlord, Tenant, as applicable, and their agents or employees, with respect to losses payable under the policy.

Section 9.5.Insurance Company Rating Requirements. All policies of insurance requiredunder this Lease shall be placed with insurance companies having claims paying ratings no lower than A.M. Best "A-" or equivalent NAIC rating, from time to time.

ARTICLE X

EMINENT DOMAIN

Section 10.1. Total Condemnation. If all or substantially all of the Premises is taken under the power of eminent domain by, or conveyed in lieu of such exercise to, any public authority, including a permanent taking of such a substantial part of the Premises resulting in the portion of the Premises remaining after such condemnation being unsuitable for the Permitted Use, as determined by Tenant in the exercise of good faith

business judgment (and Tenant provides to Landlord an officer's certificate executed by an officer of Landlord certifying to the same) (a "**Total Condemnation**") then Tenant's obligations under this Lease shall terminate as of the date upon which title to the Premises shall become vested in the condemning authority, all condemnation proceeds, awards and damages payable for any condemnation of the Premises (the "**Award**") shall belong to Landlord, and the Lease shall automatically terminate, and the Term hereof shall come to an end with the same force and effect as if the Term of the Lease, by the terms and provisions hereof, were to expire on such date.

Section 10.2. Partial Condemnation. In the event of a taking which is not a Total Condemnation (a "**Partial Condemnation**"), Tenant's obligations as to the Premises shall not terminate, Rent shall not abate or be reduced, and Tenant shall, at its sole cost and expense but subject to the proceeds made available to Tenant as a result of such Partial Condemnation, restore the balance of the Premises to the same condition, as nearly as practicable, as prior to such Partial Condemnation, under the provisions of this Lease. The Award resulting from such taking or conveyance shall be payable to Landlord. Landlord shall use commercially reasonable efforts in good faith to cause such proceeds to be made available to Tenant for such purpose. Upon the written request of Tenant (accompanied by evidence reasonably satisfactory to Landlord that such amount has been paid or is due and payable and is properly part of such costs), Landlord shall promptly make available in installments, an amount up to but not exceeding the amount of any Award received by Landlord with respect to such Partial Condemnation. Landlord shall be entitled to keep any portion of the Award which may be in excess of the cost of restoration, and Tenant shall bear all additional costs of such restoration in excess of the Award. Notwithstanding anything to the contrary contained herein, if fewer than two (2) years remain in the Term at the time of the Partial Condemnation, then Tenant shall have the right to cancel and terminate this Lease upon written notice to Landlord, provided within 60 days of the date of the Partial Condemnation, in which case Landlord shall be entitled to such condemnation proceeds. Upon Tenant's notice to Landlord of Tenant's election to terminate this Lease, the Lease shall automatically terminate, and the Term hereof shall come to an end with the same force and effect as if the Term of the Lease, by the terms and provisions hereof, were to expire on such date.

ARTICLE XI

ASSIGNMENT AND SUBLETTING

Section 11.1 Assignment and Sublease upon Landlord Approval. Tenant shall not assign, mortgage or otherwise encumber this Lease or sublet the whole or any part of the Premises, whether voluntarily or by operation of law (collectively, "**Assignments**"), or permit the use or occupancy of the Premises by anyone other than Tenant or for any use other than the use described in Section 1.5 hereof, without the prior written consent of Landlord, which consent may not be unreasonably withheld, conditioned or delayed. The consent by Landlord to any Assignment, or Landlord's collection or acceptance of Rent from any such assignee, subtenant or other occupant (collectively "**Assignee**"), shall not constitute a waiver or release of Tenant of any covenant or obligation contained in this Lease or approval of any Assignment that has not been approved by Landlord in writing. Consent by Landlord in one or more instances to any Assignment shall not be construed to relieve Tenant from the requirement of obtaining Landlord's consent to any future Assignment. If Tenant desires to enter into an Assignment, Tenant shall give Landlord written notice at least thirty (30) days in advance of the date on which the Assignment is to take effect, such notice to include the terms and conditions of the proposed Assignment, financial information on the proposed Assignee and other information as Landlord may reasonably request relating to the proposed Assignment and Assignee. If Landlord fails to consent within ten (10) business days after receipt of Tenant's written request and all such other information required to be submitted to Landlord with such request, Tenant shall send Landlord written notice of such failure, which notice shall include, in all capital letters, the following: "THIS SHALL SERVE AS A SECOND NOTICE OF TENANT'S REQUEST FOR LANDLORD'S CONSENT TO A PROPOSED

ASSIGNMENT OF THE LEASE. FAILURE TO RESPOND WITHIN TEN (10) BUSINESS DAYS SHALL BE CONCLUSIVELY DEEMED LANDLORD'S APPROVAL OF SUCH REQUEST." If Landlord does not respond within ten (10) business days after receipt of such notice, Landlord shall be deemed to have consented to Tenant's request for such Assignment.

In the event of any Assignment permitted under the terms of this Article XI, then: (i) Tenant, and any subsequent assignee who in turn enters into an Assignment, shall each remain fully and primarily liable for all of the obligations of Tenant under this Lease (regardless of any subsequent amendment or modification of this Lease and regardless of any further Assignments, all of which are hereby deemed to be consented to by Tenant and subsequent Assignees); (ii) the Premises shall only be used or occupied for the use described in Section 1.5 hereof; (iii) each assignee must agree in writing to assume the obligationsof Tenant under this Lease by agreement satisfactory to Landlord and delivered to Landlord on or before the date that the Lease assignment is effective.

Section 11.2 Permitted Sublease. Notwithstanding anything to the contrary contained herein, Tenant may sublet the Premises, in whole or in part, without Landlord's consent ("**Permitted Subleases**") provided that, at all times: (i) the sublease is expressly subject and subordinate to this Lease;

(ii) Tenant shall remain primarily liable for all of Tenant's obligations under this Lease; (iii) the sublease shall not contain any terms inconsistent with this Lease (or if so, the terms of this Lease shall control);

(iv) the rent due under any Permitted Sublease shall be fixed rent and shall not be based on the net profits of any subtenant; (v) Tenant shall promptly provide Landlord with any notice of default received by Tenant from any subtenant or any notice of default sent by Tenant to any subtenant and Tenant shall furnish Landlord with any and all information requested by Landlord reasonably necessary for a determination of the status of any sublease; and (vi) unless otherwise mutually agreed upon by Landlord and the related subtenant, the Permitted Sublease shall terminate upon the expiration or sooner termination of this Lease (including any renewals hereof), provided that the related subtenant agrees to attorn to Landlord if Landlord elects to assume the Permitted Sublease following a termination of this Lease. Tenant agrees to promptly notify Landlord in writing of all Permitted Subleases the Tenant enters into under this Lease. Landlord may accept Rent, Additional Rent, and any other sums that may become due under this Lease directly from any subtenant as agent for Tenant, provided that Landlord shall apply any sums so accepted as a credit towards Rent owed by Tenant. Tenant shall obtain Landlord's prior written approval for any other subleases, which approval may not be unreasonably withheld, conditioned or delayed.

Section 11.3 Intentionally omitted.

Section 11.4 Permitted Assignment. Notwithstanding anything to the contrary contained in this Article XI and provided that no Event of Default has occurred and is continuing at the time of the proposed assignment or other transfer, and provided further that any assignee agrees to assume all of Tenant's obligations under this Lease, Tenant shall have the right to assign or otherwise transfer all, but not less than all, of its interest in, to and under this Lease without Landlord's consent to (i) an Affiliate of Tenant, (ii) any entity which purchases or otherwise acquires all or substantially all of the assets or equity interest of Tenant in a bona fide sale for fair market value, or (iii) a Qualified Operator (each, a "**Permitted Transfer**"). A "**Qualified Operator**" shall mean an individual, partnership, corporation, limited liability company, trust, unincorporated organization, governmental authority or any other form of entity (a "**Person**") who, following the consummation of the assignment contemplated herein, for two (2) consecutive years immediately prior to the date of assignment or transfer, (A) has a CFCCR (defined below) of at least 2.0x; (B) generates EBITDAR (defined below) of at least $10,000,000, and (C) has an Effective Debt to EBITDAR ratio no greater than 4.0x; *provided, however,* that Tenant may satisfy the foregoing conditions of a Qualified Operator by providing, or

causing to be provided, a guaranty agreement, in form and substance reasonably acceptable to and approved by Landlord, in writing, which guaranty shall be from an entity that meets the requirements of (A), (B) and (C) set forth in this Section

11.04. In the event that Tenant effects a Permitted Transfer pursuant to clause (iii), Tenant shall be released from any liability arising under this Lease from and after the date of such assignment. In the event that Tenant effects a Permitted Transfer pursuant to clauses (i) or (ii), Lessee shall not be released from liability under this Lease.

For purposes hereof:

"*CFCCR*" means with respect to the twelve month period of time immediately preceding the date of determination, the ratio calculated for such period of time, each as determined in accordance with GAAP, of (i) the sum of Consolidated Net Income (excluding non-cash income), Depreciation and Amortization, Interest Expense, income taxes, Operating Lease Expense and non-cash expenses to (ii) the sum of Operating Lease Expense (excluding non-cash rent adjustments), scheduled principal payments of long term Debt, scheduled maturities of all Capital Leases, dividends and Interest Expense (excluding non-cash interest expense and amortization of non-cash financing expenses). For purposes of calculating the CFCCR, the following terms shall be defined as set forth below:

"*Capital Lease*" shall mean all leases of any property, whether real, personal or mixed, by a Person, which leases would, in conformity with GAAP, be required to be accounted for as a capital lease on the balance sheet of such Person. The term "Capital Lease" shall not include any operating lease.

"*Consolidated Net Income*" shall mean with respect to the period of determination, the net income or net loss of a Person. In determining the amount of Consolidated Net Income, (i) adjustments shall be made for nonrecurring gains and losses or non-cash items allocable to the period of determination, (ii) deductions shall be made for, among other things, Depreciation and Amortization, Interest Expense, Operating Lease Expense, and (iii) no deductions shall be made for income taxes or charges equivalent to income taxes allocable to the period of determination, as determined in accordance with GAAP.

"*Debt*" shall mean with respect to a Person, and for the period of determination (i) indebtedness for borrowed money, (ii) subject to the limitation set forth in sub item (iv) below, obligations evidenced by bonds, indentures, notes or similar instruments, (iii) obligations under leases which should be, in accordance with GAAP, recorded as Capital Leases, and (iv) obligations under direct or indirect guarantees in respect of, and obligations (contingent or otherwise) to purchase or otherwise acquire, or otherwise to assure a creditor against loss in respect of, indebtedness or obligations of others of the kinds referred to in clauses (i) through (iv) above, except for guaranty obligations of such Person, which, in conformity with GAAP, are not included on the balance sheet of such Person.

"*Depreciation and Amortization*" shall mean the depreciation and amortization accruing during any period of determination with respect to a Person, as determined in accordance with GAAP.

"*Interest Expense*" shall mean for any period of determination, the sum of all interest accrued or which should be accrued in respect of all Debt of a Person, as determined in accordance with GAAP.

"*Operating Lease Expense*" shall mean the sum of all payments and expenses incurred by a Person, under any operating leases during the period of determination, as determined in accordance with GAAP.

"EBITDA" means for the twelve (12) month period ending on the date of determination, the sum of a Person's net income (loss) for such period plus, in each case to the extent previously deducted in calculating

net income (loss): (i) income taxes, (ii) interest payments on all of its debt obligations (including any borrowings under short term credit facilities), (iii) all non-cash charges including depreciation and amortization, and (iv) Non-Recurring Items (defined below).

"*EBITDAR"* means the sum of a Person's EBITDA and its total land and building rent for the twelve (12) month period ending on the date of determination.

"*Effective Debt*" shall mean, for the period of determination, the sum of (i) the Person's Debt and

(ii) eight (8) multiplied by the annual rental payments due under leases which should not be, in accordance with GAAP, recorded as Capital Leases.

"*Lease Adjusted Leverage"* means with respect to a Person, as of any applicable date, the sum of

(i) ten (10) times such Person's total land and building rent for the twelve (12) month period ending onthe date of determination, and (ii) the total current balance of such Person's total debt obligations (including any borrowings under short term credit facilities) on such date, divided by EBITDAR.

"*Non-Recurring Items"* shall mean with respect to a Person, items of the sum (whether positive or negative) of revenue minus expenses that, in the judgment of Landlord, are unusual in nature, occur infrequently and are not representative of the ongoing or future earnings or expenses of such Person.

ARTICLE XII

END OF TERM

Tenant shall surrender actual and exclusive possession of the entirety of the Premises to Landlord at the end of the Term, in good condition with all maintenance and repairs required under Section 6.1 complete, and otherwise in compliance with this Lease, subject only to such subleases, tenancies and occupancies permitted to remain in effect beyond the expiration of the Term. Additionally, upon request by Landlord at least sixty (60) days prior to the end of the Term, on or before the expiration date of the Term, Tenant shall remove the laboratory space improvements and repair any damage caused by such removal.

ARTICLE XIII

EVENTS OF DEFAULT; LANDLORD'S REMEDIES; EXPENSES OF ENFORCEMENT

Section 13.1. Events of Default. The occurrence of any one or more of the following shallconstitute an "**Event of Default**" under this Lease:

(i) Tenant shall fail to pay when due any Rent or other amount owed to Landlord under this Lease, and such failure shall continue for a period of five (5) days from the date such payment was due; provided, however, in any given twelve (12) month period (the "**Period**"), Tenant shall be entitled to written notice from Landlord for the first occasion in such Period that Tenant has not paid the foregoing amounts when due, and Tenant shall not be in default hereunder until five (5) days after such written notice has been given by Landlord; and further provided, Landlord shall not be obligated to give more than one (1) such written notice in any Period, and any failure by Tenant to pay the foregoing amounts within five (5) days after the same are due in any Period after Landlord has given Tenant one (1) previous written notice shall be considered an Event of Default; or

(ii) Tenant shall fail to perform any other covenant or agreement in this Lease or the Title Matters and such failure shall continue for a period of thirty (30) days after receipt of written notice from

Landlord (or if such failure is not capable of being cured within thirty (30) days, provided that Tenant has commenced such cure within the thirty (30) day period and is diligently proceeding to cure such failure), or if any such failure involves a hazardous condition or a failure to maintain insurance required by the Lease, such failure is not cured by Tenant promptly upon notice to Tenant; or

(iii) Tenant or Guarantor shall make a general assignment for the benefit of creditors, or shall admit in writing its inability to pay its debts as they become due, or shall file or have filed against it a petition in any proceeding seeking any reorganization, arrangement, composition, readjustment, liquidation, dissolution or similar relief under any present or future statute, law or regulation or seeking appointment of a receiver, trustee, custodian or other similar official for it or for all or any substantial part of its property, and such proceeding shall not be vacated or discharged within thirty (30) days, or shall be adjudicated insolvent or bankrupt, or a receiver, trustee, custodian or other similar official shall be appointed for Tenant or for all or any substantial part of its property, or a substantial part of its property shall be attached, executed upon or otherwise impressed with a lien in favor of one or more creditors, and such appointment, attachment, execution or lien shall not be vacated or discharged within thirty (30) days; or

(iv) Tenant dissolves or liquidates; or

(v) There is an Event of Default or other breach under the Guaranty continuing beyond the passage of all applicable notice and cure or grace periods; or

(vi) Prior to any expiration of the Letter of Credit (defined below), Tenant shall fail to provide to Landlord evidence satisfactory to Landlord in its sole discretion that either (i) the Letter of Credit will be renewed by Tenant's Lender (defined below) upon the same termsand conditions, or (ii) Landlord's first position lien on Tenant's Personalty set forth in Section 15.7 of this Lease shall be restored such that Landlord's first position lien is no longersubordinate to Tenant's Lender or any other parties.

Section 13.2. Termination of Lease; Releting. Upon the occurrence of any Event of Default, in addition to any other remedies provided by law, Landlord may terminate this Lease, or Landlord may, without terminating this Lease, re-enter the Premises or any property comprising part of the Premises and dispossess Tenant and remove Tenant's effects and relet the portion of the Premises occupied by Tenant for the account of Tenant for such rent and on such terms as shall be satisfactoryto Landlord, crediting the actual proceeds of reletting (after deducting the costs and expenses of re- entry, alterations and additions and the expense of reletting) to the unpaid amounts due under this Lease during the remainder of the Term and Tenant shall remain liable to Landlord for the balance owed. Tenant shall not be entitled to any rents received by Landlord which exceed the balance owed by Tenant to Landlord calculated as provided in the immediately preceding sentence. Landlord shall use reasonable efforts to relet the Premises or any part thereof for such Rent and upon such terms as Landlord shall reasonably determine (including the right to relet the Premises for a greater or lesser Term than that remaining under this Lease, the right to relet the Premises as a part of a larger area, and the right to change the character or use made of the Premises) and Landlord shall not be required to accept any tenant offered by Tenant, to observe any instructions given by Tenant about such reletting, to lease the Premises prior to other vacant space owned, controlled or managed by Landlord or an affiliate of Landlord, to expend sums to lease the Premises, or to lease the Premises at below market rates. In any such case, Landlord may make repairs, alterations and additions in or to the Leased Premises, and redecorate the same to the extent Landlord deems necessary or desirable, and Tenant shall, upon demand, pay the cost thereof, together with Landlord's expenses of reletting including, without limitation, any broker's commission incurred by Landlord. If the consideration collected by Landlord upon any such reletting plus any sums previously collected from Tenant are not sufficient to pay the full amount of all Rent, including any amounts treated as Additional Rent hereunder and other sums reserved in this Lease for the remaining Term hereof, together with the costs of repairs, alterations, additions, redecorating, and Landlord's expenses of reletting and the collection of the Rent

accruing therefrom (including attorneys' fees and brokers' commissions), Tenant shall pay to Landlord the amount of such deficiency upon demand and Tenant agrees that Landlord may file suit to recover any sums falling due under this Paragraph from time to time on one or more occasions, without the necessity of Landlord's waiting until expiration of the Term

Section 13.3. Termination of Lease; Money Judgment. Upon termination of this Lease as a result of the occurrence of an Event of Default, Landlord shall be entitled as final and liquidated damages to a money judgment against Tenant in the amount of the aggregate of the following: (i) all unpaid Rent due on or before the date of termination, together with interest thereon at the InterestRate; (ii) the excess, if any, of all Rent which would have become due on or before the date of the judgment but for the termination over the fair market rental value of the Premises for such period, taking into account a reasonable vacancy and lease up factor, together with interest thereon at the Interest Rate; and (iii) the excess, if any, of all Rent which would come due after the date of the judgment but for the termination of this Lease over the fair rental value of the Premises for such period, taking into account a reasonable vacancy rate and lease up factor, discounted to present value using as a discount factor the discount rate of the Federal Reserve Bank of Chicago in effect at the time of judgment.

Section 13.4. Expenses of Enforcement. If, at any time during the Term of this Lease, either Landlord or Tenant shall institute any action or proceeding against the other which is related to or arises out of the provisions of this Lease or any default hereunder, then the non-prevailing party shall pay the reasonable costs and expenses of the prevailing party, including, without limitation, reasonable attorneys' fees and expenses.

Section 13.5. Landlord's Right to Cure. Landlord may assign its rights under this Section to the Landlord’s Mortgagee. If Tenant shall fail to make any payment, or to perform any act required to be made or performed under this Lease and to timely cure the same, Landlord, without waiving or releasing any obligation or Event of Default, may (but shall be under no obligation to) at any time thereafter make such payment or perform such act for the account and at the expense of Tenant, and may, to the extent permitted by law, enter upon the Premises (or the Property comprising the Premises) for such purpose and take all such action thereon as, in Landlord's opinion, may be necessary or appropriate therefore, and no such entry shall be deemed an eviction of Tenant. Tenant shall immediately repay the same to Landlord, upon demand, together with all costs and expenses so incurred, together with a late charge thereon, all to the extent permitted by law, at the Overdue Rate from the date on which such sums or expenses are paid or incurred by Landlord. The obligations of Tenant and rights of Landlord contained in this Article shall survive the expiration or earlier termination of this Lease.

Section 13.6. Bankruptcy of Tenant.

(a) In the event that Tenant shall become a debtor in a case filed under Chapter 7 of the Bankruptcy Code and Tenant's trustee or Tenant shall elect to assume this Lease for the purpose of assigning the same or otherwise, such election and assignment may be made only if the provisions of Section 13.6.(b) and Section 13.6.(c) are satisfied as if the election to assume were made in a case filed under Chapter 11 under Title 11 of the United States Code (the “Bankruptcy Code”).

(b) (i) In the event that Tenant shall become a debtor in a case filed under Chapter 11 of the Bankruptcy Code, or in a case filed under Chapter 7 of the Bankruptcy Code which is converted to a case under Chapter 11 of the Bankruptcy Code, Tenant's trustee or Tenant, as debtor-in- possession, must elect to assume this Lease within the time period specified by Section 365(d)(4) of the Bankruptcy Code or Tenant's trustee or the debtor-in- possession shall be deemed to have rejected this Lease. In the event that Tenant, Tenant's trustee or the debtor-in-possession has failed to perform all of Tenant's obligations under this Lease within the time periods (excluding grace periods) required for such performance, no election by Tenant's

trustee or the debtor-in-possession to assume this Lease, whether under a case filed under Chapter 7 or Chapter 11, shall be permitted or effective unless each of the following conditions has been satisfied:

(1) Tenant's trustee or Tenant, as debtor-in- possession, has cured all Events of Default under this Lease (except any Events of Default that Tenant's trustee or Tenant, as debtor-in- possession, are excused from curing under Section 365(b)(1)(A) of the Bankruptcy Code) , or has provided Landlord with adequate assurance that Tenant will promptly cure all Events of Default (except any Events of Default that Tenant's trustee or Tenant, as debtor-in- possession, are excused from curing under Section 365(b)(1)(A) of the Bankruptcy Code) within a reasonable period of time as determined by the Bankruptcy Court.

(2) Tenant's trustee or Tenant, as debtor-in-possession, has compensated Landlord, or has provided Landlord with adequate assurance that Tenant's trustee or Tenant, as debtor-in-possession, will promptly compensate Landlord, for any actual pecuniary loss incurred by Landlordarising from the default of Tenant, Tenant's trustee, or Tenant as debtor-in-possession under the Lease.

(3) Tenant's trustee or Tenant, as debtor-in-possession, has provided Landlord with adequate assurance of future performance under the Lease.

(4) The assumption of this Lease will not breach or cause a default under any provision of any other lease, mortgage, financing arrangement or other agreement by which Landlord is bound.

(ii) For purposes of this Section 13.6(b), Landlord and Tenant acknowledge that adequate assurance of future performance shall mean: (1) Tenant's trustee or the debtor-in- possession has and will continue to have sufficient unencumbered assets after the payment of all secured obligations and administrative expenses to assure Landlord that sufficient funds will be available to fulfill the obligations of Tenant under this Lease, (2) there shall have been deposited with Landlord, or the Bankruptcy Court shall have entered an order segregating, sufficient cash payable to Landlord, (3) Tenant's trustee or the debtor-in-possession shall have granted a valid and perfected first lien and security interest and/or mortgage in property of Tenant, Tenant's trustee or the debtor-in-possession, acceptable as to value and kind to Landlord, to secure to Landlord the obligation of Tenant, Tenant's trustee or the debtor-in-possession to cure the Events of Default under this Lease, monetary and/or non-monetary, or (4) the Bankruptcy Court has determined that Tenant's trustee or Tenant, as debtor-in- possession, has provided Landlord with adequate assurance of future performance as required under Section 365(b)(1)(C) of the Bankruptcy Code and applicable law.

(c) If Tenant's trustee or the debtor-in-possession has assumed this Lease pursuant to the terms and provisions of Section 13.6.(a) or Section 13.6.(b) for the purpose of assigning (or elects to assign) this Lease, this Lease may be so assigned only if the proposed Assignee provides Landlord with adequate assurance of future performance of all of the terms, covenants and conditions of this Lease as required by Section 365(f)(2)(B) of the Bankruptcy Code. Landlord shall be entitled to receive all cash proceeds of such assignment; provided that, Tenant's trustee or Tenant, as debtor-in-possession, shall be entitled to receive any proceeds that exceed the full amount of Landlord’s right to a monetary cure claim amount, if any. As used herein "adequate assurance of future performance" shall mean no less than that each of the following conditions has been satisfied:

(i) The Bankruptcy Court has determined that Assignee has provided Landlord with adequate assurance of future performance as required under Section 365(f)(2)(B) of the Bankruptcy Code and applicable law, or the Assignee has furnished Landlord with either (2) (x) a copyof a credit rating of Assignee which Landlord reasonably determines to be sufficient to assure the future performance by Assignee of Tenant's obligations under this Lease and (y) a current financial statementof Assignee audited by a certified public accountant indicating a net worth and working capital in amounts which Landlord reasonably determines to be sufficient to assure the future performance by Assignee of Tenant's obligations under this Lease, or (3) a guarantee or guarantees, in form andsubstance satisfactory to Landlord, from one or more persons with a credit rating and net worth equal to or exceeding the credit rating and net worth of Tenant as of the date hereof.

(ii) Landlord has obtained all consents or waivers from others required underany lease, mortgage, financing arrangement or other agreement by which Landlord is bound to permit Landlord to consent to such assignment.

Section 13.7. Tenant Dispute. Landlord shall not seek to terminate the Lease or Tenant’s right of possession for reason of a monetary default, other than a default for failure to pay Base Rent, if Tenant is then in good faith contesting the existence of such default or the amount of money due to Landlord, provided that the Tenant shall pay to Landlord the amount the Tenant concedes is due plus fifty percent (50%) of the difference between the amount Tenant concedes is due and the amount Landlord claims is due and shall agree in writing to remedy the default if the amount the Landlord claims is due issubsequently determined to be correct.

Section 13.8. Landlord Default. If Landlord fails to perform any of Landlord’s obligations underthis Lease, which failure continues for more than thirty (30) days after Tenant’s delivery of written notice to Landlord specifying such failure, or if such failure is of a nature to require more than thirty (30) days for

remedy and continues beyond the time reasonably necessary to cure (and Landlord has not undertaken procedures to cure the failure within such thirty (30) day period and diligently pursued such efforts to complete such cure), Tenant may, in addition to any other remedy available at law or in equity, after a second written notice to Landlord and Landlord's failure to cure within ten (10) business days after receipt of such second written notice, at its option, incur any expense necessary to perform the obligation of Landlord specified in such notice and invoice Landlord for the cost thereof. Landlord shall reimburse Tenant for the cost thereof within thirty (30) days of Landlord's receipt of any such invoice.

ARTICLE XIV

HOLDING OVER IN POSSESSION

If Tenant shall retain possession of all or any part of the Premises beyond the expiration or termination of this Lease, Tenant (i) shall pay to Landlord one hundred twenty five percent (125%) of the Base Rent payable for the last month of the Term of this Lease and any Additional Rent due to Landlord for each month that Tenant holds possession of any part of the Premises after expiration or termination of this Lease; (ii) shall also pay all actual costs incurred and damages sustained by Landlord on account of such holding over; and (iii) such tenancy shall be month to month and otherwise upon such terms and conditions (including rent) as Landlord shall specify.

ARTICLE XV

MORTGAGES

Section 15.1. Subordination and Attornment. This Lease shall at all times be automatically subject and subordinate to the lien of any Mortgage that may be placed upon the Premises by Landlord, or any part thereof, and to all amounts secured thereby, and to all renewals, replacements and extensions of any of the foregoing, except to the extent that any Mortgage provides otherwise, upon the condition that Tenant shall have the right to remain in possession of the Premises under the terms of this Lease, notwithstanding any default in such Mortgage, or after the foreclosure of such Mortgage, so long as no Event of Default shall have occurred and be continuing. Tenant further agrees that, in the event of a foreclosure of any Mortgage or of a conveyance in lieu thereof, it will attorn to the mortgagee or to the purchaser at any foreclosure sale, as the case may be, upon the condition that such mortgagee or purchaser shall agree in writing to recognize Tenant and this Lease, so long as Tenant is not then in default. Tenant shall at Landlord's request execute a commercially reasonable subordination, nondisturbance and attornment agreement ("**SNDA**") or such further instruments or assurances as any mortgagee or purchaser may request to evidence: (i) the subordination of this Lease or to acknowledge the superiority of this Lease, as the case may be, (ii) Tenant's attornment agreement, and/or (iii) the acknowledgment of the express obligations of Tenant to the Landlord's Mortgagee that are provided for in this Lease, provided that such instruments and assurances are on terms reasonably acceptable to Tenant.

Section 15.2. No Personal Liability. In no event shall any mortgagee of the Premises, or any part thereof, its nominee, or the purchaser at a foreclosure sale have any personal liability whatsoever for any representations, warranties, covenants or agreements of Landlord hereunder or in connection herewith, or any liability for any security deposit or other sums deposited with Landlord, or for any previous prepayment of Rent to Landlord.

Section 15.3. Notices to Mortgagee and Mortgagee Right to Cure. Provided Tenant receives written notice of the name and address of Landlord's Mortgagee having an interest in the Premises, Tenant agrees that in the event of any default by Landlord hereunder, Tenant shall send written notice of the default to Landlord's

Mortgagee. The rights of Landlord's Mortgagee upon receipt of such notice shall be as set forth in the SNDA. Nothing in this Section 15.3. shall be construed to require Landlord's Mortgagee to cure a default by Landlord.

Section 15.4. Foreclosure; Deed in Lieu of Foreclosure. The provisions of this Article XV shall apply in the event of a foreclosure of any Mortgage or conveyance in lieu of foreclosure, notwithstanding the fact that the mortgagee thereunder may, directly or indirectly, own or have an interest in Landlord or an interest in the Premises in addition to its interest under such Mortgage.

Section 15.5. Estoppel Certificates. From time to time upon written request of Landlord or Tenant, the other shall deliver to the requesting party within fifteen (15) days, a statement in writing by such party or its duly authorized representative having knowledge of the following facts, certifying (i) that this Lease is unmodified and in full force and effect or, if there have been modifications, an itemized description of such modifications and that this Lease as modified is in full force and effect; (ii) the dates to which Rent and other amounts payable hereunder have been paid; (iii) that the requesting party is not in default under any provision of this Lease, or, if in default, the nature thereof in detail; and (iv) such further matters as may be reasonably requested by the requesting party. It is the intention of the parties that any such statement may be relied upon by any auditors, accountants, lenders, prospective lenders, mortgagees or prospective mortgagees, or any prospective or subsequent purchaser or transferee of all or a part of Landlord's interest in the Premises. In connection with the financing, sale or transfer of the Premises by Landlord, Tenant shall execute and deliver to Landlord whatever instruments may be required by Landlord for such purposes, or Tenant shall be in default under this Lease upon the expiration of such 15-day period.

Section 15.6. Mortgage and Other Obligations Binding on Tenant. Any and all obligations of and limitations on Landlord under any Mortgage on the Premises, or any part thereof, including, without limitation, payment of property taxes and expense reimbursements, lien prohibitions, maintenance, repair, alterations, replacements and restoration obligations, required insurance coverages, and restrictions on use of insurance and condemnation proceeds, shall be binding on and be the responsibility of Tenant, subject to the provisions of this Lease and the provisions of the SNDA. Tenant shall not be permitted to mortgage, pledge, grant or assign a security interest in its leasehold and contract rights hereunder without Landlord's prior written consent, which shall not be unreasonably withheld, conditioned or delayed. Landlord and Tenant shall not modify this Lease without the express prior written consent of the Landlord's Mortgagee.

Section 15.7. Landlord's Lien and Security Interest. Tenant agrees that Landlord shall have a landlord's lien, and Tenant additionally hereby separately grants to Landlord a first and prior security interest, in, on and against all of Tenant's right, title and interest in, to and under all "goods" (excluding "inventory," and including, without limitation, all "equipment," "fixtures," appliances and furniture (as "goods," "inventory," "equipment" and "fixtures" are defined in the applicable Uniform Commercial Code then in effect in the applicable jurisdiction)) from time to time situated on or used in connection with the Premises, whether now owned or held or hereafter arising or acquired, together with all replacements and substitutions therefore (including insurance proceeds and any title and UCC insurance proceeds) and products thereof, and, in the case of tangible collateral, together with all additions, attachments, accessions, parts, equipment and repairs now or hereafter attached or affixed thereto or used in connection therewith (collectively, the "**Personalty**"), which lien and security interest shall secure the payment of all Rent and other monetary obligations payable by Tenant to Landlord under the terms hereof and all other obligations of Tenant to Landlord under this Lease. Notwithstanding anything to the contrary contained herein, Landlord's security interest shall not apply to cash or accounts receivables. Tenant agrees that Landlord may file such documents as Landlord then deems appropriate or necessary to perfect and maintain said lien and security interest, and expressly acknowledges and agrees that, in addition to any and all other rights and remedies of Landlord whether hereunder or at law or in equity, in the event of an Event of Default of Tenant hereunder, Landlord

shall have any and all rights and remediesgranted a secured party under the Uniform Commercial Code then in effect in the state where the Premises is located. Tenant covenants to promptly notify Landlord of any changes in Tenant's name and/or organizational structure which may necessitate the execution and filing of additional financing statements; *provided*, *however*, the foregoing shall not be construed as Landlord's consent to suchchanges.

As of the Effective Date, Landlord has agreed to subordinate its first position lien on Tenant's Personalty to Hamilton State Bank ("**Tenant's Lender**"); provided that Tenant provides Landlord with a letter of credit from Tenant's Lender for the benefit of Landlord in an amount equal to $509,780.97 and inform and substance reasonably acceptable to Landlord (the "**Letter of Credit**"), as additional security under the Lease.

ARTICLE XVI

CERTAIN RIGHTS OF LANDLORD

Section 16.1. Right of Entry. Upon at least twenty-four (24) hours advance written notice, except in the event of an emergency, in which case Landlord shall only be required to give such notice as is reasonably practical under the circumstances, and at such times reasonable under the circumstances, Landlord reserves, and shall at all times have, the right to enter the Premises, or any part thereof, accompanied by a representative of the Tenant, to inspect the same, to supply any service to be provided by Landlord to Tenant hereunder, to show the Premises, or any part thereof, and to alter, improve, or repair the Premises and any portion of the Premises without abatement of rent, and may for that purpose erect, use and maintain scaffolding, pipes, conduits and other necessary structures in and through the Premises, or any part thereof, where required by the character of the work to be performed; provided entrance to the Premises, or any part thereof, shall not be denied Tenant, further provided that the business of Tenant shall not be interfered with unreasonably, and further provided that Landlord's right ofentry shall not include access to secured files of the Tenant or any subtenant of Tenant's, or secured areas used by the Tenant or a subtenant of Tenant to store pharmaceuticals or medical devices. Tenant hereby waives any claim for damages for any injury, inconvenience to or interference with Tenant's business, any loss of occupancy or quiet enjoyment of the Premises, and any other loss occasioned thereby. For each ofthe aforesaid purposes, Landlord shall at all times have and retain keys with which to unlock all of the doors in, upon or about the Premises, or any part thereof, and Landlord shall have the right to use any and all means which Landlord may deem reasonably necessary or proper to open such doors in an emergency in order to obtain entry. Tenant is aware that Landlord may deposit keys to the Premises, or any part thereof, in lock boxes for the benefit of the local fire departments, and Tenant hereby waives any and all claims against Landlord resulting from Landlord's deposit of keys in the lock boxes. If Tenant changes the locks to any doors in the Premises, or any part thereof, Tenant shall immediately provide Landlord with a key for such new lock. Tenant shall permit Landlord (or its designees) to enter the Premises, or any part thereof, to erect, use, maintain, replace and repair pipes, cables, conduits, plumbing, vents and telephone, electric and other wires or other items in, to and through the Premises, or any part thereof, as and to the extent that Landlord may now or hereafter deem necessary or appropriate for the proper operation and maintenance of the Premises, or any part thereof. In the event Landlord needs access to anyunder floor duct, Landlord's liability for the carpet replacement shall be limited to replacement of thepiece removed to gain such access. All such work shall be done, so far as practicable, in such manner as to minimize interference with Tenant's use of the Premises, or any part thereof. Nothing in this Section

16.1 shall create maintenance obligations for Landlord. Landlord's obligations with respect to maintenance of the Premises are expressly provided for, if at all, in the other provisions of this Lease.

Section 16.2. Sale or Transfer of Premises. Landlord shall have the right to sell, assign or otherwise transfer, in whole or in part, its interest in the Premises and the Property without Tenant's consent.

ARTICLE XVII

MISCELLANEOUS

Section 17.1. Effect of Payments by Tenant. No payment by Tenant or receipt by Landlord of a lesser amount than the total amount then due and payable shall be deemed to be other than on account, nor shall any such payment be deemed an accord and satisfaction. Landlord may accept any payment without prejudice to any outstanding demand or action for possession, notice of default or notice of termination. No payment by Tenant after termination of this lease shall reinstate this Lease or extend the Term or waive or affect any notice given or proceedings commenced.

Section 17.2. Waiver of Jury Trial. LANDLORD AND TENANT HEREBY KNOWINGLY, VOLUNTARILY AND INTENTIONALLY WAIVE THE RIGHT EITHER MAY HAVE TO A TRIAL BY JURY WITH RESPECT TO ANY AND ALL ISSUES PRESENTED IN ANY ACTION, PROCEEDING, CLAIM OR COUNTERCLAIM BROUGHT BY EITHER OF THE PARTIES HERETO AGAINST THE OTHER OR ITS SUCCESSORS WITH RESPECT TO ANY MATTER ARISING OUT OF OR IN CONNECTION WITH THIS LEASE, THE RELATIONSHIP OF LANDLORD AND TENANT, TENANT'S USE OR OCCUPANCY OF THE PREMISES, AND/OR ANY CLAIM FOR INJURY OR DAMAGE, OR ANY EMERGENCY OR STATUTORY REMEDY. THIS WAIVER BY THE PARTIES HERETO OF ANY RIGHT EITHER MAY HAVE TO A TRIAL BY JURY HAS BEEN NEGOTIATED AND IS AN ESSENTIAL ASPECT OF THEIR BARGAIN. FURTHERMORE, EACH PARTY HEREBY KNOWINGLY, VOLUNTARILY AND INTENTIONALLY WAIVES THE RIGHT IT MAY HAVE TO SEEK PUNITIVE, CONSEQUENTIAL, SPECIAL AND INDIRECT DAMAGES FROM THE OTHER PARTY AND ANY OF THE AFFILIATES, OFFICERS, DIRECTORS, MEMBERS, MANAGERS OR EMPLOYEES OF THEREOF OR ANY OF THEIR SUCCESSORS WITH RESPECT TO ANY AND ALL ISSUES PRESENTED IN ANY ACTION, PROCEEDING, CLAIM OR COUNTERCLAIM BROUGHT WITH RESPECT TO ANY MATTER ARISING OUT OF OR IN CONNECTION WITH THIS LEASE OR ANY DOCUMENT CONTEMPLATED HEREIN OR RELATED HERETO. THE WAIVER BY THE PARTIES OF ANY RIGHT IT MAY HAVE TO SEEK PUNITIVE, CONSEQUENTIAL, SPECIAL AND INDIRECT DAMAGES HAS BEEN NEGOTIATED BY THE PARTIES HERETO AND IS AN ESSENTIAL ASPECT OF THEIR BARGAIN.

Section 17.3. No Joint Venture. This Lease does not create a joint venture or partnership between Landlord and Tenant or Landlord and the Landlord's Mortgagee or the Landlord's Mortgagee and Tenant.

Section 17.4. Effect of Waiver. No waiver of performance of any agreement in this Lease shall be binding against the party alleged to have waived unless the waiver shall be in writing. No waiver shallbe extended by implication, custom or practice to any situation or circumstance not expressly described and shall not be interpreted as applying to any obligations of a recurring nature, unless so stated with particularity.

Section 17.5. Real Estate Brokers. Landlord and Tenant each represents and warrants to the other that it has not dealt with any real estate broker or brokers in connection with this Lease. In the event that any claim for any broker's or finder's fee or commission in connection with the negotiation, executionor consummation of this Lease is made by any person or entity, each party shall defend, indemnify and hold the other harmless from and against any such claim.

Section 17.6. Recitals. The recitals hereto are hereby incorporated into and made a part of this Lease.

Section 17.7. Time of Essence. Time is of the essence of this Lease and each and every provision

hereof.

Section 17.8. Communications. All communications provided for herein shall be in writing and shall be deemed to be given or made upon receipt or refusal of receipt. All communications shall be served personally, via overnight delivery, or deposited in the United States mail, registered or certified, return receipt requested, postage prepaid, addressed as follows:

If to Landlord: STORE Master Funding IX, LLC
8501 E. Princess Drive, Suite 190
Scottsdale, Arizona 85255
Attn: Mr. Michael T. Bennett, Executive Vice President – GeneralCounsel

with a copy to: Kutak Rock, LLP
1801 California Street, Suite 3000
Denver, Colorado 80202
Attn: Whitney A. Kopicky, Esq.

If to Tenant: Cytometry Specialists, Inc.
2580 Westside Parkway
Alpharetta, GA 30004 Attn:
Mr. Ron Ghafary

with a copy to: Arnall Golden Gregory LLP
171 17th Street NW, Suite 2100
Atlanta, Georgia 30363 Attn:
Michael Golden, Esq.

Or to such party at such other address as such party may designate by notice duly given in accordancewith this Section to the other party.

Section 17.9. Successors and Assigns. The rights and obligations of the parties to this Lease shall inure to the benefit of, and shall be binding upon, their respective successors, and assigns.

Section 17.10. Severability. In the event any provision of this Lease shall be held invalid or unenforceable by any court of competent jurisdiction, such holding shall not invalidate or render unenforceable any other provision hereof.

Section 17.11. Execution of Counterparts. This Lease may be simultaneously executed in several counterparts, each of which shall be an original and all of which shall constitute but one and the same instrument.

Section 17.12. Entire Agreement. This Lease sets forth all of the covenants, promises, agreements, conditions and understandings of the parties relating to the subject matter of this Lease, and there are no covenants, promises, agreements, conditions or understandings, either oral or written, between them other than as are herein set forth. This Lease supersedes all prior written and oral communications relating to the subject matter of this Lease.

Section 17.13. Modification, Waiver and Termination. This Lease and each provision hereof may not be modified, amended, changed, altered, waived, terminated or discharged unless consented to by a written instrument signed by Landlord's Mortgagee and the party sought to be bound by such modification,

amendment, change, alteration, waiver, termination or discharge.

Section 17.14. Construction.

(a) The words "hereof," "herein," "hereunder," and other words of similar import refer to this Lease as a whole not to the individual Sections in which such terms are used.

(b) References to Sections and other subdivision of this Lease are to the designated Sections and other subdivision of this Lease as originally executed.

(c) The headings of this Lease are for convenience only and shall not define or limit the provisions hereof.

(d) Where the context so requires, words used in the singular shall include the pluraland vice versa, and words of one gender shall include all other genders.

Section 17.15. Governing Law. This Lease shall be governed exclusively by and construed in accordance with the applicable laws of the State of Georgia without giving effect to its choice of law or conflicts of laws provisions.

Section 17.16. Limitation of Landlord's Liability. Anything contained in this Lease to the contrary notwithstanding, Tenant agrees that it shall look solely to the estate and property of the Landlord in the Premises and Property, including rents and proceeds therefrom, for the collection of any judgment (or other judicial process) requiring the payment of money by Landlord for any default or breach by Landlord of any of its obligations under this Lease, subject, however, to the prior rights of any ground or underlying landlord or the holder of any mortgage covering the Improvements or of Landlord's interest therein. No other assets of the Landlord shall be subject to levy, execution or other judicial process for the satisfaction of Tenant's claim. Anything in this Lease to the contrary notwithstanding, Landlord and Tenant each hereby waives any and all rights of recovery, claim, action or cause-of-action, against the partners (both general and limited), officers, directors, shareholders, employees or representatives of the other. Nothing herein contained shall be construed to limit any right of injunction against the Landlord, where appropriate.

Section 17.17. No Merger. In no event shall the leasehold interests, estates, or rights of Tenant hereunder merge with any interests, estates, or rights of Landlord or of any mortgagee in or to any and all of the Premises, it being understood that such leasehold interests, estates, and rights of Tenant hereunder shall be deemed to be separate and distinct from Landlord's and any mortgagee's interests, estates, and rights in or to the Premises, notwithstanding that any such interests, estates, or rights shall at any time or times be held by or vested in the same person or entity.

Section 17.18. Security Deposit. Intentionally omitted.

Section 17.19. Financial Statements. Within forty five (45) days after the end of each fiscal quarter and within one hundred twenty (120) days after the end of each fiscal year of Tenant, Tenant will provide Landlord with a copy of its most recent financial statements, consisting of a balance sheet, earnings statement, statement of changes in financial position, statement of changes in owner's equity, andall other related schedules for the fiscal period then ended, such statements to detail separately interest expense, income taxes, non-cash expenses, non-recurring expenses, operating lease expense and current portion of long-term debt – capital leases, and related footnotes. All such financial statements shall be prepared in accordance with generally accepted accounting principles. Such financial statements must be either certified by a certified public accountant or sworn to as to their accuracy by an officer of Tenant. The financial statements provided must be as of a date not more than twelve (12) months prior to the date of request. Landlord shall retain such statements in confidence, but may provide copies to lenders and potential lenders as required. The financial statements delivered to Landlord need not be audited, but Tenant shall deliver to Landlord copies of any audited financial statements of the Tenant which may be prepared, as soon as they are available. Notwithstanding the foregoing, in the event that Tenant fails to timely deliver the financial statements hereunder, such failure shall not constitute an Event of Default hereunder unless and until Landlord shall have given Tenant written notice thereof and a period of thirty

(30) calendar days shall have elapsed, during which period Tenant shall provide such financial statements,and upon failure of which an Event of Default shall be deemed to have occurred hereunder without further written notice or demand of any kind being required.

Section 17.20. Tenant Representations and Warranties. The representations and warranties of Tenant contained in this Section 17.20 are being made to induce Landlord to enter into this Lease, and Landlord has relied, and will continue to rely, upon such representations and warranties. Tenant represents and warrants to Landlord as follows (except as may be disclosed in writing by Tenant to Landlord within thirty (30) days of Tenant obtaining knowledge of any exceptions to such representationsand warranties):

(a) *Organization, Authority and Status of Tenant.* Tenant has been duly organized or

formed, is validly existing and in good standing under the laws of its state of formation and is qualified as a foreign corporation to do business in any jurisdiction where such qualification is required. All necessary corporate action has been taken to authorize the execution, delivery and performance by Tenant of this Lease and of the other documents, instruments and agreements provided for herein. Tenant is not, and if Tenant is a "disregarded entity," the owner of such disregarded entity is not, a "nonresident alien," "foreign corporation," "foreign partnership," "foreign trust," "foreign estate," or any other "person" that is not a "United States Person" as those terms are defined in the Internal Revenue Code of 1986, as may be amended from time to time, and the regulations promulgated thereunder. The Person who has executed this Lease on behalf of Tenant is duly authorized to do so.

(b) *Litigation.* There are no suits, actions, proceedings or investigations pending, or to its actual knowledge, threatened against or involving Tenant, Guarantor or the Premises before any arbitrator or governmental authority which might reasonably result in a material adverse effect on (i) the Premises, including without limitation, the operation of the Premises for any Permitted Use and/or the value of the Premises; (ii) the contemplated business, condition, worth or operations of Tenant; (iii) Tenant's ability to perform its obligations under this Lease; (iv) Landlord's interests in the Property or this Lease; or (v) Guarantor's ability to perform its obligations under the Guaranty (hereinafter, collectively referred to as a **"Material Adverse Effect"**).

(c) *Absence of Breaches or Defaults.* Tenant has not received written notice that Tenant is in default under any document, instrument or agreement to which Tenant is a party or by which Tenant, the Premises or any of Tenant's property is subject or bound, which has had, or could reasonably be expected to result in, a Material Adverse Effect. The authorization, execution, delivery and performance of this Lease and the documents, instruments and agreements provided for herein will not result in any breach of or default under any document, instrument or agreement to which Tenant is a party or by which Tenant, the Premises or any of Tenant's property is subject or bound.

(d) *Compliance with OFAC Laws.* Neither Tenant or any individual or entity owning directly or indirectly any interest in Tenant, is an individual or entity whose property or interests are subject to being blocked under any of the **OFAC Laws** or is otherwise in violation of any of the OFAC Laws; provided, however, that the representation contained in this sentence shall not apply to any Person to the extent such Person's interest is in or through a U.S. Publicly Traded Entity. For purposes hereof, "OFAC Laws" means Executive Order 13224 issued by the President of the United States, and all regulations promulgated thereunder, including, without limitation, the Terrorism Sanctions Regulations (31 CFR Part 595), the Terrorism List Governments Sanctions Regulations (31 CFR Part 596), the Foreign Terrorist Organizations Sanctions Regulations (31 CFR Part 597), and the Cuban Assets Control Regulations (31 CFR Part 515), and all other present and future federal, state and local Laws, ordinances, regulations, policies, lists (including, without limitation, the Specially Designated Nationals and Blocked Persons List) and any other requirements of any Governmental Authority (including without limitation, the U.S. Department of the Treasury Office of Foreign Assets Control) addressing, relating to, or attempting to eliminate, terrorist acts and acts of war, each as supplemented, amended or modified from time to time after the Commencement Date, and the present and future rules, regulations and guidance documents promulgated under any of the foregoing, or under similar Laws, ordinances, regulations, policies or requirements of other states or localities.

(e) *Solvency.* Tenant does not have unreasonably small capital to conduct its business. There is no contemplated, pending or threatened Insolvency Event or similar proceedings, whether voluntary or involuntary, affecting Tenant or Guarantor. For purposes hereof, "**Insolvency Event**" shall mean (i) such Person's (A) failure to generally pay its debts as such debts become due; (B) admitting in writing its inability to pay its debts generally; or (C) making a general assignment for the benefit of creditors; (ii) any proceeding being instituted by or against such Person (A) seeking to adjudicate it bankrupt or insolvent; (B) seeking

liquidation, dissolution, winding up, reorganization, arrangement, adjustment, protection, relief, or composition of it or its debts under any law relating to bankruptcy, insolvency, or reorganization or relief of debtors; or (C) seeking the entry of an order for relief or the appointment of a receiver, trustee, or other similar official for it or for any substantial part of its property, and in the case of any such proceeding instituted against such Person, either such proceeding shall remain undismissed for a period of one hundred twenty (120) days or any of the actions sought in such proceeding shall occur; or (iii) such Person taking any corporate action to authorize any of the actions set forth above in this definition.

(f) *Ownership*. To Tenant's actual knowledge, no Person that actually or constructively owns ten percent (10%) or more of the outstanding capital stock of STORE Capital Corporation owns, directly or indirectly, ten percent (10%) or more of the total value of capital stock of Tenant.

[*Remainder of Page Intentionally Left Blank; Signature Pages to Follow*]

IN WITNESS WHEREOF the parties have executed this Lease as of the date first above written.

LANDLORD:

STORE MASTER FUNDING IX, LLC,
a Delaware limited liability company

By: /s/ Michael J. Zieg
Printed Name: Michael J. Zieg
Title: Executive Vice President

IN WITNESS WHEREOF the parties have executed this Lease as of the date first above written.

TENANT:

CYTOMETRY SPECIALISTS, INC.,
a Georgia corporation

By: /s/ Row Ghafary
Printed Name: Row Ghafary
Title: Owner

STORE/ CSI Lab

Exhibit 21.1

SUBSIDIARIES OF FULGENT GENETICS, INC.

Name of Subsidiary	State or Other Jurisdiction of Incorporation or Organization
Fulgent Therapeutics LLC	California
Fulgent Investment Development Limited	Hong Kong
Cytometry Specialists, Inc.	Georgia

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in Registration Statement No. 333-239964 on Form S-3 and Nos. 333-248962 and 333-213912 on Form S-8 of our reports dated February 28, 2022, relating to the financial statements of Fulgent Genetics, Inc. and effectiveness of Fulgent Genetics, Inc.'s internal control over financial reporting appearing in this Annual Report on Form 10-K for the year ended December 31, 2021.

/s/ DELOITTE & TOUCHE LLP

Los Angeles, California
February 28, 2022

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, 2021 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: February 28, 2022

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, 2021 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: February 28, 2022

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, 2021 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: February 28, 2022

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

Date: February 28, 2022

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.