2022 Annual Report

fulgent

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, 2022

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. ☒

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to § 240.10D-1(b). ☐

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, 2022 (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 $977.9 million. For purposes of this calculation, it has been assumed that all shares of the registrant's common stock held by directors, executive officers and persons beneficially owning 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, 2023, there were 29,518,811 outstanding shares of the registrant's common stock.

DOCUMENTS INCORPORATED BY REFERENCE

Certain portions of the registrant's definitive proxy statement for its 2023 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 plans for our business;
- our ability to integrate any acquired businesses and technologies and to realize the value of any acquired entities, joint ventures, or investments;
- our operating performance, including our ability to stabilize the historical fluctuations in our performance and to achieve, maintain, or grow profitability;
- the rate and degree of market acceptance and adoption of our tests and testing services and other anticipated trends in our industry;
- our competitive advantages and our ability to remain competitive, particularly if the testing markets continue to expand, and competition becomes more acute;
- our ability to continue to expand our test menu and introduce other improvements to our tests;
- our continued ability to offer affordable pricing for our tests, to maintain the low internal costs of our business model, and to record acceptable margins on our sales;
- our ability to develop our therapeutic candidates, to satisfy the U.S. Food and Drug Administration's, or FDA's, regulatory requirements, and to commercialize our therapeutic candidates;
- the success of our competitors' research and development efforts for therapeutic candidates seeking to treat similar or the same indication as our therapeutic candidates;
- 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;
- our reliance on a limited number of suppliers and their ability to adapt to possible disruptions in their operations;
- our use of our laboratory facilities and our ability to adapt in the event we need to relocate or in the event any of our facilities are damaged or rendered inoperable;
- our plans for future sales and marketing efforts;
- advancements in technology by us and our competitors;
- our use of technology and ability to prevent security breaches; unauthorized use or disclosure of health information, personal information, or sensitive personal information; 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 laws and regulations applicable to our business, and our ability to comply with these regulations;
- our ability to effectively respond to any litigation or governmental investigations;
- 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, pressures or incentives to reduce healthcare costs while expanding individual benefits, and 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 ability to obtain and maintain protection of our trade secrets, licensed intellectual property, patent rights, and other intellectual property rights and to not infringe the rights of others;
- our expectations regarding inflation and 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-based company with a well-established clinical diagnostic business and a therapeutic development business. Our clinical diagnostic business offers molecular diagnostic testing services, comprehensive genetic testing, and high-quality anatomic pathology laboratory services designed to provide physicians and patients with clinically actionable diagnostic information to improve the quality of patient care. Our therapeutic development business is focused on developing drug candidates for treating a broad range of cancers using a novel nanoencapsulation and targeted therapy platform designed to improve the therapeutic window and pharmacokinetic profile, or PK profile, of new and existing cancer drugs. We aim to transform from a genomic diagnostic business into a fully integrated precision medicine company.

Mission and Vision

Founded in 2011, Fulgent began with two simple ideas: flexibility and affordability. We offer and develop flexible and affordable diagnostic and genetic tests and testing services designed to improve patient care and quality of life. We strive to provide the most effective and wide-ranging genetic and diagnostic testing menu on the market. Our long-term vision is to transform from a diagnostic business into a fully integrated precision medicine company focused on oncology through the addition of Fulgent Pharma Holdings, Inc., or Fulgent Pharma.

Our Clinical Diagnostic Tests and Testing Services

We have broad testing capabilities with a testing and testing services menu that is scalable and affordable to our customers. Our testing and testing services include:

Our comprehensive anatomic pathology tests and testing services include gastrointestinal pathology, dermatopathology, urologic pathology, breast pathology, neuropathology, and hematopathology. We plan to leverage our existing managed care contract networks and physician relationships to provide diagnostic testing and testing services complimentary to this testing portfolio. These tests and testing services are supported by our expansive geographic presence with several CLIA-licensed laboratories in the United States.

Our specialized oncology tests and testing services utilize a wide array of technologies. These test and testing services utilize flow cytometry, cytogenetic analysis, florescence in-situ (FISH), immunohistochemistry, molecular genetics, NGS, and consultations in hematopathology and surgical pathology.

We also offer NGS services and have experienced recent traction in NGS services related to hereditary cancer, cardiovascular genetics, reproductive health, neurodegenerative genetics, and our recently launched pharmacogenetic tests.

Picture Individual customers may also purchase certain tests and testing services through our direct-to-consumer Picture Genetics platform. These Picture Genetics tests help customers identify important health markers in their personal DNA.

Our Technology Platform

Our business is built on our proprietary technology platform, which includes proprietary gene probes, data suppression and comparison algorithms, adaptive learning software, and proprietary laboratory information management systems. This platform provides a broad test menu, the ability to rapidly develop and launch new tests, customizable test offerings, lower costs per test, and high efficiency. As an example, this technology platform allowed us to rapidly respond to the COVID-19 pandemic and scale our business to provide COVID-19 tests with reliable results and rapid turnaround time in a way that surpassed even our largest competitors. We are proud that through this effort we supplied approximately 19.3 million COVID-19 tests from 2020 through 2022, generating over $1.7 billion in revenue.

Our Customers

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; and (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. 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 19% and 26% of our total revenue in 2022 and 2021, respectively.

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 field-based sales representatives who are knowledgeable about our tests. The field sales team grew significantly in 2022, mostly driven by the acquisition of Symphony Buyer, Inc., or Inform Diagnostics, and Cytometry Specialists, Inc., or CSI. Historically, we have significantly relied on organic growth and word-of-mouth among our customers to generate interest in our tests, which we believe demonstrates the value of our offering. In recent 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. On a regular basis, we continue to evaluate the need to grow the size of our sales team and market resources.

Our Suppliers

We rely on a limited number of suppliers for certain laboratory substances used in the chemical reactions incorporated into our tests and testing services, 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; on Roche Holdings AG for certain laboratory equipment, supplies, and services for our immunohistochemistry services; on Beckman Coulter Diagnostics for certain laboratory equipment, supplies, and services for our flow cytometry tests and testing services; and on Abbott Laboratories for certain laboratory equipment, supplies, and services for our FISH tests and testing services. While there are several sequencer suppliers that we believe could replace Illumina, and while we believe that we have sufficient alternative suppliers for our other needs, our laboratory operations could be interrupted if we encounter delays or difficulties in connection with securing these supplies, services, reagents, sequencers, other equipment, 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 pathology, genetic, and diagnostic testing services, including specialty and reference laboratories that offer traditional single-gene and multi-gene tests and other diagnostic test providers, as well as drug delivery platform companies and 505(b)(2) drug developers in the cancer therapeutics area. Principal competitors include companies such as Quest Diagnostics Incorporated; Laboratory Corporation of America Holdings; Abbott Laboratories; Ambry Genetics, a subsidiary of Konica Minolta Inc.; Baylor Genetics; Caris Life Sciences; GeneDx Holdings Corp.; Invitae Corporation; Myriad Genetics, Inc.; Natera, Inc.; NeoGenomics Laboratories, Inc.; Perkin Elmer, Inc.; Tempus; and other commercial and academic laboratories. 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 or diagnostic testing we would otherwise perform for them. In this regard, continued development of, and potential associated relative 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, 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 clinical diagnostic testing field continues to undergo significant consolidation, permitting larger clinical laboratory service providers to increase cost efficiencies and service levels and potentially resulting in more intense competition.

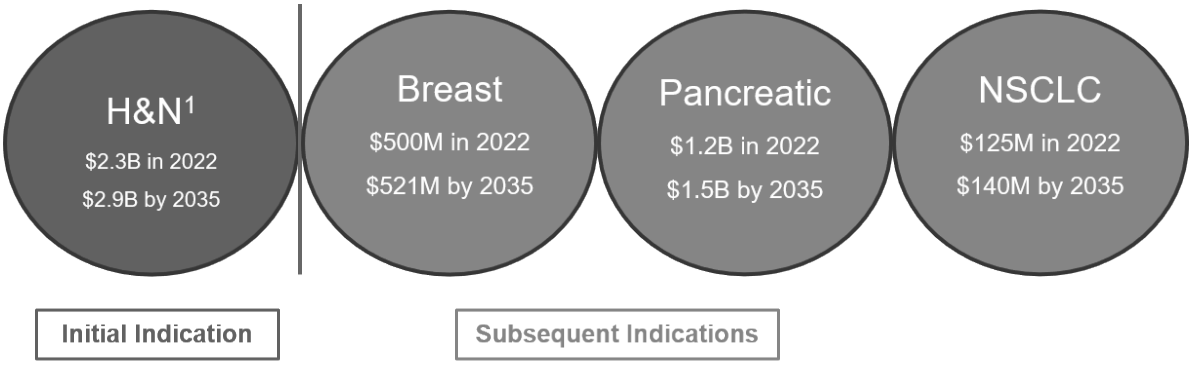
We believe we compare favorably with our competitors. However, many of our competitors have longer operating histories; larger customer bases; more expansive brand recognition; deeper market penetration; substantially greater financial, technological, and research and development resources; and selling 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. Further, companies or governments that effectively control access to genetic or diagnostic 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.

Fulgent Pharma

In 2022, we completed our acquisition of Fulgent Pharma Holdings, Inc., or Fulgent Pharma. Our efforts at Fulgent Pharma are based on a novel nano-drug delivery platform technology capable of delivering various water insoluble or poorly soluble drugs. Unlike some of the drug delivery materials such as Human Serum Albumin, or HSA, which is only soluble in water, our nano-drug delivery materials used for drug candidate development are soluble not only in water, but also in various organic solvents, as well as capable of hot melt mixing with active pharmaceutical ingredients, or APIs. We believe these advantages will allow us to generate a

much broader range of drug candidate formulations, particularly amorphous drug candidate formulations, which can be used for both IV and oral formulations with a goal to improve PK profile, as well as safety and efficacy.

The first product candidate from this platform is FID-007, a nanoencapsulated paclitaxel, and the target markets we have chosen to investigate for this drug candidate are large and well-established, including head and neck, or H&N, pancreatic, breast, and non-small cell lung cancer, or NSCLC, as shown in the figures below:



Note: U.S. opportunity shown
Sources: Evaluate Pharma, Wall Street research, and management pricing expectations
1.H&N market opportunity for both 2ndline and 3rd line therapy

FID-007 is currently being investigated in the United States in a Phase I clinical trial in patients diagnosed with various cancers including head and neck, ampullary, and pancreatic cancer. Top-line data from this trial is expected in the second quarter of 2023. Assuming positive data, we intend to seek regulatory approval in the United States using the 505(b)(2) pathway, which may shorten the clinical trial process and accelerate potential commercialization. We also plan to initiate Phase II clinical trials investigating the use of FID-007 in patients diagnosed with recurrent or metastatic head and neck and other cancers in late 2023 and 2024, respectively.

Other 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.

Intellectual Property

We rely on a combination of registered and unregistered intellectual property rights, including trade secrets, certain licenses, patents, 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

Federal Regulations Applicable to Our Laboratory Operations

As we operate clinical laboratories in the United States, 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, Massachusetts, Arizona, and New York are CLIA-certified and are accredited by the College of American Pathologists, or CAP, a Centers for Medicare & Medicaid Service, or CMS, approved accrediting organization.

CLIA requires that we hold certificates for each of our laboratories applicable to the categories of testing that each laboratory performs and that we comply with various standards with respect to personnel qualifications, facility administration, proficiency testing, quality control and assurance, and inspections. Each of our laboratories must obtain a certificate from 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 and El Monte, California; Houston and Irving, Texas; Needham, Massachusetts; Phoenix Arizona; Alpharetta, Georgia; and New York, New York. Each CLIA certification is valid for two years from the date of issuance. If one or more of our laboratories are 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. An 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 Clinical Laboratory Licensure

Our clinical laboratories are required to maintain various state licenses issued by the respective Department of Health, based on all applicable state laws and regulations. State laws establish standards for day-to-day operations of our laboratories, including requirements with respect to the training and skills required of personnel, quality control, and proficiency testing requirements. If our clinical reference laboratories are out of compliance with the applicable state regulations, state agencies may suspend, restrict, or revoke our license to operate our clinical laboratories, assess substantial civil money penalties or impose specific corrective action plans. Any such actions could materially affect our business. Currently, we maintain good standing with all state authorities.

Additionally, several states require licensure for the out-of-state laboratories that accept specimens originate from those states. For example, our Texas laboratories hold the out-of-state licenses from California, New York, Maryland, Pennsylvania, and Rhode Island to perform testing on specimens from these states; and our Temple City, California laboratory holds the required out-of-state

laboratory licenses from New York, Maryland, Pennsylvania, and Rhode Island in order to perform testing on specimens from these states. For laboratories holding licenses from New York, the laboratory director of those laboratories must also maintain a Certificate of Qualification issued by New York's Department of Health, Clinical Laboratory Evaluation Program, or CLEP, in the permitted categories. The New York state laboratory laws and regulations impose stringent requirements for personnel qualifications, specimen retention, and consent for testing. Among other things, CLEP also requires approval on a test-specific basis before testing can be performed 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 Oversight of Our Tests and Testing Services

The tests and testing services that we offer may be considered medical devices. Pursuant to its authority under the Federal Food, Drug, and Cosmetic Act, or FDC Act, the 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 laws and regulations governing the marketing of IVDs are evolving, are 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.

We believe our tests fall within the definition of laboratory developed tests, or LDT. LDTs, which are a subset of IVDs that are intended for clinical use and designed, manufactured and used within a single laboratory. 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 LDTs. 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. If and when the FDA begins to actively enforce its premarket submission regulations with respect to LDTs generally or to any of 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 pre-market approval application, or 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 tests and testing services 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.

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, fines, injunctions, criminal prosecution, consent decrees, repairs, replacements, refunds, recalls or seizures of products, 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.

Regulations Regarding Advertising of Laboratory Services or LDTs

Our advertising for laboratory services and 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.

Rules and Regulations Relating to Payor Reimbursement for our Tests and Testing Services

CPT Codes

We bill third-party payors, both commercial and government, for our tests and testing services 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 may be billed under a miscellaneous code for an unlisted molecular pathology procedure. Many third-party payors do not have a set reimbursement rate for this miscellaneous code. Prior to performing a test, we may 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 or our inability to get reimbursed.

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, or 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 ADLT. 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. The Consolidated Appropriations Act, 2023, enacted on December 29, 2022, delayed the next PAMA reporting period to January 1, 2024 through March 31, 2024. New CLFS rates for CDLTs will be established based on that data beginning in 2025, subject to phase-in limits. As a result, Medicare payment rates determined by data reported in 2017 will continue through December 31, 2026.

In addition, under PAMA, as amended, the payment reduction cap will be 15% per test per year in each of the years 2024 through 2026.

Rules and Regulations Applicable to Our Research and Development Activities

We engage in research and development activities, including research and development activities through our wholly owned subsidiary, Fulgent Pharma. Development of therapeutic products is subject to extensive regulation by the FDA and other regulatory agencies. Therapeutic products require government authorization before they may be clinically tested and commercially marketed for

human therapeutic use in the United States and other countries. The precise regulatory requirements with which we will have to comply are undergoing periodic revisions and refinement.

The steps required before a therapeutic product may be marketed in the United States are numerous and include, but are not limited to, the following:

- completion of non-clinical laboratory tests, animal studies, chemical process development, and formulation studies according to good laboratory practices and other applicable regulations and guidance;
- the submission to the FDA of an investigational new drug application, or IND, which must become effective before clinical trials may commence;
- performance of adequate and well-controlled clinical trials according to good clinical practices, or GCPs, to establish the safety and efficacy of the therapeutic candidate for its intended use;
- the submission of a New Drug Application, or NDA, to the FDA;
- satisfactory completion of an FDA inspection of the manufacturing facility or facilities at which the therapeutic candidate is produced to assess readiness for commercial manufacturing and conformance to the manufacturing-related elements of the application, to conduct a data integrity audit, and to assess compliance with current Good Manufacturing Practices, or cGMPs, to assure that the facilities, methods and controls are adequate; and
- FDA review and approval of the NDA.

The testing and formulation processes required to market a therapeutic product involves substantial time, effort, and financial resources; and we cannot be certain that any approvals for any of our future therapeutic products will be granted on a timely basis, if at all.

An institutional review board, or IRB, for each institution participating in the clinical trial must review and approve a new clinical protocol before a clinical trial commences at that institution and must also approve the information regarding the trial and the consent form that must be provided to each research subject or the subject's legal representative, monitor the trial until completed, and otherwise comply with IRB regulations. There are also requirements governing the reporting of ongoing clinical trials and completed clinical trial results to public registries.

Clinical trials are typically conducted in three sequential phases that may overlap or be combined:

- Phase 1: Initial safety study in healthy human subjects or patients where the candidate therapy is tested for safety, dosage tolerance, absorption, distribution, metabolism, and excretion.
- Phase 2: Studies in a limited patient population designed to identify possible adverse effects and safety risks, to determine the efficacy of the product for specific targeted diseases, and to determine tolerance and optimal dosage.
- Phase 3: Studies in an expanded patient population to further evaluate clinical efficacy and to further test for safety.

We cannot be certain that we will successfully complete Phase 1, Phase 2, or Phase 3 testing of any product candidate within any specific time period, if at all. Post-approval trials, sometimes referred to as "Phase 4" clinical trials, may be conducted after initial marketing approval. These trials are used to gain additional experience from the treatment of patients in the intended therapeutic indication. In certain instances, FDA may mandate the performance of "Phase 4" clinical trials.

Furthermore, the FDA or the sponsor may suspend clinical trials at any time on various grounds, including a finding that the research subjects or patients are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the IRB's requirements, or if the therapeutic candidate has been associated with unexpected serious harm to patients.

Assuming successful completion of the required clinical testing, the results of the non-clinical studies and clinical trials, along with detailed descriptions of the product's chemistry, manufacturing and controls (CMC), proposed labeling and other relevant information are submitted to the FDA as part of a NDA requesting approval to market the product. Most innovative drug products obtain FDA marketing approval pursuant to an NDA submitted under Section 505(b)(1) of the FDC Act, commonly referred to as a traditional or "full NDA." In 1984, with passage of the Drug Price Competition and Patent Term Restoration Act, informally known as the Hatch-Waxman Act, that established an abbreviated regulatory scheme authorizing the FDA to approve generic drugs based on an innovator or "reference" product, Congress also enacted Section 505(b)(2) of the FDC Act, which provides a hybrid pathway combining features of a traditional NDA and a generic drug application. Section 505(b)(2) enables the applicant to rely, in part, on the FDA's prior findings of safety and efficacy data for an existing product, or published literature, in support of its application. Section 505(b)(2) NDAs may provide an alternate path to FDA approval for new or improved formulations or new uses of previously

approved products; for example, an applicant may be seeking approval to market a previously approved drug for new indications or for a new patient population that would require new clinical data to demonstrate safety or effectiveness. Section 505(b)(2) permits the filing of an NDA in which the applicant relies, at least in part, on information from studies made to show whether a drug is safe or effective that were not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use. A Section 505(b)(2) applicant may eliminate or reduce the need to conduct certain non-clinical or clinical studies, if it can establish that reliance on studies conducted for a previously-approved product is scientifically appropriate.

Even if a product receives marketing approval, the approval may be limited to specific indications and dosages or the indications for use may otherwise be limited, which could restrict the commercial value of the product. Further, the FDA may require that certain contraindications, warnings, or precautions be included in the product labeling. The FDA may impose restrictions and conditions on product distribution, prescribing, or dispensing in the form of a risk mitigation plan, or otherwise limit the scope of any approval. In addition, the FDA may require post marketing clinical trials and/or testing and surveillance programs to monitor the safety of approved products that have been commercialized. After approval, some types of changes to the approved product, such as adding new indications, manufacturing changes, and additional labeling claims, are subject to further testing requirements and FDA review and approval.

Satisfaction of the above FDA requirements or similar requirements of foreign regulatory agencies typically takes several years, and the actual time required may vary substantially, based upon the type, complexity, and novelty of the product or indication. Government regulation may delay or prevent marketing of potential products for a considerable period of time and impose costly procedures upon us or our partners' activities. The FDA or any other regulatory agency may not grant any approvals on a timely basis, if at all. Success in early-stage clinical trials does not assure success in later-stage clinical trials. Data obtained from clinical activities is not always conclusive and may be susceptible to varying interpretations that could delay, limit, or prevent regulatory approval. Even if a product receives regulatory approval, the approval may be significantly limited to specific indications and dosages. Delays in obtaining, or failures to obtain regulatory approvals may have a material adverse effect on our business. In addition, we cannot predict what adverse governmental regulations may arise from future U.S. or foreign governmental action.

Following approval of a new therapeutic product, the manufacturer and the approved product are subject to pervasive and continuing regulation by the FDA, including, among other things, monitoring and record-keeping activities; reporting of adverse experiences with the product, samples, and distribution restrictions; complying with promotion and advertising requirements, which include restrictions on promoting drugs for unapproved uses or patient populations (i.e., "off-label use") and limitations on industry-sponsored scientific and educational activities. Although physicians may prescribe legally available products for off-label uses, manufacturers may not market or promote such uses.

Moreover, if there are any modifications to the product, including changes in indications, labeling or manufacturing processes or facilities, the applicant may be required to submit and obtain FDA approval of a new NDA or an NDA supplement, which may require the applicant to develop additional data or conduct additional non-clinical studies and clinical trials. Even if such trials are conducted, the FDA may not approve any expansion of the labeled indications for use in a timely fashion, or at all.

In addition, FDA regulations require that products be manufactured in specific approved facilities and in accordance with cGMP. The cGMP regulations include requirements relating to organization of personnel, buildings and facilities, equipment, control of components and drug product containers and closures, production and process controls, packaging and labeling controls, holding and distribution, laboratory controls, records and reports, and returned or salvaged products. Drug manufacturers and other entities involved in the manufacture and distribution of approved therapeutics are required to register their establishments with the FDA and certain state agencies and are subject to periodic unannounced inspections by the FDA to assess compliance with cGMP and other requirements. Accordingly, both sponsors and manufacturers must continue to expend time, money, and effort in the area of production and quality control to maintain cGMP compliance and other aspects of quality control and quality assurance, and to ensure ongoing compliance with other statutory requirements of the FDC Act. We cannot be certain that we or our suppliers will be able to comply with cGMP regulations and other FDA regulatory requirements.

Accordingly, even after a new drug approval is granted, the FDA may withdraw the approval if compliance with regulatory requirements and standards is not maintained, or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information; imposition of post-market studies or clinical trials to assess new safety risks; or the imposition of distribution or other restrictions. Other potential consequences of regulatory non-compliance include, among other things, fines, warning letters or other enforcement-related letters or clinical holds on post-approval clinical trials; product seizure or detention, or refusal to permit the import or export of products; injunctions or the imposition of civil or criminal penalties; and/or consent decrees, corporate integrity agreements, debarment, or exclusion from federal health care programs.

Privacy and Security Laws and Regulations and Patient Information Access Laws and Regulations Applicable to Our Business

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, or 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 approximately $1.9 million per violation of the same requirement per calendar year (as of March 2022, subject to annual inflation adjustments). A single breach incident can violate multiple requirements, resulting in potential penalties in excess of $1.9 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 HITECH and HIPAA Regulations; and in some instances, we 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 PHI.

CMIA

The HIPAA privacy, security, and breach notification regulations establish a uniform federal "floor" but do not supersede state laws that are more stringent or that 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.

CCPA/CPRA

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 established a new privacy framework for covered businesses by creating an expanded definition of personal information, establishing new data privacy rights for California consumers, imposing special rules on the collection of consumer data from minors, and creating a new and potentially severe statutory damages framework for businesses that violate the CCPA and/or 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 is within the scope of the CCPA and does not fall under the CCPA exception. Additionally, the California Privacy Rights Act, or CPRA, which expanded the CCPA, became effective on January 1, 2023 and, among other things, it established 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 has the power to levy fines and bring other enforcement actions and is in the process of implementing further regulations that could have operational impacts. In addition to California, other states have similar privacy laws taking effect in 2023, including Virginia, Colorado, Connecticut, and Utah. There are also several federal privacy proposals under consideration in Congress, and other states have already introduced privacy legislation for consideration in 2023. The CPRA and other state privacy laws could impact our operations or that of our collaborators and business partners and impose new regulatory requirements and increase costs of compliance.

Information Blocking Rules

The National Coordinator for Health Information Technology, or 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, which took effect in 2021. We 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, are subject to civil monetary penalties for violations of the Information Blocking Rule, up to $1 million per violation.

Foreign Laws and Other 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 regulations 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 generally and for genetic data specifically. 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 foreign 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 provides for 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. 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 legal and regulatory 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. For example, increasing concerns about health information privacy have recently prompted the federal government to issue guidance, taking a newly expansive view of the scope of the laws and regulations that they enforce. 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 damages 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 and more broadly protect the privacy and security of medical records or health 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, in certain instances, 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 applicable laws regarding the protection of such information.

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 is 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, is 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.

Healthcare Fraud and Abuse Laws Applicable to Our Business

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 Laws and Regulations

We are also subject to the U.S. federal law directed at "self-referrals," commonly known as the "Stark Law," which 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 subject to substantial fines 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 substantial civil monetary penalties of up to, 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 Applicable to Our Business

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 Verifying Accurate, Leading-edge IVCT Development Act, or 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. We also may become subject to these requirements if any therapeutic products currently in development are successfully approved by FDA and commercialized in the United States.

Anti-Bribery Laws Applicable to Our Business

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 Applicable to Our Business

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. Future changes or additions to the ACA, the Medicare and Medicaid programs, 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. For example, in August 2022, President Biden signed into the law the Inflation Reduction Act of 2022, or the IRA. Among other things, the IRA has multiple provisions that may impact the prices of drug products that are both sold into the Medicare program and throughout the United States. Starting in 2023, a manufacturer of drugs or biological products covered by Medicare Parts B or D must pay a rebate to the federal government if their drug product's price increases faster than the rate of inflation. This calculation is made on a drug product by drug product basis and the amount of the rebate owed to the federal government is directly dependent on the volume of a drug product that is paid for by Medicare Parts B or D. Additionally, starting for payment year 2026, CMS will negotiate drug prices annually for a select number of single source Part D drugs without generic or biosimilar competition. CMS will also negotiate drug prices for a select number of Part B drugs starting for payment year 2028. If a drug product is selected by CMS for negotiation, it is expected that the revenue generated from such drug will decrease.

Prohibitions on the 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 facilities are 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 15, 2023, we had 1,012 full-time employees, engaged in bioinformatics, genetic, 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 December 31, 2022, underrepresented minorities (which include women, Asian, and Hispanic persons) 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 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, harassment, HIPAA, insider trading, anti-corruption and anti-bribery internally and/or through third-party providers. We offer a comprehensive compensation program that is designed to attract and reward talented individuals who possess the skills necessary to support our business objectives, assist in the achievement of our strategic goals and create long-term value for our stockholders. We provide competitive salaries, stock-based compensation, and bonus programs. We also provide an expansive benefit offering including medical, dental, and vision health care coverage, life and AD&D coverage; optional legal, pet insurance, hospitalization, critical illness and accident coverage; insurance and disability coverage; 401(k) investment plans with Company matching; tax-advantaged savings accounts; paid time off and leaves of absence; and wellness programs. We provide added work life balance to our employees through hybrid work arrangements. 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.

The following persons currently serve as the directors and executive officers of Fulgent:

Directors and Executive Officers	Position
Ming Hsieh	Chairman of the Board of Directors and Chief Executive Officer
Paul Kim	Chief Financial Officer
Hanlin (Harry) Gao, M.D., Ph.D., D.A.B.M.G., F.A.C.M.G.	Chief Scientific Officer
Jian (James) Xie	President and Chief Operating Officer
Regina (Reggie) Groves	Non-Employee Director
Linda Marsh	Non-Employee Director
Michael Nohaile, Ph.D.	Non-Employee Director

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 headquarters 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.
- We have a history of losses, and we may not be able to sustain profitability. We anticipate that revenues resulting from our COVID-19 testing will continue to decrease as and if the prevalence of COVID-19 decreases.
- 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.
- Actual or attempted security breaches, loss of data, or other disruptions could expose us to material liability and materially and adversely affect our business and our reputation.
- 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 depend on our information technology systems and any material failure of these systems, due to hardware or software malfunctions, delays in operation, and/or material failures to implement new or enhanced systems or cybersecurity breaches, could materially harm our business.
- 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.

Reimbursement Risks

- 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
- 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.

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 materially and 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 material disruptions to our business.
- 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 materially significant, penalties, materially damage our reputation and materially harm 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 and material penalties.
- We may be required to modify our business practices, pay fines, incur significant expenses or experience losses due to litigation or governmental investigations.

Risk Related to the Development of Therapeutic Candidates

- Fulgent Pharma’s therapeutic candidates are in early stages of development and may fail or suffer delays that materially and adversely affect their future commercial viability.
- Any therapeutic product candidate that Fulgent Pharma may attempt to develop, manufacture or market in the United States will be subject to extensive regulation by the FDA, including regulations relating to development, preclinical testing, performance of clinical trials, manufacturing and post-approval commercialization and will be subject to extensive

regulations outside of the United States. Satisfaction of these and other regulatory requirements is costly, time consuming, uncertain and subject to unanticipated delays. The time required to obtain FDA approval, and any other required approvals for pharmaceutical products, including any accelerated approval, is unpredictable but typically requires years to several years and may never be obtained.

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 or developing therapeutic candidates.
- If we fail to comply with our obligations under license or technology agreements with third parties, we could lose license rights that are critical to our business. If our third-party licensors fail to comply with the terms of our license arrangements, we may be forced to engage in litigation to protection our rights, which may not be successful.

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

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 our tests and testing services, the prices we charge for our tests and testing services, customer or payor mix, general price degradation for our tests and testing services or other competitive factors, the rate and timing of our billings and collections, and the timing and amount of our commitments and other payments, as well as the other risk factors discussed in this report. 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. For instance in 2020, we developed and began offering a series of COVID-19 tests. We experienced substantial revenue growth in recent years due primarily to the sales of, and growing demand, for these COVID-19 tests. We expect demand for these tests to continue to decline when and as the pandemic recedes. 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.

We have a history of losses, and we may not be able to sustain profitability. We anticipate that revenues resulting from our COVID-19 testing will continue to decrease as and if the prevalence of COVID-19 decreases.

We have a history of losses. Although we achieved profitability for the years ended December 31, 2020, 2021 and 2022, we may not be able to maintain profitability in future periods. Further, our revenue levels may not grow at historical rates or at all. We may incur additional losses in the future. While we experienced significant profitability in connection with the sale of our COVID-19 tests, the demand for these tests has declined and we anticipate will continue to decrease as the prevalence of COVID-19 decreases. Even if there is a reoccurrence of demand for our COVID-19 tests, we may be unable to again manage our resources to effectively respond to this demand such that our revenues will again materially increase. 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. A failure to sustain or grow our revenue levels and to maintain profitability may negatively affect our business, financial condition, results of operations and cash flows, and could cause the market price of our common stock to decline.

We 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 acquisitions of CSI, Fulgent Pharma, and Inform Diagnostics, 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 a business, which may be material, and 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 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 acquisitions of CSI, Fulgent Pharma, and Inform Diagnostics), investments in other companies (such as our investment in Helio Health), technology licensing arrangements, joint ventures, or other strategic relationships. As an organization, we have relatively 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 future 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, and our liquidity needs could be materially affected by market fluctuations and general economic conditions." 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.

Our mix of customers fluctuates from period to period, and our revenue is often 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 often fluctuates 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 19% of our total revenue during the year ended December 31, 2022. 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 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. These demand fluctuations, particularly for any key customers, often 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 negatively impacts 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.

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

We operate our business in very competitive and evolving fields. Our competitors include dozens of companies focused on pathology, genetic, and diagnostic testing services, including specialty and reference laboratories that offer traditional single-gene and multi-gene tests. As such, we face intense competition from other life science, biotechnology, pharmaceutical, research and development, and diagnostic companies. This competition is subject to rapid change, could be significantly affected by new product or testing introductions and may intensify further in the future. While we believe that we compare favorably to these competitors, some of our competitors may have technical, competitive, or other advantages over us for the development of technologies and processes or greater experience in particular diagnostics or therapeutic development areas, and consolidation among pharmaceutical, diagnostic, and biotechnology companies can enhance such advantages.

Many of our 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. We may not be able to compete effectively against these organizations. If we are unable to compete effectively, this could have a material adverse effect on our business and results of operations.

Actual or attempted security breaches, loss of data, or other disruptions could expose us to material liability and materially and adversely affect our business and our reputation.

In the ordinary course of our business, we generate, collect and store sensitive data, including 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. 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, one of our subsidiaries has experienced security incidents to its information systems that resulted in the unauthorized access, use, and disclosure of PHI and other confidential information. To date, these incidents have not materially affected our business. A breach or interruption could result in material legal claims or proceedings and could result in material 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 materially significant, penalties, materially 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 material failure of these systems, due to hardware or software malfunctions, delays in operation, and/or material failures to implement new or enhanced systems or cybersecurity breaches, could materially harm our business."

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 and El Monte, California; Irving, Texas; Needham, Massachusetts; Phoenix, Arizona; Alpharetta, Georgia; and New York, New York. 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 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 could be materially 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 materially and adversely affect 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 materially and adversely affected.

We depend on our information technology systems and any material failure of these systems, due to hardware or software malfunctions, delays in operation, and/or material failures to implement new or enhanced systems or cybersecurity breaches, could materially 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 portal 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 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, one of our subsidiaries has experienced security incidents to its information systems that resulted in the unauthorized access, use, and disclosure of PHI and other confidential information. To date, these incidents have not materially affected our business, however such incidents could cause significant downtime or failures of our systems or those used by our third-party service providers. 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. 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 significant fines, damages, reputational harm, litigation and enforcement actions, and we could lose trade secrets, the occurrence of which could materially harm our business, in addition to possibly requiring substantial and material expenditures of resources to remedy.

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 used in the chemical reactions incorporated into our tests and testing services, 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; on Roche Holdings AG for certain laboratory equipment, supplies and services for our immunohistochemistry services; on Beckman Coulter Diagnostics for certain laboratory equipment, supplies and services for our flow cytometry tests and testing services; and on Abbott laboratories for certain laboratory equipment, supplies and services for our FISH tests and testing services. We do not have long-term agreements with most of our suppliers and, as a result, they could cease supplying these materials and equipment generally 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), pandemics and health events, and disruptions of the global supply chain. While there are several sequencer suppliers that we believe could replace Illumina, and while we believe that we have sufficient alternative suppliers for our other needs, 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 our operations could be materially disrupted; and our business, financial condition, results of operations and reputation could be adversely affected.

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 focus on growing our business. If we lose one or more of these 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.

Our reputation and business could be damaged by negative publicity.

We have been and may again be subject to negative publicity. 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 related services has subjected us to negative publicity. 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.

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 and testing service offerings and develop and sell new tests and testing services 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; 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 and data protection 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 venturers, 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 our tests and services 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 (e.g. the war in Ukraine), terrorism and political unrest, outbreak of disease, 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 our joint venture. Moreover, any joint venture we may seek to establish may never produce sufficient revenue for 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, and particularly with respect to pathology tests, 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 or to detect disease, 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.

Fulgent Pharma's business may involve the testing of new drugs on patients in clinical trials in the future and, if marketing approval is granted, the availability of these drugs to be prescribed to patients. Our involvement in the clinical trials and development process creates a risk of liability for personal injury to or death of patients, particularly those with life-threatening illnesses, resulting from adverse reactions to the drugs administered during testing or after product launch, respectively. Although we maintain the types and amounts of insurance we view as customary and appropriate in the industries and countries in which we operate, if we are required to pay significant damages or incur significant defense costs in connection with any personal injury claim that is outside the scope of indemnification agreements we have with our clients, if any indemnification agreement is not performed in accordance with its terms or if our liability exceeds the amount of any applicable indemnification limits or available insurance coverage, our financial condition, results of operations and reputation could be materially and adversely affected.

In addition, insurance coverage is increasingly expensive and difficult to obtain. Inability to obtain or maintain sufficient insurance coverage at an acceptable cost or to otherwise protect against potential product or other legal or administrative liability claims could prevent or inhibit customer relationships, the clinical development, commercial production, and sale of any of our products and product candidates, which could adversely affect our business.

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, other commercial operations, and research and development activities. As of December 31, 2022, we had cash, cash equivalents, and marketable securities of approximately $852.9 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, 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 and some investment banks and economists are predicting a recession in 2023. These circumstances and high volatility in capital markets generally 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.

Inflation may adversely affect us by materially increasing our costs.

Recently, inflation has increased throughout the U.S. economy. Inflation can adversely affect us by materially increasing the costs of clinical trials and research, the development of our tests and product candidates, administration and other costs of doing business. We may experience material increases in the prices of labor and other costs of doing business. In an inflationary environment, cost increases may materially outpace our expectations, causing us to use our cash and other liquid assets faster than forecasted. If this happens, we may need to raise additional capital to fund our operations, which may not be available in sufficient amounts or on reasonable terms, if at all, sooner than expected.

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 2022, 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 materially 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.

Our investments in marketable securities are subject to certain risks which could affect our overall financial condition, results of operations, or cash flows.

We invest a portion of our available cash and cash equivalents by purchasing marketable securities in a managed portfolio and direct investments in a variety of debt securities, including corporate debt securities, municipal bonds, U.S. government and agency debt securities, and debt instruments issued by foreign governments. The primary objective of our investment activity is to maintain the safety of principal, preserve capital and provide for future liquidity requirements while maximizing yields without significantly increasing risk. Should any of our investments or marketable securities lose value or have their liquidity impaired, it could materially affect our overall financial condition. Additionally, should we choose or are required to sell these securities in the future at a loss, our consolidated operating results or cash flows may be materially and adversely affected.

We have been the subject of a shareholder class action, which was recently dismissed without prejudice; and may be subject to further shareholder litigation in the future; our costs of defending such litigation, arbitration and other proceedings and any adverse outcome of such litigation, arbitration, or other proceeding may have a material adverse effect on our business and the results of our operations.

We have been, and may from time to time in the future be, involved in and subject to material litigation and other legal proceedings. These proceedings may not always resolve in our favor and may materially and adversely affect our business. While the recent shareholder class action was dismissed, it was dismissed without prejudice, so there is no assurance that another complaint may not be filed in the future. 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.

Reimbursement Risks

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.

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 through a program administered by HRSA. However, HRSA announced that the program ceased accepting COVID-19 testing claims as of March 22, 2022, due to a lack of sufficient funds. While we believe we are entitled to all claims submitted to HRSA, we may be unable to fully collect payment for any unpaid claims submitted to HRSA prior to that time. 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 and testing services, these customers may slow, or stop altogether, their purchases of our tests. Moreover, our ability to collect payment for our tests and testing services 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 and testing services, our potential for growth and our ability to collect revenue for these tests and testing services could be limited and our results of operations may be materially and adversely affected.

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 tests we perform can be limited and uncertain. Our customers may not order our tests or testing services 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, the patient for whom the test is ordered typically will owe a greater co-insurance, deductible or co-payment amount or may be expected 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 amount of tests and testing services we sell to our healthcare provider customers and any corresponding revenue depends 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 depends on a number of factors, including a payor's determination that a test or testing service 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 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 testing services 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 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 tests and testing 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.

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.

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 materially and 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 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.

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. Most recently the VALID Act has been garnering bipartisan and bicameral support. 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.

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 and experience material 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 and El Monte, California; Irving, Texas; Needham, Massachusetts; Phoenix, Arizona; Alpharetta, Georgia; and New York, New York.

In addition to CLIA requirements, we elect to have our laboratories accredited by 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 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 and El Monte, 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 materially significant, penalties, materially 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, which applies to all European Union member states. 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. Additionally, the California Privacy Rights Act, or CPRA, took full effect on January 1, 2023. The CPRA amends and expands the CCPA significantly, potentially resulting in further uncertainty, additional costs and expenses in an effort to comply, and additional harm and liability for failure to comply. Among other things, the CPRA established 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 has 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. Virginia, Connecticut, Utah, and Colorado enacted their own consumer privacy laws similar to CCPA and CPRA, all of which will take effect at various points in 2023. Other states are considering similar legislation, adding to the complexity, costs, and risk of compliance. Like the GDPR and CCPA, many of these state laws categorize medical or health data, genetic data, and biometric data that can be identify a natural person as "sensitive data" and the processing or collection of such will require additional compliance obligations.

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 or inclusive over time. For example, increasing concerns about health information privacy have recently prompted the federal government to issue guidance taking a newly expansive view of the scope of the laws and regulations that they enforce. 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 material civil or criminal penalties, materially harm our reputation and materially adversely affect our business.

Many states, such as California and Massachusetts, have also implemented genetic testing and privacy laws imposing specific patient consent requirements and requirements for protecting certain test results. As regulatory focus on genetic 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.

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.

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 and material 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 health care programs, 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 Payments Sunshine 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. 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 materially 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, which could materially harm our reputation, business, prospects or results of operations.

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 have been and again 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. As previously disclosed, 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. As we also disclosed in prior filings, we are also aware that the SEC is conducting a non-public formal investigation, which appears to relate to the matters raised in the CID requests and our Exchange Act reports filed for 2018 through 2020. We are fully cooperating with both the SEC and the U.S. Department of Justice and are responding promptly to their requests. We do not presently expect these matters to have a material adverse impact on our business. However, we cannot predict when the investigations will be resolved, the outcome of the investigations, or the potential impact on our business, which may ultimately be greater than we expect. In addition, government investigations and litigation generally may divert the attention of our management team and 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 be subject to other 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.

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, and recent momentum appears to be building around a comprehensive bill called the VALID Act. 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. 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. 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) payable by a "health care benefit program" (which includes private insurance companies), 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.

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.

Risks Related to the Development of Therapeutic Candidates

Fulgent Pharma's therapeutic candidates are in early stages of development and may fail or suffer delays that materially and adversely affect their future commercial viability.

Fulgent Pharma is early in its development efforts, with only one therapeutic candidate having entered clinical trials (FID-007). Generally, before obtaining marketing approval for the commercial distribution of therapeutic candidates, Fulgent Pharma must conduct preclinical tests and clinical trials to demonstrate sufficient safety and efficacy of its therapeutic candidates in patients. Failure can occur at any time during the development or clinical trial process and Fulgent Pharma's future clinical trial results may not be successful. As a result, we may not have, or we may deem it imprudent to use, additional financial resources to continue development of a therapeutic candidate if there are issues that could delay or prevent marketing approval of, or ability to commercialize, Fulgent Pharma's therapeutic candidates, including:

- negative or inconclusive results from clinical trials, or the clinical trials of others for similar therapeutic candidates, leading to a decision or requirement to conduct additional preclinical testing or clinical trials or abandon a program;
- therapeutic-related side effects experienced by participants in its clinical trials or by individuals using drugs or other therapeutic products similar to its therapeutic candidates;
- delays in submitting investigational new drug applications, or INDs, or comparable foreign clinical trial applications or delays or failure in obtaining the necessary approvals from regulators to commence a clinical trial, or a suspension or termination of a clinical trial once commenced;
- conditions imposed by the FDA or comparable foreign authorities regarding the scope or design of clinical trials;
- delays in enrolling research subjects or high drop-out rates of research subjects enrolled in clinical trials;
- delays or difficulties in its clinical trials due to quarantines or other restrictions resulting from the COVID-19 pandemic or other public health emergencies;
- unfavorable FDA or other regulatory agency inspection and review of a clinical trial site or the manufacturing location(s) for a therapeutic candidate;
- inadequate supply or quality of therapeutic candidate clinical material or other raw materials or supplies necessary for the conduct of our clinical trials;
- failure of third-party contractors or investigators to comply with regulatory requirements or otherwise meet their contractual obligations in a timely manner, or at all;
- delays and changes in regulatory requirements, policy and guidelines, including with respect to our technology in particular; or
- varying interpretations of data by the FDA and similar foreign regulatory agencies.

The therapeutic candidates Fulgent Pharma pursues or has pursued may not demonstrate the necessary safety or efficacy requirements for marketing approval. Further, a clinical trial may be suspended or terminated by the company, the institutional review boards, or IRBs, of the institutions in which such trials are being conducted, the Data Safety Monitoring Board, or DSMB, for such trial or by the FDA or other regulatory authorities due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA or other regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using an investigational drug, changes in governmental regulations, administrative actions or lack of

adequate funding to continue the clinical trial. Clinical holds may be placed prior to a clinical trial even beginning, in order to address potential safety and risk concerns of regulatory authorities, and partial or complete clinical holds can be imposed at any time during a trial. Furthermore, while Fulgent Pharma performs certain similar functions internally, we expect it to rely on contract research organizations, or CROs, and clinical trial sites to ensure proper and timely conduct of our clinical trials and while we expect it to enter into agreements governing those CROs' committed activities we and Fulgent Pharma have limited influence over their actual performance.

If there are delays in the completion of, or termination of, any clinical trial of therapeutic candidates, the commercial prospects of those therapeutic candidates may be harmed. In addition, any delays in completing clinical trials will increase costs, slow down product development and approval processes, and jeopardize the ability to commence product sales and generate revenue. Any of these occurrences may materially and adversely affect our or Fulgent Pharma's business, financial condition, results of operations and prospects. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of marketing approval of therapeutic candidates.

Any therapeutic product candidate that Fulgent Pharma may attempt to develop, manufacture or market in the United States will be subject to extensive regulation by the FDA, including regulations relating to development, preclinical testing, performance of clinical trials, manufacturing and post-approval commercialization and will be subject to extensive regulations outside of the United States. Satisfaction of these and other regulatory requirements is costly, time consuming, uncertain and subject to unanticipated delays. The time required to obtain FDA approval, and any other required approvals for pharmaceutical products, including any accelerated approval, is unpredictable but typically requires years to several years and may never be obtained.

Any product that Fulgent Pharma may wish to develop, manufacture or market in countries other than the United States will also be subject to numerous foreign regulatory requirements governing the conduct of clinical trials, manufacturing and marketing, pricing and third-party reimbursement among other things in such countries. The foreign marketing approval process includes all of the risks and uncertainties associated with FDA approval described above as well as risks attributable to the satisfaction of local regulations in such foreign jurisdictions.

Obtaining marketing approval for pharmaceutical products requires the submission of extensive preclinical and clinical data and supporting information to FDA and comparable regulatory authorities for each therapeutic indication to establish the product candidate's safety and efficacy. Securing marketing approval also typically requires the submission of information about the product manufacturing process, and in many cases the inspection of manufacturing, processing, and packaging facilities by the regulatory authorities. Our product candidates may not be effective, may be only moderately effective or may prove to have undesirable or unintended side effects, toxicities or other characteristics that may preclude our obtaining marketing approval or prevent or limit commercial use, or there may be deficiencies in manufacturing compliance by Fulgent Pharma or by its contract manufacturing organizations that could result in the candidate not being approved. Moreover, neither we nor Fulgent Pharma have obtained marketing approval for any therapeutic candidate in any jurisdiction and it is possible that none of our existing therapeutic candidates or any therapeutic candidates we may seek to develop in the future will ever obtain marketing approval.

Therapeutic candidates could fail to receive, or could be delayed in receiving, marketing approval for many reasons, including any one or more of the following:

- the FDA, European Medicines Agency, or EMA, or comparable foreign regulatory authorities may disagree with the design or implementation of clinical trials;
- Fulgent Pharma may be unable to demonstrate to the satisfaction of the FDA, EMA or comparable foreign regulatory authorities that a product candidate is safe and effective for its proposed indication(s) for use;
- the results of clinical trials may not meet the level of statistical significance required by the FDA, EMA or comparable foreign regulatory authorities for marketing approval;
- Fulgent Pharma may be unable to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks;
- the FDA, EMA or comparable foreign regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials;
- the data collected from clinical trials of product candidates may not be sufficient to support the submission of an application to obtain marketing approval in the United States or elsewhere;
- upon review of clinical trial sites and data, the FDA or comparable foreign regulatory authorities may find record keeping or the record keeping of clinical trial sites to be inadequate or may identify other deficiencies related to the trials;

- the manufacturing processes or facilities of third-party manufacturers with which we or Fulgent Pharma contract for clinical and commercial supplies may fail to meet the requirements of the FDA, EMA or comparable foreign regulatory authorities; or
- the medical standard of care or the approval policies or regulations of the FDA, EMA or comparable foreign regulatory authorities may significantly change in a manner that renders our clinical data insufficient for approval.

It is possible that none of the therapeutic candidates we or Fulgent Pharma may develop will obtain the marketing approvals necessary for us or our collaborators to sell the products either in the United States or any other country. Furthermore, approval by the FDA of a therapeutic product does not assure approval by regulatory authorities outside the United States or vice versa. Even if approval for a therapeutic product is obtained, such approval may be subject to limitations on the indicated uses or appropriate patient population that could result in a significantly reduced potential market size for the product.

Fulgent Pharma expects to utilize the FDA's Section 505(b)(2) pathway for most of its product candidates, which are being developed using its nano-drug delivery platform technology. If that pathway is not available, the development of such product candidates will likely take significantly longer, cost significantly more and entail significantly greater complexity and risk than currently anticipated, and, in any case, may not be successful.

Fulgent Pharma intends to develop and seek approval for its product candidates developed using its nano-drug delivery platform technology, including FID-007 and other candidates it may develop, pursuant to the FDA's 505(b)(2) pathway. If the FDA determines that it may not use this regulatory pathway, then it would need to seek regulatory approval via a "full" or "stand-alone" new drug application, or NDA, under Section 505(b)(1) of the Federal Food, Drug, and Cosmetic Act, or FDCA. This would require Fulgent Pharma to conduct additional clinical trials, provide additional safety and efficacy data and other information, and meet additional standards for regulatory approval, including possibly nonclinical data. If this were to occur, the time and financial resources required to obtain FDA approval, as well as the development complexity and risk associated with these programs, would likely substantially increase, which could have a material adverse effect on our business and financial condition.

The Drug Price Competition and Patent Term Restoration Act of 1984, informally known as the Hatch-Waxman Act, added Section 505(b)(2) to the FDCA. Section 505(b)(2) permits the filing of an NDA where at least some of the information required for approval comes from studies and information that were not conducted by or for the applicant and for which the applicant has not obtained a right of reference. Utilization of the Section 505(b)(2) NDA pathway could expedite the development program for Fulgent Pharma's lead product candidate, FID-007.

Notwithstanding the approval of an increasing number of products by the FDA under Section 505(b)(2) over the last few years, certain brand-name pharmaceutical companies and others have objected to the FDA's interpretation of Section 505(b)(2). If the FDA's interpretation of Section 505(b)(2) is successfully challenged, or Congress were to amend the statute to alter the currently available regulatory pathway, the FDA may change its 505(b)(2) policies and practices, which could delay or even prevent the FDA from approving any NDA Fulgent Pharma submits under Section 505(b)(2). In addition, the pharmaceutical industry is highly competitive, and Section 505(b)(2) NDAs are subject to special requirements designed to protect the patent rights of sponsors of previously approved drugs referenced in a Section 505(b)(2) NDA. Even if Fulgent Pharma is able to utilize the Section 505(b)(2) regulatory pathway for one or more of its candidates, there is no guarantee this would ultimately lead to faster product development or earlier approval.

Moreover, any delay resulting from Fulgent Pharma's inability to pursue the FDA's 505(b)(2) pathway could result in new competitive products reaching the market more quickly than its product candidates, which may have a material adverse impact on its competitive position and prospects. Even if Fulgent Pharma is allowed to pursue the FDA's 505(b)(2) pathway for one or more of its drug product candidates, we cannot assure you that such candidates will receive the requisite approvals for commercialization.

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 or developing therapeutic candidates.

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 our testing and testing services. 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.

We may be subject to claims challenging the inventorship of our patents and other intellectual property.

We may be subject to claims that former employees, collaborators or other third parties have an interest in our owned patents, trade secrets, or other intellectual property as an inventor or co-inventor. For example, we may have inventorship disputes arise from conflicting obligations of consultants or others who are involved in developing our products or product candidates and other proprietary technologies we may develop. Litigation may be necessary to defend against these and other claims challenging inventorship or our ownership of our owned patents, trade secrets or other intellectual property. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, intellectual property that is important to our products, product candidates and other proprietary technologies we may develop. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

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 product candidates, products, 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 or developing therapeutic candidates."

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.

If we fail to comply with our obligations under license or technology agreements with third parties, we could lose license rights that are important to our business. If our third-party licensors fail to comply with the terms of our license arrangements, we may be forced to engage in litigation to protection our rights, which may not be successful.

We license certain intellectual property, including technologies and patents, from third parties, that is important to our research and development efforts, and in the future we may enter into additional agreements that provide us with licenses to valuable intellectual property or technology. If we fail to comply with any of the obligations under our license agreements, we may be required to pay damages and the licensor may have the right to terminate the license. Termination by the licensor could cause us to lose valuable rights, prevent us from continuing related research and development activities or otherwise materially and negatively impact our business. If our licensors fail to abide by the terms of a license agreement, fail to enforce licensed intellectual property against infringing third parties, if the licensed intellectual property are found to be invalid or unenforceable, or if we are unable to enter into necessary license agreements on acceptable terms or at all, we may be forced to engage in litigation to enforce our rights. This litigation may not be successful and may consume substantial amounts of time and resources. These circumstances could have a material adverse effect on our business, development efforts, financial condition or results of operations.

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 28% of our outstanding voting equity as of December 31, 2022. 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 testing and testing services, 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;
- 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 44% of our outstanding voting equity as of December 31, 2022, and of this, Mr. Hsieh, our founder, Chief Executive Officer and Chairman of our board of directors, by himself beneficially owns approximately 28% of our outstanding voting equity as of December 31, 2022. 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. 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 2024. 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 Irving, Texas; Alpharetta, Georgia; Phoenix, Arizona; Needham, Massachusetts; and New York, New York. In Irving, Texas, we lease and occupy approximately 172,000 square feet under a lease that will expire in May 2024. In Alpharetta, Georgia, we lease and occupy approximately 65,000 square feet under a lease that will expire in March 2028. In Phoenix, Arizona, we lease and occupy approximately 25,000 square feet under a lease that will expire in November 2025. In Needham, Massachusetts, we lease and occupy approximately 21,000 square feet under a lease that will expire in September 2027. In New York, New York, we lease and occupy approximately 400 square feet under a lease that will expire in September 2024. 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 have built a CLIA-certified laboratory 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.

On September 20, 2022, the Company and two of its executive officers were named as defendants in a putative class action complaint filed in the U.S. District Court for the Central District of California (Case No. 2:22-cv-06764) on behalf of individuals who purchased or otherwise acquired the Company's securities between March 22, 2019 and August 4, 2022. The Complaint asserted claims under Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 based on allegations that the Company and certain of its executive officers made false and/or misleading statements and/or failed to disclose laboratory testing, billing for laboratory testing, and remuneration received or provided that purportedly violated the Anti-Kickback Statute and Stark Law, and purportedly are the subject of the CID discussed in Note 8*, Debt, Commitments and Contingencies*, of our condensed consolidated financial statements included in this report. The Complaint sought recovery of unspecified damages, interest, costs, attorneys' fees and other relief.

On November 30, 2022, the Court appointed Co-Lead Plaintiffs and Co-Lead Counsel. On February 21, 2023, Co-Lead Plaintiffs filed a Notice of Voluntary Dismissal of all claims against defendants, and without any payment by us or our insurers. The voluntary dismissal is without prejudice so there is no assurance that another complaint may not be filed in the future.

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, 2023, there were 12 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

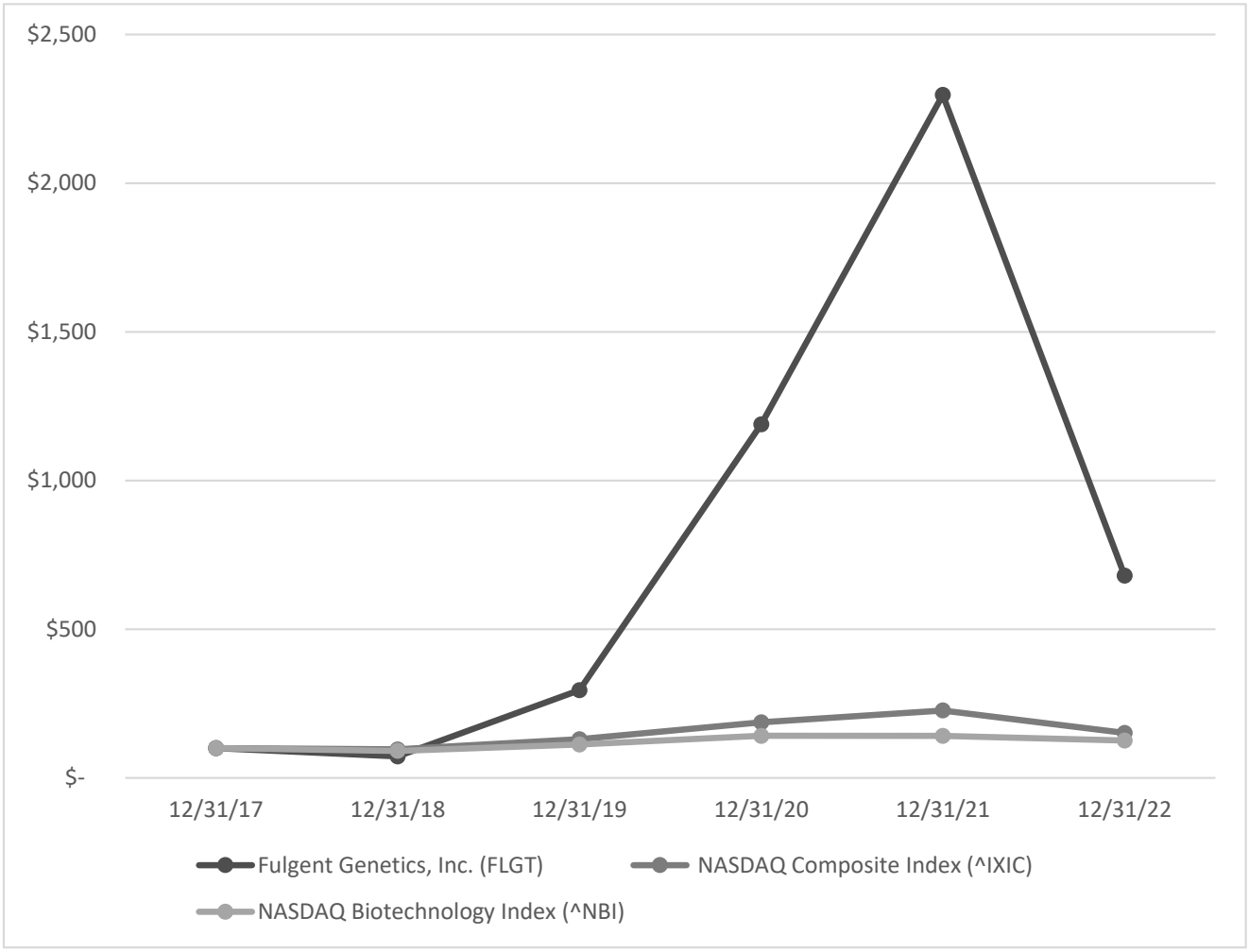
We currently anticipate that we will retain any future earnings to finance the continued development, operation and expansion of our business. As a result, we do not anticipate declaring or paying any cash dividends or other distributions in the foreseeable future. Any determination to pay dividends 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

To date, we have used $85.9 million of the net proceeds from sales of our common stock, of which, $4.5 million was used for contributions to FF Gene Biotech prior to the FF Gene Biotech Acquisition and $81.4 million was used to fund the Company's operation and a business combination. All other net proceeds from sales of our common stock are invested in investment-grade and interest-bearing securities, such as corporate bonds, municipal bonds, and U.S. government and U.S. agency debt securities. There has been no material change in the planned use of proceeds from the sales of our common stock from that described in the Prospectus.

Common Stock Performance Graph

The following graph compares the cumulative total stockholder return, calculated on a dividend-reinvested basis, in Fulgent's Common Stock, the NASDAQ Composite Index, and the NASDAQ Biotechnology Index for the five years ended December 31, 2022. The comparison assumes that $100 was invested in the Company's Common Stock, the NASDAQ Composite Index, and the NASDAQ Biotechnology Index as of the market close on December 31, 2017. Note that historic stock price performance is not necessarily indicative of future stock price performance.



Information on Share Repurchases

The number of shares of common stock repurchased by the Company during the year ended December 31, 2022 and the average price paid per share are as follows:

Period	(a) Total Number of Shares Purchased	(b) Average Price Paid Per Share (1)	(c) Total Number of Shares Purchased As Part of Publicly Announced Plans or Programs	(d) Maximum Dollar Value that May Yet Be Purchased Under the Plans or Programs
May 2022 (5/1/2022 - 5/31/2022)	30,000	$ 49.56	30,000	$ 248,515,000
June 2022 (6/1/2022 - 6/30/2022)	185,000	$ 48.97	185,000	$ 239,429,000
August 2022 (8/1/2022 - 8/31/2022)	247,000	$ 47.68	247,000	$ 227,657,000
September 2022 (9/1/2022 - 9/30/2022)	533,000	$ 43.04	533,000	$ 204,752,000
October 2022 (10/1/2022 - 10/31/2022)	244,000	$ 37.33	244,000	$ 195,661,000
November 2022 (11/1/2022 - 11/30/2022)	234,000	$ 35.83	234,000	$ 187,276,000
December 2022 (12/1/2022 - 12/31/2022)	337,000	$ 34.32	337,000	$ 175,718,000
Total	1,810,000		1,810,000	

(1) Includes commissions for the shares repurchased under the stock repurchase program.

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 2020 results where it would be redundant to the discussion previously included in Item 7 of our 2021 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-based company with a well-established clinical diagnostic business and a therapeutic development business. Our clinical diagnostic business offers molecular diagnostic testing services, comprehensive genetic testing, and high-quality anatomic pathology laboratory services designed to provide physicians and patients with clinically actionable diagnostic information to improve the quality of patient care. Our therapeutic development business is focused on developing drug candidates for treating a broad range of cancers using a novel nanoencapsulation and targeted therapy platform designed to improve the therapeutic window and pharmacokinetic profile, or PK profile, of new and existing cancer drugs. We aim to transform from a genomic diagnostic business into a fully integrated precision medicine company.

We recorded revenue and income from operations of $619.0 million and $143.4 million, respectively, in 2022, compared to revenue and income from operations of $992.6 million and $507.4 million, respectively, in 2021.

2022 Developments

Opening of New State-of-the-Art Oncology Laboratory in El Monte, California

In May 2022, we opened a new state-of-the-art oncology laboratory in El Monte, California, near our global headquarters in Temple City. This new CLIA-certified lab enables us to expand our capabilities in somatic molecular diagnostics and cancer testing and more efficiently serve oncology clients on the West Coast of the United States.

Acquisition of Inform Diagnostics

In April 2022, we completed the acquisition of Inform Diagnostics, a leading national independent pathology laboratory based in Irving, Texas, and a portfolio company of Avista Capital Partners. Inform Diagnostics, formerly known as Pathology Partners, was founded in 1996 and has since become one of the largest national pathology laboratories in the United States, with offerings across gastrointestinal pathology, dermatopathology, urologic pathology, and hematopathology, among others. Inform Diagnostics currently provides services to approximately 1,300 clients who represent over 2,700 physicians. Inform Diagnostics is committed to providing physicians and the patients they serve with efficient, dependable, and high-quality service to facilitate faster treatment for patients and more efficient workflows for clinicians. The acquisition extends our capabilities into the pathology testing market, with the goal of continuing to innovate healthcare by developing new NGS based tests, among other technologies, to further serve the combined companies' large, nationwide customer base. With the addition of Inform Diagnostics' extensive testing capabilities, nationwide

salesforce, and significant managed care contracts, we believe we are better positioned to become a one-stop shop for diagnostic services throughout the healthcare continuum and across the United States. We see valuable cross-selling opportunities with Inform Diagnostics' national GI and GU specialist client base, including our newly launched liquid biopsy test for Hepatocellular carcinoma, HelioLiver, as well as an upcoming molecular test for urology, which is pending launch. In addition, we expect to offer high-value NGS-based oncology services to Inform Diagnostics' hematology clients. We believe Inform Diagnostics' client relationships will enable us to access more patients along key touchpoints to provide a comprehensive suite of diagnostic products and services leading to improved healthcare. The acquisition extends our in-network relationships with managed care organizations to over 300 million covered lives and expands our geographic footprint with the addition of CLIA, CAP, and NY State certified laboratories in California, New York, Arizona, Massachusetts, and Texas.

Acquisition of Fulgent Pharma

In November 2022, we completed the acquisition of Fulgent Pharma, a clinical-stage, therapeutics development company focused on the development of innovative cancer treatments. Through this acquisition and assuming successful development and the requisite approvals, we plan to offer a vertically integrated solution to combat cancer with the potential to create value for both this therapeutic and diagnostic our businesses. Fulgent Pharma and Fulgent Genetics were previously both owned by Fulgent Therapeutics until 2016, when the businesses were separated ahead of the Initial Public Offering of Fulgent Genetics. The companies have operated as separate entities since 2016, enabling each business to focus on and achieve core objectives across genetic testing and therapeutic drug development. Fulgent Pharma has developed a novel nanoencapsulation and targeted therapy platform, which is designed to improve the therapeutic window and pharmacokinetic profile of new and existing cancer drugs. Fulgent Pharma's lead candidate, FID-007, is currently being investigated in the United States in a Phase I clinical trial in patients diagnosed with various cancers including head and neck cancers, ampullary and pancreatic cancer. Top-line data from this trial is expected in the second quarter of 2023. Assuming positive data, we intend to seek regulatory approval in the United States using the 505(b)(2) pathway, which may shorten the clinical trial process and accelerate potential commercialization. We also plan to initiate Phase II clinical trials investigating the use of FID-007 in patients diagnosed with recurrent, or metastatic head and neck and other cancers in late 2023 and 2024, respectively.

Factors Affecting Our Performance

Genetic Testing 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.

COVID-19 Testing Services

We have experienced volume growth after the launch of our COVID-19 testing services in 2020. 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 resulted in a substantial change in our business. However, due to decreased demand of testing, we experienced decreasing revenues from our COVID-19 testing services and we do not expect substantial revenue from COVID-19 testing in 2023.

Mix of Tests Delivered

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 tests delivered in any period, and the customers that order these tests, impacts our financial results for the period.

Mix of 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 hospitals and affiliated specialties related to our service offerings. 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. These efforts may not lead to meaningful or any increases in our customer base 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 genetic 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 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.

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 our costs.

Moreover, changes in our other operating expenses, due to investments in these aspects of our business or other factors, are not taken into account but impact our overall results, which can limit the utility of cost as an overall cost measurement tool.

Ability to Obtain Reimbursement

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. 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 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 test and testing services. 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 and if we increase the number of tests we deliver.

Operating Expenses

Our operating expenses are classified into five categories: research and development; selling and marketing; general and administrative; amortization of intangible assets; and restructuring costs. For each category except for amortization of intangible assets, 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 and treatments. 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 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.

Amortization of Intangible Assets

Amortization of intangible assets consist of amortization expense on customer relationships, royalty-free technology, trade name, laboratory information system platform and in-place intangible assets that arose from the business combinations and a patent acquired. We amortize finite lived intangible assets over the period of estimated benefit using the straight-line method. Indefinite lived intangible assets are tested for impairment annually or whenever events or circumstances indicate that the carrying amount of the asset may not be recoverable. If impairment is indicated, we measure the amount of the impairment loss as the amount by which the carrying amount exceeds the fair value of the asset.

Restructuring Costs

Restructuring costs represent one-time employee termination benefits provided to employees associated with a newly acquired entity that were involuntarily terminated. A plan of termination was approved and authorized by management in the second quarter of 2022. The plan identified specific employees to be terminated and established terms of benefits those employees would receive upon termination. No additional costs are expected to be incurred under the plan of termination post 2022, and the payable balance is expected to be paid off by August 2023.

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,		$	%
	2022	2021	Change	Change
Statement of Operations Data:	(dollars in thousands)			
Revenue	$ 618,968	$ 992,584	$ (373,616)	(38)%
Cost of revenue	252,067	215,533	36,534	17%
Gross profit	366,901	777,051	(410,150)	(53)%
Operating expenses:				
Research and development	28,910	24,219	4,691	19%
Selling and marketing	38,918	24,439	14,479	59%
General and administrative	111,074	50,732	60,342	119%
Amortization of intangible assets	6,497	1,708	4,789	280%
Restructuring costs	2,975	—	2,975	*
Total operating expenses	188,374	101,098	87,276	86%
Operating income	178,527	675,953	(497,426)	(74)%
Interest and other income, net	5,498	1,347	4,151	308%
Income before income taxes and gain on equity-method investment	184,025	677,300	(493,275)	(73)%
Provision for income taxes	42,102	174,795	(132,693)	(76)%
Income before gain on equity-method investment	141,923	502,505	(360,582)	(72)%
Gain on equity-method investment	—	3,734	(3,734)	(100)%
Net income from consolidated operations	141,923	506,239	(364,316)	(72)%
Net loss attributable to noncontrolling interests	1,480	1,125	355	32%
Net income attributable to Fulgent	$ 143,403	$ 507,364	$ (363,961)	(72)%

* Percentage not meaningful.

Revenue

Revenue decreased $373.6 million, or 38%, from $992.6 million in 2021 to $619.0 million in 2022. The decrease in revenue between periods were primarily due to decreased orders for our COVID-19 tests.

Revenue from non-U.S. sources increased $2.2 million, or 16%, from $13.6 million in 2021 to $15.8 million in 2022. 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 $9.2 million in total revenue in 2022.

Aggregating customers that are under common control, one of our customers, County of Los Angeles, contributed 19% and 26% of our revenue in 2022 and 2021, respectively.

Cost of Revenue

Cost of revenue increased $36.5 million, or 17%, from $215.5 million in 2021 to $252.1 million in 2022. The increase was primarily due to increases of $45.1 million in personnel costs including equity-based compensation, $6.6 million in allocated overhead expenses including security expenses, and $3.8 million in shipping and handling expense primarily due to additions of Inform Diagnostics and CSI, and $13.0 million in depreciation expenses primarily due to additions in fixed assets for production, remaining useful lives of COVID-related equipment and addition of Inform Diagnostics, partially offset by decreases of $27.2 million in reagent and supply expenses, $5.0 million in external customer engagement platforms, and $2.3 million in consulting and outside labor expense related to the decreased tests delivered.

Our gross profit decreased $410.2 million, or 53%, from $777.1 million in 2021 to $366.9 million in 2022. The decrease in gross profit was primarily due to the decrease in revenue from our COVID-19 tests and increases in cost of revenue described above. Our gross profit as a percentage of revenue, or gross margin, decreased from 78.3% to 59.3% due to changes in product mix.

Research and Development

Research and development expenses increased $4.7 million, or 19%, from $24.2 million in 2021 to $28.9 million in 2022. The increase was primarily due to increases of $6.5 million in personnel costs including equity-based compensation expense related to increased headcount, $415,000 in depreciation expense, and $235,000 in allocated overhead expenses, partially offset by decreases of $1.5 million in reagent and supply expenses related to decreased reagent usage for research and $1.2 million in donations to COVID-19 research fund and colorectal cancer research made in 2021.

Selling and Marketing

Selling and marketing expenses increased $14.5 million, or 59%, from $24.4 million in 2021 to $38.9 million in 2022. The increase was primarily due to increases of $7.1 million in personnel costs including equity-based compensation expense related to increased headcount, $3.6 million in software expense from Inform Diagnostics, $1.0 million in travel expenses, $967,000 in commission expenses from CSI, $704,000 in consulting and outside labor related to marketing projects in 2022 and $632,000 in allocated overhead expenses due to addition of Inform Diagnostics.

General and Administrative

General and administrative expenses increased $60.3 million, or 119%, from $50.7 million in 2021 to $111.1 million in 2022. The increase was primarily due to increases of $23.7 million in increased provision for credit losses stemming from the cessation of funding for the HRSA program in March 2022, $14.0 million in personnel costs including equity-based compensation expense related to increased headcount, $6.2 million in acquisition-related costs, $4.9 million in legal and professional fees primarily related to general corporate matters, $3.2 million in allocated overhead expenses, $3.1 million in license and permit expense and $2.4 million in depreciation expense primarily from Inform Diagnostics, $2.2 million in insurance expense, and $1.5 million in accounting expenses related to financial statement and internal control audit and reviews, partially offset by a decrease of $790,000 in consulting and outside labor expense.

Amortization of Intangible Assets

Amortization of intangible assets represents amortization expenses on the intangible assets that arose from the business combinations in 2022 and 2021 and a patent purchased in 2021. The increase in amortization of intangible assets was primarily due to additions in intangible assets from business combinations in 2022.

Restructuring Costs

Restructuring expenses represent one-time employee termination benefits provided to employees that were involuntarily terminated in association with the acquisition of a new entity in 2022.

Interest and Other Income, Net

Interest and other income, net is primarily comprised of net interest income, which was $5.3 million and $1.3 million for 2022 and 2021, respectively. This interest income related to interest earned on various investments in marketable securities including realized and holding gain (loss) on marketable equity securities, net of interest expenses incurred on our notes payable and a margin loan.

Provision for Income Taxes

Provision for income taxes were $42.1 million and $174.8 million in 2022 and 2021, respectively. The effective income tax rate was 22.7% and 25.8% of income before income taxes for 2022 and 2021, respectively. The decrease in the effective tax rate for 2022 relative to 2021 was primarily attributable to international restructuring costs that were incurred in 2021 but not 2022.

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

Gain on Equity-Method Investment

Gain on equity-method investment in 2021 related to our preexisting equity interest at Fujian Fujun Gene Biotech Co., Ltd., or FF Gene Biotech as a result of remeasuring to fair value our 30% equity interest held before the acquisition of FF Gene Biotech, or 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.

Net Loss Attributable to Noncontrolling Interest

Net loss attributable to noncontrolling interest represents net loss attributable to minority shareholders from entities not wholly owned.

Liquidity and Capital Resources

Liquidity and Sources of Cash

We had $852.9 million and $935.5 million in cash, cash equivalents and marketable securities as of December 31, 2022 and 2021, respectively. Our marketable securities primarily consist of equity securities and corporate bonds, municipal bonds, and U.S. government and U.S. agency debt securities, U.S. treasury bills, and Yankee debt securities as of December 31, 2022 and 2021.

Our primary uses of cash are to fund our operations and to fund strategic acquisitions 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.

We believe our existing cash, cash equivalent, and short-term marketable securities will be sufficient to meet our anticipated cash requirements for at least the next 12 months. Cash provided by operations has significantly contributed to our ability to meet our liquidity needs, including paying for capital expenditures, however, 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 demand for our tests, the amount and timing of sales, 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 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. Additional funding may not be available to us when needed, on acceptable terms or at all. 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,	
	2022	2021
	(in thousands)	
Net cash provided by operating activities	$ 253,520	$ 538,577
Net cash used in investing activities	$ (261,314)	$ (546,548)
Net cash (used in) provided by financing activities	$ (77,141)	$ 85,405

Operating Activities

Cash provided by operating activities in 2022 was $253.5 million. The difference between net income and net cash provided by operating activities for the period was primarily due to the effect of $32.7 million in the depreciation and amortization, $32.6 million in equity-based compensation expenses, $32.6 million in provision for credit losses, $9.1 million in unrecognized tax benefits, $4.9 million in noncash lease expenses, $4.8 million in amortization of premium on marketable securities, and partially offset by $8.3 million in deferred taxes. Changes in operating assets and liabilities primarily consisted of a decrease of $68.6 million in accounts receivable mainly due to the timing of collections, and partially offset by a negative impact on decreases of $31.3 million in other current and non-current liabilities related to decreased accrued liabilities, customer deposits and contract liabilities, $25.3 million in

accounts payable mainly due to the timing of payments, and $4.8 million in operating and finance lease liabilities and an increase of $4.3 million in other current and long-term assets.

Cash provided by operating activities in 2021 was $538.6 million. The difference between net income and net 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. Changes in operating assets and liabilities primarily consisted of 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.

Investing Activities

Cash used in investing activities in 2022 was $261.3 million, which primarily related to $418.0 million in purchase of marketable securities, $172.7 million related to business acquisitions, $18.8 million related to the purchase of fixed assets consisting mainly of medical laboratory equipment and building improvement, $15.0 million related to the purchase of redeemable preferred stock and $10.0 million related to contingent consideration payouts related to business acquisitions, partially offset by $232.5 million related to maturities of marketable securities and $140.2 million related to proceeds from sales of marketable securities.

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 the purchase of fixed assets consisting mainly of medical laboratory equipment and building improvement, and $20.0 million related to the 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.

Financing Activities

Cash used in financing activities in 2022 was $77.1 million, which primarily related to $74.3 million used in the repurchase of common stock and $1.8 million used in common stock withholding for employee tax obligations.

Cash provided by financing activities in 2021 was $85.4 million, which primarily related to $89.5 million proceeds from an equity distribution agreement, partially offset by $4.2 million in common stock withholding for employee tax obligations.

Stock Repurchase Program

In March 2022, our Board authorized a $250.0 million stock repurchase program. The stock repurchase program has no expiration from the date of authorization. Under the stock repurchase program, the Company may repurchase shares from time to time in the open market or in privately negotiated transactions.

During the year ended December 31 2022, we repurchased 1.8 million shares of our common stock at an aggregate cost of $74.3 million under the stock repurchase program. As of December 31, 2022, a total of approximately $175.7 million remained available for future repurchases of our common stock under our stock repurchase programs.

Material Cash Requirements and Contractual Obligations as of December 31, 2022

As of December 31, 2022, we have an outstanding balance of $15.0 million under our margin account, $5.2 million in notes payable to Xilong Scientific, which is due in March 2023, and $3.8 million of an installment loan, of which, the current portion is $461,000. See Note 8, *Debt, Commitments and Contingencies*, of our consolidated financial statements included in this report.

The following summarizes our contractual obligations as of December 31, 2022:

	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]	$ 15,879	$ 6,590	$ 6,190	$ 2,882	$ 217
Finance lease obligations[2]	2,932	986	1,580	366	—
Purchase obligations[3]	10,089	7,544	2,545	—	—
Total contractual obligations	$ 28,900	$ 15,120	$ 10,315	$ 3,248	$ 217

(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. 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 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 our 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 Income.

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.

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.

We are exposed to market risks from fluctuations in interest rates and foreign currency translation, which may adversely affect our results of operations and financial condition.

Interest Rate Risk

We invest in marketable debt securities, including corporate debt securities, municipal bonds, U.S. government and agency debt securities, and debt instruments issued by foreign governments. Our investment policy and strategy are focused on the preservation of capital and supporting our liquidity requirements. We typically invest in highly rated securities, with the primary objective of minimizing the potential risk of principal loss. Our investments in fixed rate interest earning securities carry a degree of interest rate risk. Fixed rate securities may have their fair market value adversely affected due to a rise in interest rates. Unrealized gains or losses on our marketable debt securities are primarily due to interest rate fluctuations as compared to interest rates at the time of purchase. We measure our debt securities at fair value with gains and losses recorded in Other Comprehensive Income until the securities are sold, less any expected credit losses.

To provide a meaningful assessment of the interest rate risk associated with our investment portfolio, we performed a sensitivity analysis to determine the impact a change in interest rates would have on the value of the investment portfolio assuming a 100-basis point parallel shift in the yield curve. Based on investment positions as of December 31, 2022, a hypothetical 100 basis point increase in interest rates across all maturities would result in a $7.3 million incremental decline in the fair market value of the portfolio. Such losses would only be realized if we sold the investments prior to maturity.

Foreign Currency Risk

We transact business in multiple currencies, in addition, we translate the assets and liabilities of our non-U.S. dollar functional currency subsidiaries into U.S. dollars. Foreign assets, liabilities, revenues, as well as costs and expenses denominated in foreign currencies, expose us to the risk of fluctuations in foreign currency exchange rates against the U.S. dollar. Our foreign currency exposures are primarily concentrated in the Chinese yuan. For the purpose of analyzing foreign currency exchange risk, we considered the historical trends in foreign currency exchange rates and determined that it was reasonably possible that adverse changes in exchange rates of 10% could be experienced in the near term.

If an adverse 10% foreign currency exchange rate change was applied to total monetary assets denominated in currencies other than the functional currencies at the balance sheet date, it would have resulted in decrease on income before income taxes of approximately $844,000 as of December 31, 2022.

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, 2022. 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, 2022.

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 year ended December 31, 2022, that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

In 2022, we completed the acquisition of Inform Diagnostics and Fulgent Pharma. See Note 15 of "Notes to Consolidated Financial Statements" for more information. We are currently integrating Inform Diagnostics and Fulgent Pharma 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 business of Inform Diagnostics and Fulgent Pharma, 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, 2022 excludes Inform Diagnostics and Fulgent Pharma 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, 2022. Management reviewed the results of its assessment with our Audit and Compliance Committee. The effectiveness of our internal control over financial reporting as of December 31, 2022 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 2022, we acquired Inform Diagnostics and Fulgent Pharma. 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 the acquired businesses from our assessment of the effectiveness of internal control over financial reporting as of December 31, 2022. The Inform Diagnostics and Fulgent Pharma business represented 14% of our revenue and 20% of our total assets as of and for the year ended December 31, 2022.

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, 2022, 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, 2022, 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, 2022, of the Company and our report dated February 28, 2023, 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 the internal control over financial reporting at Inform Diagnostics, Inc. and Fulgent Pharma Holdings, Inc. which were acquired on April 26, 2022 and November 7, 2022, respectively, and whose financial statements constitute 14% of revenues and 20% of total assets of the consolidated financial statement amounts as of and for the year ended December 31, 2022. Accordingly, our audit did not include the internal control over financial reporting at Inform Diagnostics, Inc. and Fulgent Pharma Holdings, 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 the accompanying "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, 2023

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 2023 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, 2022.

Item 11. Executive Compensation.

The information required by this item is incorporated by reference to the definitive proxy statement for our 2023 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, 2022.

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 2023 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, 2022.

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 2023 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, 2022.

Item 14. Principal Accounting Fees and Services.

The information required by this item is incorporated by reference to the definitive proxy statement for our 2023 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, 2022.

PART IV

Item 15. Exhibits and 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.					X
10.1#	Form of Indemnification Agreement between the registrant and each of its officers and directors.	S-1	333-213469	10.1	9/2/2016	
10.2#	Amended and Restated 2015 Equity Incentive Plan of Fulgent Therapeutics LLC.	S-1	333-213469	10.2	9/2/2016	
10.3#	Form of Notice of Option Grant and Option Agreement under the Amended and Restated 2015 Equity Incentive Plan of Fulgent Therapeutics LLC.	S-1	333-213469	10.3	9/2/2016	
10.4#	Form of Notice of Profits Interest Grant and Profits Interest Agreement under the Amended and Restated 2015 Equity Incentive Plan of Fulgent Therapeutics LLC.	S-1	333-213469	10.4	9/2/2016	
10.5#	Form of Notice of Restricted Share Unit Grant and Restricted Share Unit Agreement under the Amended and Restated 2015 Equity Incentive Plan of Fulgent Therapeutics LLC.	S-1	333-213469	10.5	9/2/2016	
10.6#	2016 Omnibus Incentive Plan of the registrant.	S-1/A	333-213469	10.6	9/26/2016	
10.7#	Form of Notice of Stock Option Award and Stock Option Award Agreement under the 2016 Omnibus Incentive Plan of the registrant.	S-1	333-213469	10.7	9/2/2016	
10.8#	Form of Notice of Restricted Stock Unit Award and Restricted Stock Unit Agreement under the 2016 Omnibus Incentive Plan of the registrant.	10-K	001-37894	10.8	3/17/2017	
10.9#	Form of Option Substitution Award under the 2016 Omnibus Incentive Plan of the registrant.	S-1	333-213469	10.9	9/2/2016	

Exhibit Number	Description	Form	File Number	Incorporated by Reference Exhibit	Filing Date	Filed Herewith
10.10#	Form of Notice of Restricted Stock Unit Substitution Award and Restricted Stock Unit Agreement under the 2016 Omnibus Incentive Plan of the registrant.	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	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	
10.25	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	
10.26	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	
10.27	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	
10.28	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	
10.29	Fulgent Genetics, Inc. Amended and Restated 2016 Omnibus Incentive Plan	8-K	001-37894	10.1	5/21/2018	
10.30	Fulgent Genetics, Inc. Amended and Restated 2016 Omnibus Incentive Plan	8-K	001-37894	10.1	9/18/2020	
10.31^	Agreement for Purchase and Sale of Property, dated July 23, 2020	8-K	001-37894	2.1	10/21/2020	
10.32^	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	
10.33	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	
10.34	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	
10.35	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	
10.36#	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	
10.37#	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	
10.38#^	Amended and Restated Non-Employee Director Compensation Policy.	10-Q	001-37894	10.1	5/7/2021	
10.39§	Restructuring Agreement of Fujian Fujun Gene Biotech Co., Ltd.	10-Q	001-37894	10.1	8/10/2021	
10.40^	Amended and Restated Commercial Lease Agreement, dated May 6, 2016, by and	10-K	001-37894	10.41	2/28/2022	

Exhibit Number	Description	Form	File Number	Incorporated by Reference Exhibit	Filing Date	Filed Herewith
	between Store Master Funding IX, LLC and Cytometry Specialists, Inc.					
10.41#	Fulgent Genetics, Inc. Incentive Compensation Recoupment Policy.	8-K	001-37894	10.1	3/29/2022	
10.42	Agreement and Plan of Merger by and among Fulgent Therapeutics LLC, solely for purpose of Section 6.20, Fulgent Genetics, Inc., Ducks Acquisition Sub, Inc., Symphony Buyer, Inc., solely in its capacity as the representative of Symphony's securityholders, Avista Capital Partners IV GP, L.P. and solely for purposes of Section 6.21, Article VIII and Section 10.14, those company stockholders set forth on the signature page thereto, dated as of April 16, 2022.	8-K	001-37894	2.1	4/26/2022	
10.43#	Amended and Restated Non-Employee Director Compensation Policy, dated as of August 1, 2022.	10-Q	001-37894	10.1	11/7/2022	
10.44#	Form of Notice of Restricted Stock Unit Award and Restricted Stock Unit Agreement under the Fulgent Pharma Holdings, Inc. 2022 Omnibus Incentive Plan	10-Q	001-37894	10.2	11/7/2022	
10.45^	Agreement and Plan of Merger, by and among Fulgent Genetics, FG Merger Sub, Inc., Fulgent Pharma Holdings, Inc. and solely for purposes of Section 2.4, Section 5.5, Article VI, Section 7.8 and Section 7.14, those company stockholders set forth on the signature page thereto, dated November 7, 2022	10-Q	001-37894	10.3	11/7/2022	
10.46	Rule 10b5-1 Issuer Repurchase Plan, by and between Fulgent Genetics, Inc. and Piper Sandler & Co., dated December 15, 2022					X
10.47	Commercial Lease Addendum (II), dated January 6, 2023, by and between Fulgent Therapeutics LLC and E&E Plaza LLC	8-K	001-37894	1.1	1/12/2023	
10.48^	Commercial Lease Agreement, dated October 20, 2008, by and between Inform Diagnostics, Inc. and iSTAR CTL I, L.P.					X
10.49	Commercial Lease Amendment (I), dated December 30, 2013, by and between Inform Diagnostics, Inc. and LC Med Property TT, LLC					X
10.50^	Commercial Lease Amendment (II), dated February 3, 2014, by and between Inform Diagnostics, Inc. and LC Med Property TT, LLC					X
10.51	Commercial Lease Agreement by and between Inform Diagnostics and Crawford Street DE, LLC					X
10.52#	2022 Fulgent Pharma Holdings, Inc. Omnibus Incentive Plan					X
21.1	Subsidiaries of the registrant.					X

Exhibit Number	Description	Form	File Number	Incorporated by Reference Exhibit	Filing Date	Filed Herewith
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, 2023

By: /s/ Ming Hsieh
Ming Hsieh
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	Chief Executive Officer and Chairman of the Board (principal executive officer)	February 28, 2023
/s/ Paul Kim Paul Kim	Chief Financial Officer (principal financial and accounting officer)	February 28, 2023
/s/ Michael Nohaile Michael Nohaile	Director	February 28, 2023
/s/ Regina Groves Regina Groves	Director	February 28, 2023
/s/ Linda Marsh Linda Marsh	Director	February 28, 2023

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, 2022, and 2021, the related consolidated statements of income, comprehensive income, stockholders' equity, and cash flows, for each of the three years in the period ended December 31, 2022, 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, 2022, and 2021, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2022, 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, 2022, 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, 2023, 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 Matters

The critical audit matters communicated below are matters arising from the current-period audit of the financial statements that were communicated or required to be communicated to the audit committee and that (1) relate 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 matters below, providing separate opinions on the critical audit matters or on the accounts or disclosures to which they relate.

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

Critical Audit Matter Description

The Company completed the acquisition of Symphony Buyer, Inc., or Inform Diagnostics on April 26, 2022, and accounted for the transaction 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 relationship intangible asset in the amount of $54.0 million. Management estimated the fair value of the customer relationship intangible asset using the multi-period excess earnings method, which is a specific discounted cash flow method. The fair value determination of the customer relationship intangible asset required management to make significant estimates and assumptions related to future cash flows and the of the discount rate.

We identified the customer relationship intangible asset for Inform Diagnostics as a critical audit matter because of the significant estimates and assumptions management makes to fair value this asset. 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 and the selection of the discount rate for the customer relationship intangible asset.

How the Critical Audit Matter Was Addressed in the Audit

Our audit procedures related to forecasts of future cash flows and the selection of the discount rate for the customer relationship intangible asset included the following, among others:

- We tested the effectiveness of controls over the valuation of the customer relationship intangible asset, including management's controls over forecasts of future cash flows and selection of the discount rate.
- We assessed the reasonableness of management's forecasts of future cash flows by comparing the projections to historical results and certain peer companies.
- With the assistance of our fair value specialists, we evaluated the reasonableness of the (1) valuation methodology and (2) discount rate by:
- We evaluated whether the estimated future cash flows were consistent with evidence obtained in other areas of the audit.

Business Combinations—Fulgent Pharma Holdings, Inc. — Refer to Notes 2 and 15 to the financial statements

The Company completed the acquisition of Fulgent Pharma Holdings, Inc. on November 7, 2022, and accounted for the transaction under the acquisition method of accounting for business combination. The Company allocated the purchase price to tangible and identified intangible assets acquired and liabilities assumed based on their respective fair values, which included an in-process research and development ("IPR&D") intangible asset, in the amount of $64.6 million. Management estimated the fair value of the IPR&D intangible asset using the multi-period excess earnings method, which is a specific discounted cash flow method. The fair value determination of the IPR&D intangible asset required management to make significant estimates and assumptions related to future cash flows and the selection of the discount rate.

We identified the IPR&D intangible asset for Fulgent Pharma Holdings, Inc. as a critical audit matter because of the significant estimates and assumptions management makes to fair value this asset. 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 future cash flows and the selection of the discount rate for the IPR&D intangible asset.

How the Critical Audit Matter Was Addressed in the Audit

Our audit procedures related to forecasts of future cash flows and the selection of the discount rate for the IPR&D intangible asset included the following, among others:

- We tested the effectiveness of controls over the valuation of the IPR&D intangible asset, including management's controls over forecasts of future cash flows and selection of the discount rate.
- We assessed the reasonableness of management's forecasts of future cash flows by comparing the projections to relevant peer companies and third-party industry reports.
- With the assistance of our fair value specialists, we evaluated the reasonableness of the (1) valuation methodology and (2) discount rate by:
- We evaluated whether the estimated future cash flows were consistent with evidence obtained in other areas of the audit.

/s/ DELOITTE & TOUCHE LLP
Los Angeles, California

February 28, 2023

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

CONSOLIDATED FINANCIAL STATEMENTS

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

	December 31,	
	2022	2021
Assets		
Current assets		
Cash and cash equivalents	$ 79,506	$ 164,894
Marketable securities	446,729	285,605
Trade accounts receivable, net of allowance for credit losses of $41,205 and $11,217	52,749	138,912
Other current assets	48,889	22,549
Total current assets	627,873	611,960
Marketable securities, long-term	326,648	485,047
Redeemable preferred stock investment	12,385	21,965
Fixed assets, net	81,353	62,287
Intangible assets, net	150,643	35,914
Goodwill	143,027	50,897
Other long-term assets	44,124	10,650
Total assets	$ 1,386,053	$ 1,278,720
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable	$ 23,093	$ 20,494
Accrued liabilities	24,981	17,689
Income tax payable	—	787
Contract liabilities	3,199	14,570
Customer deposit	10,895	19,806
Investment margin loan	14,999	15,137
Contingent consideration	—	10,000
Notes payable, current portion	5,639	6,147
Other current liabilities	5,301	680
Total current liabilities	88,107	105,310
Unrecognized tax benefits	9,836	725
Other long-term liabilities	18,235	6,805
Total liabilities	116,178	112,840
Commitments and contingencies (Note 8)		
Stockholders' equity		
Common stock, $0.0001 par value per share, 50,000 shares authorized, 31,248 shares issued and 29,438 shares outstanding and 30,160 shares issued and outstanding	3	3
Preferred stock, $0.0001 par value per share, 1,000 shares authorized, no shares issued or outstanding	—	—
Additional paid-in capital	486,585	501,908
Accumulated other comprehensive loss	(20,903)	(759)
Retained earnings	801,000	657,597
Total Fulgent stockholders' equity	1,266,685	1,158,749
Noncontrolling interest	3,190	7,131
Total stockholders' equity	1,269,875	1,165,880
Total liabilities and stockholders' equity	$ 1,386,053	$ 1,278,720

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

CONSOLIDATED FINANCIAL STATEMENTS

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

	Year Ended December 31,		
	2022	2021	2020
Revenue	$ 618,968	$ 992,584	$ 421,712
Cost of revenue	252,067	215,533	89,807
Gross profit	366,901	777,051	331,905
Operating expenses:			
Research and development	28,910	24,219	11,580
Selling and marketing	38,918	24,439	14,952
General and administrative	111,074	50,732	15,215
Amortization of intangible assets	6,497	1,708	—
Restructuring costs	2,975	—	—
Total operating expenses	188,374	101,098	41,747
Operating income	178,527	675,953	290,158
Interest and other income, net	5,498	1,347	1,526
Income before income taxes, equity loss in investee and gain (loss) on equity-method investments	184,025	677,300	291,684
Provision for income taxes	42,102	174,795	72,532
Income before equity loss in investee and gain (loss) on equity-method investments	141,923	502,505	219,152
Equity loss in investee	—	—	(488)
Gain (loss) on equity-method investments	—	3,734	(4,354)
Net income from consolidated operations	141,923	506,239	214,310
Net loss attributable to noncontrolling interests	1,480	1,125	—
Net income attributable to Fulgent	$ 143,403	$ 507,364	$ 214,310
Net income per common share attributable to Fulgent:			
Basic	$ 4.76	$ 17.25	$ 9.44
Diluted	$ 4.63	$ 16.38	$ 8.91
Weighted-average common shares:			
Basic	30,097	29,408	22,694
Diluted	30,964	30,976	24,056

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

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

	Year Ended December 31,		
	2022	**2021**	**2020**
Net income from consolidated operations	$ 141,923	$ 506,239	$ 214,310
Other comprehensive income (loss):			
Foreign currency translation (loss) gain	(2,665)	456	20
Net (loss) gain on available-for-sale debt securities, net of tax	(19,940)	(1,548)	272
Comprehensive income from consolidated operations	119,318	505,147	214,602
Net loss attributable to noncontrolling interest	1,480	1,125	—
Foreign currency translation loss (gain) attributable to noncontrolling interest	2,461	(105)	—
Comprehensive loss attributable to noncontrolling interest	3,941	1,020	—
Comprehensive income attributable to Fulgent	$ 123,259	$ 506,167	$ 214,602

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, 2020	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
Equity-based compensation	—	—	32,640	—	—	32,640	—	32,640
Exercise of common stock options	5	—	31	—	—	31	—	31
Restricted stock awards	699	—	—	—	—	—	—	—
Common stock withholding for employee tax obligations	(32)	—	(1,768)	—	—	(1,768)	—	(1,768)
Repurchase of common stock	(1,810)	—	(74,337)	—	—	(74,337)	—	(74,337)
Common stock issued in a business combination (1)	416	—	28,111	—	—	28,111	—	28,111
Other comprehensive loss, net	—	—	—	(20,144)	—	(20,144)	(2,461)	(22,605)
Net income (loss)	—	—	—	—	143,403	143,403	(1,480)	141,923
Balance at December 31, 2022	29,438	$ 3	$ 486,585	$ (20,903)	$ 801,000	$ 1,266,685	$ 3,190	$ 1,269,875

(1) As of December 31, 2022, 371,006 shares of the Company's common stock were not issued and heldback by the Company as partial security for the indemnification obligations in connection with the business combination of Fulgent Pharma.

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,		
	2022	**2021**	**2020**
Cash flow from operating activities:			
Net income from consolidated operations	$ 141,923	$ 506,239	$ 214,310
Adjustments to reconcile net income to net cash provided by operating activities:			
Equity-based compensation	32,640	15,882	8,157
Depreciation and amortization	32,662	11,004	2,962
Provision for credit losses	32,596	8,931	1,170
Noncash lease expense	4,913	1,154	409
Loss on disposal of fixed asset	502	850	672
Amortization of premium of marketable securities	4,767	7,596	857
Deferred taxes	(8,280)	(8,188)	(1,775)
Unrecognized tax benefits	9,111	348	377
Net loss on marketable securities	692	1,186	90
Equity loss in investee	—	—	488
(Gain) loss in equity-method investments	—	(3,734)	4,354
Other	(11)	(15)	8
Changes in operating assets and liabilities:			
Trade accounts receivable	68,638	42,300	(178,480)
Other current and long-term assets	(4,337)	7,804	(21,149)
Accounts payable	(25,339)	(12,206)	22,617
Accrued liabilities and other liabilities	(31,299)	13,081	32,655
Income tax payable	(827)	(52,532)	53,295
Operating and finance lease liabilities	(4,831)	(1,123)	(389)
Net cash provided by operating activities	253,520	538,577	140,628
Cash flow from investing activities:			
Purchases of fixed assets	(18,775)	(23,812)	(35,130)
Purchases of intangible assets	—	(32)	—
Proceeds from sale of fixed assets	412	63	8
Purchase of marketable securities	(417,982)	(710,490)	(324,359)
Purchase of preferred stock of privately held company	(15,000)	—	—
Contingent consideration payout related to a business acquisition	(10,000)	—	—
Purchase of redeemable preferred stock	—	(20,000)	—
Maturities of marketable securities	232,534	83,842	19,919
Proceeds from sale of marketable securities	140,176	185,749	17,095
Acquisition of businesses, net of cash acquired	(172,679)	(61,868)	—
Investment in equity-method investees	—	—	(3,971)
Net cash used in investing activities	(261,314)	(546,548)	(326,438)
Cash flow from financing activities:			
Repurchase of common stock	(74,337)	—	—
Common stock withholding for employee tax obligations	(1,768)	(4,155)	(62)
Proceeds from public offerings of common stock, net of issuance costs	—	89,475	246,190
Proceeds from noncontrolling interest	—	10	—
Proceeds from exercise of stock options	31	86	104
Principal paid for finance leases	(700)	(7)	—
Repayment of notes payable	(367)	(4)	—
Borrowing under margin account	—	—	15,019
Net cash (used in) provided by financing activities	(77,141)	85,405	261,251
Effect of exchange rate changes on cash and cash equivalents	(453)	34	20
Net (decrease) increase in cash and cash equivalents	(85,388)	77,468	75,461
Cash and cash equivalents at beginning of period	164,894	87,426	11,965
Cash and cash equivalents at end of period	$ 79,506	$ 164,894	$ 87,426
Supplemental disclosures of cash flow information:			
Income taxes paid	$ 56,193	$ 237,069	$ 20,612
Supplemental disclosures of non-cash investing and financing activities:			
Stock consideration in a business combination	$ 28,111	$ —	$ —
Maturities of marketable securities in other current assets	$ 19,120	$ —	$ —
Purchases of fixed assets in notes payable	$ 3,833	$ —	$ —
Purchases of fixed assets in accounts payable	$ 2,989	$ 1,075	$ 3,402
Finance lease right-of-use assets obtained in exchange for lease liabilities	$ 573	$ 1,693	$ —
Operating lease right-of-use assets reduced due to lease modification or termination	$ 66	$ 399	$ 1,853
Operating lease right-of-use assets obtained in exchange for lease liabilities	$ 52	$ 1,797	$ 402
Contingent consideration for business acquisition included in current liabilities	$ —	$ 10,000	$ —
Public offerings proceeds in other receivable included in other current assets	$ —	$ —	$ 17,799
Public offerings costs included in accounts payable	$ —	$ 5	$ 359

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 intercompany accounts and transactions are eliminated from the accompanying consolidated financial statements.

Nature of the Business

Fulgent Genetics, Inc., together with its subsidiaries and affiliated professional corporations, or PCs, collectively referred to as the Company, unless otherwise noted or the context otherwise requires, is a technology-based company with a well-established clinical diagnostic business and a therapeutic development business. Its clinical diagnostic business offers molecular diagnostic testing services, comprehensive genetic testing, and high-quality anatomic pathology laboratory services designed to provide physicians and patients with clinically actionable diagnostic information to improve the quality of patient care. Its therapeutic development business is focused on developing drug candidates for treating a broad range of cancers using a novel nanoencapsulation and targeted therapy platform designed to improve the therapeutic window and pharmacokinetic profile of new and existing cancer drugs. The Company aims to transform from a genomic diagnostic business into a fully integrated precision medicine company.

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. 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, (v) valuation of intangible assets and goodwill at time of acquisition and on a recurring basis, and (vi) valuation of investments.

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. Cash and cash equivalent as of December 31, 2022 includes $5.0 million restricted cash related to a share transfer agreement entered by Fulgent Pharma Holdings, Inc., or Fulgent Pharma, pre-acquisition, see Note 15, *Business Combinations*.

Marketable Securities

All marketable debt securities, which consist of corporate debt securities, municipal bonds, U.S. government and agency debt securities, U.S. treasury bills, 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 Income. 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 Income. 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. The Company compares the present value of cash flows expected to be collected from the security with the amortized cost basis of the security. If the present value of cash flows to be collected is less than the amortized basis of the security, a credit loss exists, and an allowance for credit losses is recorded for the credit loss, limited by the amount of unrealized loss. Changes in the allowance are recorded in the period of changes as credit loss expense. 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

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 Income. 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,		
	2022	2021	2020
		(in thousands)	
Allowance for credit losses at beginning of year	$ 11,217	$ 1,898	$ 751
Impact of ASU 2016-13 adoption	—	887	—
Current period provision	32,596	8,931	1,170
Write-downs	(2,608)	(499)	(23)
Allowance for credit losses at end of year	$ 41,205	$ 11,217	$ 1,898

Redeemable Preferred Stock Investment

The redeemable preferred stock investment of $12.4 million of December 31, 2022 represents the fair value of redeemable preferred stock of a private company 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 losses of $9.6 million were excluded from earnings and reported in other comprehensive income (loss) for the year ended December 31, 2022. Unrealized gains of $2.0 million are excluded from earnings and reported in other comprehensive income (loss) for the year ended December 31, 2021. Since the Company intends on holding the preferred stock, and the 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, unless determined to be indefinite-lived, 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 fourteen years. In-process research and development costs, or IPR&D, are considered to be indefinite-lived until the completion or abandonment of the associated research and development efforts. If and when development is complete, the associated assets would be deemed finite-lived and would then be amortized based on their respective estimated useful lives at that point in time. During this period, the assets will not be amortized but will be tested for impairment on an annual basis and between annual tests if we become aware of any events occurring or changes in circumstances that would indicate a reduction in the fair value of the IPR&D projects below their respective carrying amounts. 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 compares the fair value of the reporting unit in which the goodwill resides to its carrying value. Goodwill is written down when it is determined to be impaired.

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.

Reagents and Supplies

The Company maintains reagents and other consumables primarily used in 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, accrued liabilities, investment margin loan, and contingent consideration. The carrying amounts of certain of these financial instruments, including cash and cash equivalents, accounts receivable, accounts payable, accrued liabilities, investment margin loan, and contingent consideration 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, 2022, 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 19% and 26% of total revenue in the years ended December 31, 2022 and 2021, respectively, and two customers comprised 28% and 10% of total revenue in the year ended December 31, 2020. One customer comprised 17% of total accounts receivable, net, as of December 31, 2022, and no customer comprised at least 10% of total accounts receivable, net, as of December 31, 2021.

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 25% interest in BostonMolecules was accounted for using the equity method, and the carrying value was zero as of December 31, 2022 and 2021 due to the impairment loss recorded in 2020.

The Company's proportionate share of the net income or loss of these companies were 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 any equity method investments for impairment whenever events or changes in circumstances would indicate that a decline in value has occurred that is other than temporary. Evidence considered in this evaluation would include, 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 were determined to have a decline in value deemed to be other than temporary it is written down to estimated fair value.

Leases

The Company determines if an arrangement is a lease at inception 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, accrued 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. 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 when its leases do not provide an implicit or explicit 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 Income.

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 out space in buildings it owns 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 Statements of Income.

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 one 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 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, 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 Income.

Performance Obligations

Institutional and Patient Direct Pay

The Company's institutional contracts for its testing services typically have a single performance obligation to deliver 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 parties 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 Income. 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.

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 of payments received from customers in excess of their outstanding trade accounts receivable balances. These deposits will be offset against future testing receivables or refunded to the customers.

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.

Restructuring Costs

Restructuring costs represent one-time employee termination benefits provided to employees associated with a newly acquired entity that were involuntarily terminated. A plan of termination was approved and authorized by management in the second quarter of 2022. The plan identified specific employees to be terminated and established terms of benefits those employees would receive upon termination. No additional costs are expected to be incurred under the plan of termination post 2022, and the payable balance is expected to be paid off by August 2023.

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 Income 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 gain (loss) included in the accompanying Consolidated Statements of Comprehensive Income. 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. Gains and losses from these measurements are included in interest and other income, net, in the accompanying Consolidated Statements of Income. Losses from foreign currency exchange were not significant in 2022, 2021 and 2020.

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 2022 or 2021. The Company did not have reclassifications from other comprehensive income (loss) to net loss in 2020. The tax effects related to net unrealized loss on available-for-sale debt securities were $7.2 million and $437,000 in 2022 and 2021, respectively. The tax effects related to net unrealized gain on the available-for-sale debt securities were $147,000 in 2020.

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, 2022, 2021 and 2020.

	Year Ended December 31,		
	2022	2021	2020
		(in thousands)	
Testing Services by payor			
Insurance	$ 377,873	$ 555,762	$ 257,587
Institutional	239,961	435,688	163,083
Patient	1,134	1,134	1,042
Total Revenue	$ 618,968	$ 992,584	$ 421,712

The insurance revenue category above includes $83.1 million and $310.4 million for the years ended December 31, 2022 and 2021, 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. 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 14% and 86%, respectively, as of December 31, 2022 and 47% and 53%, respectively, as of December 31, 2021.

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 $14.4 million, $26.4 million and $257,000 for the years ended December 31, 2022, 2021, and 2020, 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, 2022. 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.

Note 3. Equity and Debt Securities

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

	December 31, 2022			
	Amortized Cost Basis	Unrealized Gains	Unrealized Losses	Aggregate Fair Value
	(in thousands)			
Equity securities:				
Long-term				
Preferred stock of privately held company	$ 15,000	$ —	$ —	$ 15,000
Total equity securities	15,000	—	—	15,000
Available-for-sale debt securities				
Short-term				
U.S. government debt securities	189,333	—	(3,373)	185,960
Corporate debt securities	120,480	—	(2,222)	118,258
U.S. treasury bills	69,991	—	(193)	69,798
U.S. agency debt securities	68,411	—	(342)	68,069
Money market accounts	27,455	—	—	27,455
Municipal bonds	7,371	—	(80)	7,291
Yankee debt securities	2,347	—	(5)	2,342
Less: Cash equivalents	(32,444)	—	—	(32,444)
Total debt securities due within 1 year	452,944	—	(6,215)	446,729
After 1 year through 5 years				
U.S. government debt securities	152,435	2	(6,349)	146,088
U.S. agency debt securities	92,054	—	(3,435)	88,619
Corporate debt securities	80,647	—	(4,756)	75,891
Municipal bonds	12,065	—	(217)	11,848
Yankee debt securities	753	—	(85)	668
Redeemable preferred stock investment	20,000	—	(7,615)	12,385
Total debt securities due after 1 year through 5 years	357,954	2	(22,457)	335,499
After 5 years through 10 years				
Municipal bonds	3,617	—	(83)	3,534
Total debt securities due after 5 years through 10 years	3,617	—	(83)	3,534
Total available-for-sale debt securities	814,515	2	(28,755)	785,762
Total equity and debt securities	$ 829,515	$ 2	$ (28,755)	$ 800,762

	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

Gross unrealized losses on the Company's equity and debt securities were $28.8 million and $4.3 million as of December 31, 2022 and 2021, respectively. The Company did not recognize any credit losses for its available-for-sale debt securities in 2022 and 2021.

The Company's marketable securities of $472.8 million, managed by the custodian of the Company's marketable debt security investment account, of which the Company has an outstanding margin loan, is used as collateral for the 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, 2022			
	Total	Level 1	Level 2	Level 3
	(in thousands)			
Equity securities, debt securities and cash equivalents:				
U.S. government debt securities	$ 332,048	$ —	$ 332,048	$ —
Corporate debt securities	194,149	—	194,149	—
U.S. agency debt securities	156,688	—	156,688	—
U.S. treasury bills	69,798	69,798	—	—
Money market accounts	27,455	27,455	—	—
Municipal bonds	22,673	—	22,673	—
Preferred stock of privately held company	15,000	—	—	15,000
Redeemable preferred stock investment	12,385	—	—	12,385
Yankee debt securities	3,010	—	3,010	—
Total equity securities, debt securities and cash equivalents	$ 833,206	$ 97,253	$ 708,568	$ 27,385

	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

The Company's Level 1 assets include U.S. treasury bills, money market instruments, bond funds, and exchange traded funds 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 31, 2022, the Company had preferred stock of a privately held company, which was included in other long-term assets in the accompanying Consolidated Balance Sheets, and

redeemable preferred stock of a private company that were measured using unobservable (Level 3) inputs. The fair value of redeemable preferred stock as of December 31, 2022 and 2021 was based on valuation 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. For the value of the investment in private equity securities, the Company elected to measure it at cost minus impairment, as the preferred stock of the privately held company did not have a readily determinable fair value, and no impairment loss was recorded as of December 31, 2022.

There were no transfers between fair value measurement levels in 2022, 2021, and 2020.

Note 5. Fixed Assets

Major classes of fixed assets consisted of the following:

	Useful Lives	December 31, 2022	December 31, 2021
		(in thousands)	
Medical lab equipment	5 months to 12 Years	$ 53,503	$ 35,930
Leasehold improvements	Shorter of lease term or estimated useful life	11,804	4,003
Computer software	1 to 5 Years	6,982	1,408
Computer hardware	1 to 5 Years	6,979	5,661
Building	39 Years	6,731	6,731
Aircraft	7 Years	6,400	6,503
Building improvements	6 months to 39 Years	5,865	3,936
Furniture and fixtures	1 to 5 Years	4,248	2,255
Land improvements	5 to 15 Years	904	403
Automobile	2 to 7 Years	797	825
General equipment	3 to 5 Years	44	44
Land		7,500	7,500
Assets not yet placed in service		12,877	6,718
Total		124,634	81,917
Less: Accumulated depreciation		(43,281)	(19,630)
Fixed assets, net		$ 81,353	$ 62,287

Depreciation expense on fixed assets totaled $25.5 million, $9.3 million and $3.0 million for the years ended December 31, 2022, 2021 and 2020, respectively.

Note 6. Other Significant Balance Sheet Accounts

Other current assets consisted of the following:

	December 31, 2022	December 31, 2021
	(in thousands)	
Other receivable	$ 19,836	$ 1,403
Prepaid income taxes	15,434	1,716
Prepaid expenses	6,814	4,244
Reagents and supplies	4,280	12,206
Marketable securities interest receivable	2,525	2,743
Contract assets	—	237
Total	$ 48,889	$ 22,549

Other receivable as of December 31, 2022 includes $19.1 million of maturities of marketable securities that did not settle until after period-end.

Other current liabilities primarily includes $5.0 million payable pursuant to a share transfer agreement, see Note 15, *Business Combinations.*

Other long-term liabilities primarily includes operating and finance lease liabilities, long-term, see Note 9, *Leases*, and notes payable, long-term, See Note 8, *Debt, Commitments and Contingencies*.

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, 2022 and 2021 with an insignificant amount located in China and Canada. Revenue by region for the years ended December 31, 2022, 2021 and 2020 were as follows:

	Year Ended December 31,		
	2022	2021	2020
		(in thousands)	
Revenue:			
United States	$ 603,148	$ 978,978	$ 415,334
Foreign	15,820	13,606	6,378
Total	$ 618,968	$ 992,584	$ 421,712

Note 8. Debt, Commitments and Contingencies

Debt

As of December 31, 2022, the Company had an outstanding borrowing of $15.0 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. 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. 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, 2022 was 4.59%. The related interest expenses in 2022, 2021 and 2020 were $346,000, $117,000 and $20,000, respectively.

Notes payable as of December 31, 2022, consisted of $3.8 million of notes payable related to an installment sale contract the Company entered in February 2022 for a building and $5.2 million of notes payable to Xilong Scientific Co., or Xilong Scientific, by Fujian Fujun Gene Biotech Co., Ltd., or FF Gene Biotech. The notes payable related to the installment sale are due in February 2030, and the interest rate is 1.08%. The current portion and noncurrent portion are $461,000 and $3.4 million, respectively, and the noncurrent portion is included in the other long-term liabilities in the accompanying Consolidated Balance Sheets. The notes payable to Xilong Scientific is due on March 31, 2023, and the interest rate on the loan is 4.97%. The related interest expenses in 2022 and 2021 were $304,000 and $177,000, respectively. The Company did not have the installment sale contract in 2021.

Operating and Finance Leases

See Note 9, *Leases*, for further information.

Purchase Obligations

As of December 31, 2022, the Company had non-cancelable purchase obligations of $10.1 million, of which, $3.2 million for computer software and hardware, $2.5 million for reagents and other supplies, $1.1 million for services and $746,000 for medical lab equipment are payable within twelve months. $2.2 million for computer software and $381,000 for services are payable within the next thirty-six 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.

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 various finance leases for lab equipment with varying terms through December 2026, of which, some were acquired in business combinations. 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 El Monte, California; Houston and Irving, Texas; Needham, Massachusetts; Phoenix, Arizona; Alpharetta, Georgia; and New York, New York.

The operating and finance lease right-of-use asset, short-term lease liabilities, and long-term lease liabilities as of December 31, 2022, and 2021 were as follows:

	December 31,	
	2022	2021
	(in thousands)	
Operating lease ROU asset, net	$ 14,784	$ 7,141
Operating lease liabilities, short term	$ 6,132	$ 1,842
Operating lease liabilities, long term	$ 8,795	$ 5,344
Finance lease ROU asset, net	$ 2,784	$ 1,735
Finance lease liabilities, short term	$ 943	$ 332
Finance lease liabilities, long term	$ 1,818	$ 1,398

The following was operating and finance lease expense:

	Year Ended December 31,		
	2022	2021	2020
		(in thousands)	
Operating lease cost	$ 5,429	$ 1,262	$ 566
Finance lease cost:			
Amortization of ROU assets	683	7	—
Interest on lease liabilities	95	1	—
Short-term lease cost	1,528	296	142
Total lease cost	$ 7,735	$ 1,566	$ 708

Supplemental information related to leases was the following:

	December 31, 2022
Weighted average remaining lease term - operating leases	3.24 years
Weighted average discount rate - operating leases	3.81%
Weighted average remaining lease term -finance leases	3.10 years
Weighted average discount rate - finance leases	3.98%

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,		
2023	$ 6,590	$ 986
2024	4,072	1,033
2025	2,118	547
2026	1,522	366
2027	1,360	—
Thereafter	217	—
Total lease payments	15,879	2,932
Less imputed interest	(952)	(171)
Total	$ 14,927	$ 2,761

Lessor

The Company leases out space in buildings it owns to third-party tenants under noncancelable operating leases. As of December 31, 2022, the remaining lease terms left range from 1 year to 2 years, 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 Income. Total lease income was as follows:

	Year Ended December 31,		
	2022	2021	2020
		(in thousands)	
Lease income	$ 269	$ 413	$ 144
Variable lease income	12	7	1
Total lease income	$ 281	$ 420	$ 145

Future fixed lease payments from tenants for all noncancelable operating leases as of December 31, 2022 are as follows:

	Lease Payments from Tenants
	(in thousands)
Year Ending December 31,	
2023	$ 181
2024	94
Total	$ 275

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 Income as follows:

	Year Ended December 31,		
	2022	2021	2020
		(in thousands)	
Cost of revenue	$ 8,704	$ 3,563	$ 1,452
Research and development	10,449	6,326	2,693
Selling and marketing	4,373	2,513	2,092
General and administrative	9,114	3,480	1,920
Total	$ 32,640	$ 15,882	$ 8,157

The actual tax benefit realized from windfall tax deductions related to awards vested or exercised were $2.1 million, $13.3 million, and $2.7 million for the years ended December 31, 2022, 2021 and 2020, respectively.

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, 2022, 2021 and 2020:

	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, 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
Granted	10	$ 59.54	$ 44.56		
Exercised	(5)	$ 7.16	$ 7.41		
Canceled	(9)	$ 43.30	$ 33.53		
Balance at December 31, 2022	212	$ 4.21		3.7	$ 5,420
Exercisable as of December 31, 2022	196	$ 1.22		3.3	$ 5,608

(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, 2022, 2021 and 2020 was $126,000, $76,000 and $223,000, respectively. As of December 31, 2022, the remaining unrecognized compensation expense related to all outstanding option awards was $433,000 and is expected to be recognized over a weighted-average period of 3.4 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, 2022, 2021, and 2020:

	Number of Shares (in thousands)	Weighted-Average Grant Date Fair Value
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
Granted	1,895	$ 49.98
Vested and settled	(699)	$ 34.01
Forfeited	(184)	$ 61.11
Balance at December 31, 2022	2,631	$ 47.76

The RSU awards granted in the years ended December 31, 2022, 2021 and 2020 will result in aggregate equity-based compensation expense of $94.8 million, $45.5 million and $34.5 million, respectively, to be recognized over the vesting periods from the grant date of each award granted in the period. The RSU awards granted in the year ended December 31, 2022 included 663,013 shares of RSU awards assumed as part of the Fulgent Pharma acquisition, see more details in Note 14, *Related Party,* and Note 15, *Business Combinations*. As of December 31, 2022, the remaining unrecognized compensation expense related to all outstanding RSU awards was $110.6 million and is expected to be recognized over a weighted-average period of 3.0 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, 2022, 2021 and 2020.

	Year Ended December 31,		
	2022	2021	2020
Expected term (in years)	6.1	6.1	6.1
Risk-free interest rates	2.6%	1.1%	0.4%
Dividend yield	—	—	—
Expected volatility	88.7%	94.6%	87.5%

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,		
	2022	2021	2020
		(in thousands)	
U.S. income before income taxes, equity loss in investee and gain (loss) on equity-method investments	$ 189,406	$ 681,403	$ 291,739
Foreign loss before income taxes, equity loss in investee and gain (loss) on equity-method investments	(5,381)	(4,103)	(55)
Income before income taxes, equity loss in investee and gain (loss) on equity-method investments	$ 184,025	$ 677,300	$ 291,684

Income tax expense consisted of the following:

	Year Ended December 31,		
	2022	2021	2020
		(in thousands)	
Current:			
Federal	$ 31,140	$ 131,907	$ 53,794
State	19,242	51,076	20,513
Total Current	50,382	182,983	74,307
Deferred:			
Federal	(3,763)	(7,471)	(248)
State	(4,517)	(717)	(14)
Foreign	224	669	—
Change in valuation allowance	(224)	(669)	(1,513)
Total Deferred	(8,280)	(8,188)	(1,775)
Total income tax expense	$ 42,102	$ 174,795	$ 72,532

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

	Year Ended December 31,		
	2022	2021	2020
Tax provision at federal statutory rate	21.00%	21.00%	21.00%
State taxes	7.01%	5.99%	5.68%
Uncertain tax positions	0.92%	0.05%	0.13%
Stock based compensation	-1.12%	-1.96%	-0.92%
Return to provision	-3.92%	-0.17%	-0.11%
Other permanent differences	1.33%	1.09%	0.02%
Research & development credit	-2.98%	-0.33%	-0.40%
Other	0.34%	0.19%	-0.01%
Change in valuation allowance	0.12%	-0.10%	-0.52%
Effective tax rate	22.70%	25.76%	24.87%

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.

	As of December 31,	
	2022	2021
	(in thousands)	
Deferred tax assets		
Accrued vacation and other accrued expenses	$ 1,488	$ 1,486
Provision for credit losses	10,255	2,755
Net operating losses	16,345	199
Stock based compensation	2,550	1,739
State income taxes	4,892	10,991
Excess tax basis in FF Gene Biotech net assets	2,032	—
Foreign	—	1,808
Lease liability	4,086	1,643
Unrealized gain/loss on available-for-sale debt securities	7,664	437
Section 174 research & experimental expenditures	6,573	—
Equity loss in investment	503	700
Other	199	162
Gross deferred tax assets	56,587	21,920
Less: Valuation allowance	(2,832)	(2,609)
Net deferred tax assets	53,755	19,311
Deferred tax liabilities		
Intangible assets	39,199	8,083
Depreciation	5,500	7,371
Right of use asset	4,056	1,640
Other	1,496	1,458
Total deferred tax liabilities	50,251	18,552
Net deferred tax assets	$ 3,504	$ 759

As of December 31, 2022, the Company has $58.8 million estimated federal net operating loss, or NOL, carryforwards and estimated state NOL carryforwards of $66.0 million. The Company's state NOLs are scheduled to begin expiring in 2037. The Company also has foreign NOL carryforwards of $13.8 million which are scheduled to expire from 2023 through 2027.

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 $2.8 million and $2.6 million has been recorded on these deferred tax assets as of December 31, 2022 and 2021. The increase in the valuation allowance of $224,000 for the years ended December 31, 2022 was primarily due to an increase in foreign deferred tax assets that are more likely than not to expire unrealized.

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.

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, 2022, 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, 2022, the Company remains subject to income tax examinations in the U.S. and various states for tax years 2019 through 2022; certain other states remain subject to examination for tax years 2018 through 2022. 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,		
	2022	2021	2020
	(in thousands)		
Balance at beginning of year	$ 710	$ 377	$ —
Increases to prior year positions	2,843	—	141
Increases for current year positions	6,189	333	236
Balance at end of year	$ 9,742	$ 710	$ 377

As of December 31, 2022, the Company has $9.7 million of gross unrecognized tax benefits, of which, $2.3 million of unrecognized tax benefits would affect the effective tax rate if recognized. The Company has accrued $94,000 and $15,000 for interest at December 31, 2022 and 2021, respectively, and has recognized interest expense of $94,000 and $15,000 for the years ended December 31, 2022 and 2021, 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 per Share

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

	Year Ended December 31,		
	2022	2021	2020
	(in thousands, except per share data)		
Net income attributable to Fulgent	$ 143,403	$ 507,364	$ 214,310
Weighted-average common shares - outstanding, basic	30,097	29,408	22,694
Weighted-average common shares - outstanding, diluted	30,964	30,976	24,056
Net income per common share, basic	$ 4.76	$ 17.25	$ 9.44
Net income per common share, diluted	$ 4.63	$ 16.38	$ 8.91

The following securities have been excluded from the calculation of diluted income per share because their effect would have been anti-dilutive:

	Year Ended December 31,		
	2022	2021	2020
	(in thousands)		
Options	10	5	10
RSUs	728	182	347

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 $2.5 million, $697,000 and $422,000 in the years ended December 31, 2022, 2021 and 2020, 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 $1.5 million, $3.4 million and $3.1 million in revenue in the years ended December 31, 2022, 2021 and

2020. As of December 31, 2022 and 2021, $93,000 and $556,000 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.

On November 7, 2022, the Company acquired Fulgent Pharma. See Note 15, *Business Combinations*. Prior to the acquisition, the Company and Fulgent Pharma LLC were parties to shared services arrangements where research and development, administrative services and office space and equipment are provided between the companies, on an arms-length basis. Until April 2022, Ming Hsieh was the manager and a member of Fulgent Pharma LLC. In April 2022, Fulgent Pharma LLC became a wholly-owned subsidiary of Fulgent Pharma which was 100% owned by Ming Hsieh, the Chief Executive Officer and Chairman of the Company's board of directors, and the Hsieh Family Dynasty Trust, dated January 27, 2010, or the Hsieh Trust, of which Mr. Hsieh is the grantor. Mr. Hsieh and Paul Kim, the Chief Financial Officer and Treasurer of Fulgent, also served as executive officers of Fulgent Pharma as its (i) President and Chief Executive Officer and (ii) Treasurer and Secretary, respectively. The cost of research and development services rendered by Fulgent Pharma LLC for the Company was not significant in 2022 prior to the acquisition. 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. Costs allocated to Fulgent Pharma LLC were not significant in 2022 prior to the acquisition, 2021 and 2020. As of December 31, 2021, $679,000 was owed to Fulgent Pharma LLC by the Company, which is recorded in other current liabilities in the accompanying Consolidated Balance Sheet, in connection with these relationships. As part of the acquisition, RSUs to acquire shares of common stock of Fulgent Pharma held by Paul Kim, the Company's Chief Financial Officer, Jian Xie, the Company's President and Chief Operating Officer, Hanlin Gao, the Company's Chief Scientific Officer and other employees of the Company and consultants of Fulgent Pharma LLC were assumed by the Company and became RSUs to acquire 77,585, 129,309, 51,723, 117,398, and 286,998 shares of common stock of the Company, respectively.

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, 2022, 2021 and 2020, the Company incurred $235,000, $142,000 and $343,000, respectively, in expenses for flights between California and Texas to transport employees and supplies. As of December 31, 2022 and 2021, no amount was owed to PTJ by the Company.

Ming Hsieh is also on the board of directors and a 20% owner of ANP Technologies, Inc., or ANP, from which the Company purchased COVID-19 antigen rapid test kits and entered into certain drug-related licensing and development service agreements. The President and Chief Scientific Officer of Fulgent Pharma, Ray Yin, is the Founder, President, and Chief Technology Officer of ANP. In the year ended December 31, 2022, the Company incurred $1.2 million related to the purchase of COVID-19 antigen rapid tests kits and licensing and development services. No costs were incurred in the years ended December 31, 2021 and 2020. As of December 31, 2022, $607,000 was owed to ANP by the Company in connection with these relationships, and no amount was owed to ANP as of December 31, 2021.

Note 15. Business Combinations

Inform Diagnostics

On April 26, 2022, the Company completed the acquisition of 100% of the outstanding equity of Symphony Buyer, Inc., or Inform Diagnostics, a leading national independent pathology laboratory based in Irving, Texas. Under the terms of the Agreement and Plan of Merger, dated April 16, 2022, or the Inform Merger Agreement, the total purchase price payable to the securityholders of Symphony Buyer, Inc. was approximately $170 million, as adjusted for closing cash, closing indebtedness, closing working capital, closing transaction expenses and other transaction matters. With the addition of Inform Diagnostics, the Company will further expand the Company's genomic testing footprint and extend its test menu into breast pathology, gastrointestinal pathology, dermatopathology, urologic pathology, neuropathology, and hematopathology.

The financial results of Inform Diagnostics are included in the consolidated financial statements from the date of acquisition. The Company allocated the purchase price to tangible and identified intangible assets acquired and liabilities assumed based on estimated fair values. The following tables summarizes the consideration paid and the updated amounts of the assets acquired and liabilities assumed recognized at the acquisition date:

	Amounts (in thousands)
Consideration	
Cash, net of cash received	$ 137,755
Recognized amounts of identifiable assets acquired and liabilities assumed	
Net working capital	$ (15,024)
Fixed assets	20,242
ROU assets - operating	12,653
ROU assets - finance	1,183
Deferred tax assets	3,410
Other long-term assets	4,711
Identifiable intangible assets	57,060
Operating lease liabilities	(12,653)
Finance lease liabilities	(1,183)
Income tax payable	(40)
Other long-term liabilities	(4,449)
Recognized amounts of identifiable assets acquired and liabilities assumed, net	65,910
Goodwill	71,845
Total	$ 137,755

The goodwill of $71.8 million arising from the 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 consisted of $54.0 million customer relationships with an estimated amortization life of 14 years, $2.7 million trade name with an estimated amortization life of 7 years, and $360,000 in-place lease intangible asset to be amortized over the remaining lease term of 5 years.

The fair value of the customer relationship was estimated using the Multiperiod Excess Earnings Method, or MPEEM, of the income approach. Under the MPEEM, an intangible asset's fair value is equal to the present value of the incremental after-tax cash flows attributable only to the subject intangible asset after deducting contributory asset charges. The incremental after-tax cash flows attributable to the customer relationships are then discounted to their present value at a risk-adjusted rate of return. The fair value of the trade name was estimated using the relief from royalty, or RFR, method. The RFR method estimates the portion of the Company's earnings attributable to an intangible asset based on the royalty rate the Company would have paid for the use of the asset if it did not own it. The fair value of in-place lease intangible asset was estimated using the discounted cash flow under the income approach. The useful lives of the intangible assets for amortization purposes were determined by considering the period of expected cash flows used to measure the fair values of the intangible assets adjusted as appropriate for entity-specific factors including legal, regulatory, contractual, competitive, economic and other factors that may limit the useful life. The customer relationships and trade name are amortized on a straight-line basis over their estimated useful lives.

Revenue and operating loss from the Inform Diagnostics acquisition since the acquisition date are $83.6 million and $17.0 million, respectively, which are included in the accompanying Consolidated Statements of Income.

The transaction costs associated with the acquisition of Inform Diagnostics consisted primarily of legal, regulatory and financial advisory fees of approximately $6.6 million for the year ended December 31, 2022, respectively. These transaction costs were expensed as incurred as general and administrative expense in the respective period.

Unaudited Pro Forma Financial Information

The following unaudited pro forma financial information summarizes the combined results of operations of Fulgent and Inform Diagnostics as if the companies had been combined as of the beginning of 2021. The pro forma financial information has been adjusted for the following:

Acquisition-related costs - Acquisition-related costs incurred by both Fulgent and Inform Diagnostics were excluded from the net income attributable to Fulgent, and total costs were $9.6 million for the year ended December 31, 2022.

Other adjustments to the net income attributable to Fulgent were $772,000 and $2.3 million for the year ended December 31, 2022 and 2021, respectively. Other adjustments to revenue were $962,000 and $3.9 million for or the year ended December 31, 2022 and 2021, respectively.

	Year Ended December 31,	
	2022	2021
	(in thousands)	
Revenue	$ 659,386	$ 1,140,184
Net income attributable to Fulgent	$ 140,288	$ 493,313
Basic earnings per common share attributable to Fulgent	$ 4.66	$ 16.77
Diluted earnings per common share attributable to Fulgent	$ 4.53	$ 15.93

Fulgent Pharma Holdings, Inc

On November 7, 2022, the Company completed the acquisition of 100% of the outstanding equity of Fulgent Pharma, a clinical-stage, therapeutics development company focused on perfecting drug candidates for treating a broad range of cancers. Under the terms of the Agreement and Plan of Merger, dated November 7, 2022, or the Pharma Merger Agreement, the total merger consideration was paid in a combination of cash, the Company's common stock, or the Stock Consideration, and assumed restricted stock units, or RSUs, subject to customary adjustments for closing cash, closing indebtedness, transaction expenses and other transaction matters. A portion of the Stock Consideration was held back for a duration of time after the closing of the transaction to satisfy certain indemnification obligations of the Pharma Stockholders as described in the Pharma Merger Agreement. The RSUs are subject to vesting over the four-year period immediately following the date of their original grant, subject to the holder’s continuing service. The integrated companies plan to offer a vertically integrated solution to combat cancer with the potential to unlock significant long-term upsides for both the therapeutic and diagnostic businesses, while effectively managing risk.

The financial results of Pharma are included in the consolidated financial statements from the date of acquisition. The Company allocated the purchase price to tangible and identified intangible assets acquired and liabilities assumed based on estimated fair values. The following tables summarizes the consideration paid and the updated amounts of the assets acquired and liabilities assumed recognized at the acquisition date:

	Amounts (in thousands)
Considerations	
Cash, net of cash received	$ 39,924
Stock	28,111
Total considerations	$ 68,035
Recognized amounts of identifiable assets acquired and liabilities assumed	
Debt-free net working capital	$ (3,679)
Restricted cash	5,000
Fixed assets	1,310
Identifiable intangible assets	64,590
Deferred tax liabilities	(16,172)
Long-term or non-operating liabilities	(5,069)
Recognized amounts of identifiable assets acquired and liabilities assumed, net	45,980
Goodwill	22,055
Total	$ 68,035

The goodwill of $22.1 million arising from the acquisition is attributed to Fulgent Pharma's rights to intellectual property, expected synergies, assembled workforce, and other benefits that will potentially be generated from the combination and deferred tax. The goodwill recognized is not deductible for tax purposes.

The identified intangible assets acquired consisted of $64.6 million in IPR&D. Fulgent Pharma has developed a novel nanoencapsulation and targeted therapy platform, which is designed to improve the therapeutic window and pharmacokinetic profile of new and existing cancer drugs. The lead drug candidate, FID-007, has achieved proof-of-concept in preliminary human clinical trials for the treatment of various cancer types, including head and neck, ampullary, pancreatic, non-small cell lung cancer, and breast. The fair value of the IPR&D was estimated using MPEEM. The method involves forecasting after-tax operating income from existing clients, subtracting the portions attributable to a contributory asset, and discounting the remaining earnings to present value. The useful life of IPR&D is indefinite.

Revenue and operating loss from the Fulgent Pharma acquisition since the acquisition date are zero and $816,000, respectively, which are included in the accompanying Consolidated Statements of Income.

The transaction costs associated with the acquisition of Pharma consisted primarily of legal, regulatory and financial advisory fees of approximately $1.4 million for the year ended December 31, 2022. These transaction costs were expensed as incurred as general and administrative expense in the respective period.

The $5.0 million restricted cash received represents cash consideration payable pursuant to the share transfer agreement Fulgent Pharma entered prior to Fulgent Pharma acquisition date. The cash consideration was not paid as of Fulgent Pharma acquisition date and was included in noncurrent or non-operating liabilities in above table.

Note 16. Stock Repurchase Program

In March 2022, the Company's Board authorized a $250.0 million stock repurchase program. Under the stock repurchase program, the Company may repurchase shares from time to time in the open market or in privately negotiated transactions. The stock repurchase program has no expiration from the date of authorization. During the year ended December 31, 2022, the Company repurchased 1.8 million shares of its common stock at an aggregate cost of $74.3 million under the stock repurchase program. As of December 31, 2022, a total of approximately $175.7 million remained available for future repurchases of its common stock under the stock repurchase program.

Note 17. Goodwill and Intangible Assets

Summaries of goodwill and intangible assets balances as of December 31, 2022 and 2021 were as follows:

	Weighted-Average Amortization Period	December 31, 2022	December 31, 2021
		(in thousands)	
Goodwill		$ 143,027	$ 50,897
In-process research & development	n/a	$ 64,590	$ —
Royalty-free technology	10 Years	5,364	5,803
Less: accumulated amortization		(894)	(387)
Royalty-free technology, net		4,470	5,416
Customer relationships	13 Years	82,750	28,845
Less: accumulated amortization		(6,215)	(1,125)
Customer relationships, net		76,535	27,720
Trade name	8 Years	3,790	1,090
Less: accumulated amortization		(412)	(45)
Trade name, net		3,378	1,045
In-place lease intangible assets	5 Years	360	—
Less: accumulated amortization		(46)	—
In-place lease intangible assets, net		314	—
Laboratory information system platform	5 Years	1,860	1,860
Less: accumulated amortization		(527)	(155)
Laboratory information system platform, net		1,333	1,705
Purchased patent	10 Years	29	31
Less: accumulated amortization		(6)	(3)
Purchased patent, net		23	28
Total intangible assets, net		$ 150,643	$ 35,914

Acquisition-related intangibles included in the above tables are generally finite-lived and are carried at cost less accumulated amortization, except for IPR&D, which is related to our 2022 acquisition of Fulgent Pharma and has an indefinite life until research

and development efforts are completed or abandoned. All other finite-lived acquisition-related intangibles related to the business combinations in 2022 and 2021 are amortized on a straight-line basis over their estimated lives, which approximates the pattern in which the economic benefits of the intangible assets are expected to be realized.

Changes in the carrying amount of goodwill for the year ended December 31, 2022 and 2021 are as follows:

	2022	2021
	(in thousands)	
Balance as of January 1,		
Goodwill	$ 50,897	$ —
Accumulated impairment losses	—	—
	50,897	—
Goodwill acquired during year		
Inform Diagnostics	71,845	—
Fulgent Pharma	22,055	—
CSI	—	27,484
FF Gene Biotech	—	23,082
	93,900	50,566
Net exchange differences		
FF Gene Biotech	(1,770)	331
Balance as of December 31,		
Goodwill	143,027	50,897
Accumulated impairment losses	—	—
	$ 143,027	$ 50,897

Based on the carrying value of intangible assets recorded as of December 31, 2022, 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)
2023	$ 7,864
2024	7,864
2025	7,864
2026	7,554
2027	7,225
Thereafter	47,682
Total	$ 86,053

Note 18. Selected Quarterly Financial Data (Unaudited)

The tables below set forth the Company's quarterly Consolidated Statements of Income data for the eight quarters ended December 31, 2022. 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, 2022	Sept. 30, 2022	June 30, 2022	Mar. 31, 2022	Dec. 31, 2021	Sept. 30, 2021	June 30, 2021	Mar. 31, 2021
	(dollars in thousands, except per share data)							
Statement of Operations Data:								
Revenue	$ 67,704	$105,655	$125,341	$320,268	$251,671	$227,868	$153,616	$359,429
Cost of revenue	54,717	59,560	60,065	77,725	62,134	43,466	35,858	74,075
Gross profit	12,987	46,095	65,276	242,543	189,537	184,402	117,758	285,354
Operating expenses:								
Research and development	8,509	7,507	6,905	5,989	7,464	6,021	5,312	5,422
Selling and marketing	10,253	9,859	10,866	7,940	8,200	6,012	5,219	5,008
General and administrative	28,793	26,266	30,240	25,775	22,102	12,299	8,329	8,002
Amortization of intangible assets	2,010	2,006	1,575	906	911	797	—	—
Restructuring costs	(26)	105	2,896	—	—	—	—	—
Total operating expenses	49,539	45,743	52,482	40,610	38,677	25,129	18,860	18,432
Operating (loss) income	(36,552)	352	12,794	201,933	150,860	159,273	98,898	266,922
Interest and other income (expense), net	3,090	1,405	958	45	(35)	496	604	282
(Loss) income before income taxes and gain on equity method investment	(33,462)	1,757	13,752	201,978	150,825	159,769	99,502	267,204
(Benefit from) provision for income taxes	(9,386)	414	2,653	48,421	47,148	37,545	23,589	66,513
(Loss) income before gain on equity method investment	(24,076)	1,343	11,099	153,557	103,677	122,224	75,913	200,691
Gain on equity method investment	—	—	—	—	—	—	3,734	—
Net (loss) income from consolidated operations	(24,076)	1,343	11,099	153,557	103,677	122,224	79,647	200,691
Net loss attributable to noncontrolling interests	244	376	438	422	662	298	165	—
Net (loss) income attributable to Fulgent	$(23,832)	$ 1,719	$ 11,537	$153,979	$104,339	$122,522	$ 79,812	$200,691
Net (loss) income per common share attributable to Fulgent:								
Basic	$ (0.80)	$ 0.06	$ 0.38	$ 5.09	$ 3.48	$ 4.13	$ 2.74	$ 6.96
Diluted	$ (0.80)	$ 0.06	$ 0.37	$ 4.93	$ 3.34	$ 3.93	$ 2.59	$ 6.52

Note 19. Subsequent Event

As of February 27, 2023, no subsequent events are being reported.

Developing flexible and affordable diagnostics and therapeutics that improve the everyday lives of those around us.

Fulgent Genetics is a technology-based company with a well-established clinical diagnostic business and a therapeutic development business.

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