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, 2025

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 (State or other jurisdiction of incorporation or organization)	**81-2621304** (I.R.S. Employer Identification No.)
4399 Santa Anita Avenue El Monte, CA (Address of principal executive offices)	**91731** (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, 2025 (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 $284.3 million.

As of February 23, 2026, there were 31,230,632 outstanding shares of the registrant's common stock.

DOCUMENTS INCORPORATED BY REFERENCE

Certain portions of the registrant's definitive proxy statement for its 2026 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 the Securities Act, and Section 21E of the Securities Exchange Act of 1934, as amended, or the 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 and assets, 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;
- 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;
- the timing and our ability to develop our product candidates, to satisfy the U.S. Food and Drug Administration's, or FDA's, regulatory requirements, and to commercialize our product candidates;
- the anticipated progress of our product candidate development programs, including whether our ongoing and potential future clinical trials will achieve clinically relevant results;
- our ability to generate data and conduct analyses to support the regulatory approval of our product candidates and our plans to pursue discussions with regulatory authorities, and the anticipated timing, scope and outcome of related regulatory actions or guidance;
- the success of our competitors' research and development efforts for product candidates seeking to treat similar or the same indication as our product candidates;
- our ability to strengthen our existing base of customers by maintaining or increasing demand from these customers, grow and diversify our customer base, and replace any loss of demand or revenue from our largest customer;
- 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 expectations regarding the receipt of tax credit payments and the timing of such payments;
- 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 the results of payor audits and government audits and investigations, such as our currently ongoing U.S. Department of Health Resources and Services Administration, or HRSA, audit and Civil Investigative Demands, or CIDs;
- 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;
- our beliefs that our tests marketed in the United States are, and will continue to be, laboratory developed tests;
- changes to the state of the U.S. and foreign healthcare markets, including the role of governments in the healthcare industry, 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, intellectual property, and patents, and to not infringe upon 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 that we believe are reasonable, we cannot guarantee future results, levels of activity, performance or achievements, or other future events. As a result, forward-looking statements should not be relied on or viewed as predictions of future events, and this report should be read with the understanding that our actual future results, levels of activity, performance and achievements, or other future events may be materially different than what we currently expect.

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

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

* * * * * * *

We own registered or unregistered trademark rights to FULGENT®, PICTURE GENETICS®, PICTURE®, BEACON®, INFORMDX®, LUMERA®, KNOVA™, 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 affiliated professional corporations 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 laboratory services business and a therapeutic development business. Our laboratory services business includes technical laboratory and testing services and professional interpretation of laboratory results by licensed physicians. Our therapeutic development business is focused on developing product 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.

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 laboratory 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.

Our Laboratory Services Business

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

Comprehensive anatomic pathology testing services, including gastrointestinal pathology, dermatopathology, urologic pathology, breast pathology, neuropathology, and hematopathology. These services are supported by our expansive geographic presence with the Clinical Laboratory Improvement Amendments of 1988, or CLIA, licensed laboratories in the United States. We have also made significant investment in digital pathology using artificial intelligence, or AI, technology, which allows us to digitize specimen slides instead of the traditional method of microscopy.

Precision diagnostics testing services, including next-generation sequencing, or NGS, tests for biopharma research and clinical tests for rare disease, hereditary cancer, reproductive health, and many other disease subtypes. Our precision diagnostic testing also includes specialized oncology services that utilize a wide array of technologies. These services include flow cytometry; cytogenetic analysis; fluorescence in-situ, or FISH; immunohistochemistry; molecular genetics; NGS; and consultations in hematopathology and surgical pathology.

We also offer testing services and licensing to pharmaceutical or biotech companies, contract research organizations, or CROs, or sponsored testing programs, which we call BioPharma services.

Picture is a patient-centric telemedicine platform that prioritizes patient convenience and education, giving consumers the power to initiate testing and access to clinical support. Picture tests help individuals identify important health markers to empower their personal health journey.

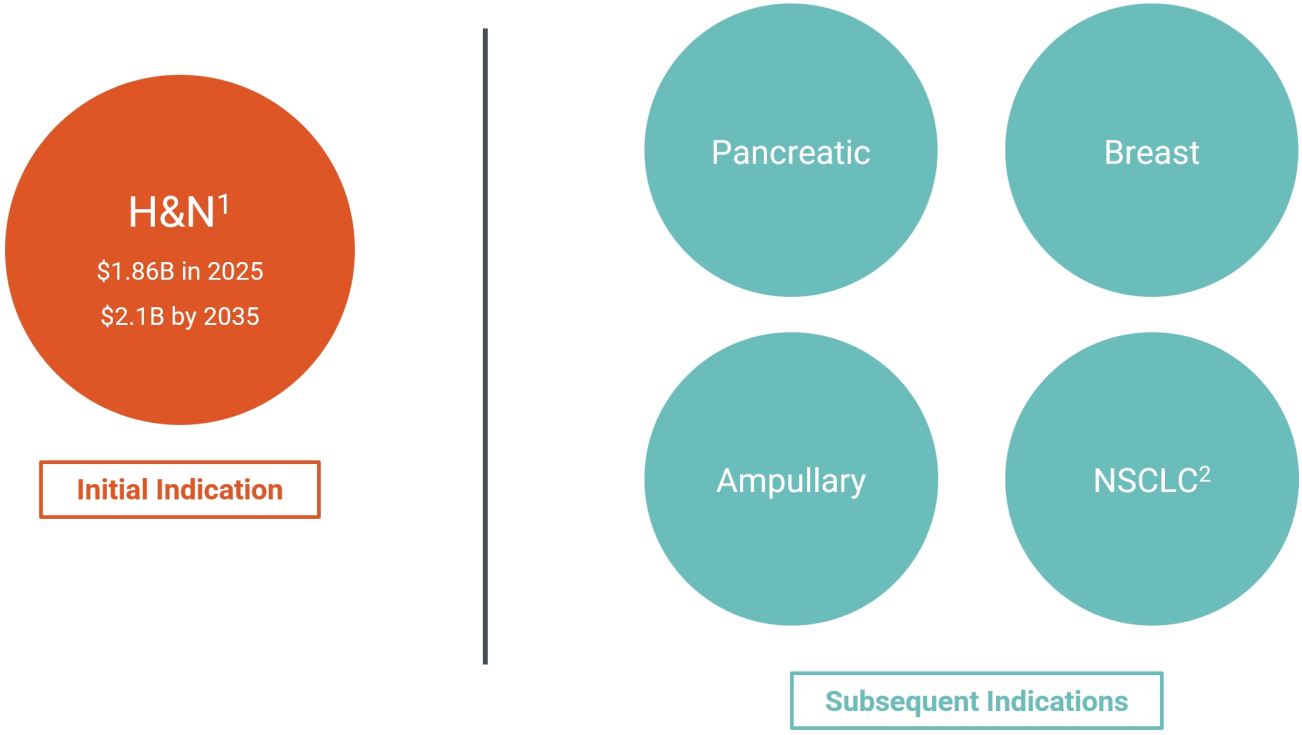
Our Laboratory Services Technology Platform

Our proprietary technology platform for our laboratory services business includes proprietary gene probes, data suppression and comparison algorithms, AI learning software, and proprietary laboratory information management systems. Additionally, we have developed our own image management system, which was created to address the growing demand for custom features necessitated by our high daily case throughput, to support all lines of business and to enable the deployment and integration of AI tools to assist pathologists in their diagnoses. These platforms provide a broad test menu, the ability to rapidly develop and launch new tests, customizable test offerings, lower cost per test, and high efficiency.

Our Therapeutic Development Business - 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. Nano-drug delivery, or nanoencapsulation, refers to a technology where active pharmaceuticals are encapsulated within miniature capsules to protect and control the release of these pharmaceuticals in a targeted manner. Unlike other nano drug delivery materials such as Human Serum Albumin, which is only soluble in water, our nano-drug delivery materials used for our product candidates in 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 product candidate formulations, particularly amorphous product candidate formulations, which can be used for both intravenous, or IV, and oral formulations with a goal to improve the PK profile, as well as safety and efficacy, for encapsulated drugs and therapeutics.

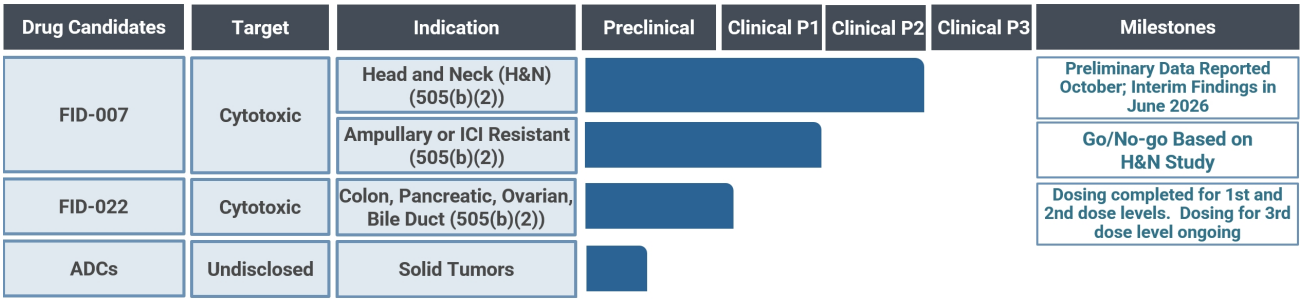
The goal of our nano-drug delivery platform is to develop product candidates to treat various diseases for which we believe the current standard of care is inadequate or may be improved. The target markets for these product candidates are large and well-established, as shown in the figures below:



Note: U.S. opportunity shown
Sources: Evaluate Pharma, Wall Street research, and management pricing expectations

1. Head & Neck, or H&N, market opportunity for both 2nd line and 3rd line therapy
2. Non-small-cell lung cancer, or NSCLC

Our current research and development progress for certain of our candidates and assets is shown in the pipeline chart below.



Our Laboratory Services Customers

We currently classify our customers in our laboratory services business by their payor types: (i) Insurance; (ii) Institutional, including hospitals, medical institutions, other laboratories, governmental bodies, and large corporations; and (iii) Patients who pay directly. Typically, we bill our Institutional customers for our tests and testing services, and they are responsible for paying us directly. A small percentage of our customers are patients who elect to pay for tests or testing services themselves, with out-of-pocket payments, after their physicians have ordered our tests or testing services.

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 and testing services. Aggregating customers that are under common control, one of our customers contributed $70.8 million or 22% of our total revenue in 2025, and $62.6 million or 22% of our total revenue in 2024.

Laboratory Services Sales and Marketing

Our sales and marketing force for our laboratory services business currently consists of internal teams of sales and marketing professionals with deep experience in our industry, as well as a network of primarily U.S. field-based sales representatives who are knowledgeable about our tests and testing services. Historically, we have relied significantly on organic growth and word-of-mouth among our customers to generate interest in our tests, which we believe demonstrates the value of our offerings. In recent years, we have invested significant time and capital to strengthen our sales and marketing efforts, including increasing the size of 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 marketing resources.

Laboratory Services 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, AI R&D engineering, and laboratory management. This team conducts all of our research and development activities related to our laboratory services business, including efforts to develop and curate our expansive library of genetic information and further expand our testing and testing services technology platform. We were pleased with the launch of our Ultra Rapid Whole Genome Sequencing service in 2025.

Fulgent Pharma-Pre-Clinical Studies and Clinical Trials

FID-007 Phase 1/1b Clinical Trial

FID-007, nanoencapsulated paclitaxel, is currently being investigated in the United States to treat patients diagnosed with various cancers including H&N, ampullary, and pancreatic cancer. We have released preliminary data and completed enrollment for a Phase 1/1b dose escalation/expansion clinical trial for evaluation of FID-007 in treating patients diagnosed with advanced solid tumors. This Phase 1/1b is being conducted at clinical trial sites in the United States and has enrolled 50 patients. In this trial and to date, we observed FID-007 to have a manageable safety profile and observed preliminary evidence of anti-tumor activity in heavily pre-treated patients across various tumor types. The PK observed was linear, dose proportional, and comparable to that of nab paclitaxel. No neuropathy above grade two was observed.

FID-007 Phase 2 Clinical Trial

We began enrollment of a Phase 2, randomized, multi-center, open-label trial of FID-007 in patients with recurrent or metastatic H&N squamous cell carcinoma at various sites in the United States in the second quarter of 2024. Up to 46 patients will be randomly assigned (1:1) to one of two treatment arms: Arm A: FID-007 (75 mg/m2) plus cetuximab or Arm B: FID-007 (125 mg/m2) plus cetuximab. We have completed the patient enrollment and expect to complete the trial by early 2026. We released the preliminary data for this trial based on 39 randomized patients at the European Society for Medical Oncology, or ESMO, in October 2025 and we anticipate announcing our interim findings for this trial in June 2026 and expect a full data readout by the second half of 2027. Assuming favorable results, we plan to investigate FID-007 in a Phase 3 registrational clinical trial in patients diagnosed with H&N squamous cell carcinoma to initiate as early as the first half of 2027, and to potentially seek regulatory approval in the United States through the 505(b)(2) pathway, which may shorten the clinical trial process and accelerate potential commercialization.

FID-022 Phase 1/1b Clinical Trial

We are also currently conducting a Phase 1/1b clinical trial to evaluate the safety and tolerability of our second product candidate, FID-022 (nanoencapsulated SN38). In our pre-clinical studies, we observed FID-022 to have superior efficacy over irinotecan in various xenograft cancer models, including colon, bile duct, ovarian, and pancreatic cancers, with no significant unexpected toxicity observed in either rat or monkey Good Laboratory Practice, or GLP, toxicity studies. We have completed the first dose level of FID-022 in December 2025, and the second dose level was completed in January 2026. We commenced dosing of the third dose level in February 2026. Our goal is to determine a maximum tolerated dose within the next year. We plan to enroll 42 patients at sites located in the United States for this Phase 1/1b trial.

ADC Pre-Clinical Development

We have also made a significant advancement in development of antibody drug conjugates, or ADCs, using our novel patented linker and payload platform technology. In pre-clinical studies, we observed our ADC to have better efficacy over different tumors with a broad range of target antigens expression level when compared to some of the best ADC benchmarks also under evaluation in pre-clinical studies. ADCs honing to novel targets using our platform technology are also being prepared with the goal of generating additional lead candidates for clinical studies.

Our Suppliers

We rely on a limited number of suppliers for certain laboratory substances used in the chemical reactions incorporated in our tests and testing services, which we refer to as reagents, as well as for the sequencers and various other equipment and materials we use in our laboratory operations. In particular, we rely on Illumina Inc., or Illumina, 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 Leica Biosystems for an automated digital scanning solution to scale up digital pathology operations; 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 or therapeutic development efforts 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

The competitors in our laboratory services business 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. Principal competitors include companies such as Ambry Genetics Corporation, a subsidiary of Tempus AI, Inc.; Baylor Genetics Management, LLC; Caris Life Sciences, LLC; Exact Sciences Corporation; Foundation Medicine, Inc.; GeneDx Holdings Corp.; Laboratory Corporation of America Holdings; Myriad Genetics, Inc.; Natera, Inc.; NeoGenomics, Inc.; PerkinElmer, Inc.; Quest Diagnostics Incorporated; Tempus AI, Inc. 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. We also expect to compete in the future with certain developers of traditional in vitro diagnostic test products, which are often packaged as commercial kits and sold for use in clinical laboratories, due to complex ongoing legal and regulatory reforms occurring in both the United States and the European Union for in-vitro testing products, among other marketplace changes.

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. Our principal competitors in this space include companies such as Laboratory Corporation of America Holdings; Natera, Inc.; Myriad Genetics, Inc.; Quest Diagnostics Incorporated; and other commercial and academic laboratories. 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 insurance 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 for us. The development and commercialization of new product candidates is highly competitive. Our competitors include drug delivery platform companies and 505(b)(2) drug developers in the cancer therapeutics area. Principal competitors include companies making nano drugs such as Bristol-Myers Squibb, academic research institutions, government agencies, and various other public and private research institutions.

We believe we compare favorably with our competitors. However, many of our competitors have longer operating histories; larger customer bases; greater brand recognition; established manufacturing capabilities and facilities; deeper market penetration; substantially greater financial, technological, research and development resources and selling and marketing capabilities and considerably more experience dealing with insurance 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, product candidates and tests, create and implement more successful strategies for the promotion and sale of their tests, obtain more favorable results from insurance 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 than us. In addition, competitors may be acquired by, receive investments from, or enter into other commercial relationships with larger, well-established, and well-financed companies. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established 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.

Intellectual Property

Intellectual property is essential to our strategy and in capturing the value of research output. 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.

We principally rely on trade secrets and know-how to protect the proprietary technology platform we use in our laboratory services business to develop and maintain our competitive position. We seek to protect our proprietary technology and processes, and obtain and maintain ownership of certain technologies, in part, through non-disclosure and intellectual property assignment agreements with our employees, consultants, and commercial partners. In general, these agreements provide that confidential information concerning our business or financial affairs developed or made known to the individual during the course of the individual's relationship with us is to be kept confidential and not disclosed to third parties, except in specific circumstances. In the case of employees, the agreements further provide that inventions and discoveries conceived or reduced to practice by the individual that are related to our business, or actual, or demonstrably anticipated, research or development, or made during normal working hours, on our premises or using our equipment, supplies, or proprietary information, are our exclusive property. In many cases, our agreements with consultants, outside scientific collaborators, sponsored researchers, and other service providers and advisors require them to assign, or grant us licenses to, inventions resulting from the work or services they render under such agreements or grant us an option to negotiate a license to use such inventions. We also seek to preserve the integrity and confidentiality of our proprietary technology and processes by maintaining physical security of our premises and physical and electronic security of our information technology systems.

Further, we seek to obtain and maintain patent rights intended to cover the technologies incorporated into, or used to produce, our product candidates, the compositions of matter of our product candidates and their methods of use and manufacture, as well as other inventions that are important to our business. The patent families comprising our patent portfolio are primarily focused on our nano-drug delivery platform technology, including FID-007 and FID-022 and other candidates we may develop, for delivery of water insoluble or poorly soluble drugs for treatments of disease conditions, including cancer. Worldwide, we own or exclusively in-license over 20 issued or allowed patents and over 10 active patent applications as of December 31, 2025. This includes nine issued or allowed U.S. patents. Patents in these patent families are expected to expire by 2034, and patent applications in these patent families,

if granted, are expected to expire as far out as 2045, subject to any patent term disclaimers, adjustments, or extensions. Patents and/or patent applications in these families are active in multiple jurisdictions, including the United States, Australia, Canada, The People's Republic of China, or the PRC or China, the European Patent Organization, Germany, New Zealand, Japan, and Switzerland. In addition to these owned and exclusively licensed patents and active patent applications, we also license patents on a non-exclusive and/or territory-restricted basis. In particular, as of December 31, 2025, we own over 20 issued patents and about 10 patent applications relating to FID-007 and related formulations. United States and foreign patents (Canada, China, Germany, France, United Kingdom, Japan, Australia, and New Zealand) were granted in these families, and these patents are expected to expire by 2034, absent any patent term extension. Individual patent terms extend for varying periods of time depending upon the date of filing of the patent application, the date of patent issuance, and the legal term of patents in the countries in which they were obtained.

Previously, in June 2017, we entered into an exclusive license agreement with ANP Technologies, Inc., or ANP, as amended on December 28, 2017, and May 1, 2024. Under the agreement, ANP granted us ownership of certain patents and patent applications, and an exclusive, worldwide, perpetual, irrevocable, and sub-licensable license to certain rights in patents and patent applications under which we may develop and commercialize FID-007 and FID-022 and related formulations for human therapeutic, prophylactic, and diagnostic uses.

In July 2025, we completed an acquisition of 100% of the outstanding equity of ANP and all rights on multiple proprietary product platforms. This acquisition enables us to secure full ownership of the patents we previously licensed from ANP to develop, strengthen, and maintain our proprietary position in the fields targeted by our product candidates, including FID-007 and FID-022, which are currently in clinical studies. This acquisition further enables us to secure ownership of technology improvements made by ANP, including improvements on nano-drug delivery platform technology.

As of December 31, 2025, we submitted at least five patent applications related to FID-022, and at least three patent applications related to ADC, that, if granted, are expected to expire as far out as 2045. We also 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.

Governmental Regulation

U.S. 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. 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, and Arizona are CLIA-certified by the Centers for Medicare & Medicaid Services, or CMS, and are accredited by the College of American Pathologists, or CAP.

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 enforces CLIA. CLIA compliance and certification are prerequisites to be eligible to bill government payors and many private payors for our tests.

Each CLIA certificate is valid for two years from the date of issuance. If one or more of our laboratories is found to be out of compliance with CLIA requirements, we may be subject to sanctions such as suspension, limitation, or revocation of our CLIA certificate; a directed plan of correction; on-site monitoring; civil monetary penalties; civil injunctive suits; criminal penalties; exclusion from the Medicare and Medicaid programs and significant adverse publicity.

In addition, we elect to participate in the accreditation program of CAP. CMS has deemed CAP standards to be equally or more stringent than CLIA regulations and has approved CAP as a recognized accrediting organization. An 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.

State and Foreign Clinical Laboratory Licensure

Our clinical laboratories are required to maintain certain state laboratory licenses. State laws establish standards for day-to-day operations of our laboratories, including requirements with respect to the training and skills of personnel, quality control, and proficiency testing. If our clinical 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 applicable state authorities.

Additionally, certain states may require licensure for out-of-state laboratories that accept specimens originated from those states. Our Texas laboratory currently holds out-of-state licenses from New York, California, Maryland, Pennsylvania, and Rhode Island to perform testing on specimens from these states, and our 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. Our laboratory located in Australia is also subject to Australian regulatory requirements.

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 continue to expand international utilization of our tests, or if jurisdictions in which we pursue operations adopt new or modified licensure requirements for U.S.-based clinical laboratories offering and providing diagnostic testing services to professionals located in those jurisdictions. 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 international data transfer or 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 broader scale.

U.S. FDA Oversight of Our Tests and Testing Services

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, including IVDs, distributed domestically are safe and effective for their intended uses. IVDs are defined in the FDA's implementing regulations as devices intended for use in the collection, preparation, and examination of specimens taken from the human body. In addition, the FDA regulates the import and export of medical devices and IVDs. Many of the instruments, reagents, kits, and other consumable products used within our laboratories are regulated as medical devices and therefore must comply with FDA quality system regulations and certain other device requirements. We have policies and procedures in place to ensure that we source such materials from suppliers that are in compliance with any applicable medical device regulatory requirements.

We believe all of our tests that have been commercialized in the United States fall within the definition of laboratory developed tests, or LDTs. LDTs are diagnostic tests that are intended for clinical use and are designed, manufactured, and used within a single laboratory. The FDA had historically exercised enforcement discretion and not enforced the FDC Act and its medical device regulations with respect to LDTs, which the agency asserted were effectively a subset of IVDs. However, as LDTs increased in complexity over recent decades, the FDA took a risk-based approach to their regulation, while Congress also signaled interest in clarifying the regulatory landscape for LDTs as stakeholders across the spectrum expressed a need for regulatory certainty and clear operating guidelines. Following several years of inaction by Congress on this issue, in May 2024, the FDA issued a final rule aimed at regulating LDTs under the medical device framework and phasing out its longstanding enforcement discretion policy for this category of diagnostic tests; the final rule became effective on July 5, 2024 and was expected to begin entering into force against non-exempt "LDT manufacturers" in May 2025.

Following issuance of the LDT final rule, the American Clinical Laboratory Association, or ACLA, and one of its members, as well as the Association for Molecular Pathology, or AMP, and one of its members, filed complaints against the FDA in the Eastern District of Texas and the Southern District of Texas, respectively. Both complaints alleged that the agency did not have authority to promulgate the LDT final rule and sought to vacate the FDA's action. The two cases were subsequently consolidated into a single action pending in the Eastern District of Texas. On March 31, 2025, the U.S. District Court for the Eastern District of Texas vacated the final rule in its entirety and remanded the matter to the FDA, holding that the rule exceeded the agency's authority under the FDC Act. The agency did not appeal the district court's decision. As a result, the phase-in deadlines established by the rule are no longer operative, and in September 2025 the FDA implemented the court's vacatur of the final rule with a formal public notice.

The *ACLA vs. FDA* court's decision removes the regulatory burden that the final rule would have imposed on laboratories such as ours had it been upheld. However, uncertainty remains regarding the future of federal oversight in this area, as Congress could

enact new legislation establishing a statutory framework for regulating all IVDs, including LDTs. Affected stakeholders continue to press for a comprehensive legislative solution to create a harmonized paradigm for oversight of LDTs by both the FDA and CMS.

Even though we presently commercialize our tests as LDTs, the FDA may disagree that our currently marketed tests are within the scope of its LDT criteria or the definition recognized by the *ACLA vs. FDA* decision. Should any of our diagnostic tests be determined to be IVDs rather than non-device laboratory-developed tests, we could in the future be required to obtain pre-market clearance under Section 510(k) of the FDC Act or approval of a pre-market approval application, or PMA, depending upon the characteristics and regulatory status of each individual test. The process for submitting a 510(k) pre-market notification and receiving FDA clearance usually takes from three to twelve 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 pre-market review is required for some or all of our tests, should they be determined to fall outside of the LDT criteria, the FDA could require that we stop selling the tests pending clearance or approval and conduct clinical testing prior to making submissions to FDA to obtain pre-market clearance or approval for such IVDs. The FDA could also require that we label such IVDs 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 for medical devices and IVDs 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.

Foreign Regulation of Diagnostic Medical Devices

Medical devices, including IVD products, are subject to extensive regulation, such as pre-market review, marketing authorization, or certification by regulatory agencies or notified bodies in other countries. Regulatory requirements and approval or certification processes are not harmonized, and vary from one country to another. International regulators and notified bodies are not bound by the findings of the FDA. The IVDR (as defined and described below) has introduced an enhanced level of EU regulatory oversight for diagnostic tests developed as LDTs, and Fulgent's commercial laboratory in California may be considered a health institution in the context of the IVDR because it provides testing for EU citizens.

In the European Union in particular, IVD products had historically been regulated under EU-Directive 98/79/EC (IVD Directive) and corresponding national provisions. The IVD Directive required that medical devices meet the essential requirements, including those relating to device safety and efficacy, set out in an annex of the Directive. According to the IVD Directive, EU Member States have presumed compliance with these essential requirements for devices that are in conformity with the relevant national standards transposing the harmonized standards, such as ISO 13485:2016, the quality system standard for medical device manufacturers.

IVD medical devices, other than devices for performance evaluation, must bear the CE mark, which stands for European Conformity, of conformity when they are placed on the European market. The CE mark is a declaration by the manufacturer that the product meets all the appropriate provisions of the applicable legislation implementing the relevant European Directive. As a general rule, the manufacturer must follow the EU declaration of conformity procedure to obtain or apply a CE mark. The advertising and promotion of medical devices is also subject to general principles set forth by EU directives which establish that devices that are CE marked may only be marketed and advertised in the EU in accordance with their intended purpose. Specific requirements defined at the EU Member State level may vary between jurisdictions and may limit or restrict a manufacturer's promotional communications with healthcare professionals.

In May 2022, the Directive was replaced by the In Vitro Diagnostic Device Regulation, or IVDR, (EU) 2017/746. Unlike the IVD Directive, the IVDR has binding legal force throughout every Member State. The major goal of the IVDR is to standardize diagnostic procedures within the EU, increase reliability of diagnostic analysis and enhance patient safety. Under the IVDR as enacted by the European Commission, or EC, IVDs are subject to additional legal requirements. Among other things, the IVDR introduced a new risk-based classification system and requirements for conformity assessments. It also imposes additional requirements relating to post-market surveillance and submission of post-market performance follow-up reports. Under the IVDR and subsequent amendments, IVDs already certified under the IVD Directive by a Notified Body may remain on the market until December 31, 2027, and IVDs certified under the IVD Directive without the involvement of a Notified Body may be placed on, or remain in, the market for up to two additional years (until December 31, 2029) depending on the classification of the IVD. Nonetheless, the manufacturers

of such devices must comply with specific requirements in the IVDR according to the timelines established, but ultimately, such products, as with all new IVDs, will have to undergo the IVDR's conformity assessment procedures. Notified Bodies are entities accredited by an EU Member State to independently assess whether a product to be placed on the market meets certain preordained standards and that manufacturing facilities and records comply with applicable requirements such as International Organization for Standardization, or ISO, standards such as ISO 13485 and ISO 27001. Such international standards establish extensive requirements for quality assurance and control as well as manufacturing and change control procedures.

The EC has designated 13 Notified Bodies to perform conformity assessments under the IVDR. MedTech Europe has issued guidance relating to the IVDR in several areas, e.g., clinical benefit, technical documentation, state of art, accessories, and EUDAMED, or European Database on Medical Devices. In December 2023, the European Commission adopted Implementing Regulation (EU) 2023/2713 designating five EU Reference Laboratories covering the following types of high-risk, class D IVDs: hepatitis and retroviruses; herpes viruses; bacterial agents; and respiratory viruses that cause life-threatening diseases. The designated EU Reference Laboratories are responsible for verifying performance of IVDs in accordance with common specifications, batch testing of class D IVDs, collaborating with Notified Bodies to develop best practices for IVD conformity assessments, and providing scientific and technical assistance on the implementation of the IVDR. Most recently, on December 6, 2025, the European Commission released a proposal to amend the IVDR with the goal of simplifying the applicable rules, reducing the administrative burden on manufacturers, and enhancing the predictability and cost-effectiveness of the certification procedure while maintaining a high level of public health protections for EU patients and consumers.

We believe that LDTs produced outside of the EU and involving samples obtained from EU citizens must fully comply with the IVDR and accordingly, we are in full compliance with ISO 13485 standards and submitted certain of our tests for conformity assessments by a designated Notified Body. In July 2025, we announced that we had received CE certification under the IVDR for our germline NGS, system, which includes FulgentExome and Fulgent Pipeline Manager, or PLM. If we are not able to obtain and maintain regulatory compliance for such CE-marked test products, we may not be permitted to market our laboratory services in the EU and/or may become subject to enforcement by EU Competent Authorities, bodies with authority to act on behalf of the government of the applicable EU Member State to ensure that the applicable regulatory requirements are met.

Our tests also may become subject to other foreign premarket review, compliance, and regulatory approval regimes applicable to IVDs as we continue to expand and offer our services internationally.

Regulations Regarding Advertising of Laboratory Services, LDTs, or IVDs

In the United States, 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 agencies under similarly broad state 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.

In addition, when marketing our diagnostic tests to clinical laboratories and medical institutions outside of the United States (including our operations in Australia), we are subject to foreign regulatory requirements governing promotional statements and IVD labeling. The legal landscape governing promotional and other marketing activities for diagnostic tests can vary widely from jurisdiction to jurisdiction, and is often more complex, less clear, or less developed than in the United States.

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

CPT Codes

We bill insurance 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 insurance 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, if required. After we file the claim, we may also need to resubmit documentation or appeal a denial. All of these issues 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 Clinical Laboratory Fee Schedule, or 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 tests, or ADLT). We do not believe that any of our tests meet the current definition of ADLT. Therefore, we 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, 2018, Medicare payments for CDLTs are based upon reported private payor rates. For a CDLT that is assigned a new or substantially revised CPT code, the initial payment rate is assigned using the gap-fill methodology, as under prior law.

Since December 2019, Congress has passed a series of laws to modify PAMA's statutory requirements related to the data reporting period and phase-in of payment reductions under the CLFS for CDLTs that are not ADLTs. Most recently, on February 3, 2026, Section 6226 of the Continuing Appropriations Act, 2026, further delayed the data reporting requirements for CDLTs that are not ADLTs as well as the phase-in of payment reductions. The next data reporting period will be from May 1, 2026, through July 31, 2026, and will be based on an updated data collection period of January 1, 2025 through June 30, 2025.

The same series of laws modified the phase-in of payment reductions resulting from private payor rate implementation so that a zero percent reduction limit was applied for calendar years, or CYs, 2021 through 2025, as compared to the payment amounts for a test the preceding year. Under Section 6226 of the Continuing Appropriations Act, 2026, a 0% payment reduction will be applied until January 30, 2027, so that the fee schedule amount for a CDLT that is not an ADLT may not be reduced compared to the payment amount for that test in CY 2026. From January 1, 2027 through December 31, 2028, payment may not be reduced by more than 15% percent per year compared to the payment amount established for a test the preceding year.

HRSA Audit and Investigation

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. This program administered by HRSA was the HRSA COVID-19 Claims Reimbursement to Health Care Providers and Facilities for Testing, Treatment, and Vaccine Administration for the Uninsured Program, or the Uninsured Program. The Uninsured Program was valid for the period between May 2020 and April 2022, and HRSA announced that the Uninsured Program ceased accepting COVID-19 testing claims as of March 22, 2022, due to a lack of sufficient funds. The Company recorded approximately $548.9 million of reimbursements from HRSA under the Uninsured Program during the years ended December 31, 2022, 2021, and 2020.

Similar to other laboratories in the industry, the Company responded to an audit inquiry from HRSA with respect to its reimbursement for COVID-19 tests furnished to patients believed to be uninsured. The Company fully cooperated with HRSA's auditors and provided all requested information. There is uncertainty with respect to the methodology HRSA will use and whether or how HRSA will extrapolate audit results. As of the date of this Annual Report, the Company has not received any final audit results from HRSA for this audit and has not received any further requests for information in connection with this audit from HRSA. The Company has also received a Civil Investigative Demand, or CID, issued by the U.S. Department of Justice, or DOJ, related to the DOJ's investigation as to whether we submitted or caused to be submitted false claims to the Uninsured Program. We are fully cooperating with the DOJ in connection with this CID.

See *"Contingencies"* in Note 8, *Debt, Commitments and Contingencies* to our consolidated financial statements, and the paragraphs under the heading entitled *"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 also subject to governmental audits and investigations that could result in material refunds or settlement. Our business, prospects and financial condition may be adversely affected as the result of the HRSA Audit and CIDs."* included in Item 1A *"Risk Factors"* of this Annual Report.

Rules and Regulations Applicable to Our Pharmaceutical Research and Development Activities

We engage in research and development activities, including pharmaceutical 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. In particular, government authorities in the United States at the federal, state, and local levels and in other countries regulate, among other things, the research, development, testing, manufacture, quality control, approval, labeling, packaging, storage, record-keeping, promotion, advertising, distribution, post-approval monitoring and reporting, marketing and export and import of therapeutic products. Generally, 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 undergo periodic revisions and refinement.

In the United States, the FDA regulates drugs under the FDC Act and its implementing regulations. The process of obtaining regulatory approvals and the subsequent compliance with applicable federal, state, local, and foreign statutes and regulations requires the expenditure of substantial time and financial resources. Failure to comply with the applicable U.S. requirements at any time during the product development process, approval process or post-market may subject an applicant to administrative or judicial sanctions. These sanctions could include, among other actions, the FDA's refusal to approve pending applications, withdrawal of an approval, a clinical hold, untitled or warning letters, product recalls or market withdrawals, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, restitution, disgorgement, and civil or criminal penalties.

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 GLP 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 product candidate for its intended use(s);
- 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 product 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
- the FDA's review and approval of the NDA.

The testing and formulation processes required to market a therapeutic product involves substantial time, effort, and financial resources. The data required to support an NDA are generated in two distinct developmental stages; non-clinical and clinical. The non-clinical developmental stage generally involves laboratory evaluations of drug chemistry, formulation, and stability, as well as potential studies to evaluate the molecule's toxicity in animals, which support subsequent clinical testing. The sponsor must submit the results of the non-clinical studies, together with manufacturing information, analytical data, any available clinical data or literature and a proposed clinical protocol, to the FDA as part of the IND. An IND is a request for authorization from the FDA to administer an investigational new drug to humans and must become effective before human clinical trials may begin.

Clinical Trials

The clinical stage of development involves the administration of the investigational product to volunteers or patients under the supervision of qualified investigators, generally physicians not employed by or under the trial sponsor's control, in accordance with GCP requirements, which include the requirement that all research subjects provide their informed consent for their participation in any clinical trial. Clinical trials are conducted under protocols detailing, among other things, the objectives of the clinical trial, dosing procedures, subject selection and exclusion criteria and the parameters to be used to monitor subject safety and assess efficacy. Each protocol, and any subsequent amendments to the protocol, must be submitted to the FDA as part of the IND. Furthermore, 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.

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

- Phase 1: Initial safety study in appropriate 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.

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, the FDA may mandate the performance of "Phase 4" clinical trials as a condition of approval of an NDA.

Progress reports detailing the results of the clinical trials, among other information, must be submitted at least annually to the FDA. Written IND safety reports must be submitted to the FDA and the investigators for serious and unexpected suspected adverse events, findings from other studies suggesting a significant risk to humans exposed to the investigational drug, findings from animal or in vitro testing that suggest a significant risk for human subjects, and any clinically important increase in the rate of a serious suspected adverse reaction over that listed in the protocol or investigator brochure. Congress also amended the FDC Act in 2022 to require sponsors of a Phase 3 clinical trial, or other "pivotal study" of a new drug to support marketing authorization (or pivotal trials of medical devices), to design and submit a diversity action plan for such clinical trial. However, President Trump issued executive orders, or EOs, in January 2025 that rescinded previous EOs mandating affirmative action and Diversity, Equity and Inclusion for federal contractors, effectively ending mandatory diversity action plans.

In addition, an IRB on behalf of each institution that is participating in the clinical trial must conduct a continuing review and reapprove the trial at least annually. Information about certain clinical trials, including details of the protocol and eventually study results, must also be submitted within specific timeframes to the National Institutes of Health, or NIH, for public dissemination on the ClinicalTrials.gov data registry. Information related to the investigational product, patient population, phase of investigation, study sites and investigators, and other aspects of the clinical trial is made public as part of the registration of the clinical trial. Sponsors are also obligated to disclose the results of their clinical trials after completion. Disclosure of the results of these trials can be delayed in some cases for up to two years after the date of completion of the trial. Competitors may use this publicly available information to gain knowledge regarding the progress of development programs. The NIH's Final Rule on ClinicalTrials.gov registration and reporting requirements became effective in 2017, and the government has begun enforcing those requirements against non-compliant clinical trial sponsors.

Clinical trials may not be completed successfully within any specified period, if at all. 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 product candidate has been associated with unexpected serious harm to patients. Additionally, some clinical trials are overseen by an independent group of qualified experts organized by the clinical trial sponsor, known as a data safety monitoring board or committee. This group provides authorization for whether a trial may move forward at designated check points based on access to certain data from the trial.

NDA Submission and FDA Review Process

Following completion of the required clinical testing, all of the data are analyzed to assess whether the investigational therapeutic product is safe and effective for its proposed indicated use or uses. The results of the non-clinical studies and clinical trials, along with detailed descriptions of the product's chemistry, manufacturing and controls, or CMC, proposed labeling and other relevant information are submitted to the FDA as part of an NDA requesting approval to market the product. To support marketing approval, the data submitted must be sufficient in quality and quantity to establish the safety and efficacy of the investigational product to the satisfaction of FDA. FDA approval of the NDA must be obtained before a drug may be marketed in the United States.

Under the Prescription Drug User Fee Act, or PDUFA, as amended, each NDA must be accompanied by a significant user fee, and the sponsor of an approved NDA is also subject to an annual program fee. The FDA typically adjusts these PDUFA user fees on an annual basis. Fee waivers or reductions are available in certain circumstances, including a waiver of the application fee for the first application filed by a small business (fewer than 500 employees). Additionally, no user fees are assessed on NDAs for products designated as orphan drugs, unless the product also includes a non-orphan indication. Congress is required to re-authorize the agency's user fee programs every five years, and current legislative provisions supporting the PDUFA program are set to expire on September 30, 2027.

The FDA reviews all submitted NDAs to ensure that they are sufficiently complete for substantive review before it accepts them for filing. It may refuse to file the application and request additional information rather than accept an NDA for filing. In this event, the application must be resubmitted with the additional information. The resubmitted application is also subject to review before the FDA accepts it for filing. The FDA must make a decision on accepting an NDA for filing within 60 days of receipt and inform the

sponsor by the 74th day after the FDA's receipt of the submission whether an application is sufficiently complete to permit substantive review. Once the submission is accepted for filing, the FDA begins an in-depth review of the NDA. Under the goals and policies agreed to by the FDA under PDUFA, the FDA has 10 months from the filing date, to complete its review of a new molecular-entity, or NME, NDA and respond to the applicant six months from the filing date of an NME NDA designated for priority review. For non-NME NDAs, such as our current and, potentially, future product candidates, the review goals are 10 months from the date of receipt for a standard application and six months from the date of receipt for a priority submission. The FDA does not always meet its PDUFA goal dates for standard and priority NDAs, and the review process is often extended by FDA requests for additional information or clarification.

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) 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 (e.g., FDA's prior findings of safety and efficacy for an existing product or published literature). 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.

Before approving an NDA, the FDA will typically conduct a pre-approval inspection of the manufacturing facilities for the new product to determine whether the manufacturing processes and facilities comply with cGMP requirements. The FDA will not approve the product unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. The FDA also may audit data from clinical trials to ensure compliance with GCP requirements by each of the entities involved in the clinical trials, including clinical investigators and any third-party clinical research organizations, or CROs.

Additionally, the FDA may refer applications for novel drug products or drug products that present difficult questions of safety or efficacy to an advisory committee, typically a panel that includes clinicians and other independent scientific experts, for review, evaluation and a recommendation as to whether the application should be approved and under what conditions, if any. The FDA is not bound by recommendations of an advisory committee, but it considers such recommendations when making final decisions on marketing approval. The FDA likely will reanalyze the clinical trial data, which could result in extensive discussions between the FDA and the applicant during the review process. The FDA also may require development of a risk evaluation and mitigation strategy, or REMS, plan if it determines that a REMS is necessary to ensure that the benefits of the drug outweigh its risks and to assure the safe use of the drug. The REMS plan could include medication guides, physician communication plans, assessment plans and/or elements to assure safe use, such as restricted distribution methods, patient registries or other risk minimization tools. The FDA determines the requirement of a REMS, as well as the specific REMS provisions, on a case-by-case basis. If the FDA concludes a REMS plan is needed, the sponsor of the NDA must submit a proposed REMS. The FDA will not approve an NDA without a REMS, if one is required.

The approval process is lengthy and often difficult, and the FDA may refuse to approve an NDA if the applicable regulatory criteria are not satisfied or may require additional clinical or other data and information. The FDA reviews an NDA to determine, among other things, whether a product is safe and effective for its intended use and whether its manufacturing is cGMP-compliant and capable of assuring and preserving the product's identity, strength, quality and purity. Based on the FDA's evaluation of the NDA and accompanying information, including the results of the inspection of the manufacturing facilities, the FDA may issue either an approval letter or a Complete Response Letter. An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications. A Complete Response Letter indicates that the review cycle of the application is complete, and that it will not be approved in its present form. A Complete Response Letter usually describes all of the specific deficiencies in the NDA and may require substantial additional testing or information for the FDA to reconsider the application. The Complete Response Letter may require additional pivotal Phase 3 clinical trial(s) and/or other significant and time-consuming requirements related to clinical data, non-clinical data or manufacturing processes, among others. In September 2025, the FDA began publishing Complete Response Letters soon after issuing them to the respective sponsors, breaking with long standing agency tradition of publishing Complete Response Letters with approval documentation only after the product is approved. If a Complete Response Letter is issued, the applicant may choose either to resubmit the NDA, addressing all of the deficiencies identified in the letter, or to withdraw the application. If and when all deficiencies have been addressed to the FDA's satisfaction in a resubmitted NDA, the FDA will issue an approval letter. The FDA has committed to reviewing such resubmissions in response to an issued Complete Response

Letter in either two or six months, depending on the type of information included. Even if such data and information are submitted, however, the FDA may ultimately decide that the NDA does not satisfy the regulatory criteria for approval. Data obtained from clinical trials are not always conclusive and the FDA may interpret data differently than the applicant interprets the same data.

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 REMS plan, or otherwise limit the scope of any approval. In addition, the FDA may require post-marketing or Phase 4 clinical trials, designed to further assess a product's safety and effectiveness, and/or testing and surveillance programs to monitor the safety of approved products that have been commercialized.

Post-Approval Requirements for Pharmaceutical Products

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; product samplings 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. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant liability.

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. In particular, securing FDA approval for new indications is similar to the process for approval of the original indication and requires, among other things, submitting data from adequate and well-controlled clinical trials to demonstrate the product's safety and efficacy in the new indication. 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. Changes to the manufacturing process, specifications or container closure system for an approved drug product are strictly regulated and often require prior FDA approval before being implemented. FDA regulations also require, among other things, the investigation and correction of any deviations from cGMP and the imposition of reporting and documentation requirements upon the NDA sponsor and any third-party manufacturers involved in producing the approved therapeutic product. 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.

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 under a REMS plan. Other potential consequences of regulatory non-compliance include, among other things:

- Restrictions on the marketing or manufacturing of the product, complete withdrawal of the product from the market or product recalls;
- fines, warning letters or other enforcement-related letters or clinical holds on post-approval clinical trials;
- refusal of the FDA to approve pending NDAs or supplements to approved NDAs;
- product seizure or detention, or refusal to permit the import or export of products; injunctions or the imposition of civil or criminal penalties;

- consent decrees, corporate integrity agreements, debarment, or exclusion from federal health care programs; and/or
- mandated modification of promotional materials and labeling and the issuance of corrective information.

Expedited Development and Review Programs

The FDA is authorized to designate certain drug products for expedited development or review if they are intended to address an unmet medical need in the treatment of a serious or life-threatening disease or condition. These programs include fast-track designation, breakthrough therapy designation, priority review designation, and the Commissioner's National Priority Voucher pilot program.

To be eligible for a fast-track designation, the FDA must determine, based on the request of a sponsor, that a product is intended to treat a serious or life-threatening disease or condition and demonstrates the potential to address an unmet medical need by providing a therapy where none exists or a therapy that may be potentially superior to an existing therapy based on efficacy or safety factors. Fast-track designation provides opportunities for more frequent interactions with the FDA review team to expedite development and review of the product. The FDA may also review sections of the NDA for a fast-track product on a rolling basis before the complete application is submitted, if the sponsor and the FDA agree on a schedule for the submission of the application sections, and the sponsor pays any required user fees upon submission of the first section of the NDA. In addition, fast-track designation may be withdrawn by the sponsor or rescinded by the FDA if the designation is no longer supported by data emerging in the clinical trial process. The sponsor can request the FDA to designate the product for fast-track status any time before receiving NDA approval, but ideally, no later than the pre-NDA meeting.

The FDA also may designate a product for priority review if it is a drug that treats a serious condition and, if approved, would provide a significant improvement in safety or effectiveness. When a marketing application is submitted with a request for priority review, the FDA determines on a case-by-case basis whether the proposed drug represents a significant improvement in treatment, prevention or diagnosis of disease when compared with other available therapies. Significant improvement may be illustrated by evidence of increased effectiveness in the treatment of a condition, elimination or substantial reduction of a treatment-limiting drug reaction, documented enhancement of patient compliance that may lead to improvement in serious outcomes, or evidence of safety and effectiveness in a new subpopulation. A priority review designation is intended to direct overall attention and resources to the evaluation of such applications, and to shorten the FDA's goal for taking action on a marketing application from 10 months to six months from the date of filing for an NME NDA, or from 10 months to six months from the date of receipt for a non-NME NDA.

Additionally, a drug may be eligible for designation as a breakthrough therapy if the product is intended, alone or in combination with one or more other drugs or biologics, to treat a serious or life-threatening condition and preliminary clinical evidence indicates that the product may demonstrate substantial improvement over currently approved therapies on one or more clinically significant endpoints. The FDA must take certain actions with respect to breakthrough therapies, such as holding timely meetings with and providing advice to the product sponsor, intended to expedite the development and review of an application for approval of a breakthrough therapy.

In 2025, the FDA created a new voucher program called the Commissioner's National Priority Voucher, or CNPV, with the goal of radically expediting the drug and biological product review and approval process. The agency may award a CNPV to a company or a specific product candidate that demonstrates alignment with certain national health priorities. The FDA aims to take action on a marketing application for which a CNPV is used within one to two months after the filing date.

Even if a product qualifies for one or more of these programs, the FDA may later decide that the product no longer meets the conditions for qualification or decide that the time period for FDA review or approval will not be shortened. None of these programs change the standards for approval but may expedite the development or approval process.

Accelerated Approval Pathway

Products studied for their safety and effectiveness in treating serious or life-threatening illnesses and that provide meaningful therapeutic benefit over existing treatments may receive accelerated approval from the FDA and may be approved on the basis of adequate and well-controlled clinical trials establishing that the drug product has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit. The FDA may also grant accelerated approval for such a drug when the product has an effect on an intermediate clinical endpoint that can be measured earlier than an effect on irreversible morbidity or mortality, or IMM, which is reasonably likely to predict an effect on IMM or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments or on the basis of an effect on a clinical endpoint other than survival or irreversible morbidity. As a condition of approval, the FDA may require that a sponsor of a drug receiving accelerated approval perform adequate and well-controlled post-marketing clinical trials to verify and describe the predicted effect on IMM or other clinical

endpoint, and the product may be subject to expedited withdrawal procedures. If the FDA concludes that a drug shown to be effective can be safely used only if distribution or use is restricted, it will require such post-marketing restrictions, as it deems necessary to assure safe use of the product. Drugs granted accelerated approval must meet the same statutory standards for safety and effectiveness as those granted traditional approval.

For the purposes of accelerated approval, a surrogate endpoint is a marker, such as a laboratory measurement, radiographic image, physical sign, or other measure that is thought to predict clinical benefit but is not itself a measure of clinical benefit. Surrogate endpoints can often be measured more easily or more rapidly than clinical endpoints. An intermediate clinical endpoint is a measurement of a therapeutic effect that is considered reasonably likely to predict the clinical benefit of a drug, such as an effect on IMM. The FDA has limited experience with accelerated approvals based on intermediate clinical endpoints but has indicated that such endpoints generally may support accelerated approval when the therapeutic effect measured by the endpoint is not itself a clinical benefit and basis for traditional approval, if there is a basis for concluding that the therapeutic effect is reasonably likely to predict the ultimate long-term clinical benefit of a drug.

The accelerated approval pathway is most often used in settings in which the course of a disease is long, and an extended period of time is required to measure the intended clinical benefit of a drug, even if the effect on the surrogate or intermediate clinical endpoint occurs rapidly. For example, accelerated approval has been used extensively in the development and approval of drugs for treatment of a variety of cancers in which the goal of therapy is generally to improve survival or decrease morbidity and the duration of the typical disease course requires lengthy and sometimes large clinical trials to demonstrate a clinical or survival benefit.

The accelerated approval pathway is usually contingent on a sponsor's agreement to conduct, diligently, additional post-approval confirmatory studies to verify and describe the drug's clinical benefit. As a result, a product candidate approved on this basis is subject to rigorous post-marketing compliance requirements, including the completion of Phase 4 or post-approval clinical trials to confirm the effect on the clinical endpoint. In addition, as part of the Consolidated Appropriations Act for 2023, Congress provided the FDA additional statutory authority to mitigate potential risks to patients from continued marketing of ineffective drugs previously granted accelerated approval. Under these recent amendments to the FDC Act, the agency may require a sponsor of a product granted accelerated approval to have a confirmatory trial underway prior to approval. The sponsor must also submit progress reports on a confirmatory trial every six months until the trial is completed, and such reports will be published on the FDA's website. Failure to conduct required post-approval studies, or to confirm the predicted clinical benefit of the product during post-marketing studies, allows the FDA to withdraw approval of the drug. Congress also amended the law to give the FDA the option of using expedited procedures to withdraw product approval if the sponsor's confirmatory trial fails to verify the claimed clinical benefits of the product. All promotional materials for products approved for marketing under the accelerated approval program are subject to prior review by the FDA.

Patent Listing and Regulatory Exclusivity under the Hatch-Waxman Act

As noted above, Congress created the 505(b)(2) NDA pathway in 1984 as part of the Hatch-Waxman Act amendments to the FDC Act. At the same time, it also established an abbreviated regulatory scheme authorizing the FDA to approve generic drugs that are shown to contain the same active ingredients as, and to be bioequivalent to, drugs previously approved by the FDA pursuant to NDAs. To obtain approval of a generic drug, an applicant must submit an abbreviated new drug application, or ANDA, to the agency. An ANDA is a comprehensive submission that contains, among other things, data and information pertaining to the active pharmaceutical ingredient, bioequivalence, drug product formulation, specifications and stability of the generic drug, as well as analytical methods, manufacturing process validation data and quality control procedures. ANDAs are "abbreviated" because they cannot include non-clinical and clinical data to demonstrate safety and effectiveness. Instead, in support of such applications, a generic manufacturer must rely on the non-clinical and clinical testing conducted for a drug product previously approved under an NDA, known as the reference listed drug, or RLD. Unlike the ANDA pathway, which does not allow applicants to submit new clinical data other than bioavailability or bioequivalence data, the 505(b)(2) regulatory pathway does not preclude the possibility that a follow-on applicant would need to conduct additional clinical trials or non-clinical studies to demonstrate safety or effectiveness of the proposed change(s) being made to a previously approved drug.

In order for an ANDA to be approved, the FDA must find that the generic version is identical to the RLD with respect to the active ingredients, the route of administration, the dosage form, the strength of the drug and the conditions of use of the drug. At the same time, the FDA must also determine that the generic drug is "bioequivalent" to the innovator drug. Under the statute, a generic drug is bioequivalent to a RLD if "the rate and extent of absorption of the drug do not show a significant difference from the rate and extent of absorption of the listed drug." Upon approval of an ANDA, the FDA indicates whether the generic product is "therapeutically equivalent" to the RLD in the publication, Approved Drug Products with Therapeutic Equivalence Evaluations, or the Orange Book. Physicians and pharmacists consider a therapeutic equivalent generic drug to be fully substitutable for the RLD. In addition, by operation of certain state laws and numerous health insurance programs, the FDA's designation of therapeutic

equivalence often results in substitution of the generic drug without the knowledge or consent of either the prescribing physician or patient.

As part of the NDA review and approval process, applicants are required to list with the FDA each patent that has claims that cover the applicant's product or method of therapeutic use. Upon approval of a new drug, each of the patents listed in the application for the drug is then published in the Orange Book. Drugs listed in the Orange Book can, in turn, be cited by potential follow-on competitors in support of approval of an ANDA or a 505(b)(2) NDA that relies in full or in part on the reference product.

When an ANDA applicant submits its application to the FDA, it is required to certify to the FDA concerning any patents listed for the reference product in the FDA's Orange Book. Specifically, the ANDA applicant must certify that: (i) the required patent information has not been filed; (ii) the listed patent has expired; (iii) the listed patent has not expired, but will expire on a particular date and approval is sought after patent expiration; or (iv) the listed patent is invalid or will not be infringed by the new product. Moreover, to the extent that the Section 505(b)(2) NDA applicant is relying on studies conducted for an already approved product, the applicant also is required to certify to the FDA concerning any patents listed for the NDA-approved product in the Orange Book to the same extent that an ANDA applicant would.

If the follow-on applicant does not challenge the innovator's listed patents, the FDA will not approve the ANDA or 505(b)(2) application until all the listed patents claiming the referenced product have expired. A certification that the new product will not infringe the already approved product's listed patents, or that such patents are invalid, is called a Paragraph IV certification. If the follow-on applicant has provided a Paragraph IV certification to the FDA, the applicant must also send notice of the Paragraph IV certification to the NDA and patent holders once the ANDA or 505(b)(2) NDA has been accepted for filing by the FDA. The NDA and patent holders may then initiate a patent infringement lawsuit in response to the notice of the Paragraph IV certification. The filing of a patent infringement lawsuit within 45 days of the receipt of a Paragraph IV certification automatically prevents the FDA from approving the ANDA or 505(b)(2) NDA until the earlier of 30 months, expiration of the patent, settlement of the lawsuit, or a decision in the infringement case that is favorable to the ANDA/505(b)(2) applicant.

An ANDA or 505(b)(2) NDA also will not be approved until any applicable non-patent exclusivities listed in the Orange Book for the referenced product have expired. The Hatch-Waxman Act amendments to the FDC Act provide a five-year period of non-patent data exclusivity within the United States to the first applicant to gain approval of an NDA for a new chemical entity, or NCE. For the purposes of this provision, an NCE is a drug that contains no active moiety that has previously been approved by the FDA in any other NDA. An active moiety is the molecule or ion responsible for the physiological or pharmacological action of the drug substance. In cases where such NCE exclusivity has been granted, an ANDA or 505(b)(2) NDA may not be filed with the FDA until the expiration of five years unless the submission is accompanied by a Paragraph IV certification, in which case the applicant may submit its application four years following the original product approval.

The FDC Act also provides for a period of three years of data exclusivity if an NDA or NDA supplement includes reports of one or more new clinical investigations, other than bioavailability or bioequivalence studies that were conducted or sponsored by the applicant, are deemed by the FDA to be essential to the approval of the application or supplement. This three-year exclusivity period often protects changes to a previously approved drug product, such as new indications, dosage forms, route of administration or combination of ingredients. Three-year exclusivity would be available for a drug product that contains a previously approved active moiety, provided the statutory requirement for a new clinical investigation is satisfied. Unlike five-year NCE exclusivity, an award of three-year exclusivity does not block the FDA from accepting ANDAs or 505(b)(2) NDAs seeking approval for generic versions of the drug as of the date of approval of the original drug product; rather, this three-year exclusivity covers only the conditions of use associated with the new clinical investigations and, as a general matter, does not prohibit the FDA from approving follow-on applications for drugs containing the original active ingredient.

Five-year and three-year exclusivity also will not delay the submission or approval of a traditional NDA filed under Section 505(b)(1) of the FDC Act; however, an applicant submitting a traditional NDA would be required to conduct or obtain a right of reference to all of the non-clinical studies and adequate and well-controlled clinical trials necessary to demonstrate safety and effectiveness.

Patent Term Extension

A patent claiming a prescription drug or medical device for which FDA approval is granted may be eligible for a limited patent term extension under the FDC Act, which permits patent restoration of up to five years for patent term lost during product development and the FDA regulatory review provided that certain statutory and regulatory requirements are met. The length of the patent term extension is related to the length of time the drug or medical device is under regulatory review while the patent is in force. The restoration period granted on a patent covering a new FDA-regulated medical product is typically one-half the time between the date a clinical investigation on human beings is begun and the submission date of an application for pre-market approval of the

product, plus the time between the submission date of an application for approval of the product and the ultimate approval date. Patent term restoration cannot be used to extend the remaining term of a patent past a total of 14 years from the product's approval date. Only one patent applicable to an eligible FDA-approved product is eligible for the extension, and the application for the extension must be submitted prior to the expiration of the patent in question. A patent that covers multiple products for which approval is sought can only be extended in connection with one of the marketing approvals. The U.S. Patent and Trademark Office, or USPTO, reviews and approves the application for any patent term extension or restoration in consultation with the FDA.

Rules and Regulations Relating to Companion or Complementary Diagnostics

The success of one or more of our product candidates may depend, in part, on the development and commercialization of either a companion diagnostic or a complementary diagnostic. Companion diagnostics and complementary diagnostics can identify patients who are most likely to benefit from a particular drug; identify patients likely to be at increased risk for serious side effects as a result of treatment with a particular drug; or monitor response to treatment with a particular drug for the purpose of adjusting treatment to achieve improved safety or effectiveness. Companion diagnostics and complementary diagnostics are regulated as medical devices by the FDA. The level of risk associated with a new diagnostic test combined with available controls to mitigate risk determines whether a companion diagnostic device requires PMA approval from the FDA or if it can be cleared by the agency through the 510(k) pre-market notification process based on a showing of substantial equivalence to a commercially available device. For a novel drug for which a companion diagnostic device is essential for the safe and effective use of the product, the companion diagnostic device should be developed and PMA-approved or 510(k)-cleared contemporaneously with the FDA's approval of the drug. The use of the companion diagnostic device will be stipulated in the labeling of the drug, and vice versa.

Recently, FDA issued a proposed rule to reclassify certain nucleic acid-based test systems indicated for use with a corresponding approved oncology therapeutic product from Class III (PMA) into Class II, subject to premarket notification with special controls. The proposal is based in part on the history of safe and effective use of several FDA-approved oncology therapeutic nucleic acid-based test systems for their intended uses. This change, if finalized in 2026, will decrease the regulatory burden on industry because manufacturers of these kinds of IVDs will no longer have to submit a PMA and receive FDA approval before marketing the test.

Rules and Regulations Relating to Coverage, Pricing, and Reimbursement for Prescription Pharmaceutical Products

Sales of pharmaceutical products approved for marketing by the FDA and foreign regulatory authorities will depend, in part, on the extent to which such products will be covered by insurance payors, such as government health programs, commercial insurance and managed care organizations. In the United States no uniform policy of coverage and reimbursement for human drug products exists. Accordingly, decisions regarding the extent of coverage and the amount of reimbursement to be provided for any of our future drugs will be made on a payor-by-payor basis. As a result, the coverage determination process is often a time-consuming and costly process that will require us to provide scientific and clinical support for the use of our drugs to each payor separately, with no assurance that coverage and adequate reimbursement will be obtained.

The United States government, state legislatures and foreign governments have shown significant interest in implementing cost containment programs to limit the growth of government-paid health care costs, including price-controls, restrictions on reimbursement and requirements for substitution of generic products for branded prescription drugs. For example, the federal law contains provisions that may reduce the profitability of drug products through increased rebates for drugs reimbursed by Medicaid programs, extension of Medicaid rebates to Medicaid managed care plans, mandatory discounts for certain Medicare Part D beneficiaries and annual fees based on pharmaceutical companies' share of sales to federal health care programs. Adoption of general controls and measures, coupled with the tightening of restrictive policies in jurisdictions with existing controls and measures, could limit payments for pharmaceutical drugs. The Medicaid Drug Rebate Program requires pharmaceutical manufacturers to enter into and have in effect a national rebate agreement with the Secretary of the Department of Health and Human Services, or HHS, as a condition for states to receive federal matching funds for the manufacturer's outpatient drugs furnished to Medicaid patients. The Patient Protection and Affordable Care Act, or ACA, enacted in 2010, made several changes to the Medicaid Drug Rebate Program and expanded the universe of Medicaid utilization subject to drug rebates by requiring pharmaceutical manufacturers to pay rebates on Medicaid managed care utilization and by enlarging the population potentially eligible for Medicaid drug benefits. In addition, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, or MMA, established the Medicare Part D program to provide a voluntary prescription drug benefit to Medicare beneficiaries. Under Part D, Medicare beneficiaries may enroll in prescription drug plans offered by private entities that provide coverage of outpatient prescription drugs. Unlike Medicare Part A and B, Part D coverage is not standardized. While all Medicare drug plans must give at least a standard level of coverage set by Medicare, Part D prescription drug plan sponsors are not required to pay for all covered Part D drugs, and each drug plan can develop its own drug formulary that identifies which drugs it will cover and at what tier or level. However, Part D prescription drug formularies must include drugs within each therapeutic category and class of covered Part D drugs, though not necessarily all the drugs in each category or class. Any formulary used by a Part D prescription drug plan must be developed and reviewed by a pharmacy and therapeutic

committee. Government payment for some of the costs of prescription drugs may increase demand for products that receive marketing approval in the future. However, any negotiated prices for future products covered by a Part D prescription drug plan likely will be lower than the prices we might otherwise obtain. Moreover, while the MMA applies only to drug benefits for Medicare beneficiaries, private payors often follow Medicare coverage policy and payment limitations in setting their own payment rates. Any reduction in payment that results from the MMA may result in a similar reduction in payments from non-governmental payors.

For a drug product to receive federal reimbursement under the Medicaid or Medicare Part B programs or to be sold directly to U.S. government agencies, the manufacturer must extend discounts to entities eligible to participate in the 340B drug pricing program. The maximum amount that a manufacturer may charge a 340B covered entity for a given product is the average manufacturer price, or AMP reduced by the rebate amount paid by the manufacturer to Medicaid for each unit of that product. As of 2010, the ACA expanded the types of entities eligible to receive discounted 340B pricing, although, under the current state of the law, with the exception of children's hospitals, these newly eligible entities will not be eligible to receive discounted 340B pricing on orphan drugs. In addition, as 340B drug pricing is determined based on AMP and Medicaid rebate data, the revisions to the Medicaid rebate formula and AMP definition described above could cause the required 340B discount to increase. Pharmaceutical manufacturers, their vendors, and the federal agency responsible for administering the 340B program, HRSA, have been actively challenging various aspects of the program and litigation is pending in multiple jurisdictions. The outcome of such ongoing lawsuits, as well as potential legislative changes enacted by Congress or programmatic changes implemented at HRSA by the Trump Administration, may impact the 340B program in the future.

Moreover, there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drug products. HHS has solicited feedback on various measures intended to lower drug prices and reduce the out-of-pocket costs of drugs and has implemented others under its existing authority. For example, in August 2022 President Biden signed into law the Inflation Reduction Act, 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 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, CMS is negotiating drug prices annually for a select number of single source Part D drugs without generic competition. CMS is also negotiating 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. CMS has begun to implement these new authorities, announcing the first round of negotiated prices for the first 10 drugs in August 2024, which became effective as of January 1, 2026 (payment year 2026). The second round of negotiated prices for 15 drug products was announced in November 2025. However, the IRA's impact on the pharmaceutical industry in the United States remains uncertain, in part because multiple large pharmaceutical companies and other stakeholders (e.g., the U.S. Chamber of Commerce) have initiated federal lawsuits against CMS arguing the program is unconstitutional for a variety of reasons, among other complaints. Those lawsuits are currently ongoing.

Separately, the Trump Administration announced the creation of a government website called TrumpRx, which will allow consumers to purchase certain prescription drugs at reduced prices as negotiated between the drug manufacturers and the administration. As of January 2026, the Trump Administration secured deals with 15 major drug manufacturers to offer certain drugs at most-favored-nation prices.

At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures. In December 2020, the U.S. Supreme Court held unanimously that federal law does not preempt the states' ability to regulate pharmacy benefit managers, or PBMs, and other members of the health care and pharmaceutical supply chain, an important decision that has led to further and more aggressive efforts by states in this area. In mid-2022, the FTC also launched sweeping investigations into the practices of the PBM industry and published an interim report with its findings in mid-2024 that could lead to additional federal and state legislative or regulatory proposals targeting such entities' operations, pharmacy networks, or financial arrangements, including in the 2025-2026 congressional session. Significant efforts to change the PBM industry as it currently exists in the United States may affect the entire pharmaceutical supply chain and the business of other stakeholders, including pharmaceutical product developers like us.

The "One Big Beautiful Bill Act," or OBBBA, which was signed by President Trump in 2025 is expected to reduce enrollment in Medicaid and state insurance exchanges enacted under the ACA, limiting access to insurance coverage for certain populations. A resulting decrease in the number of insured individuals could also affect coverage of and reimbursement for our products.

As noted above, the marketability of any products for which we receive regulatory approval for commercial sale may suffer if the government and insurance payors fail to provide adequate coverage and reimbursement. We expect that the increasing emphasis on cost containment measures in the United States will continue to increase the pressure on pharmaceutical pricing. Coverage policies and insurance reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for one or more products for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

In addition, in most foreign countries, the proposed pricing for a medicinal product must be approved before it may be lawfully marketed. The requirements governing drug pricing and reimbursement vary widely from country to country. Some countries provide that drug products may be marketed only after a reimbursement price has been agreed.

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 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, 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, or HIPAA Security Rule, require the implementation of administrative, physical, and technical safeguards and the adoption of written security policies and procedures. The HIPAA Security Rule is currently undergoing a proposed update, which, if implemented, will impose more stringent security measures on covered entities.

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 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 $2.1 million per violation of the same requirement per calendar year (as of January 2026, subject to annual inflation adjustments). A single breach incident may violate multiple requirements, resulting in potential penalties in excess of $2.1 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.

State Health Information Privacy Laws

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 and Washington, have implemented comprehensive health 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. Washington's My Health My Data Act broadly defines consumer health data, places restrictions on processing consumer health data, provides consumers with certain rights with respect to their health data, and creates a private right of action to allow individuals to sue for violations of the law.

The California Consumer Privacy Act, or CCPA, and the California Privacy Rights Act, or CPRA, set forth a privacy framework for covered businesses by creating an expanded definition of personal information, establishing data privacy rights for California consumers and employees, 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, including through our direct-to-consumer Picture Genetics platform, is within the scope of the CCPA and does not fall under the CCPA exception. Additionally, the CPRA protects the rights of our employees who are California residents and provides the California Privacy Protection Agency, or CPPA, with the power to administer and enforce 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, a growing number of other states have passed or are considering similar privacy laws. There are also several federal privacy proposals under consideration in Congress, and other states may introduce privacy legislation for consideration in 2026. These various privacy laws could impact our operations or that of our collaborators and business partners and impose new regulatory requirements and increase costs of compliance.

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.

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 continue to 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 "disincentives" for violations of the Information Blocking Rule. HHS and ONC released a final rule establishing disincentives for health care providers that have

committed information blocking on June 24, 2024. In September 2025, HHS, together with OIG and ONC, announced plans to increase enforcement of violations of the information blocking rules.

Foreign Privacy Laws

We are also subject to foreign privacy laws in the jurisdictions in which we sell our tests, and collect patient samples. The interpretation, application, and interplay of consumer and health-related data protection laws in the United States, Australia, Asia, Canada, Europe, and elsewhere are often uncertain, contradictory, and in flux. For example, the Privacy Act 1988 applies to personal data in Australia. Additionally, the General Data Protection Regulation, or GDPR, and Cybersecurity Directive applies to personal data in the European Union. 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 dollars for violations of privacy laws.

Artificial Intelligence

In many activities, including operational use of Artificial Intelligence, or AI, tools, we are subject to emerging regulations and guidelines. AI is increasingly shaping industries worldwide, including life sciences and health care. AI innovation introduces risks and challenges that could impact our business. AI algorithms may be flawed; datasets may be insufficient or biased, and ineffective AI development or deployment could lead to compliance violations, cybersecurity risks, and other adverse consequences. Potential risks include breaches of confidentiality and privacy obligations, noncompliance with emerging laws and regulations, threats to intellectual property rights, including not only the leakage of our proprietary information but also the risk that AI-generated outputs may infringe third-party intellectual property rights or be deficient or inaccurate; and the misuse of confidential, proprietary, or personally identifiable information, including PHI. In the United States, all 50 states and territories have introduced AI legislation, and more than 30 states already regulate AI. These legislative initiatives in the United States include active or proposed legislation to regulate AI and its use in healthcare, including in California, Georgia, Massachusetts, and Texas, where we conduct operations. Generally, such regulations aim to protect individuals such as consumers, employees, and/or job applicants from bias, discrimination, and invasion of privacy and to promote transparency with respect to use of AI by companies. The European Union's Artificial Intelligence Act, or the AI Act, which entered into force on August 1, 2024, and will be fully effective later this year, is broad in scope, defines high-risk AI activities, and seeks to prohibit certain AI uses. The AI Act will potentially regulate entities that intend to utilize AI applications in the EU. Anticipated range of fines for entities that are found to violate the AI Act may reach up to EUR 35 million or up to 7% of the Company's total worldwide annual turnover for the preceding financial year, whichever is higher.

Additionally, the FTC recently published guidance for companies selling genetic testing products on securing DNA data and outlined enforcement priorities, anticipating close monitoring of genetic testing companies' use of AI, including DNA algorithms. The FTC guidance instructs companies to safeguard consumers from potential detrimental effects of AI usage such as bias, invasion of privacy, and accuracy; notes that protection of genetic data is FTC's top priority; and reminds companies to prepare notices regarding their collection, use, and disclosure of genetic information and to consider affirmative express consent requirements.

Other Applicable Privacy Laws

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 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 undertake 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 or AI laws and directives, 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, the United States and certain other countries have enacted various data protection legislation or directives, which further increase the complexity of cross-border data transfers and of doing international business and transferring sensitive personal information from those countries to the United States or from the United States to certain other countries.

The privacy and security of PHI and personally identifiable information stored, maintained, received, or transmitted, including electronically, including genetic data, 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 financial condition, prospects, reputation, and operations.

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 for the Department of Health and Human Services, or OIG), the DOJ, individual U.S. Attorney's Offices within the DOJ, and state and local governments. We also may be subject to foreign fraud and abuse laws in the European Union, Australia, Canada, Japan, Taiwan, and other foreign countries because we market or sell our diagnostic testing services to health care providers, medical institutions, and clinical laboratories located in those jurisdictions.

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 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, the Eliminating Kickbacks in Recovery Act of 2018, or EKRA, is an all-payor 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 healthcare programs but applies more broadly to services covered by "healthcare 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 DOJ 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 criminal 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 commercial insurers. A violation of this statute is a felony and may result in fines, imprisonment or exclusion from government healthcare programs such as Medicare and Medicaid. 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. A violation of this statute is also a felony and may result in fines, imprisonment or exclusion from government payor programs.

We have adopted policies and procedures designed to comply with these laws, and in the ordinary course of our business, we conduct internal reviews of our compliance with these laws. However, the rapid growth and international expansion of our diagnostic testing business may increase the potential of violating these and applicable foreign fraud and abuse laws and regulations. Efforts to ensure that our internal operations and business arrangements with foreign clinical laboratories and other third parties comply with applicable laws and regulations will involve substantial costs. Any action brought against us or against our international employees, customers, or commercial partners for alleged violations of foreign laws or regulations can result in significant penalties, and even if we successfully defend against such an action, can cause us to incur significant legal expenses and divert our management's attention from the operation of our business.

False Claims Act

Another development affecting the U.S. 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 substantial per-claim civil penalties.

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 insurance payor and not merely a government payor program. We have received a CID issued by the DOJ 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. Among other things, this CID requests information and records relating to certain of the Company's customers named in this CID. Certain of our executive officers and employees have also received CIDs relating to these matters. We are fully cooperating with the DOJ in connection with these CIDs. See Note 8, *Debt, Commitments and Contingencies* to our consolidated financial statements.

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 Medicaid 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 Medicaid, 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 healthcare 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 clinical 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 an assessment of up to three times the amount claimed, substantial per-claim penalties, and possible exclusion from participation in government healthcare programs. 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. 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.

Physician Payment Sunshine and Anti-Gift Laws Applicable to our Business

The U.S. 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. A number of states also have laws similar to the Sunshine Act.

Because we manufacture our own LDTs solely for use by or within our own laboratory, we believe we are exempt from these reporting requirements. We may become subject to such reporting requirements under the terms of current CMS regulations, however, if the FDA requires us to obtain pre-market authorization for our tests as medical devices because the agency determines that one or more of the tests do not fall within the scope of the agency's existing LDT definition or if Congress enacts legislative reforms to the federal oversight of LDTs to subject them to FDA regulation and/or the reporting requirements of the Sunshine Act.

Many EU member states have adopted specific anti-gift statutes that further limit commercial practices for medical devices, including IVD medical devices, in particular, vis-à-vis health care professionals and organizations. Additionally, there has been a recent trend of increased regulation of payments and transfers of value provided to health care professionals or entities and many EU member states have adopted national "Sunshine Acts," which impose reporting and transparency requirements (often on an annual basis), similar to the requirements in the United States, on medical device manufacturers. Certain countries also mandate implementation of commercial compliance programs.

We also may become subject to these requirements, as well as applicable state-level Sunshine Acts for payments or gifts made to physicians, if any therapeutic products currently in development are successfully approved by FDA, commercialized in the United States, and become eligible for reimbursement under a federal healthcare program such as Medicare or Medicaid.

Anti-Bribery Laws Applicable to our Business

FCPA

We are subject to the 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, 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.

U.S. Prohibitions on the Corporate Practice of Medicine

Numerous states have enacted laws prohibiting business corporations, such as ours, from practicing medicine and directly 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. In recent years, a number of states have enacted or considered legislation aimed at further regulating the relationships between business corporations and licensed physicians. Although we have structured our management services arrangements with our affiliated professional corporations to comply with applicable state corporate practice of medicine laws, changes to these laws may require adjustments to our existing operations. Additionally, 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 Applicable to Our U.S. Laboratory Operations

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 depend 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 laboratory and for healthcare employees, including requirements to develop and implement programs to protect workers from exposure to bloodborne pathogens by preventing or minimizing any exposure through needlestick or similar penetrating injuries.

Sustainability

We are committed to operating sustainably and have dedicated the last couple of years to establishing the proper foundation and internal functions that would enable us to monitor and grow our sustainability strategy. We placed our sustainability efforts and initiatives under the purview and oversight of the Nominating and Governance Committee. We have also implemented various policies that outline commitments and establish internal processes with respect to our sustainability efforts. Additionally, we established a sustainability working group, made up of members of our executive team and senior management.

Environmental Impact

At Fulgent, we prioritize a holistic view of protecting and preserving our precious natural resources, as outlined in our Climate Policy. We strive to incorporate climate-related risk assessments as part of our leadership team's regular agenda. Our board of directors provides general oversight of energy management, climate risk and opportunities, strategy, and performance. The board of directors, through our sustainability working group, provides additional oversight on climate-related projects, goals, and related opportunities.

Employees and Human Capital Resources

We believe growing and retaining a strong team is crucial to our success. As of December 31, 2025, we had 1,315 (U.S. and international) full-time employees for our laboratory services business, engaged in precision diagnostic and anatomic pathology testing, BioPharma services, software engineering, laboratory management, sales and marketing, and corporate and administrative activities, and we have 29 (U.S.-based) full-time employees engaged in anatomic pathology testing, research and development, and corporate and administrative activities for our therapeutic development business. 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, equity-based compensation, and bonus programs. We also provide an expansive benefit offering including medical, dental, and vision healthcare coverage; life and accidental death and dismemberment 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, leaves of absence and wellness programs. None of our employees are represented by a labor union or covered by collective bargaining agreements, and we believe our overall 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	Chairperson 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 Dong	Non-Employee Director
Michael Nohaile, Ph.D.	Non-Employee Director

Employee Training and Engagement

Our dedicated and growing team of over 1,300 employees is a source of pride. They continuously work to expand our testing solutions and consistently provide the highest quality of care and accuracy. In an effort to recruit the best talent pool and to encourage the professional and personal development of every 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. In the past several years, employees have applied for a variety of courses, including the Cisco Certified Network Associate certificate at Stanford Center for Professional Development, Google Project Management, Clinical Genetic Molecular Biologist Scientist Training Program, American Society for Clinical Pathology Board of Certificate programs, Certified Genetic Counselor credential program, and Bachelor's degrees. We also provide mandatory training courses that we believe are important to our culture, corporate goals, our business and the continued development of our employees, on a variety of topics, including discrimination, harassment, HIPAA, insider trading, privacy, anti-corruption and anti-bribery, internally and/or through third-party providers. In 2025, we conducted a recurrent employee feedback survey and utilized the survey results to enhance employee engagement, implement various improvements to extend continuous learning opportunities and refine our benefit plans for 2026. In 2025, the Training & Development team hosted a series of training sessions for team members, covering key topics such as "Leadership & Influence: Manager or Leader?", "Performance Management", "Peer to Supervisor Transition", "Developing

Emotional Intelligence", "Servant Leadership", "Critical Thinking", "Work life Balance", "Lean Six Sigma", "Unconscious Bias", and "Supervisor-in Training."

Workplace Safety and Health

We are committed to promoting a safe and healthy work environment, to establishing policies and procedures that support the safety program, and to fostering a workplace that is free from hazards, substance abuse, and violence. We currently operate five CLIA-certified and CAP-accredited labs across the United States. We seek to surpass the highest standards of diagnostic testing and to follow applicable safety laws and regulations. We encourage reporting of concerns across all of our physical locations. Because the health and safety of our employees is our priority, we have established policies and procedures aimed at reducing the risk of workplace injuries, and we provide regular training to all personnel on workplace safety. In 2025 and 2024, we had 10 and 16 recordable injuries, respectively.

Access and Affordability

Our top priority is the health of patients. We believe no one should have to sacrifice their health due to financial considerations or other reasons. We work hard to provide patients with access to quality diagnostic testing, regardless of their economic status. We provide numerous flexible and affordable pay options, which include: acceptance of commercial insurance plans; availability of cash pricing at a discounted rate to make our tests more accessible; financial assistance resources based on various criteria for patients who are insured with commercial insurance but need additional financial help; a self-pay option for patients who do not meet insurance coverage policies for testing, have high-deductible plans, or have no insurance coverage; and our Compassionate Care Program, which offers financial assistance and non-interest payment plans for patients in the United States with no medical insurance and limited financial resources.

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 our stockholders immediately following the Reorganization.

Our headquarters are located at 4399 Santa Anita Avenue, El Monte, California 91731. 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. The SEC maintains an internet site that contains reports, proxy and information statements, and other information regarding issuers that file electronically with the SEC at *www.sec.gov*.

Item 1A. Risk Factors.

Summary of 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.

Cybersecurity Risks

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

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 regain or sustain profitability.
- 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 liabilities as a result of our acquisitions, including liabilities not reflected or contemplated in the financial statements of these acquired businesses.
- Our mix of customers fluctuates from period to period, and our revenue is often concentrated among a single large customer or a small number of larger customers, and the loss of or a reduction in sales to these customers could materially harm our business and results of operations.
- If any of our laboratory facilities become inoperable or inaccessible, if we are forced to vacate a facility, or if we are unable to obtain additional laboratory space as and when needed, we may be unable to perform our tests or maintain desired turnaround times, and our business and results of operations could 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, material failures to implement new or enhanced systems and/or cybersecurity breaches or attacks, 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. If we raise funds by issuing equity securities, our stockholders may experience substantial dilution.
- Impairment charges relating to our goodwill and intangible assets could negatively affect our financial performance.

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 tests and testing services could result in significant monetary damages and penalties and exclusion from the Medicare and Medicaid programs and corresponding foreign reimbursement programs. We are also subject to governmental audits and investigations, such as the HRSA Audit and CIDs, that could result in material refunds or settlements. Our business, prospects, and financial condition may be adversely affected as the result of the HRSA Audit and CIDs.

Regulatory Risks

- Any changes in federal laws, regulations or enforcement policies with respect to the marketing of clinical laboratory tests, 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 and 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 have and may again be required to modify our business practices, pay fines, incur significant expenses, or experience losses due to litigation, governmental investigations, or as a result of voluntary disclosure processes.

Risks Related to the Development of Product Candidates

- Our product candidates are in early stages of development and may fail or suffer delays that materially and adversely affect their future commercial viability.
- Any product candidate that we 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, non-clinical testing, performance of clinical trials, manufacturing, and post-approval commercialization and will also 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 accelerated approval, is unpredictable but typically requires up to several years and may never be obtained.

Intellectual Property Risks

- If we are unable to obtain and maintain patent protection for any product candidate we develop, our competitors could develop and commercialize products or technology similar to ours, and our ability to successfully commercialize any product candidate we may develop, and our technology, may be adversely affected.
- We rely on trade secret protection, non-disclosure agreements, and invention assignment agreements to protect our proprietary information, which may not ultimately 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 product candidates.
- We may be subject to claims challenging the inventorship of our patents and other intellectual property.
- Developments in patent law could have a negative impact on our business.
- Obtaining and maintaining our patent protection depends on compliance with various procedures, document submission, fee payment, and other requirements imposed by government patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.
- Our future issued patents covering product candidates we develop could be found invalid or unenforceable if challenged in court or before administrative bodies in the United States or abroad.
- Patent terms may be inadequate to protect the competitive position of our products and services for an adequate amount of time.
- If we do not obtain patent term extension and/or data exclusivity for any product candidate that we may develop, our business may be materially harmed.
- We may not be able to enforce our intellectual property rights outside the United States.
- Third parties may assert that our employees or consultants have wrongfully used or disclosed confidential information or misappropriated trade secrets.

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 stockholders could lose all or part of their 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.

Cybersecurity Risks

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

In the ordinary course of our business, we generate, collect, and store sensitive data, including personal health information, or PHI; personally identifiable information; intellectual property and proprietary and other business-critical information, such as research and development data, commercial data, and other business and financial information. We manage, maintain, collect, and store data utilizing a combination of on-site systems and cloud 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, 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. While we perform regular audits of our information systems security, we cannot audit our vendors, suppliers, and customers' systems in the same way and cannot monitor containment or the spread of malware on those systems, with a potential adverse impact on our systems.

On occasion, we do encounter attempted security incidents. To date, these incidents have not materially affected our business. While we are not currently aware of any cyber breaches, attacks, malicious software, or hardware that would materially and adversely affect our business, such a security incident could be present in any of our or our subsidiaries' systems or in the systems of our suppliers, customers, vendors, or contractors. When discovered, these incidents could cause us to suffer a material data breach. 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."

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; whether large customers continue to order our tests; general price degradation for our tests and testing services or other competitive factors; the rate and timing of our billings and collections; weather conditions; our ability to obtain reimbursement for our tests from insurance payors; our ability to maintain a broad and flexible testing menu; the timing and amount of our commitments and other payments; and exchange rate fluctuations, 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. The 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 regain or sustain profitability.

We have a history of losses, and we may not again be profitable in any future periods. Further, our revenue levels may not grow at historical rates or at all. We may incur additional losses in the future. Any losses would have an adverse effect on our stockholders' equity and working capital, which could negatively impact our operations and stockholders' investment in our company. A failure to sustain or grow our revenue levels or to regain profitability may negatively affect our business, financial condition, results of operations, cash flows, and the market price of our common stock.

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 liabilities as a result of our acquisitions, including liabilities not reflected or contemplated in the financial statements of these acquired businesses.

Our ability to integrate any organizations or technology that we may acquire 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;
- failure of an acquired business to perform as originally expected;
- possible impairment of relationships with employees and clients as a result of any integration of new businesses and management personnel;
- impairment of goodwill, such as the impairment charge we incurred in the fourth quarter of 2023;
- 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.

In particular, we have based our revenue projections on the timely and successful completion of the Bako Diagnostics and StrataDx acquisitions (which is subject to the risks discussed above), and on these businesses performing as expected following closing. If we are unable to successfully integrate these businesses, for the reasons above or for any reason, our expectations and projections concerning these businesses could ultimately be wrong. 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. 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. Further, the acquisition and integration of businesses may not be managed effectively, and any failure to manage the integration process could lead to disruptions in our overall activities, 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. These circumstances could materially harm our business, results of operations, and prospects.

We have previously acquired, and may again in the future acquire, businesses or assets, form joint ventures, make investments in other companies and technologies, or establish other strategic relationships, any of which could harm our operating results or dilute our stockholders' ownership. These transactions may be subject to federal and state anti-trust laws and regulations, and any failure to comply, or alleged failure to comply, with these laws and regulations, may adversely affect our business, operating results and prospects.

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 Cytometry Specialist, Inc., or CSI; Fulgent Pharma; Symphony Buyer, Inc., or Inform Diagnostics; and ANP), 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, collaborations, or licensing arrangements. To the extent these financing transactions call for the issuance of shares of our capital stock, our existing stockholders 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 below 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. If we raise funds by issuing equity securities, our stockholders may experience substantial dilution." 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 and that could harm our prospects. If we raise funds by issuing equity securities, our stockholders may experience substantial dilution.

Any acquisitions we may currently have in progress, including in our acquisition of Dermatopathology Experts, LLC (a.k.a. StrataDx) and of certain assets of Bako Pathology Holdings, Inc. and its affiliates (a.k.a. Bako Diagnostics), are subject to a number of closing conditions, which may not occur or be fulfilled. We may ultimately fail to close acquisitions in progress as of the date of this Annual Report, or these acquisitions may close later than we expect. Our acquisitions of laboratory and healthcare regulated entities and businesses, such as our anticipated acquisition of StrataDx and of certain assets of Bako Diagnostics, are subject to review by various state regulatory agencies and entities, and our consummation of future acquisitions may be delayed and may further encounter scrutiny under federal and state antitrust laws. In particular, our future acquisitions may be subject to notification under the Hart-Scott Rodino Antitrust Improvements Act of 1976 and to a waiting period and possible review by the DOJ and the FTC or additional waiting periods mandated by various state regulatory agencies. Any delays, injunctions, conditions or modifications by any of these federal or state agencies could have a negative effect on us and result in the abandonment of all or part of these acquisitions or otherwise attractive acquisition opportunities. In recent years, a number of states have also adopted health care transaction review laws aimed at increased transparency and health care market oversight. When triggered, these laws require significant time and resources, which could further delay future acquisitions. There can be no assurance as to the cost, scope or impact on our business, results of operations, financial condition or prospects of the actions that may be required to obtain regulatory approvals. Further, even following completion of an acquisition, applicable government agencies may disagree with our interpretation of complicated applicable statutes and regulations. These disagreements, violations, or alleged violations could result in significant civil or criminal penalties and/or equitable actions not in our favor. Any such circumstances, delayed closings, failures to close acquisitions in progress, violations, or alleged violations could have a material adverse effect on our business and substantially diminish the synergies and other advantages which we expect from such acquisition.

Our mix of customers fluctuates from period to period, and our revenue is often concentrated among a single large customer or a small number of customers, and the loss of or a reduction in sales to these customers could materially harm our business and results of operations.

The composition and concentration of our customer base often fluctuates from period to period, and in certain prior periods, a small number of customers, or a single large customer has 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 of our laboratory customers contributed $70.8 million or 22% of our total revenue during the year ended December 31, 2025. We continue to see significant concentration in this single large customer. For this laboratory customer, and for our 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 began to see lower than anticipated testing volume from this large customer in the fourth quarter of 2025, and going forward, we expect reduced revenues from this large laboratory customer in 2026 (particularly through the second quarter of 2026) as this customer begins performing certain tests and testing services internally, rather than purchasing these tests and testing services from us. We believe we may be able to offset, or partially offset, this decrease in revenues from this laboratory customer through the development of existing customers, or by capturing new customers (including through the Bako Diagnostics and Strata Dx acquisitions), but these efforts may not be successful. Our traditional laboratory and testing services customers can also experience significant volatility in their testing demand from period to period in the ordinary course of their operations or in periods of distress.

As an example, during 2023 and 2024, several projects for our BioPharma services clients were scaled back or terminated; and during 2024 and 2025, some of our laboratory services customers went into bankruptcy. This was primarily due to those clients experiencing significant financial distress, undergoing restructuring, shifting their focus, reacting to changing market dynamics, or concluding large clinical trials. We have also experienced recent growth in demand from fertility clinics and other laboratory customers as a result of our Beacon Expanded Carrier, or Beacon screen. However, if demand for IVF or other assisted reproductive technologies declines, demand for our Beacon tests and services may also decline. In light of the overturning of *Roe v. Wade*, the recent political climate and state court decisions, there is uncertainty regarding the potential regulatory treatment of embryos, which may cause demand for IVF, or other assisted reproductive technologies, to decline or to decline in certain jurisdictions. We believe some of these fluctuations in customer demand may be attributable, in part, to the nature of our business. Demand fluctuations, particularly for any large customers, often have a significant impact on our period-to-period performance regardless of their cause. Our ability to maintain or increase sales to our existing customers also 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 businesses in very competitive and evolving fields. While we believe that we compare favorably to these competitors, some of our competitors may have technical, competitive, marketing, 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 these advantages.

More specifically, many of our competitors have longer operating histories, larger customer bases, larger research and development staffs, more expansive brand recognition, established manufacturing capabilities and facilities, deeper market penetration, substantially greater financial, technological, and research and development resources and selling and marketing capabilities with established sales forces; and considerably more leverage and experience dealing with insurance 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, product candidates, and tests; create and implement more successful strategies for the promotion and sale of their tests; obtain more favorable results from insurance 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, which may result in even more resources being concentrated among our competitors. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. Our laboratory services 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, laboratory, 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. With respect to our Fulgent Pharma research and development business, these competitors also compete with us in recruiting and retaining top qualified scientific and management personnel and establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs. Commercial opportunities for our product candidates could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, less expensive, more convenient or easier to administer, or have fewer or less severe side effects than any products or product candidates that we may develop. Our competitors also may obtain FDA, European Medicines Agency, or EMA, or other regulatory approval for their products more rapidly than we may obtain approval for our products or product candidates, which could result in our competitors establishing a strong market position before we are able to enter the market. Even if our product candidates achieve marketing approval, they may be priced at a significant premium over competitive products if any have been approved by then. The key competitive factors affecting the success of our product candidates are likely to be their efficacy, safety, and availability of reimbursement, and products or product candidates may compare more favorably than our product candidates. We may not be able to compete effectively against competitive organizations. If we are unable to compete effectively, this could have a material adverse effect on our business and results of operations.

If any of 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 may be unable to perform our tests, maintain desired turnaround times and our business and results of operations could be harmed.

We perform our tests at our CLIA-certified laboratories in El Monte, California; Coppell, Texas; Needham, Massachusetts; Phoenix, Arizona; and Alpharetta, Georgia. 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 severe weather events, 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 adversely affected turnaround times, 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 are amplified as we maintain laboratory space outside the United States. 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, provide test results within acceptable turnaround times, 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 from the United States and outside the United States, 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), labor strikes, work stoppages, or boycotts, pandemics or epidemics, terrorist acts or threats, force majeure events, or for other reasons, could adversely affect specimen integrity and our ability to process specimens in a timely manner, provide test results within acceptable turnaround times and otherwise service our customers. These circumstances could 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, material failures to implement new or enhanced systems and/or cybersecurity breaches or attacks, 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. 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, social engineering, and other means to compromise the confidentiality, integrity, and availability of our information technology 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 materially 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 any 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 and various other equipment and materials we use in our laboratory operations. In particular, we rely on Illumina 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 Leica Biosystems for an automated digital scanning solution to scale up the digital pathology operations; 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; our anticipated turnaround times or ability to deliver our testing services in a timely manner could be adversely impacted; our development efforts may be delayed or interrupted; 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 Chairperson of our board of directors; Paul Kim, our Chief Financial Officer; Dr. Hanlin Gao, our Chief Scientific Officer and Laboratory Director; and Jian Xie, our President and Chief Operating Officer. Additionally, the success of our Fulgent Pharma business depends in large part on the skill, experience, and performance of Dr. Ray Yin, its President and Chief Scientific 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, and advance our research and development efforts with Fulgent Pharma. All of our executives and employees, including Messrs. Hsieh, Kim, and Xie; Dr. Yin; 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, professional liability, malpractice, 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, access to fertility services has been a politically controversial topic, and we may again be subject to negative publicity in connection with our testing services provided to fertility clinics or provided in support of assisted reproductive technology. 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 or testing services, 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, diagnostic and testing service offerings and to develop and sell new tests, diagnostic services 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 or services we may develop; in expanding into any new or existing markets; and, even if we are successful, the demand for our tests, diagnostic or testing services could decrease or may not continue to increase at historical rates. Development of new tests, diagnostic and testing services is time-consuming and costly, as development and marketing of new tests, diagnostic and testing services often requires us to conduct research and development activities regarding the new tests, diagnostic and testing services 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, diagnostic or testing services 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 insurance 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 or testing services could negatively impact our ability to attract and retain customers, our revenue, and prospects.

Our development and use of AI presents risks and challenges that can impact our business, including by posing security risks to our confidential information, proprietary information, and personal data and could give rise to legal and/or regulatory actions, damage our reputation, or otherwise materially harm our business.

AI is increasingly being used in the biopharmaceutical, pharmaceutical, technology, and consumer health industries. We evaluate different AI technologies and identify areas where we can apply AI to improve our operations. We have developed and incorporated AI technology in certain of our testing and services, including for digital pathology. Issues relating to the use of new and evolving technologies such as AI, machine learning, generative AI, and large language models, may cause us to experience perceived or actual brand or reputational harm, technical harm, competitive harm, legal liability, cybersecurity risks, privacy risks, compliance risks, security risks, ethical issues, and new or enhanced governmental or regulatory scrutiny; and we may incur additional costs to resolve such issues. Litigation or government regulation related to the use of AI may also adversely impact our ability to develop and offer tests and services that use AI, as well as increase the cost and complexity of doing so. In addition, uncertainties regarding developing legal and regulatory requirements and standards may require significant resources to modify and maintain business practices to comply with U.S. and non-U.S. laws concerning the use of AI, the nature of which cannot be determined at this time. In addition, the European Union's AI Act entered into force in August 2024 and, with some exceptions, will be fully effective by August of 2026, and in the United States, the 2023 Executive Order concerning AI influences federal rule-making applicable regulations. Further, market demand and acceptance of AI technologies are uncertain, and we may be unsuccessful in our product development efforts.

As necessary, we have developed policies governing the use of AI to encourage appropriate use of AI by our employees, contractors, and authorized agents and that our assets, including intellectual property, competitive information, personal information we may collect or process, and customer information, are protected. Any failure by our personnel, contractors, or other agents to adhere to any policies that we may establish could violate confidentiality obligations or applicable laws and regulations, jeopardize our intellectual property rights, cause or contribute to unlawful discrimination, or result in the misuse of personally identifiable information or the injection of malware into our systems, any of which could have a material adverse effect on our business, results of operations, and financial condition.

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 we expand our direct test sales in other countries, we are increasingly subject to varied and complex foreign and international laws and regulations, and as part of our expansion strategy, we aim to conduct targeted marketing outreach activities and, if opportunities arise, engage distributors or establish 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, tariffs, 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 United States and local laws and regulations, such as export and import permit requirements or 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;
- inflationary pressures, such as those the global market is currently experiencing, which have and may increase costs for materials, supplies, and services;
- exposure to foreign currency exchange rate fluctuations, conversions of currencies, and the risk of repatriation of certain foreign currencies;
- natural disasters; political and economic instability, including wars, terrorism and political unrest, such as conflicts in Ukraine and the Middle East and tensions between China and Taiwan; 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. Our international business activities are subject to U.S. economic and trade sanctions, which restrict or otherwise limit our ability to do business in certain designated countries.

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; trade wars and tariffs; local differences in customer demands and preferences and the regulatory environment and regulatory requirements; the interpretation or enforcement of laws, regulations, and rules in China 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.

We could face substantial liabilities that exceed our resources for litigation relating to product or professional liability.

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 or pathology services and testing that often rely on human interpretation. Substantial judgment is often required in order to interpret the results of each test we perform and to produce a report summarizing these results. This is particularly true for our pathology testing services. 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, abnormal cells or to detect disease, subject us to product liability and professional liability claims. These claims against us could result in substantial damages that materially and adversely affect our results of operations and are costly and time-consuming to defend. Although we maintain liability insurance, including for errors and omissions, our insurance may not fully protect us from a material and adverse financial impact arising out of defending against these types of claims or any judgments, fines, or settlement costs arising out of any such claims. As an example, we recorded an accrual of $14.5 million in connection with the settlement of a professional liability matter further described in Note 8, *Debt, Commitments and Contingencies* of our consolidated financial statements included in this Annual Report for which we may receive partial coverage from our liability insurance, subject to customary retentions, exclusions and limits. Any liability claim brought against us, with or without merit, could materially increase our insurance rates or prevent us from securing adequate insurance coverage in the future. Moreover, any liability lawsuit could materially 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 involves the testing of our product candidates on patients in clinical trials and will continue to involve the additional testing of our product candidates on patients in the future. 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 product candidates, which could materially and 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. If we raise funds by issuing equity securities, our stockholders may experience substantial dilution.

As of December 31, 2025, we had cash, cash equivalents, and marketable securities of approximately $705.5 million. 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. 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. 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 has and may again materially and adversely affect us by materially increasing our costs.

In recent years, inflation has increased throughout the U.S. economy. Inflation has adversely affected us and may again 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 have and may again 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 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. We have incurred and expect to continue to incur significant expenses and devote substantial management effort toward compliance with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act. Although we have implemented systems, processes and controls and performed this evaluation as of the end of 2025, 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, which will increase our operating expenses.

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, 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 maintain cash deposits in excess of federally insured limits. Adverse developments affecting financial institutions, including bank failures, could adversely affect our liquidity and financial performance.

We maintain our cash, cash equivalents, and marketable securities with high quality, accredited financial institutions. However, some of these accounts exceed the Federal Deposit Insurance Corporation, or FDIC, insurance limit of $250,000 and, while we believe the Company is not exposed to significant credit risk due to the financial strength of these depository institutions or investments, if any such depository institution fails to return our deposits, or if a depository institution is subject to other adverse conditions in the financial or credit markets, this could further impact access to our invested cash or cash equivalents and could adversely impact our operating liquidity and financial performance. Further, 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 have been the subject of a stockholder class action, which was dismissed without prejudice; and we may be subject to further stockholder 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, including stockholder litigation. These proceedings may not always resolve in our favor and may materially and adversely affect our business. Regardless of outcome, litigation can have an adverse impact on us due to defense and settlement costs, diversion of management resources, negative publicity, and reputational harm, among other factors.

Political uncertainty may have an adverse impact on our operating performance and results of operations.

General political uncertainty within the United States and foreign jurisdictions may have an adverse impact on our operating performance and results of operations. The global economy may be adversely affected by the current or anticipated impact of political uncertainty, including military conflicts, such as the ongoing conflicts between Russia and Ukraine, and Israel and Hamas, terrorism, or other geopolitical events. Changing regulatory policies resulting from the changing political environment could impact our regulatory and compliance costs and future revenues, all of which could materially and adversely affect our business, financial condition, and operating results. In particular, the United States continues to experience significant political events that cast uncertainty on global financial and economic markets. It is presently unclear as to all of the actions the current administration in the United States will implement, and if implemented, how these actions may impact us or how we operate in the United States or the pharmaceutical and diagnostics industries in the United States. In addition, the current administration may institute significant changes to certain federal regulatory agencies, including the IRS, FDA, DOJ, and SEC, such as reductions in funding levels or restructuring of such agencies that could adversely impact us. Any actions taken by the current administration, including the many recent executive orders, may have a negative impact on the United States economies and on our business, financial conditions, and results of operations.

Impairment charges relating to our goodwill and intangible assets could negatively affect our financial performance.

We are pursuing and may again in the future pursue acquisitions of complementary businesses or assets, and we may not realize all the economic benefit from those acquisitions, which could cause an impairment of goodwill or intangibles. We assess goodwill and indefinite-lived intangible assets for impairment at least annually or whenever events or changes in circumstances indicate the carrying value may not be recoverable. Events and conditions that could result in an impairment of our goodwill and intangible assets include a decline in our stock price and market capitalization, reduced future cash flow estimates, slower growth rates in industry segments in which we participate, or other factors leading to reduction in expected long-term growth or profitability. We may be required to record a significant charge in our consolidated financial statements during the period in which any impairment of our goodwill or amortizable intangible assets is determined, which may negatively affect our financial condition and results of operations. For example, during our fiscal 2023 annual goodwill impairment analysis, we fully impaired goodwill of $71.8 million associated with the acquisition of Inform Diagnostics, $27.5 million associated with the acquisition of CSI, and $21.0 million associated with the restructuring of Fujian Fujun Gene Biotech Co., Ltd., or FF Gene Biotech, which was principally driven by a sustained decline in our market price and capitalization.

Changes in financial accounting standards or practices may cause adverse, unexpected financial reporting fluctuations and affect our reported operating results.

Accounting principles generally accepted in the United States, or U.S. GAAP, is subject to interpretation and modification by the Financial Accounting Standards Board, or FASB, the SEC, and various bodies formed to promulgate and interpret appropriate accounting principles. A change in accounting standards or practices can have a significant effect on our reported results and may even affect our reporting of transactions completed before the change is effective. New accounting pronouncements and varying interpretations of accounting pronouncements have occurred and may occur in the future. Changes to existing rules or the questioning of current practices may adversely affect our reported financial results or the way we conduct our business.

We incur costs and demands upon management as a result of complying with the laws and regulations affecting public companies in the United States, which may adversely affect our operating results.

As a public company listed in the United States, we incur significant additional legal, accounting, and other expenses. In addition, changing laws, regulations and standards relating to corporate governance and public disclosure, including regulations implemented by the SEC and The Nasdaq Stock Market LLC, may increase legal and financial compliance costs and make some activities more time-consuming. These laws, regulations and standards are subject to varying interpretations, and as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. We invest resources to comply with evolving laws, regulations and standards, and this investment may result in increased general and administrative expenses and a diversion of management's time and attention from revenue-generating activities to compliance activities. If, notwithstanding our efforts to comply with these laws, regulations and standards, we fail to comply, regulatory authorities may initiate legal proceedings against us, and our business may be harmed.

Further, if we fail to comply with these laws, regulations and standards, it might also be more difficult for us to obtain certain types of insurance, including director and officer liability insurance, and we might be forced to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. The impact of these events could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, on committees of our board of directors, or as members of senior management.

U.S. federal government contracts are generally subject to terms more favorable to the customer than commercial contracts. If the U.S. federal government significantly decreased or ceased doing business with us, our business, financial condition, and results of operations would be materially and adversely affected.

In 2024, we were awarded a contract by the U.S. Department of Veterans Affairs, or VA, to provide hereditary cancer, pharmacogenetic and other genetic testing to veterans and to their family members. We are also party to a number of other government contracts.

U.S. federal government contracts, including our contract with the VA, generally contain provisions and are subject to laws and regulations that give the federal government rights and remedies not typically found in commercial contracts, including provisions permitting the federal government to:

- terminate our existing contracts;
- reduce potential future income from our existing contracts;
- modify some of the terms and conditions in our existing contracts;
- suspend or permanently prohibit us from doing business with the federal government or with any specific government agency;
- impose fines and penalties;
- subject the award of some contracts to protest or challenge by competitors, which may require the contracting federal agency or department to suspend our performance pending the outcome of the protest or challenge and which may also require the government to solicit new proposals for the contract or result in the termination, reduction or modification of the awarded contract; and
- decline to exercise an option to extend an existing multiple year contract.

The U.S. federal government may also terminate a contract either "for convenience" (for instance, due to a change in its perceived needs or its desire to consolidate work under another contract) or if a default occurs by failing to perform under the contract. If the federal government terminates a contract for convenience, we generally would be entitled to recover only our incurred or

committed costs, settlement expenses, and profit on the work completed prior to termination. If the federal government terminates a contract based upon a default, we generally would be denied any recovery for undelivered work, and instead may be liable for excess costs incurred by the federal government in procuring undelivered items from an alternative source and other damages as authorized by law. In addition, many government contracts are awarded through a rigorous competitive process, which may emphasize price over other qualitative factors. The U.S. federal government has increasingly relied upon multiple-year contracts with multiple contractors that generally require those contractors to engage in an additional competitive procurement process for each task order issued under a contract. This process may result in us facing significant additional pricing pressure and uncertainty and incurring additional costs. Further, to the extent our performance under a contract does not meet a government agency's expectations, the customer might seek to terminate the contract prior to its scheduled expiration date, provide a negative assessment of our performance to government-maintained contractor past-performance data repositories, fail to award us additional business under existing contracts or otherwise, direct future business to our competitors, or suspend or debar us from contracting with the federal government or any significant agency, including the VA. These various uncertainties, restrictions, and regulations by government authorities as well as profit and cost controls, could have a material adverse impact on our business, financial condition, and results of operations.

Our tax returns and positions are currently, and may again in the future be, subject to review and audit by the Internal Revenue Service, or the IRS, and other tax authorities, and any adverse outcomes resulting from any examination of our tax returns could adversely affect our liquidity and financial condition.

We are currently under tax audit by the IRS and other state and local authorities and may again in the future be subject to further tax audits by these authorities. The positions taken in our U.S. federal, state and local income tax return filings require significant judgments and the interpretation and application of complex tax laws. Our income tax returns are subject to examination by the IRS and other tax authorities. While we believe our tax return positions are proper and supportable, these judgments and interpretations are under review during an audit. An unfavorable outcome of any current or future tax audit could result in our need to utilize available cash to satisfy such tax liabilities and any interest or penalties thereon rather than for our business operations. As a result, the occurrence of an unfavorable outcome with respect to any future tax audit could have a material adverse effect on our liquidity and financial condition.

Reimbursement Risks

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

If insurance payors do not provide coverage and adequate reimbursement for our tests and 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 insurance payors, including managed care organizations, other 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 insurance 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 insurance 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 insurance 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 insurance payors.

Coverage and reimbursement by an insurance payor depend 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 the 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 insurance 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 result in 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 cannot obtain sufficient clinical information in support of our tests, insurance 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 insurance 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 insurance payors 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 insurance 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 physician or other practitioner 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 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 insurance 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.

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.

Failure to comply with government laws and regulations related to submission of claims for our tests and testing services could result in significant monetary damages and penalties and exclusion from the Medicare and Medicaid programs and corresponding foreign reimbursement programs. We are also subject to governmental audits and investigations that could result in material refunds or settlement. Our business, prospects and financial condition may be adversely affected as the result of the HRSA Audit and CIDs.

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, HRSA, and other state, federal and foreign healthcare programs; the amounts that we may bill for our services; and the party to which we must submit claims. Our failure to comply with applicable laws and regulations could result in our inability to receive payment for our services or in attempts by state and federal healthcare programs, such as HRSA, Medicare and Medicaid, to recover payments already made. Submission of claims in violation of these laws and regulations, identified through an audit or through the Company's control processes, can result, as noted above, in recoupment of payments already received, substantial civil monetary penalties, and exclusion from state and federal healthcare 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 programs within 60 days of identifying its existence also 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. We have received a CID issued by the DOJ 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. Among other things, this CID requests information and records relating to certain of the Company's customers named in this CID. Certain of the Company's executive officers and employees have also received CIDs relating to these matters. Similar to other laboratories in the industry, the Company responded to an audit inquiry by HRSA with respect to its reimbursement for COVID-19 tests furnished to patients believed to be uninsured pursuant to HRSA's Uninsured Program, which covered COVID-19 testing during the pandemic. We have fully cooperated with HRSA's auditors and provided all requested information. As of the date of this Annual Report, the Company has not received any final audit results from HRSA for this audit. There is uncertainty with respect to the methodology HRSA will use and whether and how HRSA will extrapolate audit results. We have also received a CID issued by the DOJ related to the DOJ's investigation as to whether we submitted or caused to be submitted false claims to HRSA's Uninsured Program and, as noted below, in February 2026, a qui tam claim related to our reimbursement for COVID-19 testing was unsealed and subsequently dismissed. We are fully cooperating with the DOJ in connection with the CIDs that we, or our employees, have received.

We cannot currently predict when these CIDs and HRSA audit matters will be resolved, the reasonable or likely outcome of these matters, or their potential impact, which may materially and adversely affect our business, prospects, and financial condition. Discussions and investigations remain ongoing. As such, we cannot reasonably estimate the loss or range of loss, if any, that may result from any material government investigations, audits, claims, and reviews in which we are currently involved, given the inherent difficulty in predicting regulatory action, fines and penalties, if any, and the various remedies and levels of judicial review available to us in the event of an adverse finding.

See "*Contingencies*" in Note 8, *Debt, Commitments and Contingencies*, for additional information.

Billing and collection 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 face increasing risks 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 collection functions and have contracted with third-party providers as needed to assist in our collection efforts, but these systems and internal and external collection functions may fail or may fail to operate as we intend, particularly as billing for many of our tests from insurance payors is a very complex process. As a result, these billing complexities, along with the related uncertainty in obtaining payment for our tests, could negatively affect our revenue and cash flows, 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 federal laws, regulations, or enforcement policies with respect to the marketing of clinical laboratory tests, 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, are extremely complex, and in many instances, have no significant regulatory or judicial interpretations of these laws and regulations. Pursuant to its authority under the FDC Act, the FDA has jurisdiction over medical devices, including IVDs, which are defined in the FDA's implementing regulations as devices intended for use in the collection, preparation, and examination of specimens taken from the human body. The FDA regulates the research, testing, manufacturing, safety, labeling, storage, recordkeeping, pre-market clearance or approval, marketing and promotion, and sales and distribution of IVDs and medical devices in the United States to ensure that such products distributed domestically are safe and effective for their intended uses. In addition, the FDA regulates the import and export of medical devices, including IVDs. Many of the instruments, reagents, kits, and other consumable products used within our laboratories are regulated as medical devices and therefore must comply with FDA quality system regulations and certain other device requirements.

We believe all of our tests that have been commercialized in the United States fall within the definition of laboratory developed tests, or LDTs. LDTs are diagnostic tests that are intended for clinical use and are designed, manufactured, and used within a single laboratory. The FDA had historically exercised enforcement discretion and not enforced the FDC Act and regulations with respect to LDTs, which the agency asserted were effectively a subset of IVDs. However, in May 2024, the FDA issued a final rule aimed at regulating LDTs under the medical device framework and phasing out its longstanding enforcement discretion policy for this category of diagnostic tests over several years; the final rule became effective on July 5, 2024, and was expected to begin entering into force against non-exempt "LDT manufacturers" in May 2025.

In May 2024, ACLA and one of its members filed a complaint against the FDA in the Eastern District of Texas, alleging that the agency did not have authority to promulgate the LDT final rule and seeking to vacate the FDA's action. A second lawsuit was also

filed against the FDA by AMP and one of its members in the Southern District of Texas, and subsequently the two cases were consolidated into a single action in the Eastern District of Texas. On March 31, 2025, the U.S. District Court for the Eastern District of Texas vacated the final rule in its entirety and remanded the matter to the FDA, holding that the rule exceeded the agency's authority under the FDC Act. The FDA did not appeal the district court's decision. As a result, the phase-in deadlines established by the rule are no longer operative, and in September 2025 the FDA implemented the court's vacatur of the final rule with a formal public notice.

The court's decision removes the regulatory burden that the final rule would have imposed on laboratories such as ours had it been upheld. However, uncertainty remains regarding the future of federal oversight in this area, as Congress could enact new legislation establishing a statutory framework for regulating all IVDs, including LDTs. Affected stakeholders continue to press for a comprehensive legislative solution to create a harmonized paradigm for oversight of LDTs by both the FDA and CMS.

If future legislative changes expand FDA's oversight to allow the agency to regulate LDTs, or if the FDA disagrees with our assessment that our tests meet the criteria to be marketed as LDTs, we could, for the first time, be subject to enforcement of a variety of regulatory requirements that are presently applicable to IVDs, including registration and listing, medical device reporting and quality control. We could also be required to obtain pre-market clearance or approval for existing tests or new tests we may develop that may meet the definition of an IVD, which may force us to cease or not begin marketing such tests until we obtain the required clearance or approval. The pre-market review process can be lengthy, expensive, time-consuming and unpredictable. Further, obtaining pre-market authorization 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. As a result, we could experience significantly increased development costs and a delay in generating additional revenue from such tests.

In addition, while we qualify the materials used in our tests and testing services in accordance with the regulations and guidelines of CLIA, the FDA could promulgate regulations or make policy decisions that may negatively impact our ability to purchase materials necessary for the performance of our tests within the laboratory. 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 diagnostic 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 healthcare programs, as well as many private insurance payors, for our tests. We have obtained CLIA certification to conduct our tests at our laboratories in El Monte, California; Coppell, Texas; Needham, Massachusetts; Phoenix, Arizona; and Alpharetta, Georgia.

In addition, 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 California. California laws establish standards for day-to-day operation of our clinical reference laboratory in 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 California 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.

We are subject to on-site routine and complaint-driven inspections under California state laboratory laws and regulations. If we are found to be out of compliance with California requirements, the CA Department of Public Health may suspend, restrict, or revoke our license or laboratory permit, and it 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 continue to expand international utilization of our tests or if jurisdictions in which we pursue operations adopt new or modified licensure requirements for U.S.-based clinical laboratories offering and providing diagnostic testing services to professionals located in those jurisdictions. 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 domestic transport or importation of human blood or other tissue necessary for us to perform our tests that may limit our ability to make our tests more widely 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.

Failure to obtain necessary foreign regulatory approvals or certifications may adversely affect our ability to expand our operations internationally.

An important part of our business strategy is to expand and offer our tests internationally, with patient specimens collected by laboratory and health care professional customers in foreign countries for processing by our California laboratory. As we continue to expand our diagnostic offerings into new markets, including in Australia, we will become increasingly subject to or impacted by the regulatory requirements of foreign jurisdictions, which are varied and complex. Our tests, and certain components of our tests, may be subject to the regulatory approval requirements in each foreign country in which they are sold by us or a laboratory partner, and our future performance may depend in part on obtaining any necessary regulatory approvals in a timely manner. For example, in July 2025, we announced that we had obtained a CE Mark from the European Commission for certain IVDs being offered to customers in Europe. We were required to secure, and must maintain, International Standards Organization certification of our quality management system to comply with the IVDR. We have also obtained National Association of Testing Authorities accreditation in Australia.

We are occasionally required to address inquiries from regulatory authorities in various countries, such as those in the European Union, regarding the regulatory status of our diagnostic test offerings. If we do not continue to satisfactorily address any such questions in the future, we may be required to cease offering our products in the relevant country. This may in turn result in similar concerns, and subsequent cessation of our sources of revenue, in other countries.

Regulatory approval can be a lengthy, expensive, and uncertain process. In addition, regulatory processes are subject to change, and new or changed regulations can result in unanticipated delays and cost increases. For example, the European Commission's modernized regulations for in vitro diagnostic products, the IVDR, became effective in May 2022. Among others, the new regulations introduce risk-based classification for IVDs and will require Notified Body involvement for various classes of devices, including certain of our tests, which will require us to submit clinical evidence and post-market performance data to regulators. On December 6, 2025, the European Commission released a proposal to amend the IVDR with the goal of simplifying the applicable rules, reducing the administrative burden on manufacturers, and enhancing the predictability and cost-effectiveness of the certification procedure while maintaining a high level of public health protections for EU patients and consumers.

We may not be able to obtain foreign regulatory approvals or authorizations for our tests on a timely basis, if at all, which may cause us to incur additional costs or prevent us from marketing our tests in certain foreign countries.

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 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 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, 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.

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. Additionally, the HIPAA Security Rule is currently undergoing a proposed update, which, if implemented, will impose more stringent security measures on covered entities.

In the ordinary course of business, we transfer personal data from Europe, Australia, and other jurisdictions to the United States or other countries and may be subject to the GDPR and UK GDPR as well as other foreign data protection laws. Europe and other jurisdictions have enacted laws requiring data to be localized or limiting the transfer of personal data to other countries and impose other restrictions on processing of sensitive personal data, including genetic information and testing. In particular, the EEA and the UK have significantly restricted the transfer of personal data to the United States and other countries whose privacy laws it generally believes are inadequate. Other jurisdictions may adopt or have already adopted similarly stringent data localization and cross-border data transfer laws. In July 2023, the European Commission adopted an adequacy decision for a new mechanism for transferring personal data from the European Union to the United States, the EU-U.S. Data Privacy Framework, which provides EU individuals with several new rights, including the right to obtain access to their data, or obtain correction or deletion of incorrect or unlawfully handled data. In addition, the EU-U.S. Data Privacy Framework offers additional redress avenues for violations, including free of charge independent dispute resolution mechanisms and an arbitration panel. The UK followed the European Commission in October of 2023 and adopted its "extension" to the EU-U.S. Data Privacy Framework. The European Commission and the UK will continually review developments in the United States along with their adequacy decisions. Adequacy decisions can be adapted or even withdrawn in the event of developments affecting the level of protection in the applicable jurisdiction. Future actions of European Union and UK data protection authorities are difficult to predict.

If there is no lawful manner for us to transfer personal data from the EEA, the UK, Australia, or other jurisdictions to the United States, or if the requirements for a legally-compliant transfer are too onerous, we could face significant adverse consequences, including the interruption or degradation of our operations at significant expense, increased exposure to regulatory actions, substantial fines and penalties, the inability to transfer data and work with partners, vendors and other third parties, and injunctions against our processing or transferring of personal data necessary to operate our business. Additionally, companies that transfer personal data out of the EEA and UK to other jurisdictions, particularly to the United States, are subject to increased scrutiny from regulators, individual litigants, and activist groups. Some European regulators have ordered certain companies to suspend or permanently cease certain transfers out of Europe for allegedly violating the GDPR's cross-border data transfer limitations. Regulators in the United States such as the Department of Justice are also increasingly scrutinizing certain personal data transfers and, effective October of 2025, the DOJ has implemented what is known as the Bulk Transfer Rule restricting transfers of bulk sensitive personal data (like health, genomic, or financial info) and U.S. government-related data to "countries of concern" (e.g., China, Russia) or related entities, focusing on national security by preventing adversary access. It requires U.S. companies to implement data security programs, audit compliance, and maintain records, with significant penalties for violations, aiming to safeguard sensitive U.S. data from foreign adversaries.

In addition, many states, such as California, have implemented similar privacy laws and regulations, such as the CMIA, 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 CMIA, California's CCPA, as amended and expanded by the CPRA, applies to personal data of consumers, business representatives and employees who are California residents and requires businesses to provide specific disclosures in privacy notices and honor requests of individuals to exercise certain privacy rights. The CCPA provides for fines and allows private litigants affected by certain data breaches to recover significant statutory damages. Among other things, the CCPA established the 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 has issued multiple enforcement actions in the past year. The CCPA could impact our operations or that of our collaborators and business partners and impose new regulatory requirements and increase costs of compliance. In addition to California, a number of other states have passed similar privacy laws. Other states are considering similar legislation, adding to the complexity, costs, and risk of compliance. Like the GDPR and CCPA, many of these state and foreign laws categorize medical or health data, genetic data, and biometric data that can be used to 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, including California, New York, and Massachusetts, have also implemented genetic testing, informed consent, or other 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.

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 that apply to medical devices and IVDs;
- federal and state laws and standards affecting reimbursement by government healthcare programs, including certain coding requirements to obtain reimbursement and certain changes to the payment mechanism for clinical laboratory services resulting from 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 healthcare program;
- the federal Stark Law, which generally prohibits a physician from making a referral for certain designated health services covered by the Medicare and Medicaid programs, including clinical 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;
- 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 healthcare benefit programs (including commercial insurers) unless a specific exception applies;
- the 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 insurance payor, including private payors;
- 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;
- 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 OIG and a variety of states' Attorneys General have issued fraud alerts regarding a variety of cancer genetic testing fraud schemes, and the DOJ has announced civil settlements, 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 insurance payors, and these activities allegedly violated the federal Anti-Kickback Statute, other criminal laws, and the federal False Claims Act. 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.

We are also subject to the "No Surprises Act" which prohibits balance billing in certain circumstances and also requires delivery of good faith estimates of expected charges to an uninsured or self-pay patient upon the patient's request or when a patient schedules a service. Civil penalties of up to $10,000 per occurrence can be imposed for knowing violations not remediated within a certain timeframe.

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. In relation to a recent advisory opinion issued by the OIG, the Company's subsidiary, Inform Diagnostics, initiated a voluntary disclosure process with the appropriate government contact. During 2024, the Company settled and paid $3.0 million in connection with this voluntary disclosure. 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, (including in connection with the voluntary disclosure process described above), we may be subject to material 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 have and may again 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, negligent testing, 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. Healthcare providers and other participants in the healthcare industry have become subject to an increasing number of lawsuits alleging professional liability or medical malpractice and related legal theories such as negligent hiring, supervision, and credentialing. As previously disclosed in our periodic reports, we have received a CID, issued by the DOJ, 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. Among other things, this CID requests information and records relating to certain of our customers named in the CID. Certain of our executive officers and employees have also received CIDs relating to these matters.

Similar to other laboratories in the industry, we received an audit request from HRSA with respect to our reimbursement for COVID-19 tests furnished to patients believed to be uninsured pursuant to the Uninsured Program. We recorded approximately $548.9 million of reimbursements from HRSA under the Uninsured Program during the years ended December 31, 2022, 2021, and 2020. There is uncertainty with respect to the methodology HRSA will use in its audit and whether and how HRSA will extrapolate audit results. The Company has fully cooperated with HRSA's auditors and provided all requested information. We have also received a CID issued by the DOJ pursuant to the False Claims Act related to the DOJ's investigation as to whether we submitted or caused to be submitted false claims to the Uninsured Program.

As is typical for companies seeking reimbursement from government payors, from time to time the Company is named as defendant in claims pursuant to the qui tam provisions of the False Claims Act and comparable state laws. Often, these proceedings remain under seal such that the Company does not have access to the specific information included in them. Seals often remain in place for extended periods of time while the U.S. government, or applicable regulatory authority, decides whether to intervene on behalf of the qui tam plaintiff. As a result, the Company may not be aware of all qui tam claims that have been filed against the Company. In or around February 2026, the United States District Court for the Central District of California unsealed a qui tam complaint (and certain related proceedings) filed against Fulgent Genetics, Inc. and Fulgent Therapeutics LLC by a qui tam plaintiff (known as a relator) on behalf of the United States. This complaint alleged that the Company filed false claims for reimbursement for COVID-19 tests in violation of the False Claims Act. The complaint was subsequently dismissed without prejudice as to the relator and the U.S. government following the U.S. government's filing of a motion to dismiss, meaning the relator and the U.S. government retained the right to refile and may refile under seal.

We are fully cooperating with the DOJ in connection with the CIDs that we or our employees have received. We cannot currently predict when these CID and HRSA audit matters will be resolved, the reasonable or likely outcome of these matters, or their potential impact, which may materially and adversely affect our business, prospects, and financial condition. Discussions and investigations remain ongoing. As such, we cannot reasonably estimate the loss or range of loss, if any, that may result from any material government investigations, audits, and reviews in which we are currently involved, given the inherent difficulty in predicting regulatory action, fines and penalties, if any, and the various remedies and levels of judicial review available to us in the event of an adverse finding. As a result, we have not recorded any liability related to these CID or audit matters.

We cannot predict when these investigations, audits, and related matters will be resolved, the outcome of the investigations and matters, or the potential impact on our business, which may ultimately be greater than we expect. Adverse developments in existing litigation claims or legal proceedings involving us or new claims could require us to establish or increase litigation reserves or enter into unfavorable settlements or satisfy judgments for monetary damages for amounts in excess of current reserves, which could adversely affect our financial results. 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 targeting 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.

The ACA has also been the focus of ongoing legal challenges that could materially affect insurance coverage for our products and services. For example, in *Braidwood Management v. Becerra*, the Fifth Circuit Court of Appeals in June 2024 upheld a lower court ruling that found the ACA's mandate requiring insurance coverage for certain preventive services without cost sharing to be unconstitutional. However, in June 2025, the U.S. Supreme Court overturned the Fifth Circuit's decision in *Braidwood Management v. Becerra* and upheld the ACA's requirement that insurance cover certain preventive services, in a ruling now captioned *Kennedy v. Braidwood Management, Inc*. Future health care reform initiatives, whether at the federal or state level, intended to reduce health care costs may instead have the effect of discouraging third-party payors from covering certain types of medical products and services.

In addition, OBBA is expected to reduce enrollments in Medicaid and state insurance exchanges under the ACA, which could limit access to insurance coverage for certain patient populations. To the extent these changes decrease the number of insured individuals or alter reimbursement rates for our products and services, our volumes and revenues could be adversely affected.

In April 2014, Congress passed PAMA, which included substantial changes to the way in which clinical laboratory services are paid under Medicare CLFS. 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 CDLTs 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.

Additionally, state legislatures have increasingly passed legislation and implemented regulations designed to control the cost of health care services, including clinical laboratory and pathology services, as well as prescription drug prices. States may pursue a variety of strategies to control spending growth in health care and pharmaceutical markets, including but not limited to promoting competition, reducing prices through regulation, imposing spending targets and promoting payment reform. These cost containment strategies may result in less favorable reimbursement rates and in some cases could negatively impact our ability to change or expand our clinical testing operations in certain states.

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. For example, since 2017, Congress has considered legislation to create an LDT and IVD regulatory framework that would be separate and distinct from the existing medical device regulatory framework.

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 "healthcare 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, consultants, 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 these laws could have a negative effect on our business.

Changes in U.S. trade policy and the impact of tariffs may have a material adverse effect on our business, results of operations, and financial condition.

While we do not believe our business has been materially affected by the recent tariff environment and recent developments in U. S. trade policy as of the date of this Annual Report, our business, results of operations, and financial condition may be adversely affected by uncertainty and changes in U.S. trade policies, including tariffs, quotas, trade agreements, or other trade restrictions imposed by the U.S. or other governments. International trade policy may continue to evolve. Several tariff announcements have been followed by announcements of limited exemptions, revisions, temporary pauses, and cancellations resulting in significant uncertainty.

While the majority of our equipment, materials and reagents are sourced in the United States, or locally where our testing services are performed or processed, our supply chain and international operations could be adversely affected by changes in U.S. trade policies. Any imposition of, or increase in, tariffs or other restrictions on imports of reagents, equipment, or other materials (or the components of these materials) could increase the cost for such materials and also increase the prices for such materials available domestically or locally, if any, which in turn could increase our costs. We would likely be unable to pass all or potentially any such cost increases on to our customers, and such cost increases could materially and adversely affect our business, results of operations, and financial condition, including our gross margins. Tariffs or other trade restrictions may lead to continuing uncertainty and volatility in U.S. and global financial and economic conditions and commodity markets, declining consumer confidence, significant inflation, and diminished expectations for the economy. Such conditions could also have a material adverse impact on our business, results of operations, and financial position.

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 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. If the Chinese government determines that our joint venture does not comply with applicable regulations, our business could be adversely affected. If the regulatory agencies of the People's Republic of China, or the PRC, determine that the agreements that establish the structure and relationship for our operations in China do not comply with PRC regulatory restrictions on foreign investment, we could be subject to severe penalties.

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. Trade policies between the United States and China continue to evolve. We may be materially and adversely affected by changes in international trade policy between the United States and China.

Additionally, 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 U.S. 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.

In addition, there are uncertainties regarding the interpretation and application of PRC laws, rules, and regulations, including, but not limited to, the laws, rules and regulations governing the validity and enforcement of our joint venture in China. Because many laws and regulations are relatively new, the interpretations of many laws, regulations and rules are not always uniform. Moreover, the interpretation of statutes and regulations may be subject to government policies reflecting domestic political agendas. Enforcement of existing laws or contracts based on existing law may be uncertain and sporadic. We cannot assure stockholders that the PRC regulatory authorities will not determine that our joint venture in China does not violate PRC laws, rules, or regulations. If the PRC regulatory authorities determine that our current joint venture or any joint ventures, we may enter into in the future are in violation of applicable PRC laws, rules or regulations, our joint venture in China may become invalid or unenforceable, which will substantially affect our operations adversely. The PRC has broad discretion in dealing with violations of laws and regulations, including levying fines, revoking business and other licenses, and requiring actions necessary for compliance. In particular, licenses and permits issued or granted by relevant governmental agencies may be revoked at a later time by other regulatory agencies. We cannot predict the effect of the interpretation of existing or new PRC laws or regulations on our business. Any of these or similar actions could significantly disrupt our operations or restrict us from conducting a substantial portion of our operations, which could materially and adversely affect our business, financial condition, and results of operations. There can be no assurance that the United States government will refrain from imposing additional restrictions or constraints on dealings or investments in China, including our joint venture.

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. 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.

In the United States, our advertising for laboratory services is subject to federal truth-in-advertising laws enforced by the FTC, as well as comparable state consumer protection agencies under similarly broad state 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 recent years, some companies and individuals have become more aggressive in attempting to assert consumer protection-type causes of action against competitors based on their advertising claims or promotional activities. In conjunction with the launch of our Picture Genetics line of at-home genetic test offerings that are initiated by consumers, we increased our advertising activities that would be subject to 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.

Outside of the United States, the legal landscape governing promotional and other marketing activities for professional laboratory services and diagnostic tests can vary widely from jurisdiction to jurisdiction, and is often more complex, less clear, or less developed than in the United States. For example, in Australia, complex laws and regulations, including the Australian Consumer Law, the Therapeutic Goods Act (with respect to devices and collection kits), and in some instances, the Health Practitioner Regulation National Law, regulate the advertising of laboratory tests, testing services, and collection devices. The penalties for violating these regulatory requirements can be severe. If our marketing activities are found to be in violation of these or other local laws, regulations or practices, we may be subject to fines and other penalties and may be required to cease marketing or commercialization activities in such jurisdiction.

Even if we receive regulatory approval or certification of our IVD medical device products, we will continue to be subject to extensive regulatory oversight.

Medical devices, including IVDs, are subject to extensive regulation by the FDA in the United States, the European authorities under the CE Mark process, and comparable regulatory agencies in other territories where we do business such as Japan and Taiwan. If any of our IVD products are approved by the FDA or other comparable foreign regulatory agencies or certified by Notified Bodies, we will be required to timely file various reports. If these reports are not filed timely, regulators may impose sanctions and sales of our products may suffer, and we may be subject to product liability or regulatory enforcement actions, all of which could harm our business. In addition, the FDA and the FTC regulate the advertising and promotion of medical devices to ensure that their promotional claims made are consistent with the applicable marketing authorizations, that there are adequate and reasonable data to substantiate the claims, and that the promotional labeling and advertising is neither false nor misleading in any respect. If the FDA or FTC determines that any of our promotional claims for IVD products are false, misleading, not substantiated or not permissible, we may be subject to enforcement actions and we may be required to revise our promotional claims and make other corrections or restitutions or pay significant penalties. Similar requirements apply in foreign jurisdictions, including the EU and Australia.

FDA, state, and comparable foreign authorities have broad enforcement powers. Our failure to comply with applicable regulatory requirements could result in enforcement action by the FDA, state, or comparable foreign regulatory agencies, which may include any of the following sanctions:

- adverse publicity, warning letters, untitled letters, fines, injunctions, consent decrees, and civil penalties;
- repair, replacement, refunds, recalls, termination of distribution, administrative detention or seizures of our products;
- operating restrictions, partial suspension or total shutdown of production;
- customer notifications or repair, replacement, or refunds;
- refusing our requests for clearances or approvals of new products, new intended uses or modifications to existing products;
- withdrawals of current clearances, approvals, or certifications, resulting in prohibitions on sales of our products;
- refusal to issue certificates needed to export products for sale in other countries; and
- criminal prosecution.

Any of these sanctions could also result in higher than anticipated costs or lower than anticipated sales of our IVD products and have a material adverse effect on our reputation, business, results of operations, and financial condition.

In addition, FDA regulations and guidance are often revised or reinterpreted by the FDA in ways that may significantly affect our business and our products. Any new statutes, regulations, or revisions or reinterpretations of existing regulations may impose additional costs or lengthen review times of any product candidates or make it more difficult to obtain marketing authorizations for, manufacture, market, or distribute any IVD product candidate we are developing. We cannot determine what effect changes in regulations, statutes, legal interpretation or policies, when and if promulgated, enacted or adopted may have on our business in the future. Such changes could, among other things, require: additional testing prior to seeking marketing authorization, changes to manufacturing methods recalls, replacement or discontinuance of our products, or additional record keeping.

The EU's regulatory landscape for IVD medical devices has also evolved in recent years with adoption of the IVDR to establish a modernized and more robust EU legislative framework, with the aim of ensuring better protection of public health and patient safety. In July 2025, we announced that we had received CE certification under the IVDR for our germline NGS system, which includes FulgentExome and Fulgent PLM. If we are not able to maintain regulatory compliance for such CE-marked test products, we may not be permitted to market our laboratory services in the European Union or may become subject to enforcement by EU Competent Authorities.

Risks Related to the Development of Product Candidates

Our product candidates are in early stages of development and may fail or suffer delays that materially and adversely affect their future commercial viability.

We are early in our development efforts. Generally, before obtaining marketing approval for the commercial distribution of product candidates, we must conduct pre-clinical tests and clinical trials to demonstrate sufficient safety and efficacy of our product candidates in patients. Failure can occur at any time during the development or clinical trial processes, and our 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 product candidate if there are issues that could delay or prevent marketing approval of, or ability to commercialize, our product candidates, including:

- negative or inconclusive results from clinical trials, or the clinical trials of others for similar product candidates, leading to a decision or requirement to conduct additional pre-clinical testing or clinical trials or abandon a program;
- therapeutic-related side effects experienced by participants in our clinical trials or by individuals using drugs or other drugs similar to our product candidates;
- delays in submitting 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 our clinical trials due to quarantines or other restrictions resulting from pandemics 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 product candidate;
- inadequate supply or quality of product 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 product candidates we pursue may not demonstrate the necessary safety or efficacy requirements for regulatory approval.

Clinical trials are costly, time consuming, and inherently risky; and we may fail to demonstrate safety and efficacy to the satisfaction of applicable regulatory authorities and may never obtain regulatory approval for, or successfully commercialize certain or any of our product candidates.

Clinical development is expensive, time consuming, and involves significant risk. We cannot guarantee that any clinical trials will be conducted as planned or completed on schedule, if at all. A failure of one or more clinical trials can occur at any stage of development. Events that may prevent successful or timely completion of clinical development include but are not limited to:

- potential delays in patient enrollment for our clinical trials due to public health emergencies or pandemics, natural disasters, staffing shortages, or other events, which may affect our ability to initiate and/or complete pre-clinical studies, conduct ongoing clinical trials, and delay initiation of planned and future clinical trials;
- inability to generate satisfactory pre-clinical, toxicology or other in vivo or in vitro data or to develop diagnostics capable of supporting the initiation or continuation of clinical trials;
- delays in reaching agreement on acceptable terms with CROs, and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and clinical trial sites;
- delays or failure in obtaining required IRB approval for clinical trial site;
- failure to obtain or delays in obtaining a permit from regulatory authorities to conduct a clinical trial;
- delays in recruiting or failure to recruit sufficient eligible volunteers or subjects in our clinical trials;
- failure by clinical trial sites or CROs or other third parties to adhere to clinical trial requirements;
- failure by our clinical trial sites, CROs, or other third parties to perform in accordance with the good clinical practices requirements of the FDA or applicable foreign regulatory guidelines;
- subjects withdrawing from our clinical trials;
- adverse events or other issues of concern significant enough for the FDA, or comparable foreign regulatory authority, to put a clinical trial or an IND on clinical hold;
- occurrence of adverse events associated with our product candidates;
- changes in regulatory requirements and guidance that require amending or submitting new clinical protocols;
- the cost of clinical trials of our product candidates;
- negative or inconclusive results from our clinical trials, which may result in us deciding, or regulators requiring us, to conduct additional clinical trials or to abandon development programs in other ongoing or planned indications for a product candidate; or
- delays in reaching agreement on acceptable terms with third-party manufacturers or an inability to manufacture sufficient quantities of our product candidates for use in clinical trials.

Any inability to successfully complete clinical development and obtain regulatory approval for one or more of our product candidates could result in additional costs to us or impair our ability to generate revenue. In addition, if we make manufacturing or formulation changes to our product candidates, we may need to conduct additional non-clinical studies and/or clinical trials to show that the results obtained from such new formulation are consistent with previous results. Clinical trial delays could also shorten any periods during which our product candidates have patent protection and may allow competitors to develop and bring products to market before we do, which could impair our ability to successfully commercialize our product candidates and may harm our business and results of operation.

Further, a clinical trial may be suspended or terminated by the Company, the 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 we perform certain similar functions internally, we expect to rely on CROs and clinical trial sites to ensure proper and timely conduct of our clinical trials and while we expect to enter into agreements governing those CROs' committed activities we have limited influence over their actual performance.

If there are delays in the completion of, or termination of, any clinical trial of product candidates, the commercial prospects of those product 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 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 product candidates.

Our nano-drug delivery platform is being researched and developed and, if approved, will be used as a delivery mechanism for other pharmaceuticals or therapeutics. To the extent these delivered substances cause undesirable side effects, encounter competition, or experience regulatory limitations either prior or following market approval or are otherwise unavailable to us due to our lack of rights or ability to utilize supplies of these candidates, the prospects for our product candidates or, as applicable, approved therapeutics could be materially and negatively affected. In such circumstances, our business, results of operations, and the value of our common stock may decline.

Product development involves a lengthy and expensive process with an uncertain outcome, and results of earlier pre-clinical studies and clinical trials, or preliminary, interim, and topline data may not be predictive of later data or future clinical trial results.

Clinical testing is expensive and generally takes many years to complete, and the outcome is inherently uncertain. Failure can occur at any time during the clinical development process. Clinical trials may produce negative or inconclusive results, and we or any current or future collaboration partners may decide, or regulators may require us, to conduct additional clinical trials or non-clinical studies. We will be required to demonstrate with substantial evidence through well-controlled clinical trials that our product candidates are safe and effective for use in a diverse population before we can seek marketing approvals for their commercial sale. The results of pre-clinical studies and early clinical trials of our product candidates may not be predictive of the results of larger, later-stage controlled clinical trials. Product candidates that have shown promising results in early-stage clinical trials may still suffer significant setbacks or failure in subsequent clinical trials. Our clinical trials to date have been conducted on a small number of subjects in a limited number of clinical trial sites for a limited number of indications. We will have to conduct larger, well-controlled trials in our proposed indications to verify the results obtained to date and to support any regulatory submissions for further clinical development. A number of companies in the biopharmaceutical industry have suffered significant setbacks or failure in advanced clinical trials due to lack of efficacy or adverse safety profiles despite promising results in earlier, smaller clinical trials.

Moreover, from time to time, we may publish or report interim or preliminary data from our clinical trials. For example, we have previously announced and included interim and preliminary data for our product candidate, FID-007, in this Annual Report. Interim or preliminary data from clinical trials that we may conduct, including any interim data we have reported for FID-007, may not be indicative of the final results of the trial and are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. Interim or preliminary data also remain subject to audit and verification procedures that may result in the final data being materially different from the interim or preliminary data. As a result, interim or preliminary data should be viewed with caution until the final data is available.

In some instances, there can be significant variability in safety and efficacy results between different clinical trials of the same product candidate due to numerous factors, including changes in trial protocols, differences in size and type of the patient populations, differences in and adherence to the dosing regimen and other trial protocols and the rate of dropout among clinical trial participants. We therefore do not know whether any clinical trials we may conduct will demonstrate consistent or adequate efficacy and safety sufficient to obtain marketing approval to market our product candidates.

Any product candidate that we 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, non-clinical testing, performance of clinical trials, manufacturing and post-approval commercialization and will also be subject to extensive regulations outside of the United States in relevant jurisdictions. 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 up to several years and may never be obtained.

Any product that we 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 insurance 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 non-clinical 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 requires the submission of information about the product manufacturing process, and in many cases the inspection of manufacturing, processing, and packaging facilities by the applicable 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 us or by our contract manufacturing organizations and partners that could result in the candidate not being approved. Moreover, we have not obtained marketing approval for any product candidate in any jurisdiction and it is possible that none of our existing product candidates or any product candidates we may seek to develop in the future will ever obtain marketing approval.

Product 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, EMA, or comparable foreign regulatory authorities may disagree with the design or implementation of clinical trials;
- we 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;
- we 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 non-clinical 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 product candidates we 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 and 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.

We intend to develop and seek approval for our product candidates developed using our nano-drug delivery platform technology, including FID-007, FID-022, and other candidates it may develop, pursuant to the FDA's 505(b)(2) pathway. If the FDA determines that we may not use this regulatory pathway, then we would need to seek regulatory approval via a "full" or "stand-alone" NDA under Section 505(b)(1) of the FDC Act. This would require us to conduct additional clinical trials, provide additional safety and efficacy data and other information, and meet additional standards for regulatory approval, including possibly non-clinical 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 FDC Act. 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 our lead product candidates, FID-007 and FID-022.

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 we submit 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 we are able to utilize the Section 505(b)(2) regulatory pathway for one or more of our candidates, there is no guarantee this would ultimately lead to faster product development or earlier approval.

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

Our commercial success will depend upon attaining significant market acceptance of our product candidates, if approved, among physicians, patients, insurance payors, and other members of the medical community.

Even if we obtain regulatory approval for our product candidates, the approved products may nonetheless fail to gain sufficient market acceptance among patients, physicians, insurance payors, and other members of the medical community, which is critical to commercial success. If an approved product does not achieve an adequate level of acceptance, we may not generate significant product revenues or any profits from operations. The degree of market acceptance of any product candidate for which we receive approval depends on a number of factors, including:

- the efficacy and potential advantages compared to alternative treatments or competitive products;
- perceptions by the medical community, physicians, and patients, regarding the safety and effectiveness of our products and the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- the size of the market for such product candidate, based on the size of the patient subsets that we are targeting, in the territories for which we gain regulatory approval and have commercial rights;
- the safety of the product candidate as demonstrated through broad commercial distribution;
- the ability to offer our product candidates for sale at competitive prices;
- the availability of adequate coverage and reimbursement for our products from governmental health programs and other insurance payors;
- relative convenience and ease of administration compared to alternative treatments;
- cost-effectiveness of our product relative to competing products;
- the prevalence and severity of any side effects;
- the adequacy of supply of our product candidates;
- the timing of any such marketing approval in relation to other product approvals;
- any restrictions on concomitant use of other medications;
- support from patient advocacy groups; and
- the effectiveness of sales, marketing and distribution efforts by us and our licensees and distributors, if any.

Our product candidates may cause undesirable side effects that could delay or prevent their marketing approval, limit the commercial profile of an approved label, or result in significant negative consequences following marketing approval, if any.

Undesirable side effects caused by our product candidates could cause us, our collaborators, or regulatory authorities, to interrupt, delay, or halt clinical trials. These circumstances could result in a more restrictive label or the delay or denial of marketing approval by the FDA or other regulatory authorities. Results of our clinical trials or the clinical trials of our collaborators could reveal a high and unacceptable severity of adverse side effects and it is possible that patients enrolled in these clinical trials could respond in unexpected ways. Such side effects could also affect patient recruitment or the ability of enrolled patients to complete the trial or result in potential product liability claims. Further, clinical trials by their nature utilize a sample of the potential patient population. Rare and severe side effects of our product candidates may only be uncovered with a significantly larger number of patients exposed to our product candidates.

In the event that any of our product candidates receives marketing approval and we, our collaborators or others identify undesirable side effects caused by a product or any other similar drugs, any of the following adverse events could occur:

- regulatory authorities may withdraw their approval of the product;
- additional restrictions may be imposed on the marketing of the particular product or the manufacturing processes for the product or any component of the product;
- we may be subject to fines, injunctions or the imposition of civil or criminal penalties;
- regulatory authorities may require the addition of safety-related labeling statements, such as a “black box” warning or a contraindication;
- we may be required to create a Medication Guide outlining the risks of such side effects for distribution to patients or to implement other aspects of a REMS such as a restricted distribution program or educational programs for prescribers;
- we could be sued and held liable for harm caused to patients;
- the product may become less competitive; and
- our reputation may suffer.

In addition, adverse side effects caused by any drugs that may be similar in nature to our product candidates or in connection with the nanoencapsulated drugs or therapeutics used in connection with our product candidates (similar to paclitaxel with FID-007) could delay or prevent marketing approval of our product candidates, limit the commercial profile of an approved label for our product candidates, or result in significant negative consequences for our product candidates following marketing approval.

Any of the above-described events could prevent us from achieving or maintaining market acceptance of our product candidates, if approved, and could delay, impede, and/or substantially increase the costs of commercializing our product candidates thus significantly impacting our ability to successfully commercialize our product candidates and generate revenue. Any of the above described occurrences may materially and adversely affect our business, financial condition, results of operations, and prospects.

If our product candidates are approved for marketing and commercialization, and we are unable to develop sales, marketing, and distribution capabilities on our own or enter into agreements with third parties to perform these functions on acceptable terms, we may be unable to commercialize successfully any such product candidates.

We currently have no sales, marketing, or distribution capabilities for prescription pharmaceutical products. If any of our product candidates is approved for marketing in the United States or elsewhere, we will need to expand our internal sales, marketing, and distribution capabilities to commercialize such approved product candidates in the United States and other territories, or we will need to enter into collaborations with third parties to perform these services. Any internal effort would be expensive and time-consuming, and we would need to commit significant financial and managerial resources to develop an internal marketing and sales force with technical expertise and the related supporting distribution, administration, and compliance capabilities. If we were to rely on additional third parties with these capabilities to market our future therapeutics or were to decide to co-promote products with any of our current or future collaborators, we would need to establish and maintain or revise existing marketing and distribution arrangements with these partners, and there can be no assurance that we will be able to enter into such arrangements on acceptable terms or at all. Further, there can be no assurance that these third parties will establish adequate sales and distribution capabilities or be successful in gaining market acceptance of any approved product. If we are not successful in commercializing any product approved in the future, either on our own or through third parties, our business, financial condition, results of operations, and prospects could be materially and adversely affected.

We rely on third parties to conduct portions of our clinical trials and certain of our non-clinical studies and intend to continue to do so. If these third parties do not perform as contractually required, fail to satisfy regulatory or legal requirements, or miss expected deadlines, our development programs could be delayed with material and adverse effects on our business, financial condition, results of operations, and prospects.

While we expect to continue our current clinical trials and expect to initiate clinical trials in the near term for other product candidates, we do not independently conduct clinical trials. In particular, while we perform certain functions internally, we currently rely and intend to continue to rely on third-party CROs, clinical data management organizations, and consultants to help us design, conduct, supervise, and monitor clinical trials of our product candidates. As a result, we will have less control over the timing, quality, and other aspects of our clinical trials than we would have had we conducted them on our own. There is a limited number of third-party service providers that specialize or have the expertise required to achieve our business objectives. If any of our relationships with these third-party CROs or clinical investigators terminate, we may not be able to enter into arrangements with alternative CROs or investigators or to do so on commercially reasonable terms.

Further, these investigators, CROs, and consultants are not our employees, and we have limited control over the amount of time and resources that they dedicate to our programs. These third parties may have contractual relationships with other entities, some of which may be our competitors, which may draw time and resources from our programs. The third parties with which we contract might not be diligent, careful, or timely in conducting our non-clinical studies or clinical trials. These third parties may also be susceptible to disruption as a result of health crises, public health emergencies, or periods of societal unrest or conflict. If we cannot contract with acceptable third parties on commercially reasonable terms, or at all, or if these third parties do not carry out their contractual duties, satisfy the legal and regulatory requirements for the conduct of non-clinical studies or clinical trials, or meet expected deadlines for any reason, our clinical development programs could be delayed and otherwise adversely affected.

In all events, we will be responsible for ensuring that each of our non-clinical studies and clinical trials is conducted in accordance with the general investigational plan and protocols for the relevant study or trial. The FDA requires non-clinical studies to be conducted in accordance with GLP and clinical trials to be conducted in accordance with GCPs including practices and requirements for designing, conducting, recording, and reporting the results of non-clinical studies and clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity, and confidentiality of clinical trial participants are protected. Our reliance on third parties we do not control will not relieve us of these responsibilities and requirements. Any adverse development or delay in our clinical trials could have a material and adverse effect on our business, financial condition, results of operations, and prospects.

We rely on third parties to supply and manufacture our product candidates, and we expect to continue to rely on third parties to manufacture and supply our therapeutics, if approved. The development of product candidates and the commercialization of any product candidates, if approved, could be stopped, delayed, or made less profitable if any of these third parties fail to provide us with sufficient quantities of product candidates or therapeutics, fail to do so at acceptable quality levels or prices, or fail to maintain or achieve satisfactory regulatory compliance.

We do not currently have, nor do we plan to acquire, the infrastructure or capability internally to develop and manufacture our product candidates for use in the conduct of our trials or for commercial supply, if our therapeutics are approved. Instead, we rely on, and expect to continue to rely on third-party providers to manufacture the supplies for our non-clinical studies and clinical trials.

We currently rely on a limited number of third-party contract manufacturers for our required raw materials and other components for our non-clinical research and clinical trials, as well as for the manufacture of supplies for our product candidates. To the extent any of our manufacturing partners are unable to fulfill these obligations in a timely manner, our clinical trials may be delayed, and our business may be adversely affected. In general, reliance on third-party providers may expose us to more risk than if we were to manufacture our product candidates ourselves. We do not control the operational processes of the contract manufacturing organizations with whom we contract, and we are dependent on these third parties for the production of our product candidates in accordance with relevant regulations (such as cGMP), which include, among other things, quality control and the maintenance of records and documentation.

Intellectual Property Risks

If we are unable to obtain and maintain patent protection for any product candidate we develop, our competitors could develop and commercialize products or technology similar to ours, and our ability to successfully commercialize any product candidate we may develop, and our technology, may be adversely affected.

Our success depends in large part on our ability to obtain and maintain patent protection in the United States and other countries with respect to any product candidate and other technologies we may develop. Given that the development of our drug and therapeutic technology is at an early stage, our intellectual property portfolio comprises applications and patents with respect to coverage of

certain aspects of our technology and any drug and any product candidates; however, there can be no assurance that any such patent applications will issue as granted patents.

Composition of matter patents for biological and pharmaceutical products are generally considered to be the strongest form of intellectual property protection for those types of products, as such patents provide protection without regard to any method of use. We cannot be certain, however, that the claims in our future patent applications covering the composition of matter of any product candidates will be considered patentable by the USPTO, or by patent offices in foreign countries, or that the claims in any of its issued patents will be considered valid and enforceable by courts in the United States or foreign countries.

Furthermore, in some cases, we may not be able to obtain issued claims covering compositions of matter relating to any product candidates we develop and instead may need to rely on filing patent applications with claims covering a method of use and/or method of manufacture. Method of use patents protect the use of a product for the specified method. This type of patent does not prevent a competitor from making and marketing a product that is identical to any product we develop for an indication that is outside the scope of the patented method. Moreover, even if competitors do not actively promote their products for its targeted indications, physicians may prescribe these products "off-label" for those uses that are covered by its method of use patents. Although off-label prescriptions may infringe or contribute to the infringement of method of use patents, the practice is common, and such infringement is difficult to prevent or prosecute. There can be no assurance that any such patent applications will issue as granted patents, and even if they do issue, such patent claims may be insufficient to prevent third parties, such as our competitors, from utilizing our technology. Any failure to obtain or maintain patent protection with respect to any product candidate we develop could have a material adverse effect on our business, financial condition, results of operations, and prospects.

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

We 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 trade secret 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 product 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, testing services, and product candidates. 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, commercialize product candidates, and enter new markets, competitors may claim that our tests or products 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, delay commercialization of any approved product candidates, 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 drugs 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 United States Congress or the 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 ribonucleic acid 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 product 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.

Obtaining and maintaining our patent protection depends on compliance with various procedures, document submission, fee payment, and other requirements imposed by government patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

Periodic maintenance fees, renewal fees, annuity fees, and various other government fees on patents and applications will be due to be paid to the USPTO and various government patent agencies outside of the United States over the lifetime of its owned patents and applications. The USPTO and various non-U.S. government agencies require compliance with several procedural, documentary, fee payment, and other similar provisions during the patent application process. In some cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. There are situations, however, in which non-compliance can result in abandonment or lapse of the patent or patent application, resulting in a partial or complete loss of patent rights in the relevant jurisdiction. In such an event, potential competitors might be able to enter the market with similar or identical products or technology, which could have a material adverse effect on our business, financial condition, results of operations, and prospects.

Worldwide, we own or exclusively in-license over 20 issued or allowed patents and about 10 active patent applications as of December 31, 2025. This includes nine issued or allowed U.S. patents. Patents in these patent families are expected to expire by 2034, and patent applications in these patent families, if granted, are expected to expire as far out as 2045, subject to any patent term disclaimers, adjustments, or extensions. Patents and/or patent applications in these families are active in multiple jurisdictions, including the United States, Australia, Canada, China, European Patent Organization, German, New Zealand, Japan, and Switzerland. In addition to these owned and exclusively licensed patents and active patent applications, we also license patents on a non-exclusive and/or territory-restricted basis. Our intellectual property portfolio includes important patents and patent applications directed to our technologies. This includes patent filings relating to our nanodrug delivery platform technology for delivery of water insoluble or poorly soluble drugs for treatments of disease conditions, including cancer. In particular, as of December 31, 2025, we own full rights of all issued patents and patent applications relating to FID-007, FID-022, and ADC. Individual patent terms extend for varying periods of time, depending upon the date of filing of the patent application, the date of patent issuance, and the legal term of patents in the countries in which they are obtained.

Previously, in June 2017, we entered into an exclusive license agreement with ANP, as amended December 28, 2017, and May 1, 2024. Under the agreement, ANP granted us ownership of certain patents and patent applications, and an exclusive, worldwide, perpetual, irrevocable, and sub-licensable license to certain rights in patents and patent applications under which we may develop and commercialize FID-007, FID-022, and related formulations for human therapeutic, prophylactic, and diagnostic uses. In July 2025, we completed an acquisition of 100% of the outstanding equity of ANP and all rights on multiple proprietary product platforms. This acquisition enabled us to secure full ownership of the patents we previously licensed from ANP. As of December 31, 2025, this intellectual property suite includes over 20 issued patents and over 10 patent applications that relate to FID-007, FID-022, and ADC. Patents and/or patent applications in these families are active in multiple jurisdictions, including the United States, Australia, Canada, China, European Patent Organization, Germany, New Zealand, Japan, and Switzerland. Patent applications in these patent families, if granted, are expected to expire in 2045, subject to any patent term disclaimers, adjustments, or extensions.

Our future issued patents covering product candidates we develop could be found invalid or unenforceable if challenged in court or before administrative bodies in the United States or abroad.

In patent litigation in the United States, defendant counterclaims alleging invalidity or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, or non-enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO, or made a misleading statement, during prosecution. Third parties may raise claims challenging the validity or enforceability of our owned patents before administrative bodies in the United

States or abroad, even outside the context of litigation. Such mechanisms include re-examination, post-grant review, *inter partes* review, interference proceedings, derivation proceedings, and equivalent proceedings in foreign jurisdictions (e.g., opposition proceedings). Such proceedings could result in the revocation of, cancellation of, or amendment to our future patents in such a way that they no longer cover its product candidate or other technologies. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art, of which we and the patent examiner were unaware during prosecution. If a third-party were to prevail on a legal assertion of invalidity or unenforceability, we would lose at least part, and perhaps all, of the patent protection on any product candidates it develops or other technologies. Such a loss of patent protection would have a material adverse impact on our business, financial condition, results of operations, and prospects.

Patent terms may be inadequate to protect the competitive position of our products and services for an adequate amount of time.

Patents have a limited lifespan. Patent terms may be shortened or lengthened by, for example, terminal disclaimers, patent term adjustments, supplemental protection certificates, and patent term extensions. Although extensions may be available, the life of a patent, and the protection it affords, is limited. Patent term extensions and supplemental protection certificates, and the like, may be impacted by the regulatory process and may not significantly lengthen patent term. Non-payment or delay in payment of patent fees or annuities, delay in patent filings or delay in extension filing, whether intentional or unintentional, may also result in the loss of patent rights important to our business. In such an event, competitors might be able to enter the market earlier than would otherwise have been the case. In addition, certain countries have compulsory licensing laws under which a patent owner may be compelled to grant licenses to other parties. Furthermore, many countries limit the enforceability of patents against other parties, including government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of any patents.

In the United States and abroad, if all maintenance fees/annuity fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest non-provisional filing date. The protection a patent affords is limited. Even if patents covering our products or product candidates are obtained, once the patent life has expired, we may be open to competition from competitive products. Given the amount of time required for the development, testing, and regulatory review of new products and product candidates, patents protecting such products or product candidates might expire before or shortly after such products or product candidates are commercialized. As a result, our future owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products or product candidates similar or identical to ours.

If we do not obtain patent term extension and/or data exclusivity for any product candidate that we may develop, our business may be materially harmed.

Depending upon the timing, duration, and specifics of any FDA marketing approval of any product candidate we may develop, one or more of our future owned U.S. patents may be eligible for limited patent term extension under the Hatch-Waxman Act. The Hatch-Waxman Act permits a patent term extension of up to five years as compensation for patent term lost during the FDA regulatory review process. A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, only one patent may be extended, and only those claims covering the approved drug, a method for using it, or a method for manufacturing it may be extended. Similar extensions as compensation for patent term lost during regulatory review processes are also available in certain foreign countries and territories, such as in Europe under a Supplementary Patent Certificate. However, we may not be granted an extension in the United States and/or foreign countries and territories because of, for example, failing to exercise due diligence during the testing phase or regulatory review process, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant future patents, or otherwise failing to satisfy applicable requirements. Moreover, the applicable time period or the scope of patent protection afforded could be less than we request. If we are unable to obtain patent term extension, or the term of any such extension is shorter than what we request, our competitors may obtain approval of competing products following our patent expiration, and our business, financial condition, results of operations, and prospects could be materially harmed.

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. Many countries have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, many countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of such patent. If we or any of our licensors is forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position may be impaired, and our business, financial condition, results of operations, and prospects may be adversely affected. 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.

We do not have intellectual property rights in every country throughout the world. Filing, prosecuting, and defending patents on product candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States and Europe can be less extensive than those in the United States. In addition, the laws of foreign countries do not protect intellectual property rights to the same extent as federal and state laws of the United States. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we have patent protection but where enforcement is not as strong as that in the United States. These products may compete with our product candidates, and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

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 protect 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. For example, our ADC program is substantially dependent upon certain intellectual property rights for certain reagents. If any third parties were to terminate their license agreement, the development and commercialization of ADC would be adversely affected, our potential for generating revenue from this program would be adversely affected and attracting new partners would be made more difficult. As a result, we would likely be subject to increased competition within our market.

We expect that other technology in-licenses that we may enter into in the future will contain similar provisions and impose similar obligations on us. 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, if they fail to enforce licensed intellectual property against infringing third parties, if the licensed intellectual property is 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 Chairperson of our board of directors, beneficially owns approximately 28.3% of our outstanding voting equity as of December 31, 2025. 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 stockholders could lose all or part of their 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 or the introduction of new products by our competitors;
- 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;
- whether and when we are able to obtain marketing approval to market any of our product candidates and the outcome of meetings with applicable regulatory agencies, including the FDA;
- the outcome, success, costs and timing of pre-clinical studies and clinical trials for our current or future product candidates;
- failure of any our product candidates, if approved, to achieve commercial success;
- 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 46.2% of our outstanding voting equity as of December 31, 2025, and of this, Mr. Hsieh, our founder, Chief Executive Officer and Chairperson of our board of directors, by himself beneficially owns approximately 28.3% of our outstanding voting equity as of December 31, 2025. 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, as amended, or the certificate of incorporation, and amended and restated bylaws, or the 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 Chairperson 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 1C. Cybersecurity.

We recognize the critical importance of maintaining the trust and confidence of customers, clients, patients, business partners, and employees toward our business and are committed to protecting the confidentiality, integrity, and availability of our business operations and systems. Our board of directors is actively involved in oversight of our risk management activities, and cybersecurity represents an important element of our overall approach to risk management. Our cybersecurity policies, standards, processes, procedures, and practices are based on recognized frameworks established by the National Institute of Standards and Technology, or NIST and other applicable industry standards. In general, we seek to address cybersecurity risks through a comprehensive, cross-functional approach that is focused on preserving the confidentiality, security, integrity, and availability of the information that we collect and store by identifying, preventing, and mitigating cybersecurity threats and effectively responding to cybersecurity incidents when they occur.

Risk Management and Strategy; Effect of Risk

We face risks related to cybersecurity such as unauthorized access, cybersecurity attacks, and other security incidents, including as perpetrated by hackers and unintentional damage or disruption to hardware and software systems, loss of data, and misappropriation of confidential information. To identify and assess material risks from cybersecurity threats, we maintain a comprehensive cybersecurity program and regular oversight of our programs for security monitoring for internal and external threats to ensure the confidentiality and integrity of our information assets. We consider risks from cybersecurity threats alongside other company risks as part of our overall risk assessment process. We employ a range of tools and services, including regular network and endpoint monitoring, vulnerability assessments, penetration testing, threat monitoring and tabletop exercises to inform our risk identification and assessment.

We also identify our cybersecurity threat risks by comparing our processes to standards set by NIST and Center for Internet Security, as well as by engaging experts to attempt to infiltrate our information systems. To provide for the availability of critical data and systems, maintain regulatory compliance, manage our material risks from cybersecurity threats, and protect against and respond to cybersecurity incidents, we also perform periodic risk assessments, which includes cybersecurity risks, monitor emerging data protection laws and implement changes to our processes that are designed to comply with such laws; through our policies, practices, and/or contracts (as applicable), require employees and certain third parties to treat confidential information and data with care; periodically update our relevant policies and procedures; employ technical safeguards that are designed to protect our information systems from cybersecurity threats, including firewalls, intrusion prevention and detection systems, anti-malware functionality, and access controls, which are evaluated and improved through vulnerability assessments and cybersecurity threat intelligence; provide

regular, mandatory training for our employees regarding cybersecurity threats as a means to equip them with effective tools and knowledge necessary to identify or address cybersecurity threats and to communicate our evolving information security policies, standards, processes and practices; conduct regular phishing email simulations to enhance awareness and responsiveness to possible threats; conduct annual cybersecurity training for our board of directors and senior management; run tabletop exercises to simulate a response to a cybersecurity incident and use the findings to improve our processes and technologies; leverage the NIST incident handling framework to help us identify, protect, detect, respond, and recover when there is an actual or potential cybersecurity incident; engage consultants to help us oversee and manage cybersecurity risks, processes, and incident response measures; and carry information security risk insurance that provides protection against the potential losses arising from a cybersecurity incident.

Our incident response plan outlines and coordinates the activities we take to prepare for, detect, respond to, and recover from cybersecurity incidents, which include processes to triage, assess severity for, escalate, contain, investigate, and remediate the incident, as well as to comply with potentially applicable legal obligations and mitigate damage to our business and reputation. Our incident response plan further outlines the roles and responsibilities of various employees, managers, and senior leadership with respect to performing a materiality assessment and responding to cybersecurity events that are deemed material, as well as provides rapid escalation procedures after a cybersecurity incident. In the event of an incident, we intend to follow our incident response plan, which outlines the steps to be followed from incident detection to mitigation, recovery, and notification, including notifying functional areas (e.g. legal), as well as senior leadership and our board of directors, as appropriate.

Our cyber risk management program is integrated within the Company's enterprise risk management program and addresses both the corporate information technology environment and customer-facing products and services. The risk management program is focused on safeguarding the organization's digital assets, ensuring continuous business operations, and minimizing the potential impact of cyber threats. Regular assessments, including penetration tests, are performed. These inputs form the basis of a risk register that is integrated into the overall enterprise risk management program to further inform the Company's strategy assessing the likelihood, impact, and velocity of these risks on a forward-looking basis.

As part of the above processes, we regularly engage with consultants, and other third parties, review our cybersecurity program to help identify areas for continued focus, improvement, and compliance. We engage them, specifically, to assist us with cybersecurity risk assessments, external threat environment reviews, internal cybersecurity policy compliance and near-term incident response. Our processes also address cybersecurity threat risks associated with our use of third-party service providers, including our key suppliers, which have access to consumer, patient, and employee data or our systems. In addition, cybersecurity considerations affect the selection and oversight of our third-party service providers. We periodically perform diligence on certain third parties that have access to our systems, data, or facilities that house such systems or data; and we monitor cybersecurity threat risks identified through such diligence.

We describe whether and how risks from identified cybersecurity threats, including as a result of any previous cybersecurity incidents, have materially affected or are reasonably likely to materially affect us, including our business strategy, results of operations, or financial condition under the heading "Actual or attempted security incidents or breaches, loss of data, or other disruptions could expose us to material liability and materially and adversely affect our business, financial condition, and reputation," which disclosures are incorporated by reference herein.

We have not experienced any material cybersecurity incidents. As of the date of this report, we do not believe that risks from any cybersecurity threats, including as a result of any previous cybersecurity incidents, have materially affected or are reasonably likely to affect us, including our business strategy, results of operations or financial condition. However, we are aware that changes in our IT systems, including those provided by third parties, could expose us to risk in the future. These threats pose a risk to the security of our systems and networks and the confidentiality, availability, and integrity of our data. Cybersecurity attacks could also include attacks targeting patient, employee, or customer data or the security, integrity, and/or reliability of the hardware and software we utilize in our business operations. It is possible that our information technology systems and networks, or those managed or provided by third parties, could have vulnerabilities, which could go unnoticed for a period of time. While various procedures and controls have been and are being utilized to mitigate such risks, there can be no guarantee that the actions and controls we have implemented and are implementing will be sufficient to protect and mitigate associated risks to our systems, information, or other property. For more information, see the risk factors included in Item 1A of this Annual Report.

Cybersecurity Governance; Management

Cybersecurity is an important part of our risk management processes and an area of focus for our board of directors and management. In general, our board of directors oversees risk management activities designed and implemented by our management and considers specific risks, including, for example, risks associated with our strategic plan, business operations, and capital structure. Our board of directors executes its oversight responsibility for risk management both directly and through delegating oversight of

certain of these risks to its committees, and our board of directors has authorized our audit committee to oversee risks from cybersecurity threats.

At least quarterly, our board of directors receives an update from management of our cybersecurity threat risk management and strategy processes, covering topics such as data security posture, any results from third-party assessments, progress towards pre-determined risk-mitigation-related goals, our incident response plan, material cybersecurity threat risks or incidents and developments, as well as the steps management has taken to respond to such risks. In such sessions, our board of directors generally receives materials that include a cybersecurity dashboard and/or other materials discussing current and emerging material cybersecurity threat risks and describing our ability to mitigate those risks, as well as recent developments, evolving standards, technological developments, and information security considerations arising with respect to our peers and third parties, and discusses such matters with our Chief Information Security Officer and/or General Counsel and Chief Privacy Officer. Our board of directors also receive prompt and timely information regarding any cybersecurity incident that meets established reporting thresholds, as well as ongoing updates regarding any such incident until it has been addressed.

Members of the board of directors are also encouraged to regularly engage in conversations with management on cybersecurity-related news and events and discuss any updates to our cybersecurity risk management and strategy programs. Material cybersecurity threat risks are also considered during separate board meeting discussions of important matters like enterprise risk management, operational budgeting, business continuity planning, mergers and acquisitions, brand management, and other relevant matters. Our Chief Information Security Officer advises our board of directors on the specific vulnerabilities we identified and the controls we put in place to mitigate our risk.

Our cybersecurity program is managed by a dedicated team, which is led by our CISO, who reports to the Chief Operating Officer and has to the ability to communicate directly to our CEO and the board if necessary. Our CISO has over 20 years of IT experience, including over 18 years of cybersecurity experience, holds an M.S. degree in Information Security, and is a Certified Information Systems Security Professional (CISSP). Our General Counsel and Chief Privacy Officer is an attorney with 19 years of experience, including experience in privacy matters and is also a Certified Information Privacy Professional (CIPP/US/E), a Certified Privacy Manager (CIPM), and a Privacy Law Specialist (PLS) with the International Association of Privacy Professionals (IAPP). As discussed above, our CISO and/or General Counsel and Chief Privacy Officer report to our board of directors about cybersecurity threat risks, among other cybersecurity related matters, on a quarterly basis.

In addition, our cybersecurity risk management and data strategy processes are further overseen by certain management team members. Together with CISO and our General Counsel and Chief Privacy Officer, these management team members are regularly informed about and routinely monitor the prevention, mitigation, detection, and remediation of cybersecurity incidents through their ongoing management of, and participation in, the cybersecurity risk management and strategy processes described above, including the operation of our incident response plan. Such individuals have extensive prior work experience in various roles involving managing information security, developing cybersecurity strategy, implementing effective information and cybersecurity programs, as well as several relevant degrees and certifications.

Item 2. Properties.

Our corporate headquarters and laboratory operations are located in El Monte, California, where we own and occupy 61,612 square feet of building space situated on 2.6 acres of land. We have built a CLIA-certified laboratory at this location. 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 Coppell, Texas; Alpharetta, Georgia; Phoenix, Arizona; and Needham, Massachusetts. In Coppell, Texas, we own and occupy approximately 96,500 square feet of building and space situated on 6.8 acres of land. In Alpharetta, Georgia, we own and occupy approximately 65,000 square feet of building and space situated on 8.5 acres of land. In Phoenix, Arizona, we previously leased and occupied approximately 25,000 square feet under a lease that expired in November 2025, and in October 2025, we entered into a new lease and occupy approximately 7,000 square feet under a lease that will expire in November 2028. In Needham, Massachusetts, we lease and occupy approximately 21,000 square feet under a lease that will expire in September 2027. We use these facilities for laboratory testing and certain administrative and other functions.

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. As disclosed in Note 8, *Debt, Commitments and Contingencies*, to our consolidated financial statements, we are engaged in certain legal investigations, and

subject to audits. The disclosure set forth in Note 8, *Debt, Commitments and Contingencies*, to our consolidated financial statements included in this report relating to these certain legal matters is incorporated herein by reference.

The outcome of these matters are inherently uncertain, and there can be no assurances that a favorable outcome will be obtained.

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

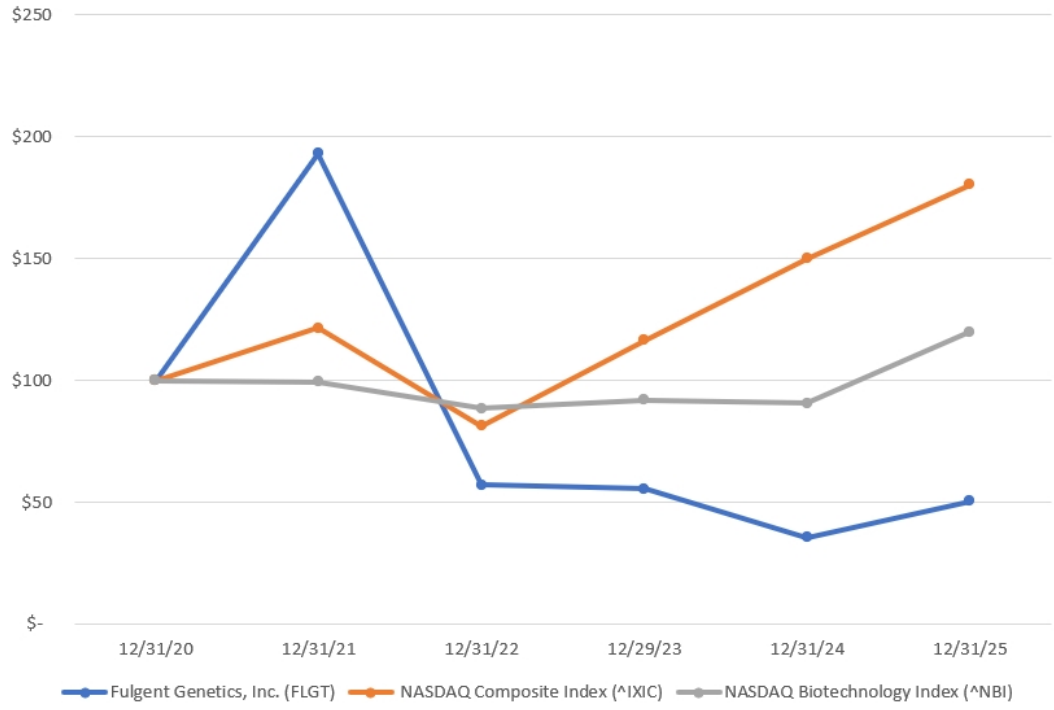
As of February 1, 2026, there were 11 holders of record of our common stock, plus an indeterminate number of additional stockholders whose shares of our common stock are held on their behalf by brokerage firms or other agents.

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**.**

Common Stock Performance Graph

The following graph compares the cumulative total stockholder return, calculated on a dividend-reinvested basis, in our common stock, the Nasdaq Composite Index, and the Nasdaq Biotechnology Index for the five years ended December 31, 2025. The comparison assumes that $100 was invested in our common stock, the NASDAQ Composite Index, and the Nasdaq Biotechnology Index as of the market close on December 31, 2020. Note that historic stock price performance is not necessarily indicative of future stock price performance.



Information on Share Repurchases

There were no shares of common stock purchased during the three months ended December 31, 2025. For further information about shares repurchased, see Note 16, *Stock Repurchase Program*, to our consolidated financial statements.

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 Exchange Act. We have omitted discussion of 2023 results where it would be redundant to the discussion previously included in Item 7 of our 2024 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 laboratory services business and a therapeutic development business. Our laboratory services business includes technical laboratory and testing services and professional interpretation of laboratory results by licensed physicians. Our therapeutic development business is focused on developing product candidates for treating a broad range of cancers using a novel nanoencapsulation and targeted therapy platform designed to improve the therapeutic window and PK profile of new and existing cancer drugs.

We recorded revenue and net (loss) from operations of $322.7 million and ($60.5) million, respectively, in 2025, compared to revenue and net (loss) from operations of $283.5 million and ($42.7) million, respectively, in 2024.

2025 Developments

Bako and StrataDx Acquisition

In December 2025, we announced that we entered into definitive agreements to acquire selected assets of Bako Diagnostics, a premier pathology laboratory headquartered in Alpharetta, Georgia and to acquire StrataDx, a premier dermatopathology laboratory located in Lexington, Massachusetts for a total combined purchase price of approximately $55.5 million, subject to adjustments, to be paid from cash on hand. The acquisition is expected to close during the first half of 2026, subject to satisfying customary closing conditions, including regulatory approvals. Refer to Note 15. *Business Combinations*, for additional details.

Purchase of Income Tax Credits

In 2025, we purchased $106.3 million worth of Investment Tax Credits, or ITCs, under the transferability provisions of the Inflation Reduction Act of 2022 for $99.5 million in cash. Refer to Note 11. *Income Taxes*, for additional details with regard to the treatment of Investment Tax Credits purchased previously.

ANP Acquisition

On July 9, 2025, we completed an acquisition of 100% of ANP, an innovation-driven company, which has developed multiple proprietary product platforms. This acquisition enables us to secure ownership of the patents previously licensed from ANP, which are currently utilized in ongoing clinical studies. By securing full ownership of these intellectual property rights, we aim to enhance our

control over the development and commercialization of related therapeutic candidates, thereby aligning with its strategic objectives to advance clinical programs. Refer to Note 15. *Business Combinations*, for additional details.

Factors Affecting Our Performance

Mix of Tests Delivered

We offer our tests and testing services 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 and testing services, 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 and Purchasing Terms

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 often fluctuate from period to period, and in certain prior periods, a small number of customers have 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 of our customers contributed $70.8 million or 22% of our total revenue during the year ended December 31, 2025. For this customer and for customers generally, tests are purchased on a test-by-test basis and not pursuant to any long-term purchasing arrangements. We expect reduced revenues moving forward into 2026 from this significant customer. We plan to continue to focus on developing other customers and capturing new customers. If these efforts are successful, we may be able to offset, or partially offset, this decrease in revenue.

We currently classify our customers into three payor types: (i) Insurance, (ii) Institutional, including hospitals, medical institutions, other laboratories, governmental bodies, 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 insurance 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 continue to make 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 or have developed 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 and Inflation

We have developed various proprietary technologies, including various AI tools, 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.

Similar to other companies in our industry, we have and may again experience the effects of inflation in the costs of labor, materials, and services in connection with the marketing of our tests and testing services and in connection with our research and development efforts.

Ability to Obtain Reimbursement and Government Audits and Investigations

Much of our revenue depends on receiving reimbursement for our tests from insurance payors, including our Insurance and Institutional customers. These payors have complicated rules and procedures regarding submissions for reimbursement, and their reimbursement practices and procedures may vary from period to period. Reimbursed amounts are often subject to audit, and our ability to collect and retain reimbursement from these payors may vary from period to period. If we are unable to obtain or retain reimbursement during any period, our rate of reimbursement is lower than expected or if reimbursement is delayed, our results of operations may be correspondingly affected and fluctuate significantly from period to period. As part of our business plan for future growth, we intend to pursue coverage and reimbursement from insurance payors at a level adequate for us to again achieve and maintain 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 insurance 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 insurance payor market and our flexibility in establishing relationships with additional insurance payors in the future. Our level of success in obtaining and maintaining adequate coverage and reimbursement from insurance 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.

These reimbursement activities also subject us to payor and government audits and investigations such as the HRSA audit and the CIDs discussed in Note 8, *Debt, Commitments and Contingencies* to our consolidated financial statements. The results of these matters and the expenses and use of resources needed in connection with these and similar matters could materially affect our results of operations.

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

Our laboratory service segment generates revenue from molecular testing, including precision diagnostics and anatomic pathology, BioPharma services, and COVID-19 testing (which is not expected to produce material revenue). 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. Our therapeutic development segment has started producing BioPharma services revenue with the acquisition of ANP.

Cost of Revenue

Cost of revenue reflects the aggregate costs incurred in delivering test results and consists of: costs of laboratory reagents and supplies; personnel costs, including salaries, employee benefit costs, bonuses and equity-based compensation expenses; depreciation of laboratory equipment; delivery and courier costs relating to the transportation of specimens to be tested; amortization of building or leasehold improvements; and allocated overhead expenses, including rent and utilities. Costs associated with performing tests are recorded as tests are processed.

Operating Expenses

Our operating expenses are classified into five categories: research and development; selling and marketing; general and administrative; amortization of intangible assets; and goodwill impairment loss, if any. For each category except for amortization of intangible assets and goodwill impairment loss, 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 and our product candidates. These costs consist of:

- personnel costs, including salaries, benefits, and other employee-related costs, such as bonuses and equity-based compensation expenses;
- consulting costs, including consulting fees and related travel expenses;
- laboratory supplies;
- costs associated with in-process research and conducting clinical studies to develop and support our products;
- costs related to production of clinical materials;
- set up costs, including electronic medical record set up costs, costs associated with setting up and conduct clinical studies at domestic and international sites;
- costs related to compliance with regulatory requirements; and
- allocated overhead expenses, including rent, information technology, equipment depreciation and utilities.

We expense all research and development costs in the periods in which they are incurred. We expect our research and development expenses will continue to increase in absolute dollars, as we expect to continue to invest in research and development activities and continue to innovate and expand the application of our testing platform. Furthermore, we expect our research and development expenses for our therapeutic development segment to increase as we incur incremental expenses associated with our product candidates that are currently under development and in clinical trials. Product candidates in later stages of clinical development generally have higher development costs, primarily due to the increased size and duration of later-stage clinical trials. Accordingly, we expect to incur significant research and development expenses in connection with our clinical trials for FID-007 and FID-022.

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 increase in absolute dollars, primarily driven by our increased investment in sales and marketing, 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 Nasdaq, additional insurance expenses, investor relations activities and other administrative and professional services.

Goodwill Impairment Loss

A goodwill impairment loss is measured as the amount by which a reporting unit's carrying value, including goodwill, exceeds its fair value, not to exceed the carrying amount of goodwill.

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.

Benefit from Income Taxes

Benefit from 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, tax credits, the reclassification of stranded tax effects from other comprehensive income, and the effect of state income taxes. 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,			
	2025	2024	$ Change	% Change
	(in thousands, except percentages)			
Statement of Operation Data				
Revenue	$ 322,671	$ 283,470	$ 39,201	14%
Cost of revenue	191,796	176,255	15,541	9%
Gross profit	130,875	107,215	23,660	22%
Operating expenses				
Research and development	53,905	48,816	5,089	10%
Selling and marketing	43,371	36,246	7,125	20%
General and administrative	116,664	88,106	28,558	32%
Amortization of intangible assets	8,031	7,965	66	1%
Total operating expenses	221,971	181,133	40,838	23%
Operating loss	(91,096)	(73,918)	(17,178)	23%
Other income (expenses)				
Interest income	30,919	31,304	(385)	(1)%
Interest expense	(75)	170	(245)	(144)%
Impairment loss	(9,926)	(10,073)	147	(1)%
Other income, net	153	561	(408)	(73)%
Total other income, net	21,071	21,962	(891)	(4)%
Loss before income taxes	(70,025)	(51,956)	(18,069)	35%
Benefit from income taxes	(8,394)	(8,136)	(258)	3%
Net loss from consolidated operations	(61,631)	(43,820)	(17,811)	41%
Net loss attributable to noncontrolling interests	1,118	1,112	6	1%
Net loss attributable to Fulgent	$ (60,513)	$ (42,708)	$ (17,805)	42%

Revenue

	Year Ended December 31,			
	2025	2024	$ Change	% Change
Revenue from laboratory services				
Precision diagnostics[1]	$ 190,472	$ 167,745	$ 22,727	14%
Anatomic pathology	106,442	97,080	9,362	10%
BioPharma services	25,310	16,338	8,972	55%
COVID-19	—	2,307	(2,307)	(100)%
Total laboratory services	322,224	283,470	38,754	14%
Revenue from therapeutic development				
BioPharma services	447	—	447	*
Total therapeutic development	447	—	447	*
Total revenue	$ 322,671	$ 283,470	$ 39,201	14%

* not meaningful

(1) Beginning in 2025, COVID-19 revenue is grouped with precision diagnostics, which was insignificant in 2025.

Revenue increased by $39.2 million, or 14%, from $283.5 million in 2024 to $322.7 million in 2025. The increase in revenue between periods was driven by increases of $22.7 million in precision diagnostics, $9.4 million in anatomic pathology, and $9.4 million in BioPharma services. However, these increases were offset by a decrease of $2.3 million in COVID-19 revenue.

The increase in precision diagnostics revenue for the year was driven by growth in our reproductive health services and continued strength in legacy diagnostic offerings. The increase in anatomic pathology services was primarily due to the absence of weather-related disruptions and client losses that had affected the prior year. The increase in BioPharma services revenue was

primarily due to the timing of service projects, though this revenue is expected to remain variable due to the long sales cycle and fluctuations in project timing. Conversely, the decrease in COVID-19 testing services resulted from the cessation of testing operations at the end of March 2023, leading to the subsequent inclusion of any remaining COVID-19 revenue to be grouped under precision diagnostics, beginning in 2025. Continuing COVID-19 revenues after March 2023 are expected to be minimal, and are typically due to variable consideration recognized for services completed in prior periods.

We believe the factors that will affect our ability to grow these revenue streams are 1) the average price point we offer and the reimbursement rate from insurance payors; 2) the concentration of our payor base; 3) the competitive advantage we have due to our broad and flexible test menu, detection rate, and turnaround times; and 4) growth in size of an addressable market. Estimated collection amounts from insurance payors are subject to the complexities and ambiguities of billing, reimbursement regulations and claims processing, as well as considerations unique to Medicare and Medicaid programs. Because our proprietary technology platform allows for rapid scaling of a broad, flexible testing menu, we can offer our customers more scalable and affordable testing. Going forward, we will strive to maintain this competitive advantage and emphasize this in our marketing efforts to grow our testing revenue.

Our customer base includes insurance, institutional, and individual payors. In some periods, our revenue is concentrated on a smaller number of customers. For the laboratory services segment, aggregating customers that are under common control, one customer comprised $70.8 million or 22% of our revenue in 2025 and $62.6 million or 22% of our revenue in 2024. We began to see lower than anticipated testing volume from our largest customer in the fourth quarter of 2025, and we expect revenues for this customer to decline in 2026 (particularly through the second quarter of 2026) as this customer begins to perform tests internally. The tests and testing services this customer has historically purchased were primarily precision diagnostic tests. To reduce this revenue risk, we will focus on developing existing customers and increasing the number of customers and thereby reducing the concentration.

Revenue from the therapeutic development segment includes amounts recognized by ANP, a recently acquired entity, from technologies licensed to pharmaceutical and biotechnology companies, as well as CROs. In addition, ANP has entered into a manufacturing and supply agreement with a customer for specific COVID-19 testing kits, under which, ANP is entitled to participate in gross-margin sharing on the sale of those kits. The timing of the gross-margin sharing revenue is dependent on the customer's downstream sales of the kits. An insignificant amount of gross-margin sharing revenue was recognized for the year ended December 31, 2025.

Revenue from non-U.S. sources increased by $1.8 million, or 7%, from $24.3 million in 2024 to $26.1 million in 2025. 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, which increased $0.3 million in 2025, as well as increases in total revenue to Australia of $0.7 million and Canada of $0.5 million.

Cost of Revenue

	Year Ended December 31,			
	2025	2024	$ Change	% Change
Cost of revenue	$ 191,796	$ 176,255	$ 15,541	9%
Cost of revenue as a % of revenue	59.4%	62.2%		

Our consolidated cost of revenue increased by $15.5 million, or 9%, from $176.3 million in 2024 to $191.8 million in 2025. The increase was primarily due to increases of $7.5 million in personnel costs, including equity-based compensation, $4.2 million in reagent and supplies cost, $1.7 million in consulting and outside labor costs for production, $1.1 million in depreciation expenses, $0.8 million in software and software licensing expenses, $0.7 million in office expenses, and $0.7 million in facilities expenses, and partially offset by a decrease of $1.1 million in shipping and handling costs.

The cost of revenue for the therapeutic development segment resulted from ANP, is insignificant for the year ended December 31, 2025.

Our consolidated cost of revenues as a percentage of revenue decreased from 62.2% to 59.4%.

Our gross profit increased by $23.7 million, or 22%, from $107.2 million in the year ended December 31, 2024, to $130.9 million in the year ended December 31, 2025. Our gross profit as a percentage of revenue, or gross margin, increased from 38% in the year ended December 31, 2024, to 41% in the year ended December 31, 2025. This was driven by the increased revenue, efforts of optimizing cost structures as discussed above, and efficiency as a result of our investments in scaling and centralizing lab operations.

Research and Development

	Year Ended December 31,			
	2025	2024	$ Change	% Change
Research and development				
Laboratory services	$ 29,575	$ 28,424	$ 1,151	4%
Therapeutic development	24,330	20,392	3,938	19%
Total research and development	$ 53,905	$ 48,816	$ 5,089	

Laboratory Services

For the laboratory services segment, the research and development expenses were mainly for advancing our technology and future testing and testing services. The expenses increased by $1.2 million, or 4%, from $28.4 million in 2024 to $29.6 million in 2025. The increase was primarily attributed to an increase of $1.3 million in personnel expenses.

In 2025, the research and development expenses primarily consisted of $26.6 million in personnel expenses, including bonuses and equity-based compensation, $1.3 million in reagent and supply costs, $0.5 million in facility expenses, $0.4 million in depreciation expense, and $0.2 million in software and licensing fees. The 2024 expenses primarily consisted of $25.3 million in personnel expenses, including bonuses and equity-based compensation, $1.4 million in reagent and supply costs, $0.6 million in facility expenses, $0.4 million in depreciation expense, and $0.4 million in software and licensing fees.

Therapeutic Development

For the therapeutic development segment, the research and development expenses in 2025 included $12.4 million in CRO costs, $10.5 million in personnel costs, including equity-based compensation, $0.5 million in facility expenses, and $0.5 million in depreciation expenses. In 2024, these expenses comprised $10.9 million in CRO costs, $8.6 million of personnel expenses, including equity-based compensation, $0.7 million in depreciation expense, and insignificant facility expenses.

Research and development expenses for the therapeutic development segment increased by $3.9 million, or 19%, from $20.4 million in 2024 to $24.3 million in 2025. The increase was primarily driven by increases of $1.9 million in personnel costs, including equity-based compensation expense, $1.5 million in CRO costs, and $0.5 million in facility expenses.

The overall increase was attributed to the advancement and continuation of the clinical study of FID-007, along with FID-022. In 2024, approximately $2.1 million was incurred for the pre-clinical development of FID-022, compared to $3.2 million in 2025 for the pre-clinical and clinical development. Expenses for our therapeutic development segment will be influenced by our ability to progress our therapeutic candidates through development with the FDA, the timing of which can be uncertain and delayed due to a variety of factors beyond our control, including recently announced staff reductions at the FDA and the effects or residual effects of the recent U.S. “government shutdowns,” which may affect the FDA’s ability to provide any required approvals or review in a timely manner or in the timelines expected.

Looking ahead, we expect research and development expenses to continue increasing as clinical trials progress for FID-007, FID-022, and other pre-clinical studies.

Selling and Marketing

Our consolidated selling and marketing expenses increased by $7.1 million, or 20%, from $36.2 million in 2024 to $43.4 million in 2025. The increase was primarily due to increases of $4.0 million personnel costs, including equity-based compensation expense, $1.9 million in advertising and marketing expenses, $0.4 million in travel expenses, $0.3 million in consulting and outside labor expenses, $0.2 million in supply and material costs, and $0.2 million in software and software licensing expenses.

General and Administrative

Our consolidated general and administrative expenses increased by $28.6 million, or 32%, from $88.1 million in 2024 to $116.7 million in 2025. The increase was primarily due to increases of $17.0 million in legal and professional fees including an accrual related to a professional liability matter, $9.4 million in provision for credit losses, $2.2 million in personnel costs, including equity-based compensation, $1.9 million in acquisition-related costs, $1.0 million in consulting and outside labor costs, $0.9 million in

insurance expenses, and $0.9 million in office expenses, and partially offset by decreases of $2.5 million in facility expenses and $1.6 million in depreciation expenses, and $0.8 million in accounting expenses.

Amortization of Intangible Assets

Our consolidated amortization of intangible assets represents amortization expenses on the intangible assets that arose from the business combinations in 2025, 2022 and 2021, and a patent purchased in 2021.

Other Income (Expenses)

Other income (expense) is primarily comprised of interest income, which was $30.9 million and $31.3 million for 2025 and 2024, respectively, and impairment of available-for-sale debt and equity securities of $9.9 million and $10.1 million in 2025 and 2024, respectively. This interest income included interest earned on marketable securities and realized gain or loss on sale of marketable securities. The decrease in interest income was primarily due to decreased interest rates on marketable securities relative to the prior comparative period.

Benefit from Income Taxes

Benefit from income taxes were $8.4 million and $8.1 million in 2025 and 2024, respectively. The effective income tax rate was 12% and 16% of loss before income taxes for 2025 and 2024, respectively.

On July 4, 2025, OBBBA was signed into law, making permanent certain provisions of the Tax Cuts and Jobs Act, including 100% bonus depreciation and domestic research cost expensing. In accordance with ASC 740, "*Income Taxes*," we have recognized the effects of the new tax law in the period of enactment. The legislation has multiple effective dates, with certain provisions effective in 2025 and others implemented through 2027. The legislation does not have a material impact on our consolidated financial statements for the year ended December 31, 2025.

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

Net Loss Attributable to Noncontrolling Interest

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

Liquidity and Capital Resources

Liquidity and Sources of Cash

We had $705.5 million and $828.6 million in cash, cash equivalents, restricted cash, and marketable securities as of December 31, 2025 and 2024, respectively. Our marketable securities primarily consist of U.S. government and U.S. agency debt securities, U.S. treasury bills, corporate bonds, municipal bonds, and Yankee debt securities as of December 31, 2025, and 2024.

Our primary uses of cash are for strategic acquisitions; capital expenditures, mainly in buildings, building improvements, and equipment; repurchases of our stock; the funding of our clinical trials; and the funding of our operations as we continue to invest in and seek to grow our business. Cash used to fund operating expenses is impacted by the timing of our expense payments, as reflected in the changes in our outstanding accounts payable and accrued expenses.

We expect our existing cash, cash equivalents, restricted cash, and marketable securities to continue to 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, whether large customers continue ordering 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. We intend to improve our profitability by improving margins and expanding in new markets for our tests, but these efforts are subject to risks, including those described in Item 1A of this Annual Report, and may not be successful. 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 raises, 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,	
	2025	2024
	(in thousands)	
Net cash (used in) provided by operating activities	$ (101,638)	$ 21,060
Net cash provided by (used in) investing activities	$ 111,371	$ (58,352)
Net cash used in financing activities	$ (14,789)	$ (4,847)

Operating Activities

During the year ended December 31, 2025, our operations used $101.6 million of cash as compared to $21.1 million provided in 2024. The decrease in cash provided from operating activities in 2025 compared to the corresponding 2024 period was primarily due to the purchase of Investment Tax Credits for $99.6 million in cash in 2025, as well as by timing of cash receipts from customers and cash payments for operating expenses. We expect to incur more operating expenses and use more cash in operating activities in the coming year as a result of our planned and ongoing clinical trials for FID-007 and FID-022, and as we continue to invest resources to grow our laboratory services business.

Investing Activities

The cash provided by or used in investing activities is impacted by capital expenditures for operation needs and timing of payments, timing of maturities of marketable securities, and discretionary business combinations and other investment.
Cash provided by investing activities in 2025 was $111.4 million, which primarily related to $211.0 million related to maturities of marketable securities, and $3.8 million related to the acquisition of ANP, and partially offset by $80.8 million in purchase of marketable securities, $22.6 million related to the purchase of fixed assets consisting mainly of building improvement and medical laboratory equipment.

Cash used in investing activities in 2024 was $58.4 million, which primarily related to $472.4 million in purchase of marketable securities, $40.3 million related to the purchase of fixed assets consisting mainly of building, building improvement, and medical laboratory equipment, and partially offset by $349.8 million related to maturities of marketable securities, $104.3 million related to proceeds from sales of marketable securities, and $0.3 million related to the sale of fixed assets.

Financing Activities

Cash used in financing activities in 2025 was $14.8 million, which primarily related to $3.0 million used in common stock withholding for employee tax obligations, $10.9 million used to repurchase common stock, and $0.5 million used in the repayment of notes payable.

Cash used in financing activities in 2024 was $4.8 million, which primarily related to $2.9 million used in common stock withholding for employee tax obligations and $1.2 million used in the repayment of notes payable.

We do not expect to use any credit facilities due to the strong cash position as of December 31, 2025.

Stock Repurchase Program

In March 2022, our board of directors 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, we may repurchase shares from time to time in the open market or in privately negotiated transactions.

During the year ended December 31, 2025, we repurchased 0.6 million shares of our common stock at an aggregate cost of $10.9 million under the stock repurchase program. During the year ended December 31, 2024, we repurchased ten thousand shares of our common stock at an aggregate cost of $0.2 million under the stock repurchase program. During the year ended December 31, 2023, we repurchased 1.0 million shares of our common stock at an aggregate cost of $25.1 million under the stock repurchase program. As of December 31, 2025, a total of approximately $139.6 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, 2025

As of December 31, 2025, we have an outstanding balance of $2.4 million on an installment loan, of which, the current portion is $0.5 million. See Note 8, *Debt, Commitments and Contingencies*, to our consolidated financial statements included in this report.

The following summarizes our contractual obligations as of December 31, 2025:

	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]	$ 6,214	$ 1,724	$ 1,849	$ 1,124	$ 1,517
Finance lease obligations[2]	366	366	—	—	—
Purchase obligations[3]	39,759	26,637	11,459	1,127	535
Total contractual obligations	$ 46,339	$ 28,727	$ 13,308	$ 2,251	$ 2,052

(1) Represents non-cancelable operating leases. For further information, refer to Note 9, *Leases,* to our consolidated financial statements.

(2) Represents non-cancelable finance leases. For further information, refer to Note 9, *Leases*, to our consolidated financial statements.

(3) Represents purchase obligations for medical lab equipment, reagents and other supplies. These purchase obligations are not unconditional, and they are generally cancellable in full or in part through the contractual provisions.

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. GAAP. The preparation of consolidated financial statements in accordance with U.S. GAAP requires management to make certain estimates, judgments, assumptions and decisions that affect the reported amounts and related disclosures, including the selection of appropriate accounting 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: (i) Insurance, (ii) Institutional customers, including hospitals, medical institutions, other laboratories, governmental bodies, and large corporations; and (iii) 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.

For insurance payors, in the absence of Medicare coverage, contractually established reimbursement rates or other coverage, we have concluded that our contracts include variable consideration because the amounts paid by Medicare or commercial health insurance carriers may be paid at less than our standard rates or not paid at all, with such differences considered implicit price concessions. Variable consideration attributable to these price concessions is measured using the "expected value" method under Accounting Standards Codification, or ASC, 606 Revenue from Contracts with Customers, or ASC 606. The amounts are determined by the historical average collection rates by test type taking into consideration the range of possible outcomes, the predictive value of our past experiences, the time period of when uncertainties expect to be resolved and the amount of consideration that is susceptible to factors outside of our influence, such as the judgment and actions of third parties. Such variable consideration is included in the transaction price only to the extent it is probable that a significant reversal in the amount of cumulative revenue recognized will not occur when the uncertainties with respect to the amount are resolved. Variable consideration may be constrained and excluded from the transaction price in situations where there is the absence of a predictable pattern and history of collectability with a payor.

We re-assess our estimated transaction price at the end of each reporting period, including our assessment of whether our estimate of variable consideration is constrained to the extent that it is probable that a significant reversal of cumulative revenue will not occur once any uncertainty is resolved. We record any necessary adjustments in the current period's revenue.

Valuation of Goodwill and Indefinite-Lived 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.

See Note 2, *Summary of Significant Accounting Policies*, to our consolidated financial statements included in this report for information about our valuation and assessment process with regard to potential impairment of goodwill and indefinite-lived

intangibles. Also see Note 17, *Goodwill and Intangible Assets*, to our consolidated financial statements included in this report for details on the valuations and results for 2025.

There can be no assurance that the estimates and assumptions management made for the purposes of the goodwill or in-process research & development, or IPR&D, impairment analysis will prove to be accurate predictions of future performance. It is possible that the conclusions regarding impairment or recoverability of goodwill or intangible assets could change in future periods. We will continue to monitor the therapeutic development reporting unit. For all IPR&D projects, there are major risks and uncertainties associated with the timely and successful completion of development and commercialization of these product candidates, including the ability to confirm their efficacy based on data from clinical trials, the ability to obtain necessary regulatory approvals, and the ability to successfully complete these tasks within budgeted costs. We are not able to market a human therapeutic without obtaining regulatory approvals, and such approvals require completing clinical trials that demonstrate a product candidate is safe and effective. In addition, the availability and extent of coverage and reimbursement from insurance payors, including government healthcare programs and private insurance plans, impact the revenues a product can generate. Consequently, the eventual realized value, if any, of these acquired IPR&D projects may vary from their estimated fair values.

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 are 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 (loss) 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, 2025 and 2024, a hypothetical 100 basis point increase in interest rates across all maturities would result in an incremental decline of $10.1 million and $14.5 million, respectively, 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 a decrease in assets of approximately $0.7 million as of December 31, 2025, and $1.1 million as of December 31, 2024. The impact to income (loss) before income tax was not significant.

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, 2025. 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, 2025.

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, 2025, that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

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

Our management is responsible for establishing and maintaining 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, 2025. 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, 2025 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.

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 shareholders 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, 2025, 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, 2025, 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, 2025, of the Company and our report dated February 27, 2026, expressed an unqualified opinion on those financial statements.

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 27, 2026

Item 9B. Other Information.

Rule 10b5-1 trading arrangements

During the quarter ended December 31, 2025, none of our directors or officers, as each term is defined in Rule 16a-1(f) of the Exchange Act, adopted or terminated "Rule 10b5-1 trading arrangement" or "non-Rule 10b5-1 trading arrangement," as each term is defined in Item 408 of Regulation S-K, except as follows:

On November 25, 2025, Hanlin Gao, our Chief Scientific Officer and Laboratory Director, entered into a Rule 10b5-1 sales plan, or the Gao Sales Plan, intended to satisfy the affirmative defense conditions of Rule 10b5-1(c) of the Exchange Act. The Gao 10b5-1 Sales Plan, which has a term that expires on January 31, 2027, provides for the sale of up to 100,000 shares of our common stock.

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 2026 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, 2025.

Item 11. Executive Compensation.

The information required by this item is incorporated by reference to the definitive proxy statement for our 2026 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, 2025.

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 2026 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, 2025.

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 2026 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, 2025.

Item 14. Principal Accountant Fees and Services.

The information required by this item is incorporated by reference to the definitive proxy statement for our 2026 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, 2025.

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 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, as amended.	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	Amended and Restated Bylaws.	10-Q	001-37894	3.2	8/4/2023	
4.1	Form of Certificate of Common Stock of the registrant.	S-1/A	333-213469	4.1	9/19/2016	
4.2	Description of the registrant's securities.	10-K	001-37894	4.2	2/28/2025	
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#	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	
10.7#	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	
10.8#	Form of Option Substitution Award under the 2016 Omnibus Incentive Plan of the registrant.	S-1	333-213469	10.9	9/2/2016	
10.9#	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	
10.10#	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	
10.11#	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	
10.12#	Amended and Restated Employment Agreement, dated May 25, 2016, by and among Fulgent Therapeutics LLC, the registrant and Hanlin Gao.	S-1	333-213469	10.13	9/2/2016	
10.13#	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	
10.14#	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	
10.15#	Severance Agreement, dated July 7, 2016, by and among Fulgent Therapeutics LLC, the registrant and Hanlin Gao.	S-1	333-213469	10.16	9/2/2016	
10.16	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	
10.17	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	
10.18§	Cooperation Agreement on the Establishment of Fujian Fujun Gene Biotech Co., Ltd., dated April 25, 2017, by and among Shenzhen Fujin Gene Science &	10-Q	001-37894	10.1	8/14/2017	

Exhibit Number	Description	Form	File Number	Incorporated by Reference Exhibit	Filing Date	Filed Herewith
	Technology Co., Ltd., Xilong Scientific Co., Ltd. and Fuzhou Jinqiang Investment Partnership (LP).					
10.19#	Employment Agreement, dated March 8, 2021, by and among Fulgent Therapeutics, LLC, the registrant and Jian Xie.	10-K	001-37894	10.37	3/8/2021	
10.20#	Severance Agreement, dated March 8, 2021, by and among Fulgent Therapeutics LLC, the registrant and Jian Xie.	10-K	001-37894	10.38	3/8/2021	
10.21**	Restructuring Agreement of Fujian Fujun Gene Biotech Co., Ltd.	10-Q	001-37894	10.1	8/10/2021	
10.22#	Fulgent Genetics, Inc. Incentive Compensation Recoupment Policy.	8-K	001-37894	10.1	3/29/2022	
10.23	Agreement and Plan of Merger, dated as of April 16, 2022, by and among Fulgent Therapeutics LLC, solely for purpose of Section 6.20, the registrant, 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.	8-K	001-37894	2.1	4/26/2022	
10.24#	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	
10.25^	Agreement and Plan of Merger, dated November 7, 2022 by and among the registrant, 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.	10-Q	001-37894	10.3	11/7/2022	
10.26^#	Amended and Restated Executive Officer Incentive Plan of the registrant.	10-Q	001-37894	10.2	11/3/2023	
10.27	Lease Agreement of Premises at 15-19 Crawford Street Needham, Massachusetts, by and between Inform Diagnostics and Crawford Street DE, LLC.	10-K	001-37894	10.51	2/28/2023	
10.28#	Fulgent Pharma Holdings, Inc. 2022 Omnibus Incentive Plan.	10-K	001-37894	10.52	2/28/2023	
10.29*^#	Amended and Restated Director Compensation Program of the registrant.	10-Q	001-37894	10.1	5/5/2023	
10.30	Executive Officer Incentive Plan of the registrant.	10-Q	001-37894	10.3	5/5/2023	
10.31	Amended and Restated 2016 Omnibus Incentive Plan of the registrant.	8-K	001-37894	10.1	5/18/2023	
10.32^	Purchase and Sale Agreement, dated December 20, 2025, by and among Bako Pathology LP, Bako Pathology Holdings Corp., BPA Holding Corp., Dermatopathology Experts, LLC, and Inform Diagnostics, Inc.	8-K	001-37894	10.1	12/22/2025	
10.33^	Asset Purchase Agreement, dated December 20, 2025, by and among Bako Pathology LP, Bako Pathology Holdings Corp., BPA Holding Corp., Bakotic Pathology Associates, L.L.C., Podceuticals L.L.C., GBRL Consulting, LLC, Fulgent Therapeutics, LLC, and Inform Diagnostics, Inc.	8-K	001-37894	10.2	12/22/2025	
19.1	Insider Trading Policy.	10-K	001-37894	19.1	2/28/2025	
21.1	Subsidiaries of the registrant.					X
23.1	Consent of Deloitte & Touche LLP, independent registered public accounting firm, relating to the financial statements of the registrant.					X
24.1	Power of Attorney (included on the signature page hereto).					X
31.1	Certification of Principal Executive Officer pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.					X
31.2	Certification of Principal Financial Officer pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.					X

Exhibit Number	Description	Form	File Number	Incorporated by Reference Exhibit	Filing Date	Filed Herewith
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
97.1^#	Amended and Restated Incentive Compensation Recoupment Policy of the registrant.	10-Q	001-37894	10.1	11/3/2023	
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 is 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.

** Pursuant to Item 601(b)(10) of Regulation S-K, certain confidential portions of this exhibit have been omitted by means of marking such portions with asterisks as the identified confidential portions (i) are not material and (ii) would be competitively harmful if publicly disclosed.

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; provided, that the Company may request confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended, for any exhibits or schedules so furnished.

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 27, 2026

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 or her true and lawful agent, proxy and attorney-in-fact, each acting alone, with full power of substitution and resubstitution, for him or her and in his or her 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 Chairperson of the Board (principal executive officer)	February 27, 2026
/s/ Paul Kim Paul Kim	Chief Financial Officer (principal financial and accounting officer)	February 27, 2026
/s/ Michael Nohaile Michael Nohaile	Director	February 27, 2026
/s/ Regina Groves Regina Groves	Director	February 27, 2026
/s/ Linda Dong Linda Dong	Director	February 27, 2026

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the shareholders 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, 2025, and 2024, the related consolidated statements of operations, comprehensive income (loss), stockholders' equity, and cash flows, for each of the three years in the period ended December 31, 2025, 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, 2025, and 2024, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2025, 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, 2025, 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 27, 2026, 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.

Goodwill and In-Process Research and Development (IPR&D) Intangible Asset —Therapeutic Development Reporting Unit—Refer to Notes 2 and 17 to the financial statements

Critical Audit Matter Description

The Company's evaluation of goodwill and IPR&D for impairment involves an initial assessment to determine whether events or circumstances change that would more likely than not reduce the fair value of the reporting unit goodwill & IPR&D to their carrying value. The Company analyzed qualitative factors, including (i) macroeconomic, industry and market conditions, (ii) cost factors, (iii) overall financial performance compared with prior projections, (iv) the excess of fair value over carrying value as of the most recent quantitative assessment performed, and (v) other relevant entity-specific events to determine whether it was more likely than not that the fair values of the reporting unit & IPR&D were less than their carrying amount as a basis for determining whether it was necessary to perform a quantitative goodwill or IPR&D impairment test.

We identified the Company's qualitative evaluation of goodwill and IPR&D impairment indicators as a critical audit matter because of the significant judgments made by management specifically to estimate the fair value of the reporting unit goodwill and IPR&D, specifically related to the timing assumption for commercial success. This required a high degree of auditor judgment and an increased extent of effort when performing audit procedures to evaluate the reasonableness of management's assumptions related to the timing of commercial success.

How the Critical Audit Matter Was Addressed in the Audit

Our audit procedures related to the Company's qualitative evaluation of goodwill and IPR&D impairment for the Therapeutic Development reporting unit included the following, among others:

- We tested the effectiveness of controls over management's qualitative evaluation of impairment indicators, such as controls related to management's assumptions related to the timing of commercial success.
- We evaluated management's ability to accurately forecast timing of commercial success by comparing actual milestones achieved to milestone assumptions in management's historical forecast.
- We evaluated the reasonableness of management's assumptions related to the timing of commercial success by comparing the current expectations with:
    - Internal communications to management and the Board of Directors.
    - Forecasted information included in Company press releases as well as in external studies.
    - Relevant regulatory approvals supporting timing of commercial success.

/s/ DELOITTE & TOUCHE LLP

Los Angeles, California
February 27, 2026

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, 2025	December 31, 2024
Assets		
Current assets		
Cash and cash equivalents	$ 50,193	$ 55,144
Marketable securities	285,884	202,962
Trade accounts receivable, net of allowance for credit losses of $21,411 as of December 31, 2025, and $20,458 as of December 31, 2024	84,762	69,021
Prepaid income taxes	107,099	3,422
Other current assets	22,552	23,022
Total current assets	550,490	353,571
Marketable securities, long-term	369,269	570,351
Fixed assets, net	112,549	105,549
In-process research & development	68,490	64,590
Other intangible assets, net	64,791	70,388
Goodwill	25,080	22,055
Other long-term assets	22,856	33,460
Total assets	$ 1,213,525	$ 1,219,964
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable	$ 18,654	$ 18,364
Accrued liabilities	34,057	24,279
Customer deposit	28,145	27,610
Contract liabilities	3,635	2,234
Notes payable, current	476	412
Total current liabilities	84,967	72,899
Deferred tax liabilities	6,936	6,370
Unrecognized tax benefits	7,283	4,563
Other long-term liabilities	7,624	6,973
Total liabilities	106,810	90,805
Commitments and Contingencies (Note 8)		
Stockholders' equity		
Common stock, $0.0001 par value per share, 50,000 shares authorized, 34,501 shares issued and 31,081 shares outstanding as of December 31, 2025, and 33,614 shares issued and 30,841 shares outstanding as of December 31, 2024	3	3
Preferred stock, $0.0001 par value per share, 1,000 shares authorized, no shares issued or outstanding as of December 31, 2025, and December 31, 2024	—	—
Additional paid-in capital	574,520	543,126
Accumulated other comprehensive income (loss)	7,512	(368)
Retained earnings	529,954	590,467
Total Fulgent stockholders' equity	1,111,989	1,133,228
Noncontrolling interest	(5,274)	(4,069)
Total stockholders' equity	1,106,715	1,129,159
Total liabilities and stockholders' equity	$ 1,213,525	$ 1,219,964

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

CONSOLIDATED FINANCIAL STATEMENTS

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

	Year Ended December 31,		
	2025	2024	2023
Revenue	$ 322,671	$ 283,470	$ 289,213
Cost of revenue	191,796	176,255	184,757
Gross profit	130,875	107,215	104,456
Operating expenses			
Research and development	53,905	48,816	41,440
Selling and marketing	43,371	36,246	41,467
General and administrative	116,664	88,106	88,999
Amortization of intangible assets	8,031	7,965	7,845
Goodwill impairment loss	—	—	120,234
Total operating expenses	221,971	181,133	299,985
Operating loss	(91,096)	(73,918)	(195,529)
Other income (expenses)			
Interest income	30,919	31,304	21,612
Interest expense	(75)	170	(488)
Impairment loss	(9,926)	(10,073)	—
Other income, net	153	561	320
Total other income, net	21,071	21,962	21,444
Loss before income taxes	(70,025)	(51,956)	(174,085)
(Benefit from) provision for income taxes	(8,394)	(8,136)	1,154
Net loss from consolidated operations	(61,631)	(43,820)	(175,239)
Net loss attributable to noncontrolling interests	1,118	1,112	7,414
Net loss attributable to Fulgent	$ (60,513)	$ (42,708)	$ (167,825)
Net loss per common share attributable to Fulgent:			
Basic	$ (1.97)	$ (1.41)	$ (5.63)
Diluted	$ (1.97)	$ (1.41)	$ (5.63)
Weighted-average common shares:			
Basic	30,777	30,235	29,784
Diluted	30,777	30,235	29,784

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

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

	Year Ended December 31,		
	2025	2024	2023
Net loss from consolidated operations	$ (61,631)	$ (43,820)	$ (175,239)
Other comprehensive (loss) income			
Foreign currency translation income (loss)	775	(511)	(1,200)
Net income (loss) on available-for-sale debt securities, net of tax	7,018	(1,204)	24,717
Net comprehensive loss from consolidated operations	(53,838)	(45,535)	(151,722)
Net loss attributable to noncontrolling interest	1,118	1,112	7,414
Foreign currency translation loss (gain) attributable to noncontrolling interest	87	142	(1,409)
Comprehensive loss attributable to noncontrolling interest	1,205	1,254	6,005
Comprehensive loss attributable to Fulgent	$ (52,633)	$ (44,281)	$ (145,717)

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 (Loss) Income	Retained Earnings	Fulgent Stockholders' Equity	Noncontrolling Interest	Total Equity
Balance at January 1, 2023	**29,438**	**$ 3**	**$ 486,585**	**$ (20,903)**	**$ 801,000**	**$ 1,266,685**	**$ 3,190**	**$ 1,269,875**
Equity-based compensation	—	—	42,922	—	—	42,922	—	42,922
Exercise of common stock options	9	—	3	—	—	3	—	3
Restricted stock awards	1,066	—	—	—	—	—	—	—
Common stock withholding for employee tax obligations	(93)	—	(2,732)	—	—	(2,732)	—	(2,732)
Repurchase of common stock	(953)	—	(25,060)	—	—	(25,060)	—	(25,060)
Common stock issued in a business combination (1)	186	—	—	—	—	—	—	—
Other comprehensive income, net	—	—	—	22,108	—	22,108	1,409	23,517
Net loss	—	—	—	—	(167,825)	(167,825)	(7,414)	(175,239)
Balance at December 31, 2023	**29,653**	**$ 3**	**$ 501,718**	**$ 1,205**	**$ 633,175**	**$ 1,136,101**	**$ (2,815)**	**$ 1,133,286**
Equity-based compensation	—	—	44,481	—	—	44,481	—	44,481
Exercise of common stock options	133	—	51	—	—	51	—	51
Restricted stock awards	1,004	—	—	—	—	—	—	—
Common stock withholding for employee tax obligations	(125)	—	(2,899)	—	—	(2,899)	—	(2,899)
Repurchase of common stock	(10)	—	(225)	—	—	(225)	—	(225)
Common stock issued in a business combination (1)	186	—	—	—	—	—	—	—
Other comprehensive loss, net	—	—	—	(1,573)	—	(1,573)	(142)	(1,715)
Net loss	—	—	—	—	(42,708)	(42,708)	(1,112)	(43,820)
Balance at December 31, 2024	**30,841**	**$ 3**	**$ 543,126**	**$ (368)**	**$ 590,467**	**$ 1,133,228**	**$ (4,069)**	**$ 1,129,159**
Equity-based compensation	—	—	39,582	—	—	39,582	—	39,582
Exercise of common stock options	2	—	1	—	—	1	—	1
Restricted stock awards	1,049	—	—	—	—	—	—	—
Common stock withholding for employee tax obligations	(165)	—	(3,036)	—	—	(3,036)	—	(3,036)
Repurchase of common stock	(646)	—	(10,884)	—	—	(10,884)	—	(10,884)
Contingently issuable shares in a business combination (2)	—	—	5,731	—	—	5,731	—	5,731
Other comprehensive income (loss), net	—	—	—	7,880	—	7,880	(87)	7,793
Net loss	—	—	—	—	(60,513)	(60,513)	(1,118)	(61,631)
Balance at December 31, 2025	**31,081**	**$ 3**	**$ 574,520**	**$ 7,512**	**$ 529,954**	**$ 1,111,989**	**$ (5,274)**	**$ 1,106,715**

(1) 371,000 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 Holdings, Inc., or Fulgent Pharma, in 2022. 186,000 shares were issued in November 2023, and the remainder were issued in May 2024 by the Company upon expiration of hold back provisions.

(2) The Company agreed to issue up to 292,682 shares of the Company's common stock in the acquisition of ANP upon achieving certain cash receipts. $5.7 million represented the fair value of the shares on the acquisition date. As of December 31, 2025, no common stock has been issued as the milestones have not been met. See details in Note 15. *Business Combinations*.

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,		
	2025	**2024**	**2023**
Cash flow from operating activities			
Net loss from consolidated operations	$ (61,631)	$ (43,820)	$ (175,239)
Adjustments to reconcile net loss to net cash (used in) provided by operating activities:			
Goodwill impairment loss	—	—	120,234
Equity-based compensation	39,582	44,481	42,922
Depreciation and amortization	24,123	24,928	26,143
Provision (adjustment) for credit losses	7,648	(1,730)	(880)
Noncash lease expense	1,764	3,760	6,412
(Gain) loss on disposal of fixed asset	(3)	320	305
Discount premium of marketable securities	(5,103)	(5,550)	(3,911)
Deferred taxes	(1,214)	(3,736)	11,466
Unrecognized tax benefits	936	(1,414)	(3,858)
Net realized (gain) loss on marketable securities	(62)	994	589
Impairment loss	9,926	10,073	—
Other	30	(7)	(21)
Changes in operating assets and liabilities:			
Trade accounts receivable	(23,251)	(16,303)	2,388
Income tax	(104,937)	9,253	2,759
Other current and long-term assets	798	199	(3,331)
Accounts payable	550	3,066	(6,896)
Contract liabilities	1,400	(639)	(325)
Customer deposits	520	4,917	11,815
Accrued liabilities and other liabilities	8,911	(3,961)	2,718
Operating lease liabilities	(1,625)	(3,771)	(6,287)
Net cash (used in) provided by operating activities	(101,638)	21,060	27,003
Cash flow from investing activities			
Purchase of marketable securities	(80,842)	(472,415)	(491,914)
Purchases of fixed assets	(22,574)	(40,315)	(22,207)
Maturities of marketable securities	211,007	349,795	508,558
Proceeds from sale of marketable securities	—	104,270	44,085
Proceeds from sale of fixed assets	5	313	775
Acquisition of businesses, net of cash acquired	3,775	—	(399)
Net cash provided by (used in) investing activities	111,371	(58,352)	38,898
Cash flow from financing activities			
Common stock withholding for employee tax obligations	(3,036)	(2,899)	(2,732)
Repayment of notes payable	(471)	(1,230)	(4,266)
Principal paid for finance lease	(399)	(544)	(730)
Repurchase of common stock	(10,884)	(225)	(25,060)
Repayment of investment margin loan	—	—	(15,000)
Proceeds from exercise of stock options	1	51	3
Net cash used in financing activities	(14,789)	(4,847)	(47,785)
Effect of exchange rate changes on cash and cash equivalents	105	(55)	(149)
Net (decrease) increase in cash, cash equivalents, and restricted cash	(4,951)	(42,194)	17,967
Cash, cash equivalents, and restricted cash at beginning of period	55,279	97,473	79,506
Cash, cash equivalents, and restricted cash at end of period	$ 50,328	$ 55,279	$ 97,473
Supplemental disclosures of cash flow information			
Income taxes paid[1]	$ 96,445	$ 27,588	$ 3,261
Interest paid	$ 52	$ 512	$ 960
Supplemental disclosures of non-cash investing and financing activities			
Contingent consideration for business acquisition included in additional paid-in capital[2]	$ 5,731	$ —	$ —
Purchases of fixed assets in accounts payable	$ 1,694	$ 1,806	$ 1,799
Holdback for acquisition of business included in other long-term liabilities[2]	$ 1,887	$ —	$ —
Operating lease right-of-use assets obtained in exchange for lease liabilities	$ 579	$ 1,158	$ 2,661
Operating lease right-of-use assets reduced due to lease modification and termination	$ (47)	$ 57	$ 142
Operating lease liabilities removed due to purchasing underlying assets	$ —	$ 2,799	$ —
Finance lease right-of-use assets reduced due to lease modification and termination	$ —	$ —	$ 696

(1) The Company adopted ASU 2023-09 on a prospective basis. As such, cash paid for income taxes for the years ended December 2024 and 2023, were not adjusted to reflect current year presentation.

(2) These non-cash activities are related to the acquisition of ANP. Refer to Note 15. *Business Combinations* for further details.

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, or U.S. GAAP, and presented in United States Dollars, or USD, the reporting currency of the Company. 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 requires otherwise), is a technology-based company with a well-established laboratory services business and a therapeutic development business. Its laboratory services business includes technical laboratory and testing services and professional interpretation of laboratory results by licensed physicians. Its therapeutic development business is focused on developing product 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. 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 goodwill and indefinite-lived intangible assets 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. 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.

Restricted Cash

Restricted cash consists of legally restricted deposits held in conjunction with a lease contract the Company entered into with a third-party landlord. A bank guarantee equivalent to six months of gross rent plus tax with an expiry date three months post the lease expiry is required under the lease contract, and the lease contract will expire in March 2034. Restricted deposit is recorded in other long-term assets in the Company's Consolidated Balance Sheets as the balance is not expected to be released to cash within the next 12 months. As of December 31, 2025, and December 31, 2024 the Company had restricted cash of $0.1 million.

Cash, Cash Equivalents, and Restricted Cash shown in the Consolidated Statements of Cash Flows

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

	Year Ended December 31,		
	2025	2024	2023
		(in thousands)	
Cash and cash equivalents	$ 50,193	$ 55,144	$ 97,473
Restricted cash included in Other long-term assets	135	135	—
Total cash, cash equivalents, and restricted cash	$ 50,328	$ 55,279	$ 97,473

Marketable Securities

All marketable debt securities, which consist of U.S. government and agency debt securities, U.S. treasury bills, corporate debt securities, municipal bonds, 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 income, in the accompanying Consolidated Statements of Operations. The cost of any marketable debt securities sold is based on the specific-identification method. The amortized cost of marketable debt securities is adjusted for amortization of premiums and accretion of discounts to maturity. Interest on marketable debt securities is included in interest income. The Company elected the practical expedient to exclude accrued interest receivable from both the amortized cost basis and fair value of available-for-sale security investments. The Company does not measure an allowance for credit losses on accrued interest receivable. Any interest receivable credit losses would be written off promptly in the current period. 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, if any, are measured at fair value with the related gains and losses, realized and unrealized, recognized in interest income, in the accompanying Consolidated Statements of Operations. The cost of any marketable equity securities sold is based on the specific-identification method.

For available-for-sale debt securities, in an unrealized loss, the Company determines whether a credit loss exists. The credit loss is estimated by considering available information relevant to the collectability of the security and information about past events, current conditions, and reasonable and supportable forecasts. 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 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 Operations. The Company assesses collectability by reviewing trade accounts receivable on a collective basis where similar risk characteristics exist and on an individual basis when it identifies specific customers that have deterioration in credit quality such that they may no longer share similar risk characteristics with the other receivables. In determining the amount of the allowance for credit losses, the Company uses a loss rate model or probability-of-default and loss given default model. Following the loss rate method, expected credit losses are determined based on an estimated historical loss rate. The probability of default method 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 loss rate and factors quarterly 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:

	2025	2024	2023
		(in thousands)	
Allowance for credit losses at beginning of year	$ 20,458	$ 25,226	$ 41,205
Current period provision (gain)	7,648	(1,730)	(880)
Write-downs	(6,921)	(11,155)	(15,099)
Recoveries of amounts previously charged off	226	8,117	—
Allowance for credit losses at end of year	$ 21,411	$ 20,458	$ 25,226

Preferred Stock Investment

The Company had 7.3 million shares of preferred stock of a privately-held, Cayman Islands company, Laboratory for Advanced Medicine, Inc., or LAMH, doing business as "Helio Health" that the Company purchased in July 2021. Helio Health is an AI-biotechnology company developing blood-based early cancer detection tests, and the Company expected to gain access to an emerging liquid biopsy testing technology, through this strategic partnership. As the preferred stock had the option to be redeemed, the investment was initially recorded as available-for-sale debt securities with changes in fair value recorded in other comprehensive income (loss).

On June 19, 2024, the Board of Directors of LAMH approved to spin out certain U.S.-based laboratory and development operations into a separate, privately-held Delaware corporation, Helio Genomics, Inc., or Helio Genomics. The Company received 7.3 million shares of preferred stock of Helio Genomics in connection with this spin-out.

Post spin-out, Helio Genomics amended and restated its certificate of incorporation on July 25, 2024, which resulted in a change in stockholder's rights where the Company no longer holds the right to redeem its preferred stock of Helio Genomics. As a result, the Company reclassified $0.4 million unrealized gain out of accumulated other comprehensive income (loss) to net income (loss) in the consolidated financial statements. The Company elected to record its preferred stock investment in Helio Genomics under the measurement alternative in accordance with ASC 321, "*Investments-Equity Securities*," defined as cost less impairment, adjusted for subsequent observable price changes and are periodically assessed for impairment when events or circumstances indicate that a decline in value may have occurred. As of July 25, 2024 and December 31, 2024, the preferred stock investment carrying value of $9.9 million was recorded as other long-term assets in the Consolidated Balance Sheets. During the year ended December 31, 2025, the Company performed a qualitative assessment to determine if this investment was impaired. Indicators considered included significant declines in the investee's operating performance, adverse changes in industry conditions, and deterioration in the investee's financial condition. As part of this review, the Company identified that Helio Genomics exhibited several adverse conditions, including a deterioration in financial condition and the inability to secure sufficient financing to support future operations. Given these developments and their impact on Helio Genomics' ability to continue funding its operations, management concluded that the Company's investment in Helio Genomics was impaired. To estimate the fair value of the investment, the Company employed a discounted cash flow analysis, using assumptions including projected revenues and expenses, discount rates, and a terminal value multiple. The resulting estimated fair value was deemed insignificant. As a result, the Company recorded $9.9 million of impairment loss during the year ended December 31, 2025. The impairment is reflected as impairment loss in the Consolidated Statement of Operations. The carrying amount of the investment in Helio Genomics on the Consolidated Balance Sheet was reduced to its fair value of an insignificant amount, which now represents its new cost basis. The Company continues to monitor its investments for changes in facts and circumstances that may indicate further impairments or observable price changes in orderly transactions.

Post spin-out, the Company retained the original right to redeem its LAMH preferred stock. As the preferred stock had the option to be redeemed, the investment was recorded as available-for-sale debt securities with changes in fair value recorded in other comprehensive income (loss). The Company considered a number of factors including, but not limited to: (i) the extent to which the fair value of the investment is less than its amortized cost; (ii) the financial condition and near-term prospects of the investee, and (iii) general market conditions. As a result, the Company recognized a $10.1 million credit loss during the year ended December 31, 2024, recorded as impairment loss in the Consolidated Statements of Operations.

The roll-forward for the allowance for credit losses related to the available-for-sale debt securities is as follows:

	2025	2024	2023
		(in thousands)	
Allowance for credit losses at beginning of year	$ —	$ —	$ —
Current period provision	—	10,073	—
Write-downs	—	(10,073)	—
Allowance for credit losses at end of year	$ —	$ —	$ —

Business Combinations

The Company uses the acquisition method of accounting and allocates the fair value of purchase consideration to the assets acquired, liabilities assumed and any noncontrolling interest in the 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.

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.

Finite-Lived Intangible Assets

Intangible assets, unless determined to be indefinite-lived, are amortized over their estimated useful lives. The Company amortizes intangible assets with definite lives on a straight-line basis generally over periods ranging from 3 to 18 years. See Note 17, *Goodwill and Intangible Assets*, for details of intangible assets.

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.

Goodwill and Indefinite-Lived Intangibles

In-process research & development, or IPR&D, costs 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.

The Company assesses goodwill and indefinite-lived intangibles for impairment on an annual basis and between annual tests if an event occurs or circumstances change that would more likely than not reduce the fair value of a reporting unit below its carrying amount. The Company may choose to bypass a qualitative assessment of impairment for any reporting unit and proceed directly to performing a quantitative assessment. An impairment loss would be recognized for the amount by which the reporting unit's carrying amount exceeds its fair value.

If a quantitative assessment is deemed necessary, the quantitative assessment includes estimating the fair value of each reporting unit and comparing it to its carrying value. The Company estimates the fair value of reporting units using both income-based and market-based valuation methods and typically engages a third-party appraisal firm to assist with the valuation. If the estimated fair value of a reporting unit exceeds its carrying value, the goodwill is not impaired, and no further review is required.

The income-based fair value methodology is based on a reporting unit's forecasted future cash flows that are discounted to the present value using the reporting unit's weighted-average cost of capital, or WACC. The income-based approach incorporates management's assumptions and judgments regarding economic conditions in the markets in which a company operates and conditions

in the capital markets, many of which are outside of management's control. The market-based fair value methodology includes (i) the guideline public company valuation method, which analyzes the valuation multiples of comparable public companies, and (ii) the merger and acquisition method, which compares the market values of similar businesses, to estimate the value of the reporting units. Under the market-based approach, judgment is required in evaluating market multiples and recent transactions.

The Company performed an annual goodwill and intangible asset impairment test on December 31, 2025, and determined it was not more likely than not that the fair value of the therapeutic development reporting unit, or the associated indefinite lived intangible asset, was less than its carrying amount. Therefore, a quantitative assessment of the reporting unit was not deemed necessary.

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 are 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, restricted cash, a preferred stock investment, accounts payable, and accrued liabilities. The carrying amounts of certain of these financial instruments, including cash and cash equivalents, accounts receivable, accounts payable, and accrued liabilities approximate fair value due to their short maturities. The fair value of marketable securities, and the preferred stock investments is disclosed in Note 4, *Fair Value Measurement*s, 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. As of December 31, 2025, 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 or a single laboratory customer have accounted for a significant portion of the Company's revenue. For the laboratory services segment, when customers who, to our knowledge, are under common control or otherwise affiliated with each other are aggregated, one of our laboratory customers contributed $70.8 million or 22% of total revenue in the year ended December 31, 2025. The same laboratory customer comprised $62.6 million or 22% of total revenue in the year ended December 31, 2024, and $35.7 million or 12% of total revenue in the year ended December 31, 2023. The same laboratory customer comprised 13% of total accounts receivable, net, as of December 31, 2025, and 15% of total accounts receivable, net, as of December 31, 2024. The Company continues to see significant concentration in this single large laboratory customer. For this laboratory customer, and for our customers generally, tests are typically purchased on a test-by-test basis and not pursuant to any long-term purchasing arrangements. Any or all of the Company's 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 the Company, which could adversely affect the Company's revenue. The Company believes some of these fluctuations in customer demand may be attributable, in part, to the nature of its business. The Company's traditional laboratory and testing services customers can experience significant volatility in their testing demand from period to period in the ordinary course of their operations. Demand fluctuations, particularly for any large customers, often have a significant impact on the Company's period-to-period performance regardless of their cause. In the therapeutic development segment, revenue is an immaterial portion of the Company's total revenue as it does not yet have any commercialized or approved product candidates.

The Company's therapeutic development business relies on ANP, for certain laboratory services, equipment, tools, and drug intermediates in connection with research and development efforts. In July 2025, the Company completed an acquisition of 100% of the outstanding equity of ANP. See more details in Note 15. *Business Combinations.* The Company also relies on a limited number of suppliers for certain laboratory substances used in the chemical reactions incorporated into its processes, referred to as reagents, as well as for the sequencers and various other equipment and materials it uses in its laboratory operations. In particular, the Company relies on a sole supplier for the next generation sequencers and associated reagents it uses to perform its genetic tests and as the sole provider of maintenance and repair services for these sequencers. The Company's laboratory operations would be interrupted if it encountered delays or difficulties securing these reagents, sequencers, other equipment or materials or maintenance and repair services, which could occur for a variety of reasons, including if the Company needs a replacement or temporary substitute for any of its limited or sole suppliers and is not able to locate and make arrangements for an acceptable replacement or temporary substitute. The Company's development efforts could also be delayed or interrupted if it is unable to procure items needed for its therapeutic

development activities. The Company believes there is currently a limited number of manufacturers capable of supplying and servicing some of the equipment and other materials necessary for its laboratory operations, including sequencers and various associated reagents.

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 a 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 leases, 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 in the accompanying Consolidated Statements of Operations.

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

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 between 1 to 10 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 those criteria and costs incurred on projects in the preliminary and post-implementation phases are expensed as incurred.

Reportable Segment and Geographic Information

Reporting segments are identified as components of an enterprise for 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. In 2023, the Company changed the structure of its internal organization and increased the number of reportable segments from one segment to two segments, a laboratory services business and a therapeutic development business. The associated financial information for the segments was recast in 2023 for comparability purposes as recommended in ASC 280-10-50-34. For further financial information about these segments, including information for each of the last three fiscal years regarding revenue, operating income (loss), and other important information, see Note 7, *Reportable Segment and Geographic Information*.

Revenue Recognition

The Company generates revenue from sales of its testing services. The Company currently receives payments from primarily three different customer types: (i) Insurance, (ii) Institutional customers, including hospitals, medical institutions, other laboratories, governmental bodies, and large corporations, and (iii) 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 ASC 606: (Step 1) identifies the contract with the customer, (Step 2) identifies the

performance obligations in the contract, (Step 3) determines the transaction price, (Step 4) allocates the transaction price to the performance obligations in the contract, and (Step 5) recognizes revenue when (or as) the entity satisfies a performance obligation.

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 such shipping and handling fees incurred are included in cost of revenue in the accompanying Consolidated Statements of Operations.

Performance Obligations

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 revenue, 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 insurance payors that are less than the contractually stated price, therefore estimation of the transaction price is considered variable consideration. In developing the estimate of variable consideration, the Company utilizes the expected value method under a portfolio approach. 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.

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. In arrangements with institutions, including hospitals, medical institutions, other laboratories, governmental bodies, 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, the Company identified the institutions, including hospitals, medical institutions, other laboratories, governmental bodies, 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.

The Company enters into contracts with research institutions to perform testing and research services. Revenue is recognized as each individual test is completed, as the Company has a right to payment upon completion of each test. While the contract represents a single performance obligation to provide testing and research services, the revenue is recognized as the individual tests are completed and the results are delivered to the customer. Each completed test is considered a measurable event that indicates the transfer of control to the customer, at which point revenue is recognized based on the output method of units delivered. The Company regularly reviews its contracts and recognizes revenue in accordance with the completion of each test, based on the right to payment and the transfer of control.

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 general and administrative expense in the Consolidated Statements of Operations. Historically, contract costs have not been significant to the financial statements.

Significant Judgments and Contract Estimates

Accounting for insurance contracts includes estimation of the transaction price, defined as the amount the Company expects to be entitled to receive in exchange for providing the services under the contract. Due to the Company's out-of-network status with various insurance payors, estimation of the transaction price represents variable consideration.

In the absence of Medicare coverage, contractually established reimbursement rates or other coverage, the Company has concluded that its contracts include variable consideration because the amounts paid by Medicare or commercial health insurance carriers may be paid at less than our standard rates or not paid at all, with such differences considered implicit price concessions. Variable consideration attributable to these price concessions is measured using the "expected value" method under ASC 606. The amounts are determined by the historical average collection rates by test type taking into consideration the range of possible outcomes, the predictive value of our past experiences, the time period during which uncertainties are expected to be resolved and the amount of consideration that is susceptible to factors outside of our influence, such as the judgment and actions of insurance payors. Such

variable consideration is included in the transaction price only to the extent it is probable that a significant reversal in the amount of cumulative revenue recognized will not occur when the uncertainties with respect to the amount are resolved. Variable consideration may be constrained and excluded from the transaction price in situations where there is no contractually agreed upon reimbursement coverage or in the absence of a predictable pattern and history of collectability with a payor.

The Company re-assesses its estimated transaction price at the end of each reporting period, including an assessment of whether the estimated variable consideration is constrained to the extent that it is probable that a significant reversal of cumulative revenue will not occur once any uncertainty is resolved. The Company records any necessary adjustments in the current period's revenue. Zero and $1.8 million variable consideration were recognized as additional revenue in the years ended December 31, 2025, and 2024, respectively, that related to collections for COVID-19 tests completed in the prior period.

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 facility, rent, and utilities, to cost of revenue and operating expense categories based on square footage. 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 building or leasehold improvements and allocated overhead. Costs associated with performing tests are recorded as tests are processed.

Research and Development Expenses

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

Selling and Marketing Expenses

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

General and Administrative Expenses

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

Income Taxes

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

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

The Company releases income tax effects from other comprehensive income (loss) under the portfolio method. In 2024, the Company reclassified certain investments out of the available-for-sale debt security category. This reclassification resulted in the removal of unrealized gains or losses previously recorded in other comprehensive income (loss). The tax effects of these adjustments have been recognized, as a benefit of $2.1 million, in net loss to avoid stranded tax effects in other comprehensive income (loss).

Equity-Based Compensation

The Company maintains stock equity incentive plans under which the Company grants incentive and nonqualified stock options, stock awards, performance awards or restricted stock units to employees, non-employee directors and consultants.

Equity-based compensation costs are reflected in the accompanying Consolidated Statements of Operations based upon each award recipient's role with the Company. The Company primarily grants restricted stock unit awards, or RSU awards, to its employees that generally vest over a specified period of time upon the satisfaction of service-based conditions or performance conditions. Compensation expense for employee RSU awards with a service-based vesting condition is recognized ratably over the vesting period of the award. Compensation expense for employee RSU awards with a performance condition is based on the probable outcome of that performance condition. The Company also grants stock options. The Company estimates the fair value of service-based stock options on the date of grant using the Black-Scholes pricing model. The Company recognizes compensation expense for service-based options over the requisite service period (generally four years).

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. These unrealized gains and losses are recognized in accumulated other comprehensive income in the equity section of the accompanying Consolidated Balance Sheets, and do not impact net 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. The carrying value of these monetary assets and liabilities will change with exchange rate fluctuations resulting in a foreign currency transaction gain or loss which is recognized in other income, net in the Consolidated Statements of Operations. Reagents and supplies, property, and other nonmonetary assets and liabilities are remeasured when the transaction is initially recognized using the historical rate that was in effect when the asset was acquired or liability was incurred. The carrying amounts do not change as a result of exchange rate fluctuations and no foreign currency transaction gain or loss is recognized. Gains and losses from foreign currency exchange were not significant in 2025, 2024, and 2023.

Comprehensive (Loss) Income

Comprehensive (loss) income is comprised of net (loss) income and other comprehensive (loss) income. Other comprehensive (loss) income 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. The tax expense of foreign currency translation income (loss) was zero for each of the years ended December 31, 2025, 2024 and 2023.

Reclassification from other comprehensive (loss) income to net loss, which includes reclassification of stranded tax effects, was $0.1 million and $3.6 million in 2025 and 2024, respectively. Reclassifications from other comprehensive income (loss) to net earnings were not significant in 2023. The tax effects related to net unrealized gain or loss on available-for-sale debt securities were

zero in each of 2025, 2024 and 2023, due to the valuation allowance in the current period that precludes the Company from recognizing the deferred tax benefit.

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, (ii) Institutional, including hospitals, medical institutions, other laboratories, governmental bodies, 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, 2025, 2024, and 2023.

	Year Ended December 31,		
	2025	2024	2023
		(in thousands)	
Revenue by payor			
Institutional	$ 184,601	$ 154,733	$ 134,191
Insurance	130,253	123,924	151,946
Patient	7,817	4,813	3,076
Total revenue	$ 322,671	$ 283,470	$ 289,213

During the year ended December 31, 2024, the Company experienced a change in estimate related to variable consideration. $1.8 million variable consideration was recognized in the year ended December 31, 2024, related to COVID-19 test services completed in the prior periods due to collection efforts, which was included as revenue from insurance in the table above. No such adjustments were recognized in the year ended December 31, 2025. The Company estimates variable consideration using the expected value method. Any changes in variable consideration estimates that affect transactions are accounted for on a cumulative catch-up basis.

Contract Balances

Receivables from contracts with customers - Receivables from contracts with customers are included within trade accounts receivable on the Consolidated Balance Sheets. Receivables from Insurance and Institutional customers each represented 50% as of December 31, 2025 and 44% and 56%, respectively, as of December 31, 2024.

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 $0.4 million, $2.5 million and $2.2 million for the years ended December 31, 2025, 2024, and 2023, respectively, related to contract liabilities at the beginning of the respective periods were recognized.

Transaction Price Allocated to Future Performance Obligations

ASC 606 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 of December 31, 2025. 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 applies 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 its testing services that extend beyond one year.

Prior Period Reclassifications

Certain amounts reported in the prior period have been reclassified to conform with the current period presentation. In the Consolidated Balance Sheets, the Company has separated prepaid income taxes from its previous inclusion in other current assets, and in-process research & development from its previous inclusion in other intangible assets, net.

Recent Accounting Pronouncements

The Company evaluates all Accounting Standards Updates, or ASUs, issued by the 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.

Adopted

In December 2023, the FASB issued ASU 2023-09, Income Taxes (Topic 740): *Improvement to Income Tax Disclosures*. This update establishes new income tax disclosure requirements in addition to modifying and eliminating certain existing requirements. Under the new guidance, entities must consistently categorize and provide greater disaggregation of information in the rate reconciliation. They must also further disaggregate income taxes paid. The standard is intended to benefit stockholders by providing more detailed income tax disclosures that would be useful in making capital allocation decisions. The guidance applies to all entities subject to income taxes and is effective for annual period beginning after December 15, 2024. The Company has adopted this standard on a prospective basis for the year ended December 31, 2025.

Issued

In November 2024, the FASB issued ASU 2024-03, *Income Statement-Reporting Comprehensive Income-Expense Disaggregation Disclosures (Subtopic 220-40): Disaggregation of Income Statement Expenses*. This update requires disclosure in the notes to financial statements of specified information about certain costs and expenses. Amendments in this update are effective for annual periods beginning after December 15, 2026, and interim reporting periods beginning after December 15, 2027. Early adoption is permitted. The Company is currently evaluating the impacts of this amendment on its consolidated financial statements and related disclosure.

In July 2025, the FASB issued ASU 2025-05, *Financial Instruments-Credit Losses (Topic 326): Measurement of Credit Losses for Accounts Receivable and Contract Assets*. This update provides all entities with a practical expedient related to the estimation of expected credit losses for current accounts receivable and current contract assets that arise from transactions accounted for under ASC 606. Amendments in this update are effective for annual periods beginning after December 15, 2025, and interim reporting periods within those annual reporting periods. Early adoption is permitted. The Company is currently evaluating the impact of this amendment on its financial statements and related disclosures.

In September 2025, the FASB issued ASU 2025-06, *Intangible - Goodwill and Other - Internal-Use Software (Subtopic 350-40): Targeted Improvements to the Accounting for Internal-Use Software*. This update simplifies the capitalization guidance by removing all references to software development project stages, so that the guidance is neutral to different software development methods. Amendments in this update are effective for annual periods beginning after December 15, 2027, and interim reporting periods within those annual reporting periods. Early adoption is permitted. The Company is currently evaluating the impacts of this amendment on its financial statements and related disclosures.

In December 2025, the FASB issued ASU 2025-11, *Interim Reporting (Topic 270): Narrow-Scope Improvements*. This update clarifies the applicability of interim reporting guidance, provides a comprehensive list of required interim disclosures, and establishes a disclosure principle that requires disclosure of material events that occurred after the end of the last annual reporting period. Amendments in this update are effective for interim reporting periods within annual periods beginning after December 15, 2027. Early adoption is permitted. The Company is currently evaluating the impact of this amendment on its financial statement and related disclosures.

In December 2025, the FASB issued ASU 2025-12, *Codification Improvements ("ASU 2025-12")*. This update makes targeted amendments to various topics within the Accounting Standards Codification intended to clarify, correct errors, or make minor improvements to existing guidance. Amendments in this update are effective for annual reporting periods beginning after December 15, 2026, and interim reporting periods within those annual reporting periods. Early adoption is permitted. The Company is currently evaluating the impacts of this amendment on its financial statements and related disclosures.

The Company does not expect that any other recently issued accounting guidance will have a significant effect on its consolidated financial statements.

Note 3. Equity and Debt Securities

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

	December 31, 2025			
	Amortized Cost Basis	Unrealized Gains	Unrealized Losses	Aggregate Fair Value
	(in thousands)			
Equity securities				
Long-term				
Preferred stock of privately-held companies	$ 15,001	$ —	$ —	$ 15,001
Total equity securities	15,001	—	—	15,001
Available-for-sale debt securities				
Short-term				
U.S. government debt securities	159,875	748	(1)	160,622
U.S. agency debt securities	86,786	133	(1)	86,918
Corporate debt securities	37,333	157	(16)	37,474
Yankee debt securities	500	—	(5)	495
Municipal bonds	375	—	—	375
Money market accounts	18,398	—	—	18,398
Less: Cash equivalents	(18,398)	—	—	(18,398)
Total debt securities due within 1 year	284,869	1,038	(23)	285,884
After 1 year through 5 years				
U.S. government debt securities	284,857	2,821	(67)	287,611
U.S. agency debt securities	70,567	123	(51)	70,639
Corporate debt securities	9,922	85	—	10,007
Municipal bonds	1,015	1	(4)	1,012
Total debt securities due after 1 year through 5 years	366,361	3,030	(122)	369,269
Total available-for-sale debt securities	651,230	4,068	(145)	655,153
Total equity and debt securities	$ 666,231	$ 4,068	$ (145)	$ 670,154

	December 31, 2024			
	Amortized Cost Basis	Unrealized Gains	Unrealized Losses	Aggregate Fair Value
	(in thousands)			
Equity securities				
Long-term				
Preferred stock of privately-held companies	$ 24,927	$ —	$ —	$ 24,927
Total equity securities	24,927	—	—	24,927
Available-for-sale debt securities				
Short-term				
U.S. government debt securities	75,054	136	(25)	75,165
U.S. agency debt securities	65,490	72	(23)	65,539
U.S. treasury bills	44,366	19	(2)	44,383
Corporate debt securities	19,177	12	(50)	19,139
Municipal bonds	3,719	1	(7)	3,713
Money market accounts	19,720	—	—	19,720
Less: Cash equivalents	(24,696)	(1)	—	(24,697)
Total debt securities due within 1 year	202,830	239	(107)	202,962
After 1 year through 5 years				
U.S. government debt securities	379,060	565	(2,283)	377,342
U.S. agency debt securities	144,398	57	(1,507)	142,948
Corporate debt securities	47,801	114	(150)	47,765
Municipal bonds	1,820	2	(4)	1,818
Yankee debt securities	501	—	(23)	478
Total debt securities due after 1 year through 5 years	573,580	738	(3,967)	570,351
Total available-for-sale debt securities	776,410	977	(4,074)	773,313
Total equity and debt securities	$ 801,337	$ 977	$ (4,074)	$ 798,240

Gross unrealized losses on the Company's equity and debt securities were $0.1 million and $4.1 million as of December 31, 2025 and 2024, respectively. Proceeds from sale of available-for-sale securities were zero, $104.3 million, and $44.1 million in 2025, 2024, and 2023, respectively. Gross realized losses on the Company's available-for-sale securities were zero, $1.1 million, and $0.6 million in 2025, 2024, and 2023, respectively, and the gross realized income was insignificant in 2025, 2024, and 2023. The cost of any marketable securities sold is based on the specific-identification method. The Company did not recognize any credit losses for its marketable available-for sale debt securities in 2025, 2024, and 2023.

See Note 2, *Summary of Significant Accounting Policies*, for the reclassification of available-for-sale securities to equity securities and subsequent impairment of $9.9 million in 2025, and a credit loss of $10.1 million recorded in 2024 related to Helio Health.

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 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, 2025			
	Total	Level 1	Level 2	Level 3
	(in thousands)			
Equity securities, debt securities and cash equivalents				
U.S. government debt securities	$ 448,233	$ —	$ 448,233	$ —
U.S. agency debt securities	157,557	—	157,557	—
Corporate debt securities	47,481	—	47,481	—
Money market accounts	18,398	18,398	—	—
Preferred stock of privately-held companies	15,001	—	—	15,001
Municipal bonds	1,387	—	1,387	—
Yankee debt securities	495	—	495	—
Total equity securities, debt securities and cash equivalents	$ 688,552	$ 18,398	$ 655,153	$ 15,001

	December 31, 2024			
	Total	Level 1	Level 2	Level 3
	(in thousands)			
Equity securities, debt securities and cash equivalents				
U.S. government debt securities	$ 452,507	$ —	$ 452,507	$ —
U.S. agency debt securities	208,487	—	208,487	—
Corporate debt securities	66,904	—	66,904	—
U.S. treasury bills	44,383	44,383	—	—
Preferred stock of privately-held companies	24,927	—	—	24,927
Money market accounts	19,720	19,720	—	—
Municipal bonds	5,531	—	5,531	—
Yankee debt securities	478	—	478	—
Total equity securities, debt securities and cash equivalents	$ 822,937	$ 64,103	$ 733,907	$ 24,927

The Company's Level 1 assets include U.S. treasury bills and money market instruments and are valued based upon observable market prices. Level 2 assets consist of U.S. government and U.S. agency debt securities, municipal bonds, corporate debt securities and Yankee debt securities. Level 2 securities are valued based upon observable inputs that include reported trades, broker/dealer quotes, bids and offers.

As of December 31, 2025, and 2024, the Company held preferred stock of two privately-held companies, which were included in other long-term assets in the accompanying Consolidated Balance Sheets, that were measured using unobservable (Level 3) inputs. For the value of the investment in private equity securities, the Company elected to measure them at cost minus impairment, as the preferred stock of the privately-held companies did not have a readily determinable fair value. See Note 2, *Summary of Significant Accounting Policies*, for an impairment of $9.9 million recognized in 2025 related to Helio Genomics. There was no impairment loss recorded as of December 31, 2025, for the other preferred stock investment.

There were no transfers between fair value measurement levels during the years ended December 31, 2025, 2024, and 2023.

Note 5. Fixed Assets

Major classes of fixed assets consisted of the following:

	Useful Lives	December 31, 2025	December 31, 2024
		(in thousands)	
Medical lab equipment	5 months to 13 Years	$ 60,691	$ 57,541
Building improvements	6 months to 39 Years	33,198	27,924
Building	25 to 39 Years	21,689	21,689
Computer hardware	1 to 5 Years	8,640	7,328
Aircraft	7 Years	6,400	6,400
Computer software	1 to 10 Years	6,300	7,214
Leasehold improvements	Shorter of lease term or estimated useful life	4,473	3,323
Furniture and fixtures	1 to 11 Years	4,128	4,109
Land improvements	5 to 15 Years	938	904
Automobile	3 to 8 Years	628	581
General equipment	5 Years	226	108
Land		17,347	17,347
Assets not yet placed in service		5,836	2,792
Total		170,494	157,260
Less: Accumulated depreciation		(57,945)	(51,711)
Fixed assets, net		$ 112,549	$ 105,549

Depreciation expense on fixed assets totaled $15.7 million, $16.4 million and $17.5 million for the years ended December 31, 2025, 2024, and 2023, respectively.

Note 6. Other Significant Balance Sheet Accounts

Other current assets consisted of the following:

	December 31, 2025	December 31, 2024
	(in thousands)	
Reagents and supplies	10,604	8,384
Marketable securities interest receivable	5,714	6,241
Prepaid expenses	5,100	6,629
Other receivable	1,134	1,768
Total	$ 22,552	$ 23,022

Accrued liabilities consisted of the following:

	December 31, 2025	December 31, 2024
	(in thousands)	
Accrued legal liabilities	$ 14,905	$ 1,101
Vacation accrual	5,236	4,088
Accrued bonus and commission	5,224	5,803
Payroll liabilities	4,383	8,210
Operating lease liabilities - short term	1,462	1,443
Other accrued liabilities	2,847	3,634
Total	$ 34,057	$ 24,279

Accrued legal liabilities included an accrual of $14.5 million related to a professional liability matter, refer to Note 8, *Debt, Commitments and Contingencies*, for additional details. Other accrued liabilities also included, short-term finance lease liabilities, health insurance liabilities, accrued property taxes, income tax payables, and third-party billing services.

Other long-term liabilities consisted of the following:

	December 31, 2025	December 31, 2024
	(in thousands)	
Operating lease liabilities, long term	$ 3,781	$ 4,120
Notes payable, long term	1,958	2,493
Other long-term liabilities	1,885	360
Total	$ 7,624	$ 6,973

Note 7. Reportable Segment and Geographic Information

The Company has two distinct reportable segments. The laboratory services operating segment offers technical laboratory and testing services and professional interpretation of laboratory results by licensed physicians who specialize in pathology and oncology. The therapeutic development operating segment is a pharmaceutical research and development entity.

The Company's Chief Executive Officer serves as its Chief Operating Decision Maker, or CODM. The CODM oversees the Company's operations and evaluates financial data for its two operating segments separately to make resource allocation decisions. The financial information regularly provided to the CODM includes various performance metrics by reporting segment, such as gross profit, operating income or loss, income or loss before income taxes, net income or loss from consolidated operations, and net income or loss attributable to Fulgent, all presented in accordance with U.S. GAAP. Although multiple financial metrics are provided, the CODM primarily relies on adjusted (non-GAAP) operating income or loss to evaluate segment performance and allocate resources. These adjusted metrics exclude the impact of equity-based compensation expenses, goodwill impairment losses, amortization of intangible assets, acquisition-related costs, and certain professional liability expenses, if applicable as determined by management. The balance sheet is presented on a consolidated basis, as the CODM does not use asset or liability information, including fixed assets, to assess segment performance. As a result, segment asset and liability details are not disclosed.

The newly acquired entity, ANP, is considered part of the therapeutic development segment as this acquisition was strategically undertaken to gain full control over the patents and technologies utilized in the development of product candidates within the therapeutic development segment. Consequently, ANP's operations are integrated into the therapeutic development segment, with shared resources and collaborative efforts, and the CODM evaluates ANP's operations as part of the therapeutic development segment's consolidated financial information. Therefore, ANP's financial results are grouped within the therapeutic development segment's reporting. ANP generates revenue from technologies licensed to pharmaceutical and biotech companies, as well as contract research organizations, or CROs.

There is no inter-segment allocation of interest expense and income taxes. There is no inter-segment revenue and operating income or loss. The Company did not allocate income tax by segment. Information regarding the Company's operations and assets for its reporting segments as well as geographic information are as follows, all dollars are in thousands:

	Laboratory Services	Therapeutic Development	Total
Fiscal year ended December 31, 2025			
Revenue	$ 322,224	$ 447	$ 322,671
Less:			
Adjusted cost of revenue	184,964	5	184,969
Adjusted research and development	21,637	19,037	40,674
Adjusted selling and marketing	40,350	5	40,355
Adjusted general and administrative	82,485	1,247	83,732
Total adjusted operating loss	$ (7,212)	$ (19,847)	$ (27,059)

	Laboratory Services	Therapeutic Development	Total
Fiscal year ended December 31, 2024			
Revenue	$ 283,470	$ —	$ 283,470
Less:			
Adjusted cost of revenue	168,456	—	168,456
Adjusted research and development	18,213	15,632	33,845
Adjusted selling and marketing	32,339	—	32,339
Adjusted general and administrative	69,374	928	70,302
Total adjusted operating loss	$ (4,912)	$ (16,560)	$ (21,472)

	Laboratory Services	Therapeutic Development	Total
Fiscal year ended December 31, 2023			
Revenue	$ 289,213	$ —	$ 289,213
Less:			
Adjusted cost of revenue	175,008	—	175,008
Adjusted research and development	19,577	6,990	26,567
Adjusted selling and marketing	36,503	—	36,503
Adjusted general and administrative	74,982	681	75,663
Total adjusted operating loss	$ (16,857)	$ (7,671)	$ (24,528)

	Year Ended December 31,		
	2025	2024	2023
Reconciliation of "adjusted operating loss" to "loss before income taxes"			
Adjusted operating loss	$ (27,059)	$ (21,472)	$ (24,528)
Less (add):			
Equity-based compensation	39,582	44,481	42,922
Professional liability expense	14,500	—	—
Acquisition-related costs	1,924	—	—
Amortization of intangible assets	8,031	7,965	7,845
Goodwill impairment loss	—	—	120,234
Interest income	(30,919)	(31,304)	(21,612)
Interest expense	75	(170)	488
Impairment loss	9,926	10,073	—
Other income, net	(153)	(561)	(320)
Total loss before income taxes	$ (70,025)	$ (51,956)	$ (174,085)

Significant items by segment excluded from the adjusted operating loss:

	Year Ended December 31,		
	2025	2024	2023
Equity-based compensation			
Laboratory services	$ 31,567	$ 36,951	$ 35,649
Therapeutic development	8,015	7,530	7,273
Total	$ 39,582	$ 44,481	$ 42,922

Revenue by segment:

	Year Ended December 31,		
	2025	2024	2023
Revenue			
Laboratory services:			
Precision diagnostics[(1)]	$ 190,472	$ 167,745	$ 131,990
Anatomic pathology	106,442	97,080	104,655
BioPharma services	25,310	16,338	25,416
COVID-19	—	2,307	27,152
Total laboratory services	322,224	283,470	289,213
Therapeutic development:			
BioPharma services	447	—	—
Total therapeutic development	447	—	—
Total	$ 322,671	$ 283,470	$ 289,213

(1) Beginning in 2025, COVID-19 revenue is grouped with precision diagnostics, which was insignificant in 2025.

Depreciation and amortization by segment:

	Year Ended December 31,		
	2025	2024	2023
Depreciation and amortization			
Laboratory services	$ 23,552	$ 24,240	$ 25,453
Therapeutic development	571	688	690
Total	$ 24,123	$ 24,928	$ 26,143

Interest income and expense by segment:

	Year Ended December 31,		
	2025	2024	2023
Interest income and expense			
Laboratory services			
Interest income	$ 30,919	$ 31,304	$ 21,612
Interest expense	(75)	170	(488)
Therapeutic development			
Interest income	—	—	—
Interest expense	—	—	—
Total	$ 30,844	$ 31,474	$ 21,124

Total assets by segment:

	December 31, 2025	December 31, 2024
Assets		
Laboratory services	$ 1,096,379	$ 1,131,117
Therapeutic development	117,146	88,847
Total	$ 1,213,525	$ 1,219,964

Geographic distribution of revenue:

	Year Ended December 31,		
	2025	2024	2023
Revenue			
United States	$ 296,552	$ 259,132	$ 268,977
Foreign			
China	12,906	12,638	11,446
Other countries	13,213	11,700	8,790
Total foreign	26,119	24,338	20,236
Total	$ 322,671	$ 283,470	$ 289,213

Geographic distribution of property, plant and equipment, net:

	December 31, 2025	December 31, 2024
Fixed assets		
United States	$ 106,250	$ 98,992
Foreign		
China	4,692	4,616
Other countries	1,607	1,941
Total foreign	6,299	6,557
Total	$ 112,549	$ 105,549

Note 8. Debt, Commitments and Contingencies

Debt

Notes payable as of December 31, 2025, consisted of $2.4 million of notes payable related to an installment sale contract the Company entered in February 2022 for a building. 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 $0.5 million and $2.0 million, respectively, and the noncurrent portion is included in the other long-term liabilities in the accompanying Consolidated Balance Sheets. The Company also had notes payable to Xilong Scientific Co., which were paid off in 2024, and had an interest rate of 4.97%. The interest expenses in 2025, 2024, and 2023 were not significant.

Operating and Finance Leases

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

Contingencies

From time to time, the Company may be subject to legal proceedings and claims arising in the ordinary course of business.

As previously disclosed in the Company's periodic reports filed pursuant to the Securities Exchange Act of 1934, as amended, or the Exchange Act, the Company has received a Civil Investigative Demand, or CID, issued by the U.S. Department of Justice, or the DOJ, 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. Among other things, this CID requests information and records relating to certain of the Company's customers named in this CID. Certain of the Company's executive officers and employees have also received CIDs relating to these matters.

Similar to other laboratories in the industry, the Company responded to an audit inquiry by the U.S. Health Resources and Services Administration, or HRSA, with respect to its reimbursement for COVID-19 tests furnished to patients believed to be uninsured. The Company recorded approximately $548.9 million of reimbursements from HRSA under the Uninsured Program during the years ended December 31, 2022, 2021, and 2020. There is uncertainty with respect to the methodology HRSA will use in its audit and whether and how HRSA will extrapolate audit results. The Company has provided HRSA's auditors with requested information in connection with its audit in an effort to resolve any issues related to its audit, including any reimbursed amounts that may need to be returned to HRSA. As of the date of this Annual Report, the Company has not received any final audit results from HRSA for this audit. The Company has not received any further requests for information in connection with this audit from HRSA. The Company has also received a CID issued by the DOJ pursuant to the False Claims Act related to the DOJ's investigation as to whether the Company submitted or caused to be submitted false claims to the Uninsured Program.

As is typical for companies seeking reimbursement from government payors, from time to time the Company is named as defendant in claims pursuant to the qui tam provisions of the False Claims Act and comparable state laws. Often, these proceedings remain under seal such that the Company does not have access to the specific information included in them. Seals often remain in place for extended periods of time while the U.S. government, or applicable regulatory authority, decides whether to intervene on behalf of the qui tam plaintiff. As a result, the Company may not be aware of all qui tam claims that have been filed against the Company. In or around February 2026, the United States District Court for the Central District of California unsealed a qui tam complaint (and certain related proceedings) filed against Fulgent Genetics, Inc. and Fulgent Therapeutics LLC by a qui tam plaintiff (known as a relator) on behalf of the United States. This complaint alleged that the Company filed false claims for reimbursement for COVID-19 tests in violation of the False Claims Act. The complaint was subsequently dismissed without prejudice as to the relator and the U.S. government following the U.S. government's filing of a motion to dismiss, meaning the relator and the U.S. government retained the right to refile and may refile under seal.

The Company is fully cooperating with the DOJ in connection with the CIDs that it, or its employees, have received. The Company cannot currently predict when these CIDs and HRSA audit matters will be resolved, the reasonable or likely outcome of these matters, or their potential impact, which may materially and adversely affect the Company's business, prospects, and financial condition. Discussions and investigations remain ongoing. As such, the Company cannot reasonably estimate the loss or range of loss, if any, that may result from any material government investigations, audits, claims, and reviews in which it is currently involved, given the inherent difficulty in predicting regulatory action, fines and penalties, if any, and the various remedies and levels of judicial review available to the Company in the event of an adverse finding. As a result, the Company has not recorded any liability related to these CIDs or audit matters.

From time to time, the Company, like other laboratories in its industry, is subject to claims and allegations relating to professional liability. The Company recorded an accrual of $14.5 million in connection with the settlement of a professional liability matter, which was included in general and administrative expense in the accompanying Consolidated Statements of Operations. The Company maintains professional liability insurance that may provide partial coverage for this matter, subject to customary retentions, exclusions, and limits.

Note 9. Leases

Lessee

The Company is party as a lessee to various non-cancelable operating leases with varying terms through March 2034 primarily for laboratory and office space and equipment. The Company has options to renew some of these leases after their expiration. 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, some of which, 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 El Monte, 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 Coppell, Texas; Needham, Massachusetts; Phoenix, Arizona; and Alpharetta, Georgia. The Company has also obtained National Association of Testing Authorities accreditation for its laboratory located in Dulwich, Australia.

The operating and finance lease right-of-use asset, short-term lease liabilities, and long-term lease liabilities as of December 31, 2025, and 2024 were as follows:

	December 31, 2025	December 31, 2024
	(in thousands)	
Operating lease ROU asset, net	$ 4,961	$ 5,395
Operating lease liabilities, short term	$ 1,462	$ 1,443
Operating lease liabilities, long term	$ 3,781	$ 4,120
Finance lease ROU asset, net	$ 339	$ 771
Finance lease liabilities, short term	$ 360	$ 398
Finance lease liabilities, long term	$ —	$ 360

The following was operating and finance lease expense:

	Year Ended December 31,		
	2025	2024	2023
		(in thousands)	
Operating lease cost	$ 1,994	$ 4,176	$ 6,875
Finance lease cost:			
Amortization of ROU assets	386	539	758
Interest on lease liabilities	18	39	80
Short-term lease cost	1,864	1,346	1,758
Total lease cost	$ 4,262	$ 6,100	$ 9,471

Supplemental information related to leases was the following:

	December 31, 2025
Weighted-average remaining lease term, operating leases	5.26
Weighted-average discount rate, operating leases	5.87%
Weighted-average remaining lease term, finance lease	1.00
Weighted-average discount rate, finance lease	3.21%

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

	Operating Leases	Finance Lease
	(in thousands)	
Year ending December 31,		
2026	1,724	366
2027	1,167	—
2028	682	—
2029	557	—
2030	567	—
Thereafter	1,517	—
Total lease payments	6,214	366
Less imputed interest	(971)	(6)
Total	$ 5,243	$ 360

Note 10. Equity-Based Compensation

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

	Year Ended December 31,		
	2025	2024	2023
		(in thousands)	
Cost of revenue	$ 6,827	$ 7,799	$ 9,749
Research and development	13,231	14,971	14,873
Selling and marketing	3,016	3,907	4,964
General and administrative	16,508	17,804	13,336
Total	$ 39,582	$ 44,481	$ 42,922

The actual tax expense realized from tax deductions related to awards vested or exercised were $3.5 million, $3.4 million and $2.7 million for the years ended December 31, 2025, 2024, and 2023, 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, 2025, 2024, and 2023:

	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, 2022	212	$ 4.21		3.7	$ 5,420
Granted	20	$ 33.14	$ 24.85		
Exercised	(9)	$ 0.38	$ 10.76		
Canceled	—	$ —	$ —		
Balance at December 31, 2023	223	$ 6.96		3.3	$ 4,906
Granted	5	$ 22.50	$ 16.42		
Exercised	(133)	$ 0.38	$ 2.58		
Canceled	—	$ —	$ —		
Balance at December 31, 2024	95	$ 17.07		4.7	$ 134
Granted	6	$ 20.04	$ 14.26		
Exercised	(2)	$ 0.38	$ 4.24		
Canceled	—	$ —	$ —		
Balance at December 31, 2025	99	$ 17.68		6.2	$ 852
Exercisable as of December 31, 2025	81	$ 14.98		3.3	

(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, 2025, 2024, and 2023 was $0.3 million, $0.3 million and $0.2 million, respectively. As of December 31, 2025, the remaining unrecognized compensation expense related to all outstanding option awards was $0.3 million and is expected to be recognized over a weighted-average period of 1.8 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, 2025, 2024, and 2023:

	Number of Shares (in thousands)	Weighted-Average Grant Date Fair Value
Balance at December 31, 2022	2,631	$ 47.76
Granted	853	$ 34.38
Vested and settled	(1,066)	$ 43.84
Forfeited	(208)	$ 54.72
Balance at December 31, 2023	2,210	$ 43.84
Granted	1,142	$ 23.47
Vested and settled	(1,004)	$ 43.66
Forfeited	(142)	$ 37.39
Balance at December 31, 2024	2,206	$ 33.85
Granted	1,166	$ 23.08
Vested and settled	(1,049)	$ 43.66
Forfeited	(90)	$ 37.39
Balance at December 31, 2025	2,233	$ 33.85

The RSU awards granted in the years ended December 31, 2025, 2024, and 2023 will result in aggregate equity-based compensation expense of $26.7 million, $26.9 million and $29.3 million, respectively, to be recognized over the vesting periods from the vesting commencement date of each award granted in the period. As of December 31, 2025, the remaining unrecognized compensation expense related to all outstanding RSU awards was $43.0 million and is expected to be recognized over a weighted-average period of 2.2 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, 2025, 2024, and 2023.

	Year Ended December 31,		
	2025	2024	2023
Expected term (in years)	6.1	6.1	6.1
Risk-free interest rates	4.1%	4.3%	3.8%
Dividend yield	—	—	—
Expected volatility	79.1%	82.2%	87.3%

Determination of Fair Value on Grant Dates and Shares Reserved

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.

The Company reserved for issuance 8.9 million shares of its common stock for the grant of incentive stock options, nonqualified stock options, stock appreciation rights, restricted stock, RSUs, dividend equivalent rights and other stock and cash-based awards under the Company's Amended and Restated 2016 Omnibus Incentive Plan, plus another 0.7 million shares of its common stock that will be available for issuance solely pursuant to the converted Fulgent, LLC awards. The options must be exercised no later than the expiration date set forth in the notice.

Note 11. Income Taxes

(Benefit from) 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 loss before income taxes:

	Year Ended December 31,		
	2025	2024	2023
		(in thousands)	
U.S. loss before income taxes	$ (61,759)	$ (46,813)	$ (147,464)
Foreign loss before income taxes	(8,266)	(5,143)	(26,621)
Loss before income taxes	$ (70,025)	$ (51,956)	$ (174,085)

(Benefit from) provision for income taxes consisted of the following:

	Year Ended December 31,		
	2025	2024	2023
		(in thousands)	
Current			
Federal	$ (6,470)	$ (2,441)	$ (5,590)
State	(965)	(2,107)	(4,722)
Foreign	175	148	—
Total Current	(7,260)	(4,400)	(10,312)
Deferred			
Federal	(7,580)	(10,313)	(12,771)
State	197	(734)	4,100
Foreign	(1,113)	602	(188)
Change in valuation allowance	7,362	6,709	20,325
Total Deferred	(1,134)	(3,736)	11,466
(Benefit from) provision for income taxes	$ (8,394)	$ (8,136)	$ 1,154

Reconciliation of the difference between the federal statutory income tax rate and the effective income tax rate for the year ended December 31, 2025, in accordance with the guidance in ASU 2023-09, is as follows:

	Year Ended December 31, 2025	
	Amount	Percent
Tax provision at federal statutory rate	$ (14,705)	21.00%
State and local income taxes, net of federal benefit[(1)]	3,133	-4.47%
Foreign tax effects		
China		
Foreign tax rate differential	835	-1.19%
NOL carryforward	(496)	0.71%
Valuation allowance	496	-0.71%
Other	175	-0.25%
Australia		
Foreign tax rate differential	888	-1.27%
NOL carryforward	1,609	-2.30%
Valuation allowance	(1,609)	2.30%
Effect of cross-border tax laws:	326	-0.47%
Tax Credits		
Research and development credits	(3,913)	5.59%
IRA tax credits	(7,035)	10.05%
Change in valuation allowance	3,727	-5.32%
Nontaxable or nondeductible items		
Equity-based compensation	3,465	-4.95%
162(m) nondeductible compensation	3,348	-4.78%
Section 280C adjustment	647	-0.92%
Other	566	-0.81%
Change in unrecognized tax benefits	565	-0.81%
Return to provision adjustments		
Federal true-ups	1,604	-2.29%
State true-ups	(2,020)	2.88%
Effective tax rate	$ (8,394)	11.99%

(1) For the year ended December 31, 2025, state and local taxes in New Jersey, Texas, and New York City made up the majority (greater than 50%) of the tax effect in this category.

Reconciliation of the difference between the federal statutory income tax rate and the effective income tax rate for the years ended December 31, 2024, and 2023, in accordance with the guidance prior to the adoption of ASU 2023-09, are as follows:

	Year Ended December 31,	
	2024	2023
Tax provision at federal statutory rate	21.00%	21.00%
State taxes	-1.70%	0.22%
Equity-based compensation	-6.79%	-1.65%
Nondeductible compensation - 162(m)	-2.10%	-0.55%
Goodwill impairment	0.00%	-10.62%
Amended state tax refunds	8.29%	0.00%
Federal return to provision	-2.07%	-0.21%
State return to provision	-0.78%	3.41%
Other permanent differences	1.83%	-1.15%
Uncertain tax positions	-1.14%	0.18%
Research & development credit	6.95%	3.19%
IRA tax credit	4.82%	0.00%
Foreign tax rate differential	-1.68%	-2.42%
Stranded tax effect	4.25%	0.00%
Foreign NOL carryforward	-1.19%	0.11%
Other	-0.29%	0.00%
Change in valuation allowance	-13.29%	-12.20%
Effective tax rate	16.11%	-0.69%

Disclosed below is a summary of income taxes paid (net of refunds received) by jurisdiction. The amounts for the year ended December 31, 2025, are presented pursuant to the disclosure requirements of ASU 2023-09.

	Year Ended December 31,
	2025
Federal	$ 99,601
State and local	(3,180)
Foreign	24
	$ 96,445

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,	
	2025	2024
	(in thousands)	
Deferred tax assets		
Accrued vacation and other accrued expenses	$ 6,133	$ 1,775
Provision for credit losses	3,460	2,990
Net operating losses	20,557	11,875
Equity-based compensation	1,478	2,022
State income taxes	272	284
Excess tax basis in FF Gene Biotech net assets	921	1,527
Lease liability	613	789
Unrealized gain/loss on available-for-sale debt securities	—	757
Research and development credits	6,405	2,762
Section 174 research & experimental expenditures	15,038	25,626
Equity loss in investment	5,478	2,965
Other	10	74
Gross deferred tax assets	60,365	53,446
Less: Valuation allowance	(27,598)	(22,702)
Net deferred tax assets	32,767	30,744
Deferred tax liabilities		
Intangible assets	29,717	29,540
Depreciation	7,963	6,198
Right of use asset	594	767
Unrealized gain/loss on available-for-sale debt securities	975	—
Other	454	609
Total deferred tax liabilities	39,703	37,114
Net deferred tax liabilities	$ (6,936)	$ (6,370)

As of December 31, 2025, the Company has $62.9 million estimated federal net operating loss, or NOL, carryforwards and estimated state NOL carryforwards of $86.5 million. The Company's state NOLs are scheduled to begin expiring in 2026. The Company also has foreign NOL carryforwards of $14.4 million which are scheduled to expire from 2026 through 2030. Utilization of our net operating loss carryforwards may be subject to annual limitations due to ownership changes as imposed by the Internal Revenue Code and similar state provisions.

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 and, accordingly, has established a full valuation allowance of $27.6 million on its deferred tax assets as of December 31, 2025. The Company maintained a full valuation allowance of $22.7 million on its deferred tax assets as of December 31, 2024. The increase in the valuation allowance of $4.9 million for the year ended December 31, 2025, was primarily due to the increase in losses in the current year.

The Organization for Economic Cooperation and Development has enacted model rules for a new global minimum tax framework ("BEPS Pillar II"). Various jurisdictions have enacted, or are in the process of enacting, legislation on these rules. Based on our assessment of the current BEPS Pillar II landscape, the Company has not met the Pillar II reporting threshold.

Uncertain Tax Positions

The Company is subject to income taxation by the U.S. 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. The Company's tax returns are subject to statutes of limitations that vary by jurisdiction. As of December 31, 2025, the Company remains subject to income tax examinations in the United States, and various states for tax years 2020 through 2025. 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.

The Company is under examination by certain tax authorities for the 2020 through 2022 tax years. While the timing of the conclusion of the examination is uncertain, the Company believes that adequate amounts have been reserved for adjustments that may result.

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

	Year Ended December 31,		
	2025	2024	2023
		(in thousands)	
Balance at beginning of year	$ 4,176	$ 5,833	$ 9,742
Increases to prior year positions	(288)	(2,692)	(3,845)
Increases for current year positions	1,783	1,035	(64)
Balance at end of year	$ 5,671	$ 4,176	$ 5,833

As of December 31, 2025, the Company has $5.7 million of gross unrecognized tax benefits, all of which would affect the effective tax rate if recognized. The Company has accrued $1.6 million and $0.4 million for interest at December 31, 2025, and 2024, 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 12 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.

The Company received $4.6 million, $40.0 million, and $12.5 million, in income tax refunds in 2025, 2024, and 2023, respectively. The income tax refunds received, which were due to overpayment in prior years, were netted in the income tax paid amounts included in the supplemental disclosure in the accompanying Consolidated Statements of Cash Flows for 2025 after the adoption of ASU 2023-09. The income tax refunds received, were not netted in the income tax paid amounts included in the supplemental disclosure in the accompanying Consolidated Statements of Cash Flows for 2024 and 2023.

In 2025, the Company purchased $106.3 million worth of Investment Tax Credits, or ITCs, under the transferability provisions of the Inflation Reduction Act of 2022 for $99.5 million in cash. The $6.8 million difference between purchase price and the face value of the credits has been recorded as an increase to the Company's income tax benefit for the period. The $99.5 million cash payment was included in the income tax paid amounts included in the supplemental disclosure in the accompanying Consolidated Statements of Cash Flows. The Company has utilized $0.2 million of the acquired credits on its 2024 tax return and carried back the remainder of $106.1 million to its 2021 and 2022 tax years and filed a request for a refund. The Company did not receive the $106.1 million of ITCs that were carried back to the 2021 and 2022 tax years in cash in 2025. We expect cash receipt in 2026.

In 2024, the Company purchased $27.1 million worth of ITCs, under the transferability provisions of the Inflation Reduction Act of 2022 for $24.6 million in cash. The $2.5 million difference between the purchase price and the face value of the credits has been recorded as an increase to the Company's income tax benefit for the period. The $24.6 million cash payment was included in the income tax paid amounts included in the supplemental disclosure in the accompanying Consolidated Statements of Cash Flows. The Company has utilized $0.4 million of the acquired credits on its 2023 tax return and carried back the remainder of $26.7 million to its 2020 tax year and filed a request for a refund. The Company has received the full amount of $26.7 million of ITCs that were carried back to the 2020 tax year in cash in 2024.

On July 4, 2025, the One Big Beautiful Bill Act, or OBBBA, was signed into law, making permanent certain provisions of the Tax Cuts and Jobs Act, including 100% bonus depreciation and domestic research cost expensing. In accordance with ASC 740, "*Income Taxes*," the Company has recognized the effects of the new tax law in the period of enactment. The legislation has multiple effective dates, with certain provisions effective in 2025 and others implemented through 2027. The legislation does not have a material impact on our consolidated financial statements for the year ended December 31, 2025.

Note 12. Income (Loss) per Share

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

	Year Ended December 31,		
	2025	2024	2023
	(in thousands)		
Net loss attributable to Fulgent	$ (60,513)	$ (42,708)	$ (167,825)
Weighted-average common shares - outstanding, basic	30,777	30,235	29,784
Weighted-average effect of dilutive securities:			
Stock options	—	—	—
Restricted stock units	—	—	—
Contingently issuable shares	—	—	—
Weighted-average common shares - outstanding, diluted	30,777	30,235	29,784
Loss per share:			
Basic	$ (1.97)	$ (1.41)	$ (5.63)
Diluted	$ (1.97)	$ (1.41)	$ (5.63)

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

	Year Ended December 31,		
	2025	2024	2023
	(in thousands)		
Stock options	99	95	224
Restricted stock units	2,233	2,206	2,210
Contingently issuable shares	293	—	186

The anti-dilutive shares described above were calculated using the treasury stock method. In the years ended December 31, 2025, 2024, and 2023, the Company had outstanding stock options and restricted stock units that were excluded from the weighted-average share calculation for continuing operations due to the Company's net loss positions.

In the year ended December 31, 2025, the Company also had contingently issuable shares for contingent consideration to the acquisition of ANP that were excluded from the weighted-average share calculation for continuing operations due to the Company's net loss positions. The milestones have not been satisfied as of December 31, 2025, thus, nothing was included in dilutive shares. See more details in Note 15. *Business Combinations*. In the year ended December 31, 2023, the Company also had contingently issuable shares for shares held back in connection with the business combination of Fulgent Pharma, or Pharma Hold Back Shares. In May 2024, the Company released the remaining Pharma Hold Back Shares such that no shares remain contingently issuable in connection with the business combination of Fulgent Pharma.

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 4% of an employee's compensation that the employee contributes to their 401(k) Plan account. Total Company matching contributions to the 401(k) Plan were $4.1 million, $3.8 million, and $3.2 million in the years ended December 31, 2025, 2024, and 2023, respectively.

Note 14. Related Party

Linda Dong, 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 an insignificant amount in revenue in the years ended December 31, 2025, and 2024, and $0.1 million in

revenue in the year ended December 31, 2023. As of December 31, 2025, and 2024, insignificant amounts were owed to the Company by AHMC, which is included in trade accounts receivable, net, in the accompanying Consolidated Balance Sheets, in connection with this relationship.

Prior to April 25, 2025, Ming Hsieh, the Chief Executive Officer and Chairperson of the board of directors, was on the board of directors and an approximately 20% owner of ANP, with which the Company 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. The Company incurred $0.6 million in expenses the year ended December 31, 2025, prior to April 25, 2025, and $2.1 million and $2.4 million in expenses the years ended December 31, 2024, and 2023, respectively, related to the licensing and development services and purchase of equipment. As of April 25, 2025, and December 31, 2024, $0.3 million and $0.2 million, respectively, were owed to ANP by the Company in connection with these relationships. The Company also entered into an employee service agreement with ANP in April 2023, an insignificant amount was recognized in revenue in the year ended December 31, 2025, prior to April 25, 2025, and $0.1 million in revenue was recognized each of the years ended December 31, 2024, and 2023. Insignificant amounts were owed by ANP in connection with the employee service agreement as of April 25, 2025, and December 31, 2024. In July 2025, the Company completed an acquisition of 100% of the outstanding equity of ANP, which included the settlement of all outstanding liabilities and receivables. See more details in Note 15. *Business Combinations.*

Note 15. Business Combinations

ANP Technologies, Inc.

On July 9, 2025, the Company completed an acquisition of 100% of the outstanding equity of ANP, an innovation-driven company, which has developed multiple proprietary product platforms. The acquisition was structured as a combination of cash and stock, net of cash received. This acquisition enables the Company to secure ownership of the patents previously licensed from ANP, which are currently utilized in ongoing clinical studies. By securing full ownership of these intellectual property rights, the Company aims to enhance its control over the development and commercialization of related therapeutic candidates, thereby aligning with its strategic objectives to advance clinical programs.

The financial results of ANP are included in the consolidated financial statements from the date of acquisition. The Company allocated the purchase price to tangible assets and identified intangible assets acquired, liabilities assumed and goodwill based on estimated fair values. As additional information becomes available, including the filing and finalization of federal and state tax returns for periods prior to the acquisition date, the Company may further update the preliminary purchase price allocation during the remainder of the measurement period (up to one year from the acquisition date).

The following tables summarize the consideration and the amounts of the assets acquired and liabilities assumed recognized at the acquisition date:

	Amounts (in thousands)
Considerations	
Cash paid	$ 14,322
Cash held back	1,887
Settlement of pre-existing accounts payable	(290)
Contingent consideration	5,731
Total considerations	$ 21,650
Recognized amounts of identifiable assets acquired and liabilities assumed	
Cash and cash equivalents	$ 18,097
Trade accounts receivable	7
Other current assets	97
ROU assets - operating	612
Other long-term assets	15
Identifiable intangible assets	6,200
Accounts payable	(75)
Accrued liabilities	(591)
Operating lease liabilities	(612)
Income tax payable	(1,562)
Other long-term liabilities	(3,563)
Recognized amounts of identifiable assets acquired and liabilities assumed, net	18,625
Goodwill	3,025
Total	$ 21,650

The acquisition includes a contingent consideration arrangement that requires the Company to issue up to 292,682 shares of the Company's common stock to the sellers of ANP upon ANP's achievement of certain minimum levels of cash receipts over the next two years. The contingent consideration is classified as equity, and the fair value of $5.7 million was calculated based on the stock price of the Company's common stock on the acquisition date. The fair value of the contingent consideration does not need to be remeasured, as the subsequent settlement will be accounted for as equity.

The merger agreement, as amended, called for the Company to hold back $1.9 million to serve as collateral for indemnification of the equity holders. $1.0 million of the holdback will be released to the sellers of ANP after the initial survival date (three years after closing), and the remaining amount is to be released four years after the closing date.

The goodwill of $3.0 million arising from the acquisition is attributed to the expected synergies, assembled workforce, and other benefits that will potentially be generated from the business combination along with deferred tax. The goodwill recognized is not deductible for tax purposes.

The identified intangible assets acquired consisted of $3.9 million IPR&D which is an indefinite-lived asset and as such is not amortized, and $2.3 million customer relationships with an estimated amortization life of 18 years.

The fair value of the IPR&D was estimated using the cost to recreate method of the cost approach. The cost to recreate method estimates the expense to the Company if the intangible assets were to be recreated. The fair value of the customer relationships was estimated using the Multiperiod Excess Earnings Method, or MPEEM, under 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 contract are then discounted to their present value at a risk-adjusted rate of return. 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 are amortized on a straight-line basis over the estimated useful lives.

The revenue and operating loss of the acquiree since the acquisition date are $0.4 million and $0.5 million, respectively, which

are included in the accompanying Consolidated Statements of Operations.

The transaction costs associated with the acquisition of ANP consisted primarily of legal, regulatory and financial advisory fees of approximately $0.4 million for the year ended December 31, 2025. These transaction costs were expensed as incurred as general and administrative expense.

Non-recurring intra-entity transactions involving long term assets and liabilities were eliminated in consolidation and did not affect earnings per share calculations.

Bako Business Combination

On December 20, 2025, Inform Diagnostics, Inc., or the Buyer, a wholly owned subsidiary of the Company, entered into a purchase and sale agreement to, or the PSA, with Bako Pathology LP, Bako Pathology Holdings Corp., BPA Holding Corp., or the PSA Seller, Dermatopathology Experts, LLC, or the Target, and Fulgent Therapeutics, LLC (solely for purposes of Section 11.16 (and Article XI as it relates to Section 11.16) of the PSA), pursuant to which the PSA Seller, among other things, agreed to sell and Buyer agreed to purchase, all of the issued and outstanding equity interests of the Target, for a base purchase price of $12.5 million in cash, subject to certain customary price adjustments.

On December 20, 2025, the Buyer also entered into an Asset Purchase Agreement, or the APA with Bako Pathology LP, or Sellers' Representative, Bako Pathology Holdings Corp., BPA Holding Corp., Bakotic Pathology Associates, L.L.C., Podceuticals L.L.C., GBRL Consulting, LLC, or collectively with Sellers' Representative, the APA Sellers, and Fulgent Therapeutics, LLC (solely for purposes of Section 11.16 (and Article XI as it relates to Section 11.16) of the APA), pursuant to which the APA Sellers, among other things, agreed to sell and Buyer agreed to purchase and assume, substantially all of the assets and certain specified liabilities related to the APA Sellers' business in dermatopathology and podiatric pathology and molecular diagnostic services and therapeutic products, for a base purchase price of $43.0 million in cash, subject to certain customary price adjustments.

The acquisition is expected to close during the first half of 2026, subject to satisfying customary closing conditions, including regulatory approvals.

Note 16. Stock Repurchase Program

In March 2022, the Company's board of directors 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, 2025, the Company repurchased 0.6 million shares of its common stock at an aggregate cost of $10.9 million under the stock repurchase program. During the year ended December 31, 2024, the Company repurchased ten thousand shares of its common stock at an aggregate cost of $0.2 million under the stock repurchase program. During the year ended December 31, 2023, the Company repurchased 1.0 million shares of its common stock at an aggregate cost of $25.1 million under the stock repurchase program. As of December 31, 2025, a total of approximately $139.6 million remained available for future repurchases of its common stock under the stock repurchase program.

Note 17. Goodwill and Intangible Assets

The Company has identified its laboratory services business and its therapeutic development business as its two operating segments, and the Company determined that the operating segments represented the two reporting units. The Company tests for goodwill impairment at the reporting unit level on December 31st of each year and more frequently if events or circumstances indicate a potential impairment. The newly acquired entity, ANP, is considered part of therapeutic development operating segment.

The goodwill of the laboratory services reporting unit had been fully impaired in 2023. Changes in the carrying amount of goodwill for the years ended December 31, 2025 and 2024 for Therapeutic Development reporting unit are as follows:

	2025	2024
	(in thousands)	
Balance at beginning of year	$ 22,055	$ 22,055
Impairment	—	—
Acquisition	3,025	—
Balance at the end of year	$ 25,080	$ 22,055

During the year ended December 31, 2025, there have been no significant changes except for the acquisition of ANP. The acquisition of ANP resulted in $3.0 million in goodwill.

Summaries of intangible assets balances as of December 31, 2025 and 2024 were as follows:

	Weighted-Average Amortization Period	December 31, 2025	December 31, 2024
		(in thousands)	
Laboratory Services			
Customer relationships	13 Years	$ 83,135	$ 83,088
Less: accumulated amortization		(25,633)	(19,079)
Customer relationships, net		57,502	64,009
Royalty-free technology	10 Years	5,291	5,069
Less: accumulated amortization		(2,469)	(1,859)
Royalty-free technology, net		2,822	3,210
Trade name	8 Years	3,790	3,790
Less: accumulated amortization		(1,896)	(1,401)
Trade name, net		1,894	2,389
Laboratory information system platform	5 Years	1,860	1,860
Less: accumulated amortization		(1,643)	(1,271)
Laboratory information system platform, net		217	589
In-place lease intangible assets	5 Years	360	360
Less: accumulated amortization		(255)	(186)
In-place lease intangible assets, net		105	174
Purchased patent	10 Years	29	27
Less: accumulated amortization		(14)	(10)
Purchased patent, net		15	17
Total		62,555	70,388
Therapeutic Development			
Customer relationships	18 Years	2,300	—
Less: accumulated amortization		(64)	—
Customer relationships, net		2,236	—
In-process research & development	n/a	68,490	64,590
Total		70,726	64,590
Total intangible assets, net		$ 133,281	$ 134,978

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 the acquisition of Fulgent Pharma in 2022 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 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.

During the year ended December 31, 2025, the Company recorded $2.3 million of customer relationships and $3.9 million of IPR&D attributable to the acquisition of ANP. See more details in Note 15. *Business Combinations*.

Amortization of intangible assets was $8.0 million, $8.0 million and $7.8 million in 2025, 2024, and 2023, respectively.

Based on the carrying value of intangible assets recorded as of December 31, 2025, 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)
Year ending December 31,	
2026	$ 7,808
2027	7,346
2028	7,311
2029	7,054
2030	6,925
Thereafter	28,347
Total	$ 64,791

The Company engaged a third-party valuation company for the valuation of the goodwill and IPR&D associated with the acquisition of ANP on the acquisition date. There is no indication of a potential impairment for the Company's goodwill and IPR&D, thus, no quantitative assessment was performed as of December 31, 2025.

There can be no assurance that the estimates and assumptions management made for the purposes of the goodwill or IPR&D impairment analysis will prove to be accurate predictions of future performance. It is possible that the conclusions regarding impairment or recoverability of goodwill or intangible assets could change in future periods. Management will continue to monitor the therapeutic development reporting unit. For all IPR&D projects, there are major risks and uncertainties associated with the timely and successful completion of development and commercialization of these product candidates, including the ability to confirm their efficacy based on data from clinical trials, the ability to obtain necessary regulatory approvals, and the ability to successfully complete these tasks within budgeted costs. The Company is not able to market a human therapeutic without obtaining regulatory approvals, and such approvals require completing clinical trials that demonstrate a product candidate is safe and effective. In addition, the availability and extent of coverage and reimbursement from insurance payors, including government healthcare programs and private insurance plans, impact the revenues a product can generate. Consequently, the eventual realized value, if any, of these acquired IPR&D projects may vary from their estimated fair values.

Note 18. Stockholders' Equity

Cash Dividends

The Company has not in the past, and the Company did not declare or pay cash dividends in the current period.

The Company does not anticipate paying dividends in the foreseeable future, however, the payment and amount of future dividends remain within the discretion of its board of directors and will depend on future earnings, financial condition, capital requirements and other factors.

Common stock

Per the Company's certificate of incorporation, as amended, the total number of shares of all classes of stock that the Company is authorized to issue is 51.0 million consisting of 50.0 million shares of Common Stock with a par value of $0.0001 and 1.0 million shares of Preferred Stock with a par value of $0.0001.

Voting Rights

The holders of our common stock are entitled to one vote for each share held on all matters submitted to a vote of our stockholders. The holders of our common stock do not have any cumulative voting rights. Because of this absence of cumulative voting, the holders of a majority of the shares of common stock entitled to vote in any election of directors have the power to elect all of the directors standing for election, if they should so choose.

Dividend Rights

Holders of the Company's common stock are entitled to receive ratably any dividends that may be declared by the Company's board of directors, from time to time out of funds legally available for that purpose, subject to any preferential dividend rights of any outstanding preferred stock.

Liquidation Rights

In the event of the Company's liquidation, dissolution or winding up, holders of the Company's common stock will be entitled to share ratably in all assets remaining after payment of all debts and other liabilities and any liquidation preference of any outstanding preferred stock.

Preemptive and Conversion Rights

The Company's common stock has no preemptive rights, conversion rights or other subscription rights or redemption or sinking fund provisions. All of the outstanding shares of the Company's common stock, as well as any shares of common stock issuable upon the conversion of any securities convertible into the Company's common stock, are (or will be upon issuance) fully paid and non-assessable.

Blank Check Preferred Stock

The Company's board of directors is authorized, subject to the limitations imposed by Delaware law, to issue up to 1.0 million shares of preferred stock, par value $0.0001 per share, in one or more series, without stockholder approval. The Company's board of directors may fix the rights, preferences, privileges and restrictions of the Company's authorized shares of preferred stock in one or more series and authorize its issuance without the approval of the Company's stockholders. These rights, preferences, privileges and restrictions could include dividend rights, conversion rights, voting rights, terms of redemption, liquidation preferences, sinking fund terms and the number of shares constituting any series or the designation of such series, any or all of which may be greater than the rights of the Company's common stock. As of the date of the filing of this report, no shares of preferred stock are outstanding.

Exhibit 21.1

SUBSIDIARIES OF FULGENT GENETICS, INC.

Name of Subsidiary	State or Other Jurisdiction of Incorporation or Organization
Fulgent Therapeutics LLC	California
Fulgent Investment Development Limited	Hong Kong
Cytometry Specialists, Inc.	Georgia
Inform Diagnostics, Inc	Delaware
Fulgent Pharma Holdings, Inc.	Delaware
Fulgent Australia Pty Ltd	Australia
ANP Technologies, Inc.	Delaware

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in Registration Statement Nos. 333-272048, 333-270135, 333-248962 and 333-213912 on Form S-8 of our reports dated February 27, 2026, relating to the financial statements of Fulgent Genetics, Inc. and effectiveness of Fulgent Genetics, Inc.'s internal control over financial reporting appearing in this Annual Report on Form 10-K for the year ended December 31, 2025.

/s/ DELOITTE & TOUCHE LLP

Los Angeles, California
February 27, 2026

Exhibit 31.1

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

I, Ming Hsieh, certify that:

1. I have reviewed this Annual Report on Form 10-K for the fiscal year ended December 31, 2025 of Fulgent Genetics, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: February 27, 2026

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

Exhibit 31.2

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

I, Paul Kim, certify that:

1. I have reviewed this Annual Report on Form 10-K for the fiscal year ended December 31, 2025 of Fulgent Genetics, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: February 27, 2026

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

Exhibit 32.1

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

In connection with the Annual Report on Form 10-K for the fiscal year ended December 31, 2025 of Fulgent Genetics, Inc. (the "Company"), as filed with the Securities and Exchange Commission on the date hereof (the "Report"), each of the undersigned hereby certifies in his capacity as the specified officer of the Company, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that, to the best of his knowledge:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

Date: February 27, 2026

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

Date: February 27, 2026

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

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