UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended March 31, 2021

or

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

For the transition period from _____ to _____

Commission File Number: 001-37894

FULGENT GENETICS, INC.

(exact name of registrant as specified in its charter)

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

(626) 350-0537

(Registrant's telephone number, including area code)

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)

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

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

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

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

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

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

As of May 1, 2021, there were 29,005,206 outstanding shares of the registrant's common stock.

Table of Contents

PART I—FINANCIAL INFORMATION

Item 1. Financial Statements.

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

	March 31, 2021	December 31, 2020
Assets		
Current assets		
Cash and cash equivalents	$ 151,461	$ 87,426
Marketable securities	258,317	211,941
Trade accounts receivable, net of allowance for credit losses of $3,850 and $1,898 as of March 31, 2021 and December 31, 2020, respectively	216,509	183,857
Other current assets	32,853	40,392
Total current assets	659,140	523,616
Marketable securities, long-term	287,626	132,502
Fixed assets, net	46,987	40,199
Other long-term assets	5,330	4,144
Total assets	$ 999,083	$ 700,461
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable	$ 17,440	$ 26,488
Income tax payable	120,522	53,319
Contract liabilities	13,960	26,576
Customer deposit	17,001	185
Investment margin loan	15,048	15,019
Other current liabilities	12,559	8,528
Total current liabilities	196,530	130,115
Unrecognized tax benefits	474	377
Other long-term liabilities	513	582
Total liabilities	197,517	131,074
Commitments and contingencies (Note 8)		
Stockholders' equity		
Common stock, $0.0001 par value per share, 50,000 shares authorized, 28,989 and 28,178 shares issued and outstanding at March 31, 2021 and December 31, 2020, respectively	3	3
Preferred stock, $0.0001 par value per share, 1,000 shares authorized, no shares issued or outstanding at March 31, 2021 and December 31, 2020	—	—
Additional paid-in capital	450,855	418,065
Accumulated other comprehensive income (loss)	(216)	438
Retained earnings	350,924	150,881
Total stockholders' equity	801,566	569,387
Total liabilities and stockholders' equity	$ 999,083	$ 700,461

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

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

	Three Months Ended March 31,	
	2021	**2020**
Revenue	$ 359,429	$ 7,753
Cost of revenue	74,075	4,057
Gross profit	285,354	3,696
Operating expenses:		
Research and development	5,422	1,978
Selling and marketing	5,008	1,597
General and administrative	8,002	2,035
Total operating expenses	18,432	5,610
Operating income (loss)	266,922	(1,914)
Interest and other income, net	282	241
Income (loss) before income taxes and equity loss in investee	267,204	(1,673)
Provision for income taxes	66,513	34
Income (loss) before equity loss in investee	200,691	(1,707)
Equity loss in investee	—	(249)
Net income (loss)	$ 200,691	$ (1,956)
Net income (loss) per common share:		
Basic	$ 6.96	$ (0.09)
Diluted	$ 6.52	$ (0.09)
Weighted-average common shares:		
Basic	28,831	21,566
Diluted	30,770	21,566

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

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

	Three Months Ended March 31,	
	2021	**2020**
Net income (loss)	$ 200,691	$ (1,956)
Other comprehensive loss:		
Foreign currency translation loss	—	(3)
Net unrealized loss on marketable securities, net of tax	(654)	(336)
Comprehensive income (loss)	$ 200,037	$ (2,295)

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

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

	Stockholders' Equity					
	Shares	Amount	Additional Paid-In Capital	Accumulated Other Comprehensive Income (Loss)	Retained Earnings	Total Equity
Balance at December 31, 2020	**28,178**	**$ 3**	**$ 418,065**	**$ 438**	**$ 150,881**	**$ 569,387**
Equity-based compensation	—	—	2,962	—	—	2,962
Exercise of common stock options	45	—	44	—	—	44
Restricted stock awards	187	—	—	—	—	—
Common stock withholding for employee tax obligations	(4)	—	(513)	—	—	(513)
Issuance of common stock at an average of $52.00 per share, net	583	—	30,297	—	—	30,297
Other comprehensive gain (loss)	—	—	—	(654)	—	(654)
Cumulative effect of accounting change	—	—	—	—	(887)	(887)
Cumulative tax effect of accounting change	—	—	—	—	239	239
Net income	—	—	—	—	200,691	200,691
Balance at March 31, 2021	**28,989**	**$ 3**	**$ 450,855**	**$ (216)**	**$ 350,924**	**$ 801,566**

	Stockholders' Equity					
	Shares	Amount	Additional Paid-In Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Equity
Balance at December 31, 2019	**21,483**	**$ 2**	**$ 146,058**	**$ 146**	**$ (63,429)**	**$ 82,777**
Equity-based compensation	—	—	924	—	—	924
Exercise of common stock options	33	—	12	—	—	12
Restricted stock awards	159	—	—	—	—	—
Repurchases of capital stock	(3)	—	(46)	—	—	(46)
Other comprehensive gain (loss)	—	—	—	(339)	—	(339)
Net loss	—	—	—	—	(1,956)	(1,956)
Balance at March 31, 2020	**21,672**	**$ 2**	**$ 146,948**	**$ (193)**	**$ (65,385)**	**$ 81,372**

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

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

	Three Months Ended March 31,	
	2021	**2020**
Cash flow from operating activities:		
Net income (loss)	$ 200,691	$ (1,956)
Adjustments to reconcile net income (loss) to net cash provided by operating activities:		
Equity-based compensation	2,962	924
Depreciation	1,922	569
Noncash lease expense	82	108
Loss on disposal of fixed asset	223	—
Amortization of premium of marketable securities	1,303	105
Provision for credit losses	1,064	121
Deferred taxes	(786)	—
Unrecognized tax benefits	96	—
Holding loss on equity securities	345	—
Equity loss in investee	—	249
Other	(8)	(42)
Changes in operating assets and liabilities:		
Trade accounts receivable	(34,595)	104
Other current and long-term assets	(9,109)	(924)
Accounts payable	(6,256)	1,907
Income tax payable	67,203	34
Other current liabilities	3,924	268
Contract liabilities	(12,616)	—
Customer deposit	16,816	—
Operating lease liabilities	(82)	(101)
Net cash provided by operating activities	233,179	1,366
Cash flow from investing activities:		
Purchases of fixed assets	(11,492)	(796)
Proceeds from sale of fixed assets	13	—
Purchase of marketable securities	(219,470)	(7,992)
Maturities of marketable securities	14,458	4,926
Net cash used in investing activities	(216,491)	(3,862)
Cash flow from financing activities:		
Proceeds from (payment for) public offerings of common stock, net of issuance costs	47,787	(130)
Proceeds from exercise of stock options	44	12
Repurchases of capital stock	(513)	(46)
Borrowing under margin account	29	—
Net cash provided by (used in) financing activities	47,347	(164)
Effect of exchange rate changes on cash and cash equivalents	—	(3)
Net increase (decrease) in cash and cash equivalents	64,035	(2,663)
Cash and cash equivalents at beginning of period	87,426	11,965
Cash and cash equivalents at end of period	$ 151,461	$ 9,302
Supplemental disclosures of cash flow information:		
Income taxes paid	$ 33	$ —
Supplemental disclosures of non-cash investing and financing activities:		
Purchases of fixed assets in accounts payable	$ 801	$ 43
Operating lease right-of-use assets obtained in exchange for lease liabilities	$ 368	$ —
Operating lease right-of-use assets reduced due to lease modification	$ 185	$ —
Purchase of marketable securities in other current liabilities	$ —	$ 500
Public offerings costs included in accounts payable	$ 50	$ 1

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

Note 1. Overview and Basis of Presentation

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

Nature of the Business

Fulgent Genetics, Inc., together with its subsidiaries, collectively referred to as the Company, unless otherwise noted or the context otherwise requires, is a technology company offering comprehensive genetic testing providing physicians with clinically actionable diagnostic information they can use to improve the quality of patient care. The Company has developed a proprietary technology platform that allows it to offer a broad and flexible test menu and continually expand and improve its proprietary genetic reference library, while maintaining accessible pricing, high accuracy and competitive turnaround times. Combining next generation sequencing, or NGS, with its technology platform, the Company performs full-gene sequencing with deletion/duplication analysis in single-gene tests; pre-established, multi-gene, disease-specific panels; and customized panels that can be tailored to meet specific customer needs. In 2019, the Company launched its first patient-initiated product, Picture Genetics, a new line of at-home screening tests that combines the Company's advanced NGS solutions with actionable results and genetic counseling options for individuals. Since March 2020, the Company has commercially launched several tests for the detection of SARS-CoV-2, the virus that causes the novel coronavirus, or COVID-19, including NGS and reverse transcription polymerase chain reaction – based, or RT-PCR-based, tests. The Company has received an Emergency Use Authorization, or EUA, from the U.S. Food and Drug Administration, or the FDA, for the RT-PCR-based tests for the detection of SARS-CoV-2 using upper respiratory specimens (nasal, nasopharyngeal, and oropharyngeal swabs) and for the at-home testing service through Picture Genetics. The Company's at-home testing service for COVID-19 and RT-PCR-based test have been granted an EUA by the FDA only for the detection of nucleic acid from SARS-CoV-2, not for any other viruses or pathogens. The Company believes its test menu offers more genes for testing than its competitors in today's market, which enables it to provide expansive options for test customization and clinically actionable results. A cornerstone of the Company's business is its ability to provide expansive options and flexibility for all clients' unique testing needs.

Unaudited Interim Financial Information

The accompanying unaudited interim condensed consolidated financial statements have been prepared on the same basis as the Company's audited consolidated financial statements as of and for the fiscal year ended December 31, 2020, which are included in the Company's annual report on Form 10-K filed with the Securities and Exchange Commission, or SEC, on March 8, 2021, or 2020 Annual Report, and, in the opinion of management, include all adjustments, which are normal and recurring in nature, necessary for a fair presentation of the Company's financial position and results of operations. Operating results for interim periods are not necessarily indicative of the results that may be expected for a full fiscal year or any other period. The accompanying Condensed Consolidated Balance Sheet as of December 31, 2020 has been derived from the Company's audited consolidated financial statements at that date but does not include all of the disclosures required by U.S. GAAP. As such, the information included in this quarterly report on Form 10-Q should be read in conjunction with the Company's audited consolidated financial statements included in the 2020 Annual Report, including the notes thereto.

Note 2. Summary of Significant Accounting Policies

See the summary of the Company's significant accounting policies set forth in the notes to its consolidated financial statements included in the 2020 Annual Report.

Use of Estimates

The preparation of condensed 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 condensed consolidated financial

statements, as well as various other factors management believes to be reasonable under the circumstances, including but not limited to the potential impacts arising from the recent global pandemic related to COVID-19. As the extent and duration of the impacts from COVID-19 remain unclear, the Company's estimates and assumptions may evolve as conditions change. Actual results could differ significantly from these estimates.

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

Foreign Currency Translation and Foreign Currency Transactions

The Company translates the assets and liabilities of its non-U.S. dollar functional currency subsidiaries into U.S. dollars using exchange rates in effect at the end of each period. Expenses for these subsidiaries are translated using rates that approximate those in effect during the period. Gains and losses from these translations are recognized in foreign currency translation included in accumulated other comprehensive income (loss) in the accompanying Condensed Consolidated Statements of Stockholders' Equity. Gains and losses from these translations were not significant in the first quarters of 2021 and 2020. The Company and its subsidiaries that use the U.S. dollar as their functional currency remeasure monetary assets and liabilities at exchange rates in effect at the end of each period, and inventories, property and nonmonetary assets and liabilities at historical rates. Losses from these remeasurements were not significant for the first quarter of 2021. Losses from these remeasurements were $85,000 in the first quarter of 2020.

Leases

The Company determines if an arrangement is a lease at inception by evaluating whether the arrangement conveys the right to use an identified asset and whether the Company obtains substantially all of the economic benefits from and has the ability to direct the use of the asset. Operating lease right-of-use, or ROU, asset, short-term lease liabilities, and long-term lease liabilities were included in other long-term assets, other current liabilities, and other long-term liabilities, respectively, in the accompanying Condensed Consolidated Balance Sheets.

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

The Company leases out space in buildings it owns in El Monte, California, to third-party tenants under noncancelable operating leases and has leased out such space since the Company purchased such buildings. The Company determines whether a lease exists at inception. The Company recognizes lease payments as income over the lease terms on a straight-line basis and recognizes variable lease payments as income in the period in which the changes in facts and circumstances on which the variable lease payment are based occur. The net rental income is included in the interest and other income, net, in the accompanying Condensed Consolidated Statement of Operations.

Concentration of Customers

In certain periods, a small number of customers have accounted for a significant portion of the Company's revenue. In the first quarter of 2021, after aggregating customers that are under common control or are affiliates, one customer contributed 25% of the Company's revenue. In the first quarter of 2020, after aggregating customers that are under common control or are affiliates, no customer contributed 10% or more of the Company's revenue. No customer comprised 10% or more of total trade accounts receivable as of March 31, 2021 and December 31, 2020. Revenue from the U.S. government was less than 10% of total revenue in the first quarters of 2021 and 2020.

Revenue from Contracts with Customers

Disaggregation of Revenue

The Company classifies its customers into three payor types: (i) Insurance, (ii) Institutional, including hospitals, medical institutions, other laboratories, governmental bodies, municipalities and large corporations, or (iii) Patients who pay directly, as the Company believes this best depicts how the nature, amount, timing, and uncertainty of its revenue and cash flows are affected by

economic factors. The following table summarizes revenue from contracts with customers by payor type for the first quarters of 2021 and 2020.

	Three Months Ended March 31,	
	2021	2020
	(in thousands)	
Testing Services by payor		
Insurance	$ 207,558	$ 134
Institutional	151,569	7,478
Patient	302	141
Total Revenue	$ 359,429	$ 7,753

Contract Balances

Receivables from contracts with customers - As of March 31, 2021 and December 31, 2020, receivables from contracts with customers were approximately $216.5 million and $183.9 million, respectively, and are included within trade accounts receivable on the Condensed Consolidated Balance Sheets.

Contracts assets and liabilities - As of March 31, 2021 and December 31, 2020, contract assets from contracts with customers were $506,000 and $1.4 million, respectively, associated with contract execution and certain costs to fulfill a contract, which is included in other current assets in the accompanying Condensed Consolidated Balance Sheets. Contract liabilities are recorded when the Company receives payment or bills prior to completing its obligation to transfer goods or services to a customer. The Company had $14.0 million and $26.6 million of contract liabilities as of March 31, 2021 and December 31, 2020, respectively. Revenues of $18.8 million and $242,000 for the first quarters of 2021 and 2020, respectively, related to contract liabilities at the beginning of the respective periods were recognized.

Transaction Price Allocated to Future Performance Obligations

The Company does not have material future obligations associated with testing services that extend beyond one year.

Reagents and Supplies

The Company maintains reagents and other consumables primarily used in sample collections and testing which are valued at the lower of cost or net realizable value. Cost is determined using actual costs on a first-in, first-out basis. The reagents and supplies was $25.7 million and $16.5 million as of March 31, 2021 and December 31, 2020, respectively, and was included in other current assets in the accompanying Condensed Consolidated Balance Sheets. While the Company has not experienced significant disruption in its supply chain and the Company does not yet know the full impact COVID-19 will have on its supply chain, the Company has increased its reagents and supplies on hand to respond to potential future disruptions that may occur.

Customer Deposit

Customer deposit in the accompanying Condensed Consolidated Balance Sheets consists primarily of payments received from customers in excess of their outstanding trade accounts receivable balances.

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 Condensed Consolidated Statements of Operations. The Company assesses collectability by reviewing trade accounts receivable on a collective basis where similar risk characteristics exist and on an individual basis when it identifies specific customers that have deterioration in credit quality such that they may no longer share similar risk characteristics with the other receivables. In determining the amount of the allowance for credit losses, the Company uses a probability-of-default and loss given default model, which allows the ability to define a point of default and measure credit losses for receivables that have reached the point of default for purposes of calculating the allowance for credit losses. Loss given default represents the likelihood that a receivable that has reached the point of default will not be collected in full. The Company will update its probability-of-default and loss given default factors annually to incorporate the most recent historical data and adjusts the quantitative portion of the reserve through its qualitative reserve overlay. The Company looks at qualitative factors such as general economic conditions in determining expected credit losses. During the first quarter of 2021, the Company recorded $1.1 million provision for credit losses for trade accounts receivable.

Marketable Securities

All marketable debt securities, which consist of corporate debt securities, U.S. government agency debt securities, and Yankee debt securities issued by foreign governments or entities and denominated in U.S. dollars, have been classified as "available for sale", and are carried at fair value. Unrealized gains and losses, net of any related tax effects, are excluded from earnings and are included in other comprehensive income (loss) and reported as a separate component of stockholders' equity until realized. Realized gains and losses on marketable debt securities are included in interest and other income, net, in the accompanying Condensed Consolidated Statements of Operations. The cost of any marketable debt securities sold is based on the specific-identification method. The amortized cost of marketable debt securities is adjusted for amortization of premiums and accretion of discounts to maturity. Interest on marketable debt securities is included in interest and other income, net. In accordance with the Company's investment policy, management invests to diversify credit risk and only invests in securities with high credit quality, including U.S. government securities, and the maximum final maturity from the date of purchase is three years.

The Company's investments in marketable equity securities are measured at fair value with the related gains and losses, realized and unrealized, recognized in interest and other income, net, in the accompanying Condensed Consolidated Statements of Operations. The cost of any marketable equity securities sold is based on the specific-identification method.

The Company will recognize an allowance for credit losses on available-for-sale debt securities on an individual basis, and no longer consider other-than-temporary impairment or immediately reduce the cost basis of the investment provided that it is more likely than not that the security will be held to recovery or maturity. Further, the Company will recognize any improvements in estimated credit losses on available-for-sale debt securities immediately in earnings and reduce the existing allowance for credit losses. Previously, a recovery of an impairment loss on an available-for-sale debt security was recognized prospectively as interest income. The Company will disaggregate its available-for-sale debt securities into the following categories: corporate debt, government and agency securities and money market funds. The Company's corporate bonds are comprised of predominantly high-grade corporate bonds while its government and agency securities are U.S. treasury bonds, and U.S. agency bonds. The Company has analyzed both corporate bonds and government and agency securities and identified that both types of securities have similar risk characteristics in that they are traded infrequently and have contractual interest rates and maturity dates. Money market funds are actively traded and short-term, and as such, the risk for these securities is not as high as for the other two security types.

In determining the impairment, the Company reviews and assesses its available-for-sale debt securities. Management reviews credit rating changes, securities trends, interest rate movements and unrealized loss at the security level. If any of these give rise to a potential credit concern, the Company performs a discounted cash flow analysis to determine the credit portion of the impairment. The discounted cash flow analysis will be performed either internally or through the assistance of a third party. Once the credit component of the impairment is determined, the Company will record the impaired amount as an allowance to the available-for-sale debt securities balance and as a charge to interest and other income, net, in the accompanying Condensed Consolidated Statements of Operations, not to exceed the amount of the unrealized loss. The Company assesses expected credit losses at the end of each reporting period and adjusts the allowance through interest and other income, net.

Recently Adopted Accounting Pronouncements

ASU No. 2016-13

In June 2016, the FASB issued *ASU No. 2016-13, Financial Instruments-Credit Losses: Measurement of Credit Losses on Financial Instruments*, or ASU No. 2016-13. ASU No. 2016-13 replaces the incurred loss impairment methodology in current U.S. GAAP with a methodology that reflects expected credit losses. The update is intended to provide financial statement users with more decision-useful information about the expected credit losses on financial instruments and other commitments to extend credit held by a reporting entity at each reporting date. Entities will apply the standard's provisions as a cumulative-effect adjustment to retained earnings as of the beginning of the first reporting period in which the guidance is effective. The standard will be effective for annual reporting periods beginning after December 15, 2019, including interim periods within those reporting periods for public business entities that meet the definition of an SEC filer, excluding entities eligible to be smaller reporting companies as defined by the SEC. For all other entities, the amendments in this update are effective for fiscal years beginning after December 15, 2022, including interim periods within those fiscal years. Early application of the amendments is permitted. The Company adopted ASU 2016-13 using the modified retrospective approach as of January 1, 2021. The cumulative effect upon adoption was $887,000 to the retained earnings in the accompanying Condensed Consolidated Statements of Stockholders' Equity and trade accounts receivable, net, in the accompanying Condensed Consolidated Balance Sheets. The cumulative tax effective was $239,000 to retained earnings and deferred tax assets included in other long-term assets in the accompanying Condensed Consolidated Balance Sheets. There was no impact related to available-for-sale debt securities.

ASU No. 2019-12

In December 2019, the FASB issued *ASU No. 2019-12, Simplifying the Accounting for Income Taxes (Topic 740)*, which is intended to reduce the complexity of accounting standards while maintaining or enhancing the helpfulness of information provided to financial statement users. The amendment in this ASU simplifies the accounting for income taxes by removing some exceptions including the incremental approach for intraperiod tax allocation, the requirement to recognize a deferred tax liability for equity method investments, the ability not to recognize a deferred tax liability for a foreign subsidiary, and the general methodology for calculating income taxes in an interim period. Other changes include requiring entities to recognize franchise tax that is partially based on income as an income-based tax and account for any incremental amount incurred as a non-income-based tax, evaluate tax basis step-up in goodwill obtained in a transaction that is not a business combination, and reflect the effect of an enacted change in tax laws or rates in the annual effective tax rate computation in the interim period that includes the enactment date, making minor codification improvements for income taxes related to employee stock ownership plans and investments in qualified affordable housing projects accounted for using the equity method, and specifying that an entity is not required to allocate the consolidated current and deferred tax expense to a legal entity that is not subject to tax in its separate financial statements. For public business entities, this amendment is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2020 with early adoption permitted. The Company adopted ASU 2019-12 in the first quarter of 2021, and the adoption had no material impact to the Company's condensed consolidated financial statements.

Note 3. Marketable Securities

The Company's marketable securities consisted of the following:

	March 31, 2021			
	Amortized Cost Basis	Unrealized Gains	Unrealized Losses	Aggregate Fair Value
	(in thousands)			
Marketable securities:				
Short-term				
Equity securities				
Bond fund	$ 163,079	$ —	$ (429)	$ 162,650
Exchange traded funds	17,629	—	(5)	17,624
Available-for-sale debt securities				
Money market accounts	54,547	—	—	54,547
Corporate debt securities	77,871	194	(22)	78,043
Less: Cash equivalents	(54,547)	—	—	(54,547)
Total short-term marketable securities	258,579	194	(456)	258,317
Long-term				
Corporate debt securities	278,907	285	(736)	278,456
Yankee debt securities	9,242	—	(72)	9,170
Total long-term marketable securities	288,149	285	(808)	287,626
Total marketable securities	$ 546,728	$ 479	$ (1,264)	$ 545,943

	December 31, 2020			
	Amortized Cost Basis	Unrealized Gains	Unrealized Losses	Aggregate Fair Value
	(in thousands)			
Marketable securities:				
Short-term				
Equity securities				
Bond fund	$ 153,269	$ 67	$ (151)	$ 153,185
Exchange traded funds	17,614	—	(5)	17,609
Available-for-sale debt securities				
Money market accounts	47,461	—	—	47,461
Corporate debt securities	41,061	101	(15)	41,147
Less: Cash equivalents	(47,461)	—	—	(47,461)
Total short-term marketable securities	211,944	168	(171)	211,941
Long-term				
Corporate debt securities	124,989	580	(117)	125,452
U.S. government agency debt securities	1,000	2	—	1,002
Yankee debt securities	6,054	4	(10)	6,048
Total long-term marketable securities	132,043	586	(127)	132,502
Total marketable securities	$ 343,987	$ 754	$ (298)	$ 344,443

Gross unrealized losses on the Company's marketable securities were $1.3 million as of March 31, 2021. Gross unrealized losses on the Company's marketable securities were $298,000 as of December 31, 2020. The Company currently does not intend to sell these securities prior to maturity. During the first quarter of 2021, the Company did not recognize credit losses.

The Company's securities of $420.2 million are used as collateral for an outstanding margin account borrowing. As of March 31, 2021, the Company had an outstanding borrowing of $15.0 million under its margin account. Margin account borrowings were used for the purchase of real property located in El Monte, California in 2020.

Note 4. Fair Value Measurements

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

Level 1: Inputs are quoted prices (unadjusted) in active markets for identical assets or liabilities that the reporting entity can access at the measurement date.

Level 2: Inputs are inputs other than quoted prices included within Level 1 that are observable for the asset or liability, either directly or indirectly.

Level 3: Inputs are unobservable inputs for the asset or liability.

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

	March 31, 2021			
	Total	Level 1	Level 2	Level 3
	(in thousands)			
Marketable securities and cash equivalents:				
Bond Fund	$ 162,650	$ 162,650	$ —	$ —
Exchange traded funds	17,624	17,624	—	—
Corporate debt securities	356,499	—	356,499	—
Yankee debt securities	9,170	—	9,170	—
Money market accounts	54,547	54,547	—	—
Total marketable securities and cash equivalents	$ 600,490	$ 234,821	$ 365,669	$ —

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

The Company's Level 1 assets include marketable equity securities and money market instruments and are valued based upon observable market prices. Level 2 assets consist of U.S. government agency debt securities, 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 March 31, 2021, the Company had no investments that were measured using unobservable (Level 3) inputs.

There were no transfers between fair value measurement levels during the first quarter of 2021.

Note 5. Fixed Assets

Major classes of fixed assets consisted of the following:

	Useful Lives	March 31, 2021	December 31, 2020
		(in thousands)	
Medical lab equipment	5 Years	$ 26,568	$ 20,849
Building	39 Years	6,731	6,731
Aircraft	7 Years	6,503	6,503
Computer hardware	3 Years	3,948	3,699
Leasehold improvements	Shorter of lease term or estimated useful life	1,618	1,580
Furniture and fixtures	2 to 5 Years	903	454
Automobile	2 to 5 Years	715	53
Building improvements	6 months to 5 Years	707	707
Computer software	3 to 5 Years	594	541
Land improvements	5 to 15 Years	403	403
General equipment	3 to 5 Years	44	44
Land		7,500	7,500
Assets not yet placed in service		3,592	2,055
Total		59,826	51,119
Less: Accumulated depreciation		(12,839)	(10,920)
Property and equipment, net		$ 46,987	$ 40,199

Depreciation expense on fixed assets totaled $1.9 million and $569,000 for the first quarters of 2021 and 2020, respectively.

Note 6. Other Current Assets

Other current assets consisted of the following:

	March 31, 2021	December 31, 2020
	(in thousands)	
Reagents and supplies	$ 25,684	$ 16,491
Prepaid expenses	4,515	3,682
Marketable securities interest receivable	2,133	1,016
Contract assets	506	1,379
Prepaid income taxes	14	14
Other receivable	1	17,810
Total	$ 32,853	$ 40,392

Reagents and supplies includes reagents and consumables used for COVID-19 testing and genetics testing and collection kits for COVID-19 testing. Other receivable primarily consists of proceeds to be received from public offerings of the Company's common stock as of December 31, 2020.

Note 7. Reporting Segment and Geographic Information

The Company views its operations and manages its business in one reporting segment. Long-lived assets were primarily located in the United States, or U.S., as of March 31, 2021 and December 31, 2020 with an insignificant amount located in Canada. Revenue by region was as follows:

	Three Months Ended March 31,	
	2021	2020
	(in thousands)	
Revenue:		
United States	$ 357,537	$ 5,639
Foreign	1,892	2,114
Total	$ 359,429	$ 7,753

Note 8. Debt, Commitments and Contingencies

Debt

As of March 31, 2021, the Company had an outstanding borrowing of $15.0 million under its margin account with the custodian of the Company's marketable debt security investment account, Pershing Advisor Solutions, LLC, a BNY Mellon Company. Margin account borrowings were used for the purchase of real property located in El Monte, California in 2020. The securities in the brokerage account were used as collateral for the margin loan. The custodian can issue a margin call at any time. The interest rate on the margin loan was the effective federal funds rate, or EFFR, plus a spread, and the EFFR and/or the spread can be changed by Bank of New York at any time. The interest was 1% at the time of withdrawal of $15.0 million from the margin account, and the interest rate at March 31, 2021 was less than 1%. The Company did not make any other withdrawals from the margin account, and the outstanding balance of $15.0 million is included in the accompanying Condensed Consolidated Balance Sheets. The related interest expenses for the first quarter of 2021 were $29,000.

Operating Leases

See Note 9, Leases, for further information.

FF Gene Biotech

See Note 14, Equity Method Investments, for a description of the Company's commitments related to its joint venture, FF Gene Biotech, as defined in Note 13, Related Parties.

Purchase Obligations

As of March 31, 2021, the Company had non-cancelable purchase obligations of $25.4 million, of which, $22.8 million for reagents and other supplies and $1.4 million for medical lab equipment are payable within twelve months, and $1.2 million for reagents is payable within the next twenty-four months.

Contingencies

From time to time, the Company may be subject to legal proceedings and claims arising in the ordinary course of business. In the opinion of management, the outcome of these matters would not have a material effect on the Company's condensed consolidated financial position, results of operations or cash flows.

Note 9. Leases

Lessee

The Company is party as a lessee to various non-cancelable operating leases with varying terms through October 2025 primarily for office space and equipment. The Company has an option to renew one of these leases for one year after its 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 does not have any finance leases or leases with variable lease payments. The Company's lease agreements do not contain any residual value guarantees, material restrictive covenants, bargain purchase options or asset retirement obligations.

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

During the first quarter of 2021, the Company entered into one long-term operating lease. Upon entering into this lease, the Company recorded lease ROU assets of $368,000 and short-term and long-term lease liabilities of $125,000 and $243,000, respectively. The Company extended the lease for its headquarters for another two years to January 31, 2023. The Company also entered into various short-term operating leases for additional office, laboratory, parking and storage space during the first quarter of 2021 and elected short-term lease recognition exemption for these leases.

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

	March 31, 2021	December 31, 2020
	(in thousands)	
Operating lease right-of-use asset	$ 928	$ 828
Operating lease liabilities, short term	$ 437	$ 267
Operating lease liabilities, long term	$ 499	$ 568

The following was operating lease expense:

	Three months ended March 31,	
	2021	2020
	(in thousands)	
Operating lease cost	$ 69	$ 149
Short-term lease cost	131	—
Total lease cost	$ 200	$ 149

Supplemental information related to leases was the following:

	March 31, 2021
Weighted average remaining lease term - operating leases	2.2 years
Weighted average discount rate - operating leases	3.41%

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

	Operating Leases (in thousands)
Year Ending December 31,	
2021 (remaining 9 months)	$ 345
2022	463
2023	159
2024	2
2025	2
2026	1
Thereafter	—
Total lease payments	972
Less imputed interest	(36)
Total	$ 936

Lessor

The Company leases out space in buildings it owns to third-party tenants under noncancelable operating leases and has leased out such space since the Company purchased such buildings in October 2020. As of March 31, 2021, the remaining lease terms left range from 1 month to 3 years and 9 months including renewal options and may include rent escalation clauses. Lease income primarily represents fixed lease payments from tenants recognized on a straight-line basis over the application lease term. Variable lease income represents tenant payments for real estate taxes, insurance and maintenance.

The lease income was $157,000 for the three months ended March 31, 2021, which was included in interest and other income, net, in the accompanying Condensed Consolidated Statements of Operations. Total lease income was as follows:

	Three months ended March 31,	
	2021	2020
	(in thousands)	
Lease income	$ 156	$ —
Variable lease income	1	—
Total lease income	$ 157	$ —

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

	Lease Payments from Tenants (in thousands)
Year Ending December 31,	
2021 (remaining 9 months)	$ 174
2022	190
2023	95
2024	61
Total	$ 520

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 Condensed Consolidated Statements of Operations as follows:

	Three Months Ended March 31,	
	2021	2020
	(in thousands)	
Cost of revenue	$ 674	$ 231
Research and development	1,223	312
Selling and marketing	426	171
General and administrative	639	210
Total	$ 2,962	$ 924

Note 11. Provision for Income Taxes

The effective tax rate used for interim periods is the estimated annual effective consolidated tax rate, based on the current estimate of full year results, except that taxes related to specific events, if any, are recorded in the interim period in which they occur. The annual effective tax rate is based upon several significant estimates and judgments, including the estimated annual pre-tax income of the Company in each tax jurisdiction in which it operates, and the development of tax planning strategies during the year. In addition, the Company's tax expense can be impacted by changes in tax rates or laws and other factors that cannot be predicted with certainty. As such, there can be significant volatility in interim tax provisions.

The Company recorded consolidated provision for income taxes of $66.5 million and $34,000 during the first quarters of 2021 and 2020, respectively, or 25% of earnings before income taxes for the first quarter of 2021, compared to -2% of loss before income taxes and equity loss in investee for the first quarter of 2020. The change in effective tax rate for the first quarter of 2021, relative to 2020, was primarily attributable to a significant increase in income for the first quarter of 2021, partially offset by increased windfall tax deductions related to stock-based compensation.

The Company is not currently under examination by any major income tax jurisdiction. During 2021, the statutes of limitations will lapse on the Company's 2017 Federal tax year and certain 2016 and 2017 state tax years. The Company does not believe the Federal or state statute lapses or any other event will significantly impact the balance of unrecognized tax benefits in the next twelve months. The net balance of unrecognized tax benefits was not material to the interim financial statements for the three months ended March 31, 2021 and 2020.

Note 12. Income (Loss) per Share

The following table presents the calculation of basic and diluted income (loss) per share for the first quarters of 2021 and 2020:

	Three Months Ended March 31,	
	2021	2020
	(in thousands, except per share data)	
Net income (loss)	$ 200,691	$ (1,956)
Weighted-average common shares—outstanding, basic	28,831	21,566
Weighted-average common shares—outstanding, diluted	30,770	21,566
Net income (loss) per common share, basic	$ 6.96	$ (0.09)
Net income (loss) per common share, diluted	$ 6.52	$ (0.09)

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

	Three Months Ended March 31,	
	2021	2020
	(in thousands)	
Options	—	307
Restricted Stock Units	37	1,367

The anti-dilutive shares described above were calculated using the treasury stock method. Due to the Company's net loss position during the first quarter of 2020, all outstanding stock options and restricted stock units were excluded from the weighted-average share calculation.

Note 13. Related Parties

Linda Marsh, who is a member of the Company's board of directors, is currently the Senior Executive Vice President of AHMC Healthcare Inc., or AHMC. The Company performs genetic testing and other testing services, on an arms-length basis, for AHMC, and the Company recognized $1.1 million in revenue in the first quarter of 2021. As of March 31, 2021, and December 31, 2020, $1.8 million was owed to the Company by AHMC, which is included in trade accounts receivable, net, in the accompanying Condensed Consolidated Balance Sheets, in connection with this relationship.

As more fully described in Note 14, Equity Method Investments, in April 2017, the Company, through an affiliated company formed for the purpose of the relationship, entered into a cooperation agreement, or JV Agreement, with Xilong Scientific Co., Ltd., or Xilong Scientific, and Fuzhou Jinqiang Investment Partnership (LP), or FJIP, to form a joint venture under the laws of the People's Republic of China, or PRC, called Fujian Fujun Gene Biotech Co., Ltd., or FF Gene Biotech. Xilong Scientific is an affiliate of Xi Long USA, Inc., a company which at one point owned greater than 10% of the Company's common stock. XiLong USA, Inc. has since reported beneficial ownership of 4.92% of the Company's common stock in a Schedule 13G filed with the SEC on June 12, 2020. FJIP was owned by key management of FF Gene Biotech, including Dr. Han Lin Gao, the Chief Scientific Officer and a large stockholder of the Company and the owner of approximately 25% of FJIP.

The Company and Fulgent Pharma LLC, the Company's former subsidiary, are party to shared services arrangements where research and development and administrative services and office space and equipment are provided between the companies, on an arms-length basis. Ming Hsieh is the Manager and a member of Fulgent Pharma LLC. During the first quarter of 2021, the cost of research development services rendered by Fulgent Pharma LLC for the Company was $108,000. Amounts for services performed by the Company for Fulgent Pharma LLC were not significant during the first quarters of 2021 and 2020. As of March 31, 2021, and December 31, 2020, $494,000 and $409,000, respectively, were owed to Fulgent Pharma LLC by the Company, which are included in accrued liabilities in the accompanying Condensed Consolidated Balance Sheets, in connection with these relationships.

Note 14. Equity Method Investments

FF Gene Biotech

April 2017, the Company, through an affiliated company formed for the purpose of the relationship, entered into the JV Agreement with Xilong Scientific and FJIP to form FF Gene Biotech, a joint venture formed under the laws of China to offer genetic testing services to customers in China. Pursuant to the terms of the JV Agreement, the Company has agreed to contribute to FF Gene Biotech genetic sequencing and other equipment with a total cost of 60.0 million renminbi, or RMB, over a five-year period for a 30% ownership interest in FF Gene Biotech, previously three-year per original agreement and amended in April 2019, Xilong Scientific has agreed to contribute to FF Gene Biotech 102.0 million RMB over a five-year period for a 51% ownership interest in the FF Gene Biotech, previously three-year per original agreement and amended in April 2019, and FJIP has agreed to contribute to FF Gene Biotech 19.0 million RMB over a ten-year period for a 19% ownership interest in FF Gene Biotech, previously five-year per original agreement and amended in April 2019. The Company's maximum exposure to fund losses of FF Gene Biotech as a result of its minority ownership of this entity is equal to its contribution obligation under the JV Agreement as described above. As of March 31, 2021, 29.7 million RMB (or approximately $4.5 million U.S. dollars) remained to be contributed to FF Gene Biotech by the Company under the terms of the JV Agreement. To date, the Company has purchased and contributed equipment with an aggregate fair value of $4.5 million pursuant to its contribution commitment under the JV Agreement. The Company accounted for this contribution in accordance with ASC 845, Nonmonetary Transactions, and recorded an investment based on the fair value of the contributed equipment, which is the same as carryover basis.

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

The Company accounts for its 30% interest in FF Gene Biotech using the equity method of accounting. The Company recorded an impairment loss to bring down the carrying value to zero in 2020 as the decline in the fair value of the investment compared to the pro forma carrying value is more than the carrying value as of December 31, 2020, and the Company believes the decline is other-than-temporary.

BostonMolecules, Inc.

In September 2020, the Company entered into a Series A Preferred Stock Purchase Agreement with BostonMolecules, Inc., or BostonMolecules, a Delaware corporation, pursuant to which the Company purchased 333 shares of Series A Preferred Stock of BostonMolecules, $0.0001 par value per share, or the BostonMolecules Shares, at a purchase price of $7,500 per share and an aggregate purchase price of $2.5 million. The BostonMolecules Shares represent an approximate 25% ownership interest in BostonMolecules.

The Company initially accounted for its 25% interest in BostonMolecules using the equity method of accounting and subsequently recorded an impairment loss to bring down the carrying value to zero in 2020.

Equity method investments as of March 31, 2021 and December 31, 2020, consisted of 30% ownership interest in FF Gene Biotech and 25% ownership interest in BostonMolecules, and the carrying value of both investments was zero due to impairment losses recorded in 2020.

Note 15. Equity Distribution Agreement

In November 2020, the Company entered into an Equity Distribution Agreement, or the November 2020 Equity Distribution Agreement, with Piper Sandler & Co. (f/k/a Piper Jaffray & Co.), Oppenheimer & Co. Inc., and BTIG LLC, as sales agents, pursuant to which the Company may offer and sell, from time to time through Piper, shares of its common stock having an aggregate offering price of up to $175.0 million. Piper may receive a commission of up to 3% of the gross proceeds received by the Company for sales pursuant to the November 2020 Equity Distribution Agreement. During the first quarter of 2021, the Company sold approximately 583,000 shares of its common stock pursuant to the November 2020 Equity Distribution Agreement at a weighted-average net selling price of $52.00.

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations.

The following discussion and analysis of our financial condition and results of operations should be read together with our condensed consolidated financial statements and related notes included in this report. Additionally, pursuant to Instruction 2 to paragraph (b) of Item 303 of Regulation S-K promulgated by the Securities and Exchange Commission in preparing this discussion and analysis, we presume that readers have access to and have read the discussion and analysis of our financial condition and results of operations included in our annual report on Form 10-K for our fiscal year ended December 31, 2020 filed with the SEC on March 8, 2021, or the 2020 Annual Report. As used in this discussion and analysis and elsewhere in this report, unless the context otherwise requires, the terms "Fulgent," the "Company," "we," "us" and "our" refer to Fulgent Genetics, Inc. and its consolidated subsidiaries.

Forward-Looking Statements

The following discussion and analysis contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, 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 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 II of this report. Moreover, we operate in a competitive and rapidly evolving industry and new risks emerge from time to time. It is not possible for us to predict all of the risks we may face, nor can we assess the impact of all factors on our business or the extent to which any factor or combination of factors could cause actual results to differ from our expectations. In light of these risks and uncertainties, the forward-looking events and circumstances described in this discussion and analysis may not occur, and actual results could differ materially and adversely from those described in or implied by any forward-looking statements we make. Although we have based our forward-looking statements on assumptions and expectations we believe are reasonable, we cannot guarantee future results, levels of activity, performance or achievements or other future events. As a result, forward-looking statements should not be relied on or viewed as predictions of future events, and this discussion and analysis should be read with the understanding that actual future results, levels of activity, performance and achievements may be materially different than our current expectations. The forward-looking statements in this discussion and analysis speak only as of the date of this report, and except as required by law, we undertake no obligation to update publicly any forward-looking statements for any reason after the date of this report to conform these statements to actual results or to changes in our expectations.

Overview

We are a technology company offering large-scale COVID-19 testing services and comprehensive genetic testing to provide physicians with clinically actionable diagnostic information they can use to improve the quality of patient care. We have developed a proprietary technology platform that allows us to offer a broad and flexible test menu and continually expand and improve our proprietary genetic reference library, while maintaining accessible pricing, high accuracy and competitive turnaround times. Combining NGS with our technology platform, we perform full-gene sequencing with deletion/duplication analysis in single-gene tests; pre-established, multi-gene, disease-specific panels; and customized panels that can be tailored to meet specific customer needs. We believe our test menu offers more genes for testing than our competitors in today's market, which enables us to provide expansive options for test customization and clinically actionable results. We believe our test menu offers more genes for testing than our competitors in today's market, which enables us to provide expansive options for test customization and clinically actionable results.

Our technology platform, which integrates sophisticated data comparison and suppression algorithms, adaptive learning software, advanced genetic diagnostics tools and integrated laboratory processes, allows us to offer a test menu with expansive genetic coverage. We believe the comprehensive data output and high detection rates of our tests, both made possible by this expansive genetic coverage, provide physicians with information they can readily incorporate into treatment decisions for their patients, which we refer to as clinical actionability. In addition, our technology platform facilitates our ability to perform customized genetic tests using our expansive library of genes, and we believe this flexibility increases the utility of the genetic data we produce. Further, our technology platform provides us with operating efficiencies that help lower our internal costs, which allows us to offer our tests at accessible price points. As a result, our efforts to build and continually enhance our technology platform allow us to deliver comprehensive, adaptable, clinically actionable and affordable genetic analysis while maintaining a low cost per billable test, enabling us to efficiently meet the needs of our growing base of customers.

Since March 2020, we have offered several tests for the detection of SARS-CoV-2, the virus that causes COVID-19, including NGS and RT-PCR-based tests. To date, we have processed orders for our COVID-19 tests from a variety of customers, including

governmental bodies, municipalities, and large corporations. In 2020, we established and operated COVID-19 testing sites for certain customers including the County of Los Angeles and the New York City public school system. We also offer at-home COVID-19 testing services through our Picture Genetics platform that is used by many customers, including individuals and large organizations, such as the New York City Test and Trace program.

We offer tests at competitive prices, averaging approximately $95 per billable test delivered in the first quarter of 2021, and at a lower cost to us than many of our competitors, averaging approximately $20 per billable test delivered in the first quarter of 2021. Our volume has grown rapidly since our commercial launch, with 3.8 million billable tests delivered in the first quarter of 2021, compared to 13,000 billable tests delivered in the first quarter of 2020. As of March 31, 2021, an aggregate of over 8.3 million billable tests have been delivered to over 1,400 customers since launching our first commercial genetic tests in 2013. We have experienced compound quarterly growth of 117.5% in the number of billable tests delivered in our last eight completed fiscal quarters. We recorded revenue and net income of $359.4 million and $200.7 million, respectively, in the first quarter of 2021, compared to revenue and net loss of $7.8 million and $2.0 million, respectively, in the first quarter of 2020. We achieved profitability in the first half of 2017, the second and third quarters of 2019, the second, third and fourth quarters of 2020 and the first quarter of 2021, but we have recorded losses in all other periods since our inception.

COVID-19 Considerations

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

In the first quarter of 2021 and for the entirety of the COVID-19 pandemic to such point, we continued to operate as an essential business in response to COVID-19. During the first quarter of 2021 and to date, the COVID-19 pandemic has not had a negative impact on our consolidated operating results. Rather, we have recognized significant revenue growth in connection with sales of our COVID-19 tests. Even after the COVID-19 outbreak has subsided, we may experience materially adverse impacts on our financial condition and results of operations. Our ability to continue to operate as currently planned, including our ability to continue to offer our COVID-19 tests with competitive results and turn-around times without any significant negative operational impact from the COVID-19 pandemic will depend in part on our, and any of our third-party service providers' and suppliers' ability to protect our respective employees and supply chains. We have endeavored to follow the recommended actions of government and health authorities to protect our employees. We intend to continue to adhere to our employee safety measures to ensure that any disruptions to our operations remain minimal during the pandemic. However, the uncertainty resulting from the pandemic could result in an unforeseen disruption to our, or our third-party service providers' and suppliers', workforce and/or supply chain.

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

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

Business Risks and Uncertainties and Other Factors Affecting Our Performance

Our business and prospects are exposed to numerous risks and uncertainties. For more information, see "Item 1A. Risk Factors" in Part II of this report. In addition, our performance in any period is affected by a number of other factors. See the description of some of the material factors affecting our performance in "Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations" of the 2020 Annual Report.

Results of Operations

The table below summarizes our results of operations for the periods indicated. For a financial overview relating to our results of operations, including general descriptions of the make-up of material line items of our statement of operations data, see "Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations" of the 2020 Annual Report.

	Three Months Ended March 31,		$	%
	2021	2020	Change	Change
Statement of Operations Data:	(dollars and billable tests in thousands, except per billable test data)			
Revenue	$ 359,429	$ 7,753	$ 351,676	4,536 %
Cost of revenue	74,075	4,057	70,018	1,726 %
Gross profit	285,354	3,696	281,658	7,621 %
Operating expenses:				
Research and development	5,422	1,978	3,444	174 %
Selling and marketing	5,008	1,597	3,411	214 %
General and administrative	8,002	2,035	5,967	293 %
Total operating expenses	18,432	5,610	12,822	229 %
Operating income (loss)	266,922	(1,914)	268,836	14,046 %
Interest and other income, net	282	241	41	17 %
Income (loss) before income taxes and equity loss in investee	267,204	(1,673)	268,877	16,072 %
Provision for income taxes	66,513	34	66,479	195,526 %
Income (loss) before equity loss in investee	200,691	(1,707)	202,398	11,857 %
Equity loss in investee	—	(249)	249	100 %
Net income (loss)	$ 200,691	$ (1,956)	$ 202,647	10,360 %
Other Operating Data:				
Billable tests delivered(1)	3,774	13	3,761	28,931 %
Average price per billable test delivered(2)	$ 95	$ 589	$ (494)	(84) %
Cost per billable test delivered(3)	$ 20	$ 308	$ (288)	(94) %

(1) We determine the number of billable tests delivered in a period by counting the number of tests which are delivered to our customers and for which we bill our customers and recognize some amount of revenue in the period.
(2) We calculate the average price per billable test delivered by dividing the amount of revenue we recognized from the billable tests delivered in a period by the number of billable tests delivered in the same period.
(3) We calculate cost per billable test delivered by dividing our cost of revenue in a period by the number of billable tests delivered in the same period.

Revenue

Revenue increased $351.7 million, or 4536%, from $7.8 million in the first quarter of 2020 to $359.4 million in the first quarter of 2021. The increase in revenue between periods was primarily due to increase in the number of billable tests delivered, primarily related to the increased orders for our COVID-19 tests, offset by a substantial decline in the average selling price per test.

The average price of the billable tests we delivered decreased $494, or 84%, from $589 in the first quarter of 2020 to $95 in the first quarter of 2021. The decrease was due to (i) lower price-points for the mix of tests we delivered, in the first quarter of 2021 versus 2020, including our COVID-19 tests launched in 2020, (ii) the mix of customers ordering tests in this period, who may order tests at different rates depending on the arrangements we have negotiated with them, and (iii) our reduction of prices for certain of our tests due to general price degradation for genetic tests and other competitive factors during the first quarter of 2021.

Revenue from non-U.S. sources decreased $222,000, or 11%, from $2.1 million in the first quarter of 2020 to $1.9 million in the first quarter of 2021. The decrease in revenue from non-U.S. sources between periods was primarily due to decreased sales of our traditional genetic testing services to customers in foreign countries adversely affected by the COVID-19 pandemic.

The number of billable tests we delivered increased 3.8 million, from 13,000 in the first quarter of 2020 to 3.8 million in the first quarter of 2021. The increase was primarily attributable to the expansion of our test menu, including our COVID-19 tests launched in 2020, and increases in sales to certain of our existing and new customers.

After aggregating customers that are under common control or are affiliates, one customer, the County of Los Angeles, contributed 25% of our total revenue in the first quarter of 2021, and no customer contributed 10% or more of our total revenue in the first quarter of 2020.

Cost of Revenue

Cost of revenue increased $70.0 million, or 1726%, from $4.1 million in the first quarter of 2020 to $74.1 million in the first quarter of 2021. The increase was primarily due to increases of $42.9 million in reagent and supply expenses related to increased billable tests delivered, $14.3 million in consulting and outside labor expense related to increased outside labor for production in the current period, $5.1 million in personnel costs including equity-based compensation related to increased headcount and market price of the Company's stock, $3.9 million in software expense related to usage of COVID-19 testing software, $1.3 million in depreciation expenses related to medical lab equipment purchased for our COVID-19 tests, and $1.1 million in facilities primarily related to certain modifications made to our mini vans used for our COVID-19 business.

Cost per billable test delivered decreased $288, or 94%, from $308 in the first quarter of 2020 to $20 in the first quarter of 2021 primarily attributable to our expanded test menu, including COVID-19 tests in 2020 which have a lower cost than our genetics tests. Our cost per billable test also decreased in part due to our efforts to leverage our technology, such as engineered chemistry and competitive analytics powered by artificial intelligence and machine learning.

Our gross profit increased $281.7 million, from $3.7 million in the first quarter of 2020 to $285.4 million in the first quarter of 2021. The increase in gross profit was primarily due to an increase in revenue between periods that exceeded the increase in cost of revenue over the same period. Our gross profit as a percentage of revenue, or gross margin, increased from 47.7% to 79.4% between periods due in part to the increase in revenue and decreases in our cost per billable test and cost of revenue described above.

Research and Development

Research and development expenses increased $3.4 million, or 174%, from $2.0 million in the first quarter of 2020 to $5.4 million in the first quarter of 2021. The increase was primarily due to increases of $1.6 million in personnel costs including equity-based compensation related to increased headcount and market price of the Company's stock, and $1.5 million in reagent and supply expenses related to increased reagent usage for COVID-19 research.

Selling and Marketing

Selling and marketing expenses increased $3.4 million, or 214% from $1.6 million in the first quarter of 2020 to $5.0 million in the first quarter of 2021. The increase was primarily due to increases of $2.2 million in personnel costs including equity-based compensation related to increased headcount and market price of the Company's stock, and $877,000 in consulting and outside labor expense and $389,000 in marketing cost related to COVID-19 testing related marketing projects in the current period.

General and Administrative

General and administrative expenses increased $6.0 million, or 293%, from $2.0 million in the first quarter of 2020 to $8.0 million in the first quarter of 2021. The increase was primarily due to increases of $2.5 million in software and licensing related to the increased number COVID-19 tests, $1.2 million in personnel costs including equity-based compensation related to increased headcount and market price of the Company's stock, $943,000 in bad debt expenses related to additional provision for credit losses in the current period, and $363,000 in legal and professional fees related to professional services obtained in the current period.

Interest and Other Income, Net

Net interest income was $230,000 and $326,000 in the first quarters of 2021 and 2020, respectively. This income related to interest earned on various investments in marketable securities including holding gain or loss on marketable equity securities.

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

Provision for Income Taxes

Provision for income taxes was $66.5 million and $34,000 for the first quarters of 2021 and 2020, respectively. The effective tax rate was 25% and -2% for the first quarters of 2021 and 2020, respectively. The change in effective tax rate for the first quarter of 2021, relative to 2020, was primarily attributable to a significant increase in income for the first quarter of 2021, partially offset by increased windfall tax deductions related to stock-based compensation.

Equity Loss in Investees

No equity losses were recorded in the first quarter of 2021 due to impairment loss recorded in 2020. Equity loss in investee related to our 30% ownership interest in FF Gene Biotech was $249,000 in the first quarter of 2020.

Liquidity and Capital Resources

Liquidity and Sources of Cash

We had $151.5 million and $87.4 million in cash and cash equivalents as of March 31, 2021 and December 31, 2020, respectively. We had $545.9 million and $344.4 million in marketable securities, primarily consisting of equity securities and corporate bonds, as of March 31, 2021 and December 31, 2020, respectively.

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

Our primary use of cash is to fund our operations as we continue to invest in and seek to grow our business. Cash used to fund operating expenses is impacted by the timing of our expense payments, as reflected in the changes in our outstanding accounts payable and accrued expenses. In addition, in April 2017, in connection with the establishment of FF Gene Biotech, we became obligated to contribute to FF Gene Biotech genetic sequencing and other equipment with a total cost of 60.0 million renminbi, or RMB, over a five-year period, previously three-year per original agreement and amended in April 2019. To date, we have purchased and contributed to FF Gene Biotech equipment with an aggregate fair value of $4.5 million, and as of March 31, 2021, 29.7 million RMB (or approximately $4.5 million U.S. dollars) of our total contribution obligations remain to be satisfied. Depending on the performance of FF Gene Biotech, this joint venture may never produce sufficient revenue to us to recover these capital and other investments and could cause our revenue to decrease if any of our direct customers in Asia choose to order genetic tests from FF Gene Biotech instead of from us, any of which could negatively affect our liquidity and cash flow. In addition, although we have in the past made cash distributions for tax and other purposes to the equity holders of our predecessor, we do not expect to use our cash to make these or any other types of distributions or dividends in the foreseeable future.

On August 30, 2019, we entered into an Equity Distribution Agreement, or the 2019 Equity Distribution Agreement, with Piper, as sales agent, which was subsequently amended on August 4, 2020. Pursuant to the 2019 Equity Distribution Agreement, we offered and sold an aggregate of 104,000 shares of our common stock at a weighted-average net selling price of $9.37 per share, which resulted in $979,000 of net proceeds to the Company during the year ended December 31, 2019, and we sold an aggregate of 1.1 million shares of our common stock at a weighted-average net selling price of $38.50 per share, which resulted in $42.7 million of net proceeds to the Company during the year ended December 31, 2020. Shares sold under the 2019 Equity Distribution Agreement are offered and sold pursuant to the Company's registration statement on Form S-3 (File No. 333-233227) filed with the SEC on August 12, 2019 and declared effective on August 23, 2019, and prospectus supplements and accompanying base prospectus filed with the SEC on August 30, 2019, May 6, 2020 and August 5, 2020.

On November 13, 2019, we entered into a purchase agreement with Piper, as representative of the several underwriters, pursuant to which we sold 2,673,750 shares of our common stock at a price of $10.52 per share, with a public offering price of $11.25 per share. We received net proceeds of approximately $27.6 million, after deducting underwriting discounts and commissions and offering expenses paid or payable by us of approximately $2.4 million. The shares issued and sold in the underwritten offering were sold pursuant to the Company's registration statement on Form S-3 (File No. 333-233227), and a prospectus supplement and accompanying base prospectus filed with the SEC on November 13, 2019.

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

On November 20, 2020, we entered into the November 2020 Equity Distribution Agreement, with Piper, Oppenheimer & Co. Inc., and BTIG LLC, as sales agents, pursuant to which we may offer and sell, from time to time through Piper, shares of our common stock having an aggregate offering price of up to $175.0 million. Piper may receive a commission of up to 3% of the gross proceeds received by the Company for sales pursuant to the November 2020 Equity Distribution Agreement. During the year ended December 31, 2020, we sold an aggregate of 2.0 million shares of our common stock pursuant to the November 2020 Equity Distribution Agreement at a weighted-average net selling price of $48.70 per share, which resulted in $99.1 million of net proceeds to the Company. During the first quarter of 2021, we sold approximately 583,000 shares of our common stock pursuant to the November 2020 Equity Distribution Agreement at a weighted-average net selling price of $52.00 per share, which resulted in $30.3 million of net proceeds to the Company. Shares sold under the November 2020 Equity Distribution Agreement were offered and sold pursuant to the Company's registration statement on Form S-3 (File No. 333-239964) filed with the SEC on July 21, 2020, as amended on August 5, 2020, and declared effective on August 12, 2020, and a prospectus supplement and accompanying base prospectus filed with the SEC on November 20, 2020.

We believe our existing cash, cash equivalent, short-term marketable securities, along with cash from operations and proceeds from our equity financings, will be sufficient to meet our anticipated cash requirements for at least the next 12 months. Much of the losses we have incurred in certain prior periods were attributable to a variety of non-cash charges, including equity-based compensation expenses. As a result, in spite of the losses we recorded during these periods, cash provided by continuing operations has been mostly positive since 2015 and has significantly contributed to our ability to meet our liquidity needs, including paying for capital expenditures. Additionally, if our business continues to grow and we are able to achieve increased efficiencies and economies of scale in line with this growth, we expect increased revenue levels would increase our ability to rely on cash from our operations to support our business in future periods, even if our expenses also increase as a result of the growth of our business. Based on these factors, we anticipate that cash from our operations will continue to play a meaningful role in our ability to meet our liquidity requirements and pursue our business plans and strategies during the next 12 months and in the longer term.

However, our expectations regarding the cash that may be provided by our operations and our cash needs in future periods could turn out to be wrong, in which case we may require additional financing to support our operations, as we do not presently have any commitments for future capital. For instance, cash provided by our operations has in the past experienced fluctuations from period to period, which we expect may continue in the future. These fluctuations can occur because of a variety of factors, including, among others, factors relating to the ongoing COVID-19 pandemic, the amount and timing of sales of billable tests, the prices we charge for our tests due to changes in product mix, customer mix, general price degradation for tests or other factors, the rate and timing of our billing and collections cycles and the timing and amount of our commitments and other payments. Moreover, even if our liquidity expectations are correct, we may still seek to raise additional capital through securities offerings, credit facilities or other debt financings, asset sales or collaborations or licensing arrangements.

If we raise additional funds by issuing equity securities, our existing stockholders could experience substantial dilution. Additionally, any preferred stock we issue could provide for rights, preferences or privileges senior to those of our common stock, and our issuance of any additional equity securities, or the possibility of such an issuance, could cause the market price of our common stock to decline. The terms of any debt securities we issue or borrowings we incur, if available, could impose significant restrictions on our operations, such as limitations on our ability to incur additional debt or issue additional equity or other restrictions that could adversely affect our ability to conduct our business, and would result in increased fixed payment obligations. If we seek to sell assets or enter into collaborations or licensing arrangements to raise capital, we may be required to accept unfavorable terms or relinquish or license to a third party our rights to important or valuable technologies or tests we may otherwise seek to develop ourselves. Moreover, we may incur substantial costs in pursuing future capital, including investment banking, legal and accounting fees, printing and distribution expenses and other similar costs. Additional funding may not be available to us when needed, on acceptable terms or at all. For example, the COVID-19 pandemic has recently caused extreme disruption and volatility in the global capital markets, which could reduce our ability to access capital. If we are not able to secure funding if and when needed and on reasonable terms, we may be forced to delay, reduce the scope of or eliminate one or more sales and marketing initiatives, research and development programs or other growth plans or strategies. In addition, we may be forced to work with a partner on one or more aspects of our tests or market development programs or initiatives, which could lower the economic value to us of these tests, programs or initiatives. Any such outcome could significantly harm our business, performance and prospects.

Cash Flows

The following table summarizes our cash flows for each of the periods indicated:

	Three Months Ended March 31,	
	2021	2020
	(in thousands)	
Cash provided by operating activities	$ 233,179	$ 1,366
Cash used in investing activities	$ (216,491)	$ (3,862)
Cash provided by (used in) financing activities	$ 47,347	$ (164)

Operating Activities

Cash provided by operating activities in the first quarter of 2021 was $233.2 million. The difference between net income and cash provided by operating activities for the period was primarily due to the effects of $3.0 million in equity-based compensation expenses and $1.9 million in the depreciation of assets. Cash provided by operating activities increased between periods primarily due to increases of $67.2 million in income tax payable due to a significant increase in income, $16.8 million in customer deposit due to payments received from customers in excess of their outstanding trade accounts receivable balances, and $3.9 million in other current liabilities related to increased payroll liabilities, partially offset by the negative impact of increases of $34.6 million in trade accounts receivable mainly due to timing of collections from customers and insurance companies and $9.1 million in other current and long-term assets related to additions in reagents and supplies, and decreases of $12.6 million in contract liabilities due to increased revenue recognized in the current period, and $6.3 million in accounts payable mainly due to timing of payments.

Cash provided by operating activities in the first quarter of 2020 was $1.4 million. The difference between net loss and cash provided by operating activities for the period was primarily due to the effects of $924,000 in equity-based compensation expenses and $569,000 in the depreciation of assets. Cash provided by operating activities increased between periods primarily due to an increase of $1.9 million in accounts payable mainly due to timing of payments, partially offset by an increase of $924,000 in other current and long-term assets primarily related to increased reagents and supplies.

Investing Activities

Cash used in investing activities in the first quarter of 2021 was $216.5 million, which primarily related to purchase of $219.5 million marketable securities, purchase of $11.5 million fixed assets consisting mainly of medical lab equipment, and partially offset by maturity of $14.5 million marketable securities.

Cash used in investing activities in the first quarter of 2020 was $3.9 million, which primarily related to purchase of $8.0 million marketable securities, purchase of $796,000 fixed assets consisting mainly of medical lab equipment, and partially offset by maturity of $4.9 million marketable securities.

Financing Activities

Cash provided by the first quarter of 2021 was $47.3 million, which primarily represents net proceeds from sale of our common stock made pursuant to the November 2020 Equity Distribution Agreement.

Cash used in the first quarter of 2020 was $164,000, which primarily represents payment for costs related to our underwritten offering in November 2019.

Critical Accounting Policies and Use of Estimates

This discussion and analysis is based on our consolidated financial statements included in this report, which have been prepared in accordance with U.S. Generally Accepted Accounting Principles, or U.S. GAAP. The preparation of consolidated financial statements in accordance with U.S. GAAP requires management to make certain estimates, judgments and assumptions and decisions that affect the reported amounts and related disclosures, including the selection of appropriate accounting principles and the assumptions on which to base accounting estimates. In making these estimates and assumptions and reaching these decisions, we apply judgment based on our understanding and analysis of the relevant circumstances, including historical data and experience available at the date of the consolidated financial statements, as well as various other factors management believes to be reasonable under the circumstances, including but not limited to the potential impacts arising from the recent global pandemic related to COVID-19. As the extent and duration of the impacts from COVID-19 remain unclear, our estimates and assumptions may evolve as conditions change. Actual results could differ from our estimates. We are committed to incorporating accounting principles, assumptions and estimates that promote the representational faithfulness, verifiability, neutrality and transparency of the accounting information included in our consolidated financial statements.

Except as set forth in Note 2 (Summary of Significant Accounting Policies) to our condensed consolidated financial statements included in this report, there have been no significant changes to our critical accounting policies and estimates as described in the 2020 Annual Report.

The JOBS Act

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

Off-Balance Sheet Arrangements

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

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

Not applicable.

Item 4. 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 and principal financial officers, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure. As required by Rule 13a-15(b) under the Exchange Act, our management, with the participation of our Chief Executive Officer and Chief Financial Officer, conducted an evaluation of the effectiveness of our disclosure controls and procedures as of March 31, 2021. Based on this evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective as of March 31, 2021.

Changes in Internal Control over Financial Reporting

There have not been any changes in our internal control (as required by Rule 13a-15(b) under the Exchange Act) over the financial reporting during the three months ended March 31, 2020 that have materially affected or are reasonably likely to materially affect our internal control over financial reporting.

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

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

PART II—OTHER INFORMATION

Item 1. Legal Proceedings.

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

Item 1A. Risk Factors.

Summary Risk Factors

The risk factors described below are a summary of the principal risk factors associated with an investment in us. These are not the only risks we face. You should carefully consider these risk factors, together with the risk factors set forth in "Item 1A. Risk Factors" of this report and the other reports and documents filed by us with the SEC.

- Our results of operations may fluctuate significantly from period to period and can be difficult to predict.
- The expansion of our COVID-19 testing business has resulted in a substantial change in our business that presents important challenges to our ability to manage our rapidly expanding business, and we anticipate that this business will eventually decrease after the development and widespread deployment of an effective vaccine.
- We have a history of losses, and we may not be able to achieve or sustain profitability.
- Our industry is subject to rapidly changing technology and new and increasing amounts of scientific data, and if we fail to keep pace with these technological advances, we may be unable to compete effectively and our business and prospects could suffer.
- If we are not able to grow and diversify our customer base and increase demand for our tests from existing and new customers, our potential for growth could be limited.
- Failure to comply with government laws and regulations related to submission of claims for our services could result in significant monetary damages and penalties and exclusion from the Medicare and Medicaid programs and corresponding foreign reimbursement programs.
- We rely on a limited number of suppliers and, in some cases, a sole supplier, for certain of our laboratory substances, equipment and other materials, and any delays or difficulties securing these materials could disrupt our laboratory operations and materially harm our business.
- Billing and collections processing for our tests is complex and time-consuming, and any delay in transmitting and collecting claims could have an adverse effect on our revenue.
- We rely on highly skilled personnel in a broad array of disciplines, and if we are unable to hire, retain or motivate these individuals, we may not be able to maintain the quality of our tests or grow our business.
- We may acquire businesses or assets, form joint ventures, make investments in other companies or technologies or establish other strategic relationships, any of which could harm our operating results, dilute our stockholders' ownership or cause us to incur debt or significant expense.
- Any changes in laws, regulations or the enforcement discretion of the FDA with respect to the marketing of diagnostic products, or violations of laws or regulations by us, could adversely affect our business, prospects, results of operations or financial condition.
- If we fail to comply with applicable federal, state, local and foreign laboratory licensing requirements, we could lose the ability to perform our tests or experience disruptions to our business.
- We conduct business in a heavily regulated industry. Complying with the numerous statutes and regulations pertaining to our business is expensive and time-consuming, and any failure by us, our consultants or commercial partners to comply could result in substantial penalties.
- Changes in laws and regulations, or in their application, may adversely affect our business, financial condition and results of operations.
- Marketing of our COVID-19 tests under the EUA from the FDA is subject to certain limitations and we are required to maintain compliance with the terms of the EUA, among other things, and the continuance of our EUA is subject to government discretion.
- We primarily rely on trade secret protection, non-disclosure agreements and invention assignment agreements to protect our proprietary information, which may not be effective.
- Litigation or other proceedings or third-party claims of intellectual property infringement or misappropriation could require us to spend significant time and money and prevent us from selling our tests.
- An active, liquid trading market for our common stock may not be sustained, which could make it difficult for stockholders to sell their shares of our common stock.
- The price of our common stock may be volatile and you could lose all or part of your investment.
- Our principal stockholders and management own a significant percentage of our capital stock and are able to exert significant control over matters subject to stockholder approval.

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

Business and Strategy Risks

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

Our results of operations have experienced fluctuations from period to period, which we expect may continue in the future. These fluctuations can occur because of a variety of factors, including, among others, the amount and timing of sales of billable tests; the prices we charge for our tests due to changes in product, customer or payor mix, general price degradation for genetic tests or other competitive factors, global health crises and pandemics which may generate demand for our tests, such as the ongoing pandemic related to COVID-19, the disease caused by the novel coronavirus since named SARS-CoV-2, the rate and timing of our billings and collections and the timing and amount of our commitments and other payments, as well as the other risk factors discussed in this report. Our results have been, and may in the future be, impacted by events that may not recur regularly, in the same amounts or at all in the future. In 2020, we developed and began offering a series of COVID-19 tests, but the pricing and margins from these tests continue to evolve. For the year ended December 31, 2020, we experienced substantial revenue growth due primarily to recent sales of, and growing demand, for these COVID-19 tests. While we believe there will be a continued demand for our COVID-19 tests in the near term, the future outcome and circumstances of the COVID-19 pandemic continue to rapidly evolve and remain uncertain. There can be no assurance our COVID-19 related growth or other growth we may experience will continue. This recent growth and other fluctuations in our operating results may render period-to-period comparisons less meaningful, and investors should not rely on the results of any one period as an indicator of future performance. These fluctuations in our operating results could cause our performance in any particular period to fall below the expectations of securities analysts or investors or guidance we have provided to the public, which could negatively affect the price of our common stock. Moreover, our limited operating history may make it difficult to determine if fluctuations in our performance reflect seasonality, pandemic-related demand or other trends or if these fluctuations are the result of other factors or events.

The expansion of our COVID-19 testing business has resulted in a substantial change in our business that presents important challenges to our ability to manage our rapidly expanding business, and we anticipate that this business will eventually decrease after the development and widespread deployment of an effective vaccine.

Since March 2020, we have commercially launched several COVID-19 tests for the detection of SARS-CoV-2, the virus that causes COVID-19, including NGS and RT-PCR-based tests. We have received an EUA from the FDA for our RT-PCR-based tests for the detection of SARS-CoV-2 using upper respiratory specimens (nasal, nasopharyngeal, and oropharyngeal swabs) and for our at-home COVID-19 testing service through Picture Genetics. Our at-home testing service for COVID-19 and RT-PCR-based tests have been granted an EUA by the FDA only for the detection of nucleic acid from SARS-CoV-2, not for any other viruses or pathogens. We are currently accepting patient samples directly to our BSL-2 certified laboratories in Temple City, California and Houston, Texas where we have the capacity to accept and process thousands of samples per day with a typical turn-around time of 24-48 hours from the time the sample was received and accepted. To date, we have processed orders for our COVID-19 tests from a variety of customers, including governmental bodies, municipalities, and large corporations. Due to the significant demand for COVID-19 testing services, our business has expanded rapidly since March 2020. This expansion has necessitated a very significant increase in our total headcount from 154 in March 2020 to over 700 as of March 31, 2021, and the volume of tests we perform on a daily basis has increased by approximately 9,000% in that time.

In addition, while most of our genetics testing business relied upon direct payments from hospitals, medical institutions and other laboratories, the majority of our revenues from our COVID-19 testing business result from reimbursements from third party payors, including private insurance and Medicare. To meet the demand for COVID-19 testing, we have increased the number of shifts at our main laboratory in Temple City, California and established a new laboratory in Houston, Texas. This substantial increase in all of our activities has caused significant changes in our business and a dramatic increase in our revenues and operating results. Each of these developments presents new challenges for our company and management team, and we cannot provide assurance that we will continue to be able to manage those challenges effectively. Our management team has not previously managed a business through such a dramatic acceleration, and the impacts of any failures, mistakes or missed opportunities could be magnified by our current rate of growth. The continued success of this business will depend upon our ability to rapidly deliver accurate results, and any failure, or perceived failure, in meeting these objectives could cause our COVID-19 testing business to decline rapidly. In addition, there are many new entrants to this market, and these competitors may cause price declines or reduced market share for us. The increase of our business with third party payors increases the regulatory scrutiny and risks that we face. While we anticipate that demand for our COVID-19 tests will eventually decrease once effective vaccines are widely deployed, we are continuing to invest in expanding our capacity to meet the increasing demand that we anticipate over the next several years. There can be no assurance that our increased investments in our COVID-19 testing capacity and capabilities will result in desirable returns, and if our operating results decline as a result of decreased demand, whether before or after the full deployment of an effective vaccine, our stock price could decline.

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

We have a history of losses. Although we achieved profitability in the first half of 2017, the second and third quarters of 2019, the second, third and fourth quarters of 2020 and the first quarter of 2021, we recorded losses in all other periods since our inception. We may not be able to maintain profitability in future periods. Further, our revenue levels may not grow at historical rates or at all, and we may not be able to achieve additional profitability or sustain profitability. We may incur additional losses in the future, particularly as we focus on investing in and growing our business and operations in response to recent demand for our COVID-19 tests. Our prior losses (and any future losses may also have) an adverse effect on our stockholders' equity and working capital, which could negatively impact our operations and your investment in our company. Any failure to sustain or grow our revenue levels and achieve or maintain profitability would negatively affect our business, financial condition, results of operations and cash flows, and could cause the market price of our common stock to decline.

We are an early-stage company with a limited operating history, which could expose us to enhanced risks and increase the difficulty of evaluating our business and prospects.

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

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

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

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

The composition and concentration of our customer base can fluctuate from period to period, and in certain prior periods, a small number of customers accounted for a significant portion of our revenue. When customers who, to our knowledge, are under common control or otherwise affiliated with each other are aggregated, one customer, the County of Los Angeles, contributed 25% of our total revenue in the first quarter of 2021. For these customers and for customers generally, tests are purchased on a test-by-test basis and not pursuant to any long-term purchasing arrangements. As a result, any or all of our customers, including affiliated customers or customers under common control who purchase large quantities of billable tests, could decide at any time to decrease, delay or discontinue their orders from us which could adversely affect our revenue. Although we believe some of these fluctuations in customer demand may be attributable, in part, to the nature of our business, in which our customers can experience significant volatility in their genetic testing demand from period to period in the ordinary course of their operations, these demand fluctuations, particularly for any key customers, can have a significant impact on our period-to-period performance regardless of their cause. In addition, the failure of any one of our customers or their payors to pay on a timely basis would negatively impact our results and cash flows. Our ability to maintain or increase sales to our existing customers depends on a variety of factors, including the other risk factors discussed in this report, many of which are beyond our control. Because of these and other factors, sales to any of our customers, including any key, affiliated or commonly controlled customers, may not continue in the amounts or at the rates as they have in the past, and such sales may never reach or exceed historical levels in any future period. The loss of any of our customers, or a

reduction in orders or difficulties collecting payments for tests ordered by any of them, could significantly reduce our revenue and adversely affect our operating results.

If we are not able to grow and diversify our customer base and increase demand for our tests from existing and new customers, our potential for growth could be limited. We may incur cost overruns as a result of fixed price contracts which could limit profits or otherwise adversely affect our business results of operations and financial condition.

To achieve our desired revenue growth, we must increase test volume by further penetrating our existing hospital and medical institution customers and by expanding sales of our COVID-19 tests to additional governmental bodies, municipalities and large corporations in need of regular COVID-19 testing for large populations. In addition, we must grow our customer base beyond hospitals, medical institutions and other laboratories and into additional customer groups, such as individual physicians, other practitioners and research institutions. To this end, we are making efforts to diversify our customer market, including building relationships with research institutions and other similar institutional customers, national clinical laboratories, governmental bodies, municipalities and large corporations in need of regular COVID-19 testing for large populations and various other organizations to facilitate access to physicians, practitioners and other new customer groups, including certain U.S. government agencies. These efforts could fail. Even if we successfully develop relationships with new customers in these or any other new customers groups, these relationships may not lead to improve our ability to achieve or sustain profitability.

Generally, when we establish these new customer relationships, we agree with the applicable payor, laboratory or other customer to provide certain of our tests at negotiated rates, but, subject to limited exceptions, most of these relationships do not obligate any party to order our tests at any agreed volume or frequency or at all. Further, any relationships we may develop with any government agencies are subject to unique risks associated with government contracts, including cancellation if adequate appropriations for subsequent performance periods are not made and modification or termination at the government's convenience and without prior notice. In particular, certain of government contracts are multi-award, indefinite-delivery and indefinite-quantity, or IDIQ, task order-based contracts, which generally provide for fixed price schedules for products and services, have no pre-set delivery schedules, have very low minimum purchase requirements, are typically competed among multiple awardees and force us to carry the burden of any cost overruns. Due to their nature, fixed-priced contracts inherently have more risk than cost reimbursable contracts. If we are unable to control costs or if our initial cost estimates are incorrect, we can lose money on these contracts. In addition, some of our contracts may have provisions relating to cost controls and audit rights, and if we fail to meet the terms specified in those contracts, we may not realize their full benefits. Low earnings caused by cost overruns and cost controls would have a negative impact on our results of operations. Since the price competition to win both IDIQ and fixed-priced contracts is intense and costs of further contracts performance cannot be predicted with certainty, there can be no assurance as to the profits, if any, that the Company will realize over the term of such contracts.

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

- the genetic testing market generally, and particularly the market for NGS genetic tests and our COVID-19 tests, is relatively new and may not grow as predicted or may decline;
- our efforts to improve our existing tests and develop and launch new tests may be unsuccessful;
- we may not be able to convince additional hospitals, medical institutions and other laboratories or additional customer groups of the utility of our tests and their potential advantages over existing and new alternatives;
- our investments in our sales and marketing functions, including our efforts to increase and restructure our sales force and re-focus and expand our marketing initiatives and strategies, may fail;
- we may be unsuccessful in convincing customers of the benefits of our broad and customizable test menu;
- genetic testing is expensive and many existing and potential new customers may be sensitive to pricing, particularly if we are not able to maintain low prices relative to our competitors;
- potential new customers, particularly individual physicians and other practitioners, may not adopt our tests if coverage and adequate reimbursement are not available;
- negative publicity or regulatory investigations into the actions of companies in our industry could raise doubts about the legitimacy of diagnostic technologies generally, and could result in scrutiny of diagnostic activities by the FDA, or other applicable government agencies; and
- our competitors could introduce new tests that cover more genes or that provide more accurate, reliable or rapid results.

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

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

With the development of NGS, the clinical genetic testing market has become increasingly competitive, and as the COVID-19 pandemic continues, potentially competitive COVID-19 tests have entered and may continue to enter the market. This competition may intensify in the future. We face competition from a variety of sources, including, among others, an increasing number of companies seeking to develop and commercialize, or who have developed and commercialized, COVID-19 tests, dozens of companies focused on molecular genetic testing services, such as specialty and reference laboratories that offer traditional single-gene and multi-gene tests, and established and emerging healthcare, information technology and service companies that may develop and sell competitive products or services, which may include informatics, analysis, integrated genetic tools and services for health and wellness.

Additionally, participants in closely related markets, such as prenatal testing and clinical trial or companion diagnostic testing, could converge on offerings that are competitive with the type of tests we perform. Instances where potential competitors are aligned with key suppliers or are themselves suppliers could provide these potential competitors with significant advantages. Further, hospitals, research institutions, individual physicians and other practitioners, governmental bodies, municipalities and corporations may also seek to perform testing, including rapid COVID-19 testing, at their own facilities rather than use our services. In this regard, access to these on site or point-of-care testing solutions and the continued development of, and associated decreases in the cost of, equipment, reagents and other materials and databases and genetic data interpretation services may enable broader direct participation in genetic testing and analysis and drive down the use of third-party testing companies such as ours. Moreover, the biotechnology and genetic testing fields continue to undergo significant consolidation, permitting larger clinical laboratory service providers to increase cost efficiencies and service levels, resulting in more intense competition.

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

Additionally, increased competition and cost-saving initiatives on the part of government entities and other third-party payors could result in downward pressure on the price for our testing services and genetic analysis and interpretation generally, which could harm our revenue levels and sales volume and our ability to gain market share. This downward pricing pressure could intensify in future periods, and we may not be able to maintain acceptable margins on our sales if we are forced to reduce prices for our tests to try to remain competitive, especially if we are also experiencing increasing expenses as we make efforts to grow our business or otherwise meet customer demands. The occurrence of these risks could materially harm our ability to achieve or sustain profitability. In addition, competitors may be acquired by, receive investments from or enter into other commercial relationships with larger, well-established and well-financed companies. Further, companies or governments that effectively control access to testing through umbrella contracts or regional preferences could promote our competitors or prevent us from performing certain tests in certain territories. If we are unable to compete successfully against current and future competitors for these or any other reasons, we may be unable to increase market acceptance and sales volume of our tests, which could prevent us from maintaining or increasing our revenue levels or achieving or sustaining profitability or could otherwise negatively affect our performance.

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

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

We believe our ability to maintain and grow sales volume in the future will depend in large part on our ability to further develop our sales team and create and implement effective sales and marketing strategies. We have been focused on these objectives and have

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

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

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

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

To continue to increase the volume of tests we offer and deliver, we must make substantial investments in our infrastructure, including our testing capacity, laboratory capacity, information systems, enterprise software systems, customer service, billing and collections systems and processes and internal quality assurance programs. We will also need to invest in our workforce by hiring additional skilled personnel, including biostatisticians, geneticists, software engineers, laboratory directors and specialists, sales and marketing experts and other scientific, technical and managerial personnel to market, process, interpret and validate the quality of results of our genetic tests and otherwise manage our operations. For example, before we deliver a report for any of our tests, including our COVID-19 tests, the results summarized in the report must be reviewed and approved by a licensed and qualified laboratory director. We currently have five laboratory directors, of which, four lab directors have all of the required licenses, including Dr. Han Lin Gao. We may need to hire additional licensed laboratory directors in the future to further scale our business. If we fail to hire additional qualified personnel when needed or otherwise develop our infrastructure sufficiently in advance of demand or if we fail to generate demand commensurate with our level of investment in our infrastructure, our business, prospects, financial condition and results of operations could be adversely affected. We are expanding our existing laboratory space and we may acquire new laboratory space, which would involve significant costs and attention from our management.

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

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

Since starting our genetic testing business, we have historically focused primarily on providing our tests to hospitals, medical institutions and other laboratories, our traditional genetic testing customer base. Our customer base for our COVID-19 tests is principally comprised of governmental bodies, municipalities, and large corporations who pay us directly or through third-party payors for our COVID-19 tests. In March 2020, the Coronavirus Aid, Relief, and Economic Security Act, or CARES Act, was enacted, and it provides for reimbursement to healthcare providers for COVID-19 tests provided to uninsured individuals, subject to continued available funding. In recent months, this reimbursement has accounted for a significant portion of our revenue. Should reimbursement under the CARES Act for COVID-19 testing cease to be available for any reason, our ability to collect payment would be adversely affected. Further, healthcare policy changes that influence the way healthcare is financed or other changes in the market that impact payment rates by institutional or non-institutional customers could also affect our collection rates. If we are unable to convince hospitals, medical institutions and other laboratories of the value and benefit provided by our tests, these customers may slow, or stop altogether, their purchases of our tests. Moreover, our ability to collect payment for our tests in a timely manner or at all from our healthcare provider customers may decline to the extent we expand our business into new healthcare provider customer groups, including individual physicians and other practitioners, from which collection rates are often significantly lower than hospitals, medical institutions and other laboratories and which involve substantial additional risks that are discussed in these risk factors below. Our collection risks also include the potential for default or bankruptcy by the party responsible for payment and other risks associated with payment collection generally. Any inability to maintain our past payment collection levels could cause our revenue and ability to achieve profitability to decline and adversely affect our business, prospects and financial condition.

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

Coverage and reimbursement by third-party payors, including managed care organizations, private health insurers and government healthcare programs, such as Medicare and Medicaid, for the types of genetic tests we perform can be limited and uncertain. Although our existing customer base consists primarily of hospitals, medical institutions, municipalities, governmental bodies, large corporations and other laboratories, from which we typically receive direct payment for ordered tests, including our COVID-19 tests, we believe our potential for future growth is dependent on our ability to attract new customer groups, including individual physicians and other practitioners. Our healthcare provider customers and laboratories may not order our tests unless third-party payors cover and provide adequate reimbursement for a substantial portion of the price of the tests. If we are not able to obtain coverage and an acceptable level of reimbursement for our tests from third-party payors, there would typically be a greater co-insurance or co-payment requirement from the patient for whom the test is ordered or the patient may be forced to pay the entire cost of the test out-of-pocket, which could dissuade practitioners from ordering our tests and, if ordered, could result in a delay in or decreased likelihood of collecting payment, whether from patients or from third-party payors. We believe our ability to increase the number of tests we sell to our healthcare provider customers and any corresponding revenue will depend in part on our ability to achieve and maintain broad coverage and reimbursement for our tests from third-party payors.

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

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

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

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

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

We believe our future success will depend in part on our ability to continue to expand our test offerings and develop and sell new tests. We may not be successful in launching or marketing any new tests we may develop, including our recently launched COVID-19 testing and Picture Genetics offerings, and, even if we are successful, the demand for our other tests could decrease or may not continue to increase at historical rates due to sales of the new tests. Our pipeline of new tests is in various stages of development and will be time-consuming and costly to fully develop and introduce, as development and marketing of new tests requires us to conduct research and development activities regarding the new tests and to further scale our laboratory processes and infrastructure to be able to analyze increasing amounts of more diverse data. Further, we may be unable to discover or develop and launch new tests for a variety of reasons, including failure of any proposed test to perform as expected, lack of validation or reference data for the test or failure to demonstrate the utility of the test. Further, any new test we are able to discover and develop may not be launched in a timely manner, meet applicable regulatory standards, successfully compete with other technologies and available tests, avoid infringing the proprietary rights of others, achieve coverage and adequate reimbursement from third-party payors, be capable of performance at

commercial levels and at reasonable costs, be successfully marketed or achieve sufficient market acceptance for us to recoup our time and capital investment in the development of the test. Any failure to successfully develop, market and sell new tests could negatively impact our ability to attract and retain customers and our revenue and prospects.

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

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

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

- compliance with the laws and regulations of multiple jurisdictions, which may be conflicting or subject to increasing stringency or other changes, including privacy regulations, tax laws, employment laws, healthcare regulatory requirements and other related approvals, including permitting and licensing requirements;
- logistics associated with the shipment of blood or other tissue specimens, including infrastructure conditions, transportation delays and the impact of U.S. and local laws and regulations, such as export and import restrictions, tariffs or other charges and other trade barriers, all of which involve increased risk related to the trade policies of the current administration, which may threaten existing and proposed trade agreements and impose more restrictive U.S. export-import regulations that impact our business;
- limits on our ability to penetrate international markets, including legal and regulatory requirements that would force us to conduct our tests locally by building additional laboratories or engaging in joint ventures or other relationships in order to offer our tests in certain countries, which relationships could involve significant time and resources to establish, deny us control over certain aspects of the foreign operations or reduce the economic value to us of these operations;
- failure by us, any joint ventures or other arrangements we may establish or any distributors or other commercial partners we may engage to obtain any regulatory approvals required to market, sell and use our tests in various countries;
- challenges predicting the market for genetic testing generally and tailoring our test menu to meet varying customer expectations in different countries and territories;
- difficulties gaining market share in territories in which we do not have a strong physical presence or brand awareness;
- complexities and difficulties obtaining protection for and enforcing our intellectual property rights;
- difficulties in staffing and managing foreign operations;
- complexities associated with managing multiple payor coverage and reimbursement regimes, government payors or patient self-pay systems;
- financial risks, such as longer payment cycles, difficulty collecting trade accounts receivable and the impact of local and regional financial conditions on demand and payment for our tests;
- exposure to foreign currency exchange rate fluctuations, including increased risk with respect to the Canadian dollar after we recently started billing certain of our Canadian hospital customers in their local currency and with respect to the RMB related to revenue received under our agreements with FF Gene Biotech;
- risks relating to conversion and repatriation of certain foreign currencies, particularly the RMB, which is subject to legal procedures and restrictions on currency conversion and movement outside China and which could impact our ability to receive the anticipated financial benefits of our FF Gene Biotech joint venture;
- natural disasters, political and economic instability, including wars, terrorism and political unrest, outbreak of disease (e.g. the COVID-19 pandemic), boycotts and other business restrictions; and
- regulatory and compliance risks related to applicable anti-bribery laws, including requirements to maintain accurate information and control over activities that may fall within the purview of these laws.

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

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

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

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

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

We perform all of our tests at our laboratories in Temple City, California and Houston, Texas. 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. This and any other laboratory facilities and equipment we may use could be damaged or rendered inoperable by natural or man-made disasters, including earthquakes, floods, fires and power outages, which could render it difficult or impossible for us to perform our tests for some period of time. The inability to perform our tests or the backlog that could develop if a laboratory becomes inoperable for even a short time could result in the loss of customers or harm to our reputation. Although we maintain insurance for damage to our property and disruption of our business, this insurance may not be sufficient to cover all of our potential losses and may not continue to be available to us on acceptable terms, if at all.

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

We face risks related to the impact of the COVID-19 pandemic and the related protective public health measures.

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

or restrictions on our employees' ability to travel, as well as temporary closures of the facilities of our suppliers, third party service providers or customers, which could impact our test volume and results of operations. In addition, a significant outbreak of contagious disease in the human population could result in a widespread health crisis that could adversely affect the economies and financial markets of many countries, resulting in an economic downturn that could affect demand for our tests and impact our results of operations.

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

We rely on a limited number of suppliers for certain of our laboratory substances, including reagents, as well as for the sequencers and various other equipment and materials we use in our laboratory operations. In particular, we rely on Illumina, Inc. as the sole supplier of the next generation sequencers and associated reagents we use to perform our genetic tests and as the sole provider of maintenance and repair services for these sequencers. We do not have long-term agreements with most of our suppliers and, as a result, they could cease supplying these materials and equipment to us at any time due to an inability to reach agreement with us on supply terms, disruptions in their operations, a determination to pursue other activities or lines of business or for other reasons, or they could fail to provide us with sufficient quantities of materials that meet our specifications. These suppliers may also themselves be affected by the COVID-19 pandemic or its related effects on the global supply chain. Transitioning to a new supplier or locating a temporary substitute, if any are available, would be time-consuming and expensive, could result in interruptions in or otherwise affect the performance specifications of our laboratory operations or could require that we revalidate our tests. In addition, the use of equipment or materials provided by a replacement supplier could require us to alter our laboratory operations and procedures. Moreover, we believe there are currently only a few manufacturers that are capable of supplying and servicing some of the equipment and other materials necessary for our laboratory operations, including sequencers and various associated reagents. As a result, replacement equipment and materials that meet our quality control and performance requirements may not be available on reasonable terms, in a timely manner or at all. If we encounter delays or difficulties securing, reconfiguring or revalidating the equipment, reagents and other materials we require for our tests, including as a result of the COVID-19 pandemic, our operations could be materially disrupted and our business, financial condition, results of operations and reputation could be adversely affected.

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

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

Several factors make this billing process complex, including:

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

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

Ethical, legal and social concerns related to the use of genetic information could reduce demand for our tests.

Genetic testing has raised ethical, legal and social issues regarding privacy and the appropriate uses of the resulting information. Government authorities could, for social or other purposes, limit or regulate the use of genetic information or genetic testing or prohibit testing for genetic predisposition to certain conditions, particularly for those that have no known cure. Similarly, these concerns may cause patients to refuse to use, or physicians to be reluctant to order, genetic tests such as ours, even if permissible. These and other ethical, legal and social concerns may limit market acceptance and adoption of our tests or reduce the potential markets for our tests, any of which could have an adverse effect on our business, financial condition and results of operations.

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

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

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

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

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

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

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

Any inability to obtain additional capital when needed and on acceptable terms may limit our ability to execute our business plans, and our liquidity needs could be materially affected by market fluctuations and general economic conditions.

We expect our capital expenditures and operating expenses to increase over the next several years as we seek to expand our infrastructure, sales and marketing and other commercial operations and research and development activities. As of March 31, 2021, we had cash and cash equivalents of approximately $151.5 million. We maintain our cash, cash equivalents and short-term marketable securities with high quality, accredited financial institutions. However, these accounts may exceed federally insured limits, and, while we believe the Company is not exposed to significant credit risk due to the financial strength of these depository institutions, the failure or collapse of one or more of these depository institutions could materially adversely affect our ability to recover these assets. We may seek to fund future cash needs through securities offerings, credit facilities or other debt financings, asset sales or collaborations or licensing arrangements. Additional funding may not be available to us when needed, on acceptable terms or at all. For example, the COVID-19 pandemic has recently caused extreme disruption and volatility in the global capital markets, which could 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 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.

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

New legislation or regulation which could affect our tax burden could be enacted by any governmental authority. We cannot predict the timing or extent of such tax-related developments which could have a negative impact on our financial results. U.S. federal legislation affecting the tax laws was enacted in December 2017, or the TCJA; and twice in March 2020, first in the Families First Coronavirus Response Act and again in the CARES Act. We cannot estimate how the changes in tax law from this legislation will affect our tax liability in future years.

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

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

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

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

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

We depend on information technology and telecommunications systems for significant elements of our operations, such as our laboratory information management systems, including test validation, specimen tracking and quality control; our bioinformatics analytical software systems; our reference library of information relating to genetic variants and their role in disease; personal information storage, maintenance and transmission; our customer-facing web-based software and customer service functions; our report production systems; our billing and reimbursement procedures; our scientific and medical data analysis and other research and development activities and programs; and our general and administrative activities, including disclosure controls, internal control over financial reporting and other public reporting functions. In addition, our third-party service providers depend on technology and telecommunications systems in order to provide contracted services for us. We expect we will need to continue to expand and strengthen a number of enterprise software systems that affect a broad range of business processes and functions, particularly if and as our operations grow, including, for example, systems handling human resources, financial and other disclosure controls and reporting, customer relationship management, regulatory compliance, security controls and other infrastructure functions.

Information technology and telecommunications systems are vulnerable to disruption and damage from a variety of sources, including power outages and other telecommunications or network failures, natural disasters, and the outbreak of war or acts of terrorism. Breaches resulting in the compromise, disruption, degradation, manipulation, loss, theft, destruction, or unauthorized disclosure of sensitive information, can occur in a variety of ways, including but not limited to, negligent or wrongful conduct by employees or former employees or others with permitted access to our information technology systems and information, or wrongful conduct by hackers, competitors, or certain governments. Our third-party vendors and business partners face similar risks. Moreover, despite network security and back-up measures, our servers and other electronic systems are potentially vulnerable to cybersecurity breaches, such as physical or electronic break-ins, computer viruses, ransomware attacks, phishing schemes, and similar disruptive events. Despite the precautionary measures we have taken to detect and prevent or solve problems that could affect our information technology and telecommunications systems, there may be significant downtime or failures of these systems or those used by our third-party service providers. There can be no assurance that we will promptly detect and/or intercept any such disruption or security breach, if at all. Any such downtime or failure could prevent us from conducting tests, preparing and providing reports to customers, billing payors, responding to customer inquiries, conducting research and development activities, maintaining our financial and disclosure controls and other reporting functions and managing the administrative aspects of our business. Moreover, any such downtime or failure could force us to transfer data collection operations to an alternate provider of server-hosting services, which could involve significant costs and result in further delays in our ability to conduct tests, deliver reports to our customers and

otherwise manage our operations. Further, although we carry property, business interruption and cyber lability insurance, the coverage may not be adequate to compensate for all losses that may occur in the event of system downtime or failure. Any such disruption or loss of information technology or telecommunications systems on which critical aspects of our operations depend could have a material adverse effect on our business and our reputation.

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

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

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

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

We are required to maintain internal control over financial reporting and report any material weaknesses in these internal controls. Section 404 of the Sarbanes-Oxley Act requires that we evaluate and determine the effectiveness of our internal control over financial reporting and annually provide a management report on these internal controls. Although we have implemented systems, processes and controls and performed this evaluation as of the end of 2020, we will need to maintain and enhance these controls if and as we grow, and we may need to hire additional personnel and devote more resources to our financial reporting function in order to do so.

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

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

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

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

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

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

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

The auditor for our joint venture in China, like other independent registered public accounting firms operating in China, is not permitted to be subject to inspection by the Public Company Accounting Oversight Board, and as such, investors may be deprived of the benefits of such inspection.

The independent registered public accounting firm that issues the audit reports for our joint venture in China, FF Gene Biotech, included in our reports filed with the SEC, as an auditor of companies that are traded publicly in the United States and a firm registered with the Public Company Accounting Oversight Board (United States), or PCAOB, is required by the laws of the United States to undergo regular inspections by PCAOB to assess its compliance with the laws of the United States and professional standards. On May 24, 2013, the PCAOB announced that it had signed a Memorandum of Understanding, or MOU, with Chinese securities regulators that would enable the PCAOB under certain circumstances to obtain audit work papers of China-based audit firms. The MOU establishes a framework under which the PCAOB can request and obtain audit papers and permits the PCAOB to share the work papers it obtains with the SEC, subject to certain requirements. But the MOU, which is non-binding, is also limited by its own terms. For instance, Chinese regulators may refuse to produce documents in specified circumstances, including where production would violate Chinese law or run contrary to the public interest. Moreover, the MOU does not provide the PCAOB with the ability to conduct on-the-ground inspections of auditors in China, an important part of the PCAOB's oversight function. As a result, our auditor, like other independent registered public accounting firms operating in China, is currently not inspected by PCAOB in the same way that PCAOB inspects independent registered public accounting firms operating outside China. Inspections of other firms that PCAOB has conducted outside of China have identified deficiencies in those firms' audit procedures and quality control procedures, which may be addressed as part of the inspection process to improve future audit quality. The inability of PCAOB to conduct regular inspections of independent registered public accounting firms operating in China makes it more difficult to evaluate the effectiveness of our auditor's audit procedures or quality control procedures. As a result, investors may be deprived of the benefits of PCAOB regular inspections.

Regulatory Risks

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

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

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

Even though we commercialize our tests as LDTs, our tests may in the future become subject to more onerous regulation by the FDA. For example, the FDA may disagree with our assessment that our tests fall within the definition of an LDT and seek to regulate our tests as medical devices. Moreover, the FDA issued draft guidance and a 2017 Discussion Paper to allow for further public discussion about an appropriate LDT oversight approach and to give congressional committees the opportunity to develop a legislative solution. The FDA also solicited public input and published two final guidance documents in April 2018 relating to FDA oversight of NGS-based tests. These two guidance documents describe the FDA's thinking and recommendations regarding test developer's use of FDA-recognized standards to support analytical validity, and public human genetic variant databases to support clinical validity, of these tests.

On August 19, 2020, the U.S. Department of Health and Human Services, or HHS, published a policy announcement that the FDA must go through the formal notice-and-comment rulemaking process before requiring pre-market review of LDTs rather than making such changes through guidance documents, compliance manuals, or other informal policy statements. However, laboratories may still voluntarily submit LDTs to the FDA for pre-market review. Although the ultimate impact of HHS's policy statement on the FDA's plans for regulating LDTs and its current thinking relating to such testing products is unclear, the announcement appears to confirm that laboratories may commercialize LDTs for clinical use without submitting such tests for FDA review and marketing authorization, including EUA. HHS's policy statement does not affect proposed legislation for the regulation of LDTs, which is discussed below. It is also unclear whether the Biden Administration, which assumed control of the executive branch on January 20, 2021, would take the same position as the former administration or seek to revoke or revise the HHS policy announcement from August 2020.

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

It is unclear whether the VALID Act would be passed by Congress in its current form or signed into law by President Trump. Until the FDA promulgates binding regulations through notice-and-comment rulemaking regarding LDTs, or the VALID Act or other legislation is passed reforming the federal government's regulation of LDTs, it is unknown how the FDA may regulate our tests in the future and what testing and data may be required to support any required clearance or approval.

If the FDA creates a new regulation to enforce its medical device requirements for LDTs or if the FDA disagrees with our assessment that our tests are LDTs, we could for the first time be subject to enforcement of a variety of regulatory requirements, including registration and listing, medical device reporting and quality control, and we could be required to obtain premarket clearance

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

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

Failure to comply with any applicable FDA requirements could trigger a range of enforcement actions by the FDA, including warning letters, civil monetary penalties, injunctions, criminal prosecution, recall or seizure, operating restrictions, partial suspension or total shutdown of operations and denial of or challenges to applications for clearance or approval, as well as significant adverse publicity.

If we fail to comply with applicable federal, state, local and foreign laboratory licensing requirements, we could lose the ability to perform our tests or experience disruptions to our business.

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

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

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

Moreover, certain other states require us to maintain out-of-state laboratory licenses or obtain approval on a test-specific basis to perform testing on specimens from these states. Additional states could adopt similar licensure requirements in the future, which could require us to modify, delay or discontinue our operations in such jurisdictions. We are also subject to regulation in foreign jurisdictions, which we expect will increase as we seek to expand international utilization of our tests or if jurisdictions in which we pursue operations adopt new or modified licensure requirements. Foreign licensure requirements could require review and modification of our tests in order to offer them in certain jurisdictions or could impose other limitations, such as restrictions on the transport of human blood or other tissue necessary for us to perform our tests that may limit our ability to make our tests available outside the United States. Additionally, complying with licensure requirements in new jurisdictions may be expensive, time-consuming and subject us to significant and unanticipated delays.

Failure to comply with applicable clinical laboratory licensure requirements could result in a range of enforcement actions, including license suspension, limitation or revocation, directed plan of correction, onsite monitoring, civil monetary penalties, civil injunctive suits, criminal sanctions and exclusion from the Medicare and Medicaid programs, as well as significant adverse publicity. Any sanction imposed under CLIA, its implementing regulations or state or foreign laws or regulations governing clinical laboratory licensure, or our failure to renew our CLIA certificate or any other required local, state or foreign license or accreditation, could have a material adverse effect on our business, financial condition and results of operations. In such case, even if we were able to bring our laboratory back into compliance, we could incur significant expenses and lose revenue while doing so.

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

Our business is subject to federal and state laws that protect the privacy and security of personal information, including the Health Insurance Portability and Accountability Act of 1996, or HIPAA, the Health Information Technology for Economic and Clinical Health Act, or HITECH, and similar state laws, as well as numerous other federal, state and foreign laws, including consumer protection laws and regulations, that govern the collection, dissemination, use, access to, confidentiality and security of patient health information. In addition, new laws and regulations that further protect the privacy and security of medical records or medical information are regularly considered by federal and state governments. Further, with the recent increase in publicity regarding data breaches resulting in improper dissemination of consumer information, federal and state governments have passed or are considering laws regulating the actions that a business must take if it experiences a data breach, such as prompt disclosure to affected customers. The Federal Trade Commission, or 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 Federal Trade Commission Act, or the FTC Act, and comparable state laws. In addition to data breach notification laws, some states have enacted statutes and rules requiring businesses to reasonably protect certain types of personal information they hold or to otherwise comply with certain specified data security requirements for personal information. We intend to continue to comprehensively protect all personal information and to comply with all applicable laws regarding the protection of such information.

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

The European Union formally adopted the General Data Protection Regulation, or GDPR, in 2016, which applies to all European Union member states from May 25, 2018 and replaced the European Data Protection Directive. The GDPR introduced stringent new data protection and operational requirements in the European Union for companies that receive or process personal data of European residents, as well as substantial fines for breaches of the data protection rules. It has increased our responsibility and liability in relation to personal data that we process and we are required to maintain additional mechanisms ensuring compliance with the GDPR. The GDPR is a complex law and the regulatory guidance is still evolving, including with respect to how the GDPR should be applied in the context of clinical studies and the collection, processing, and storage of sensitive personal data, including genetic information and testing. Furthermore, many of the countries within the European Union are still in the process of drafting supplementary data protection legislation in key fields where the GDPR allows for national variation, including the fields of clinical study and other health-related information. These variations in the law may raise our costs of compliance and result in greater legal risks. On July 16, 2020, the Court of Justice of the European Union or the CJEU, issued a landmark opinion in the case *Maximilian Schrems vs. Facebook* (Case C-311/18), or *Schrems II.* This decision calls into question certain data transfer mechanisms as between the European Union member states and the US. The CJEU is the highest court in Europe and the *Schrems II* decision heightens the burden on data importers to assess U.S. national security laws on their business, and future actions of European Union data protection authorities are difficult to predict at this early date. Consequently, there is some risk of any such data transfers from the European Union being halted by one or more European Union member states. Any contractual arrangements requiring the transfer of personal data from the European Union to us in the United States will require greater scrutiny and assessments as required under *Schrems II* and may have an adverse impact on cross-border transfers of personal data, or increase costs of compliance.

In addition, many states, such as California (where one of our clinical laboratories is located), have implemented similar privacy laws and regulations, such as the California Confidentiality of Medical Information Act, that impose restrictive requirements regulating the use and disclosure of patient health information and other personal information. In addition to fines and penalties imposed upon violators, some of these state laws also afford private rights of action to individuals who believe their personal information has been misused. California's patient privacy laws, for example, provide for penalties of up to $250,000 and permit injured parties to sue for damages. In addition to the California Confidentiality of Medical Information Act, California also recently enacted the California Consumer Privacy Act of 2018, or CCPA, which became effective on January 1, 2020. The CCPA has been characterized as the first "GDPR-like" privacy statute to be enacted in the United States because it mirrors a number of the key provisions of the GDPR. The CCPA establishes a new privacy framework for covered businesses in the State of California by creating an expanded definition of personal information, establishing new data privacy rights for California residents, imposing special rules on the collection of personal data from minors, and creating a new and potentially severe statutory damages framework for violations of the CCPA and for businesses that fail to implement reasonable security procedures and practices to prevent data breaches. On November 3, 2020, California voters passed the California Privacy Rights Act, or CPRA, which expands the CCPA. The CPRA will be fully effective in January of 2023 and, among other things, establishes the California Privacy Protection Agency, or CPPA, a new regulatory authority charged with administering and enforcing the CRPA and privacy rights in California. The CPPA will have the power to levy fines and bring other enforcement actions. The CPRA could impact our operations or that of our collaborators and business partners and impose new regulatory requirements and increase costs of compliance. Other states are considering expanded privacy legislation similar to the GDPR and CPRA, and several federal privacy proposals are under consideration in the current session of Congress.

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

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

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

- the HHS policy decision from August 2020 establishing that the FDA does not presently have authority to oversee LDTs;
- CLIA's and CAP's regulation of our laboratory activities;
- federal and state laws and standards affecting reimbursement by government payors, including certain coding requirements to obtain reimbursement and certain changes to the payment mechanism for clinical laboratory services resulting from the Protecting Access to Medicare Act of 2014, or PAMA;
- HIPAA and HITECH, which establish comprehensive federal standards with respect to the privacy and security of PHI, and requirements for the use of certain standardized electronic transactions with respect to transmission of such information, as well as similar laws protecting other types of personal information;
- state laws governing the maintenance of personally identifiable information of state residents, including medical information, and which impose varying breach notification requirements, some of which allow private rights of action by individuals for violations and also impose penalties for such violations;
- the federal Anti-Kickback Statute, which generally prohibits knowingly and willfully offering, paying, soliciting or receiving remuneration, directly or indirectly, in return for or to induce a person to refer to an individual any good, facility, item or service that is reimbursable under a federal health care program;
- the federal Stark Law, which generally prohibits a physician from making a referral for certain designated health services covered by the Medicare program, including laboratory and pathology services, if the physician or an immediate family member has a financial relationship with the entity providing the designated health services;

- the federal False Claims Act, which imposes civil penalties, and provides for civil whistleblower or qui tam actions, against individuals or entities for knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government;
- the federal Civil Monetary Penalties Law, which generally prohibits, among other things, the offering or transfer of remuneration to a Medicare or Medicaid beneficiary if it is likely to influence the beneficiary's selection of a particular provider, practitioner or supplier of services reimbursable by Medicare or Medicaid;
- the Affordable Care Act, or ACA, which, among other things, establishes a requirement for providers and suppliers to report and return any overpayments received from the Medicare and Medicaid programs;
- other federal and state fraud and abuse laws, such as anti-kickback laws, prohibitions on self-referral, fee-splitting restrictions, insurance fraud laws, anti-markup laws, prohibitions on the provision of tests at no or discounted cost to induce physician or patient adoption and false claims acts, some of which may extend to services reimbursable by any third-party payor, including private payors;
- the federal Physician Sunshine Payment Act and various state laws on reporting relationships with health care providers and customers, which could be determined to apply to our LDTs;
- the prohibition on reassignment of Medicare claims;
- state laws that prohibit other specified healthcare practices, such as billing physicians for tests that they order, waiving coinsurance, copayments, deductibles and other amounts owed by patients, business corporations practicing medicine or employing or engaging physicians to practice medicine and billing a state Medicaid program at a price that is higher than what is charged to one or more other payors;
- the U.S. Foreign Corrupt Practices Act, or FCPA, and applicable foreign anti-bribery laws;
- federal, state and local regulations relating to the handling and disposal of regulated medical waste, hazardous waste and biohazardous waste and workplace safety for healthcare employees;
- laws and regulations relating to health and safety, labor and employment, public reporting, taxation and other areas applicable to businesses generally, all of which are subject to change, including, for example, the significant changes to the taxation of business entities were enacted in December 2017; and
- similar foreign laws and regulations that apply to us in the countries in which we operate or may operate in the future.

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

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

We have adopted policies and procedures designed to comply with these laws and regulations and, in the ordinary course of our business, we conduct internal reviews of our compliance with these laws. Our compliance is also subject to review by applicable government agencies. It is not always possible to identify and deter misconduct by employees, distributors, consultants and commercial partners, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from government investigations or other actions or lawsuits stemming from a failure to comply with applicable laws or regulations. Additionally, we are subject to the risk that a person or government could allege such fraud or other misconduct, even if none occurred. Any action brought against us for violation of these or other laws or regulations, even if we successfully defend against it, could cause us to incur significant legal expenses, divert our management's attention from the operation of our business and harm our reputation. If our operations, including the conduct of our employees, consultants and commercial partners, are found to be in violation of any of these laws and regulations, we may be subject to applicable penalties associated with the violation, including administrative, civil and criminal penalties, damages, fines, individual imprisonment, exclusion from participation in federal healthcare programs, refunding of payments received by us and curtailment or cessation of our operations. Any of these consequences could seriously harm our business and our financial results.

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

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

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

On December 20, 2019, President Trump signed the Further Consolidated Appropriations Act, which included the LAB Act. The LAB Act delayed by one year the reporting of payment data under PAMA for clinical diagnostic laboratory tests that are not advanced diagnostic laboratory tests until the first quarter of 2021. The CARES Act, which was signed into law on March 27, 2020, delayed the reporting period by an additional year, until the first quarter of 2022.

In addition, under PAMA, as amended by the LAB Act, any reduction to a particular payment rate resulting from the new methodology is limited to 10% per test per year in 2020 and to 15% per test per year in each of the years 2021 through 2023. The CARES Act delayed the 15% cut scheduled to take effect on January 1, 2021, for one year.

We cannot predict whether or when these or other recently enacted healthcare initiatives will be implemented at the federal or state level or how any such legislation or regulation may affect us. For instance, the payment reductions imposed by the ACA and the changes to reimbursement amounts paid by Medicare for tests such as ours based on the procedure set forth in PAMA, could limit the prices we will be able to charge or the amount of available reimbursement for our tests, which would reduce our revenue. Additionally, these healthcare policy changes could be amended or additional healthcare initiatives could be implemented in the future. For instance, there is uncertainty regarding the continued effect of the ACA in its current form and in light of the policies of the certain members of Congress, who have threatened to repeal, replace or change the ACA. During his term in office, President Trump signed Executive Orders and other directives designed to delay the implementation of certain provisions of the ACA or otherwise circumvent some of the requirements for health insurance mandated by the ACA. Although Congress has not passed comprehensive repeal legislation, at least two bills affecting the implementation of certain taxes under the ACA have been signed into law. For example, the Tax Cuts and Jobs Act of 2017 repealed the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the “individual mandate.” In December 2019, the Fifth Circuit Court of Appeals upheld a district court’s finding that the individual mandate in the ACA is unconstitutional following removal of the penalty provision from the law. However, the Fifth Circuit reversed and remanded the case to the district court to determine if other reforms enacted as part of the ACA but not specifically related to the individual mandate or health insurance could be severed from the rest of the ACA so as not to have the law declared invalid in its entirety. On March 2, 2020, the Supreme Court granted the petitions for writs of certiorari to review this case and allocated one hour for oral arguments, which occurred on November 10, 2020. A decision from the Supreme Court is expected to be issued in spring 2021. It is unclear how this litigation and other efforts to repeal and replace the ACA will affect the implementation of that law and our business. However, the new Democrat-led presidential administration has been taking steps to strengthen the ACA and the 117th Congress is not expected to have the same interest in repealing the law, in part due to the healthcare economic impacts of the ongoing COVID-19 pandemic on many subsets of the U.S. population. Following his inauguration on January 20, 2021, President Biden also took immediate steps to order a regulatory freeze on all pending substantive executive actions taken by the previous administration, in order to permit incoming department and agency heads to review whether questions of fact, policy, and law may be implicated and to determine how to proceed.

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

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

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

Furthermore, the genetic testing industry as a whole is a growing industry and regulatory agencies such as HHS or the FDA may apply heightened scrutiny to new developments in the field, or the U.S. Congress may do so. Since 2017, Congress has been working on legislation to create an LDT and IVD regulatory framework that would be separate and distinct from the existing medical device regulatory framework. On March 5, 2020, U.S. Representatives Diana DeGette (D-CO) and Dr. Larry Bucshon (R-IN) formally introduced the VALID Act in the House and an identical version of the bill was introduced in the U.S. Senate by Senators Michael Bennet (D-CO) and Richard Burr (R-NC). As anticipated from a discussion draft of the legislation released for stakeholder comment in December 2018, the VALID Act would codify into law the term "in vitro clinical test" to create a new medical product category separate from medical devices, and bring all such products within the scope of the FDA's oversight. It is unclear whether the VALID Act would be passed by Congress in its current form or signed into law by President Trump.

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

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

Since March 2020, we have commercially launched several molecular tests for the detection of SARS-CoV-2, the virus that causes COVID-19, including NGS and RT-PCR-based tests as well as related antibody testing options. In May 2020, we were granted an EUA for our RT-PCR-based test for the detection of SARS-CoV-2 using upper and lower respiratory specimens (nasal, nasopharyngeal, and oropharyngeal swabs). In June 2020, we received an amendment to the EUA to add our at-home testing solution for COVID-19 through Picture Genetics.

Although there are certain regulatory requirements the FDA has waived for the duration of the EUA, we remain subject to specific conditions of the authorizations. As with other FDA-regulated tests, issues could emerge during the course of the marketing and use of our test under an EUA that could impact our ability to continue the sale and distribution of the authorized test or home collection kit. Factors that may be out of the Company's control, such as the availability of supplies and key personnel, may impact the Company's ability to maintain testing capacity and test result delivery, and its other responses to the COVID-19 pandemic, and may have an adverse impact on the Company's operations. Our EUA remains effective only until the HHS declaration is terminated or revoked, and FDA also may revoke an EUA if it determines the criteria for issuance are no longer met or other circumstances make such revocation appropriate to protect the public health or safety.

However, on August 19, 2020, HHS published a policy announcement that the FDA must go through the formal notice-and-comment rulemaking process before requiring pre-market review (including emergency use authorization) of LDTs rather than making such changes through guidance documents, compliance manuals, or other informal policy statements. Based on the HHS's policy announcement, which specifically states that LDT developers are not required to obtain an EUA or other marketing authorization from FDA prior to commercialization, we believe we may continue to market our COVID-19 tests even if our EUA is

terminated or revoked. The FDA may seek to establish a new regulation through notice-and-comment rulemaking requiring pre-market review and authorization of LDTs, and if that were to occur and if our EUA is either terminated or revoked, then in order to continue marketing our COVID-19 tests, we could be required to obtain the necessary regulatory clearances or approvals and be subject to the full and usual regulatory obligations. It is currently unclear whether the Biden Administration, which assumed control of the executive branch on January 20, 2021, would take the same position as the former administration or seek to revoke or revise the HHS policy announcement from August 2020.

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 partnerships in China subject us to risks and uncertainties relating to the laws and regulations of China and the changes in relations between the United States and China.

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

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

Our international operations are subject to various anti-bribery laws, including the FCPA and similar anti-bribery laws in the non-U.S. jurisdictions in which we operate. The FCPA prohibits companies and their intermediaries from offering, making, or

authorizing improper payments to non-U.S. or foreign officials for the purpose of obtaining or retaining business or securing any other improper advantage. These laws are complex and far-reaching in nature, and we may be required in the future to alter one or more of our practices to be in compliance with these laws or any changes to these laws or their interpretation.

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

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

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

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

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

Intellectual Property Risks

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

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

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

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

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

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

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

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

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

If we make efforts to seek patent protection for our technologies and tests, these efforts may be negatively impacted by the Prometheus, Myriad and Alice decisions, rulings in other cases or guidance or procedures issued by the USPTO. However, we cannot fully predict the impact of the Prometheus, Myriad and Alice decisions on the ability of genetic testing, biopharmaceutical or other companies to obtain or enforce patents relating to DNA, genes or genomic-related discoveries in the future, as the contours of when claims reciting laws of nature, natural phenomena or abstract ideas may meet patent eligibility requirements are not clear and may take

years to develop via interpretation at the USPTO and in the courts. There are many previously issued patents claiming nucleic acids and diagnostic methods based on natural correlations that issued before these recent Supreme Court decisions and, although many of these patents may be invalid under the standards set forth in these decisions, they are presumed valid and enforceable until they are successfully challenged, and third parties holding these patents could allege that we infringe or request that we obtain a license under such patents. Whether based on patents issued before or after these Supreme Court decisions, we could be forced to defend against claims of patent infringement or obtain license rights, if available, under these patents. In particular, although the Supreme Court has held in Myriad that isolated genomic DNA is not patent-eligible subject matter, third parties could allege that our activities infringe other classes of gene-related patent claims. There are numerous risks associated with any patent infringement claim that may be brought against us, as discussed above under "—Litigation or other proceedings or third-party claims of intellectual property infringement or misappropriation could require us to spend significant time and money and prevent us from selling our tests."

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

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

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

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

Third parties may assert that our employees or consultants have wrongfully used or disclosed confidential information or misappropriated trade secrets.

We employ individuals who were previously employed at universities and biometric solution, genetic testing, diagnostic or other healthcare companies, including our competitors or potential competitors. Further, we may become subject to ownership disputes in the future arising from, for example, conflicting obligations of consultants or others who are involved in developing our and other parties' technologies and intellectual property rights. Although we try to ensure that our employees and consultants do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or our employees or consultants have inadvertently or otherwise used or disclosed intellectual property rights, including trade secrets or other proprietary information, of a former employer or other third-party. Litigation may be necessary to defend against these claims, should they arise. If we fail in defending against any such claims, we could be subject to monetary damages and the loss of valuable intellectual property rights or personnel. Even if we are successful in defending against any such claims, litigation could result in substantial costs, distract management and other employees and damage our reputation.

Common Stock Risks

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

An active trading market for our common stock may not be sustained. Further, Mr. Hsieh, our founder, Chief Executive Officer and Chairman of our board of directors, beneficially owns 27% of our outstanding voting equity as of March 31, 2021. As a result, fewer shares are actively traded in the public market, which reduces the liquidity of our common stock. The lack of an active trading market could impair our stockholders' ability to sell their shares at the desired time or at a price considered reasonable. Further, an inactive trading market may impair our ability to raise capital by selling shares of our common stock in the future, and may impair our ability to enter into strategic relationships or acquire companies or technologies using shares of our common stock as consideration.

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

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

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

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

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

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

Our executive officers, directors, beneficial owners of 5% or more of our outstanding voting equity and their respective affiliates collectively beneficially owns approximately 37% of our outstanding voting equity as of March 31, 2021, and of this, Mr. Hsieh, our founder, Chief Executive Officer and Chairman of our board of directors, by himself beneficially owns 27% of our outstanding voting equity as of March 31, 2021. As a result, these stockholders have the ability to control matters submitted to our stockholders for approval, including elections of directors, amendments to our organizational documents or approval of any merger, sale of assets or other major corporate transaction. This concentration of ownership may prevent or discourage unsolicited acquisition proposals or offers to acquire our common stock that some of our stockholders feel are in their best interests, as the interests of these stockholders may not coincide with the interests of our other stockholders and they may act in a manner that advances their best interests and not necessarily those of all of our stockholders. Further, this concentration of ownership could adversely affect the prevailing market price for our common stock.

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

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

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

To raise capital or for other strategic purposes, we may sell common stock, convertible securities or other equity securities in one or more transactions at prices and in a manner we determine from time to time. In addition, in November 2020 we entered into an Equity Distribution Agreement, or the November 2020 Equity Distribution Agreement, with Piper, Oppenheimer & Co. Inc., and BTIG LLC, as sales agents, pursuant to which we may, from time to time, sell through Piper as our sales agent shares of our common stock with an aggregate purchase price of up to $175.0 million. During the year ended December 31, 2020, we sold an aggregate of 2.0 million shares of our common stock pursuant to the November 2020 Equity Distribution Agreement at a weighted-average net selling price of $48.70 per share. During the first quarter of 2021, we sold approximately 583,000 shares of our common stock pursuant to the November 2020 Equity Distribution Agreement at a weighted-average net selling price of $52.00 per share. We also may issue common stock or grant other equity awards for compensatory purposes under our equity incentive plan. If we issue common stock, convertible securities or other equity securities, including shares pursuant to the November 2020 Equity Distribution Agreement or equity awards under our equity incentive plan, our then-existing stockholders could be materially diluted by such issuances and, if we otherwise issue preferred stock, new investors could gain rights, preferences and privileges senior to the holders of our common stock, any of which could cause the price of our common stock to decline.

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

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

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

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

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

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

- authorize our board of directors to issue, without further action by our stockholders, up to 1.0 million shares of undesignated or "blank check" preferred stock;
- prohibit stockholder action by written consent, thus requiring all stockholder actions to be taken at a duly noticed and held meeting of our stockholders;
- specify that special meetings of our stockholders can be called only by our board of directors, the Chairman of our board of directors or our President, thereby eliminating the ability of our stockholders to call special meetings;
- permit only our board of directors to establish the number of directors and fill vacancies on the board of directors, except as may be required by law;
- permit our board of directors to amend our bylaws, subject to the power of our stockholders to repeal any such amendment;
- do not permit cumulative voting by our stockholders on the election of directors; and
- establish advance notice requirements for stockholders to propose nominees for election as directors or matters to be acted upon at annual meetings of stockholders.

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

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

Pursuant to our certificate of incorporation, our board of directors is authorized to issue up to 1.0 million shares of preferred stock without any action by our stockholders. Our board of directors also has the power, without stockholder approval, to set the terms of any series of preferred stock that may be issued, among others, including voting rights, dividend rights and preferences over our common stock with respect to dividends or in the event of a dissolution, liquidation or winding up. If we issue preferred stock in the future that has preferences over our common stock with respect to payment of dividends or upon a liquidation, dissolution or winding up, or if we issue preferred stock that is convertible into our common stock at greater than a one-to-one ratio, the voting and other rights of the holders of our common stock and the market price of our common stock could be adversely affected.

Our certificate of incorporation designates the Court of Chancery of the State of Delaware as the sole and exclusive forum for certain types of actions and proceedings that may be initiated by our stockholders, which could limit our stockholders' ability to obtain a judicial forum they consider favorable for disputes with us or our directors, officers or other employees.

Our certificate of incorporation and bylaws provide that, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware shall be the sole and exclusive forum for:

- any derivative action brought on our behalf;
- any direct action brought by a stockholder against us or any of our directors, officers or other employees, alleging a breach of a fiduciary duty;

- any action brought by a stockholder against us or any of our directors, officers or other employees, alleging a violation of the DGCL, our certificate of incorporation or our bylaws; and
- any action brought by a stockholder against us or any of our directors, officers or other employees, asserting a claim against us governed by the internal affairs doctrine.

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

Accordingly, the Exclusive Forum Provisions do not apply to actions brought to enforce a duty or liability created by the Exchange Act or the rules and regulations thereunder, or Exchange Act Claims. Further, the clause in our certificate of incorporation excepting "actions in which a federal court has assumed exclusive jurisdiction of a proceeding" from the Exclusive Forum Provisions is not intended to mean that a federal court must take any actual or affirmative action to assume jurisdiction over an Exchange Act Claim, as Section 27 of the Exchange Act creates exclusive federal jurisdiction over all Exchange Act Claims, regardless of whether a federal court takes any action. The Exclusive Forum Provisions also do not apply to federal and state suits brought to enforce any duty or liability created by the Securities Act or the rules and regulations thereunder, or Securities Act Claims. To the extent applicable or enforceable, the Exclusive Forum Provisions may limit a stockholder's ability to bring a claim in a judicial forum it finds favorable for disputes with us or our directors, officers or other employees, which may discourage these lawsuits. Alternatively, for Securities Act Claims, Exchange Act Claims or claims for which a court were to find these Exclusive Forum Provisions inapplicable or unenforceable for one or more of the specified types of actions or proceedings, we may incur additional costs associated with resolving these matters in other jurisdictions, which could adversely affect our business, financial condition or results of operations.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds.

Use of Proceeds from Registered Securities

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

To date, we have used $28.8 million of the net proceeds from the IPO, of which, $4.5 million was used for contributions to our joint venture, FF Gene Biotech, in partial satisfaction of our contribution obligations under the cooperation agreement for the joint venture and $24.3 million was used to fund the Company's operations. All other net proceeds from the IPO are invested in short-term, investment-grade, and interest-bearing securities, such as money market accounts, certificates of deposit, commercial paper and guaranteed obligations of the U.S. government. There has been no material change in the planned use of proceeds from the IPO from that described in the Prospectus.

On August 30, 2019, we entered into the 2019 Equity Distribution Agreement with Piper as sales agent, which was amended on August 4, 2020. During the year ended December 31, 2019, we sold an aggregate of 104,000 shares of our common stock pursuant to the 2019 Equity Distribution Agreement at a weighted-average net selling price of $9.37 per share, which resulted in $979,000 of net proceeds to the Company. During the year ended December 31, 2020, we sold an aggregate of 1.1 million shares of our common stock pursuant to the 2019 Equity Distribution Agreement at a weighted-average net selling price of $38.50 per share, which resulted in $42.7 million of net proceeds to the Company. Shares sold under the Equity Distribution Agreement were offered and sold pursuant to our shelf registration statement on Form S-3 (File No. 333-233227) filed with the SEC on August 12, 2019 and declared effective on August 23, 2019, and prospectus supplements and accompanying base prospectus filed with the SEC on August 30, 2019, May 6, 2020 and August 5, 2020. There has been no material change in the planned use of proceeds as described in the prospectus supplements and accompanying base prospectus.

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

On September 25, 2020, we entered into an Equity Distribution Agreement, or the September 2020 Equity Distribution Agreement, with Piper as sales agent, pursuant to which we sold 2.8 million shares of our common stock pursuant to the 2020 Equity Distribution Agreement at a weighted-average net selling price of $42.90 per share during the year ended December 31, 2020, which resulted in $122.1 million of net proceeds to the Company. Shares sold under the September 2020 Equity Distribution Agreement were offered and sold pursuant to our registration statement on Form S-3 (File No. 333-239964) filed with the SEC on July 21, 2020, as amended on August 5, 2020, and declared effective on August 12, 2020, and a prospectus supplement and accompanying base prospectus filed with the SEC on September 25, 2020. There has been no material change in the planned use of proceeds as described in the prospectus supplement and accompanying base prospectus.

On November 20, 2020, we entered into the November 2020 Equity Distribution Agreement, with Piper, Oppenheimer & Co. Inc., and BTIG LLC, as sales agents, pursuant to which we may offer and sell, from time to time through Piper, shares of our common stock having an aggregate offering price of up to $175.0 million. Piper may receive a commission of up to 3% of the gross proceeds received by the Company for sales pursuant to the November 2020 Equity Distribution Agreement. During the year ended December 31, 2020, we sold an aggregate of 2.0 million shares of our common stock pursuant to the November 2020 Equity Distribution Agreement at a weighted-average net selling price of $48.70 per share, which resulted in $99.1 million of net proceeds to the Company. During the first quarter of 2021, we sold approximately 583,000 shares of our common stock pursuant to the November 2020 Equity Distribution Agreement at a weighted-average net selling price of $52.00 per share, which resulted in $30.3 million of net proceeds to the Company. Shares sold under the November 2020 Equity Distribution Agreement were offered and sold pursuant to our registration statement on Form S-3 (File No. 333-239964) filed with the SEC on July 21, 2020, as amended on August 5, 2020, and declared effective on August 12, 2020, and a prospectus supplement and accompanying base prospectus filed with the SEC on November 20, 2020. There has been no material change in the planned use of proceeds as described in the prospectus supplement and accompanying base prospectus.

Item 6. Exhibits.

The information required by this Item 6 is set forth on the Exhibit Index that immediately precedes the signature page to this report and is incorporated herein by reference.

EXHIBIT INDEX

Exhibit No.	Exhibit Title	Filed with this Form 10-Q	Incorporated by Reference		
			Form	File No.	Date Filed
10.1^	Amended and Restated Non-Employee Director Compensation Policy	X			
31.1*	Certification of Principal Executive Officer pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.	X			
31.2*	Certification of Principal Financial Officer pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.	X			
32.1**	Certification of Principal Executive Officer and Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.	X			
101.INS*	XBRL Instance Document	X			
101.SCH*	XBRL Taxonomy Extension Schema Document	X			
101.CAL*	XBRL Taxonomy Extension Calculation Linkbase Document	X			
101.DEF*	XBRL Definition Linkbase Document	X			
101.LAB*	XBRL Taxonomy Extension Labels Linkbase Document	X			
101.PRE*	XBRL Taxonomy Extension Presentation Linkbase Document	X			

* Filed herewith.

** Furnished herewith.

^ Management Compensation Contract or Arrangement.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

FULGENT GENETICS, INC.

Date: May 7, 2021

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

Date: May 7, 2021

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

FULGENT GENETICS, INC.
AMENDED AND RESTATED
DIRECTOR COMPENSATION PROGRAM

This Amended and Restated Director Compensation Program (this "Program") sets forth the compensation payable to directors of Fulgent Genetics, Inc., a Delaware corporation (the "Company"), as consideration for their service as directors of the Company. This Program does not constitute a legally binding contract or arrangement and may be changed or rescinded at any time upon the approval of the Company's Board of Directors (the "Board").

A. Cash Compensation and Reimbursement.

1. Each director of the Company (each, a "Director") shall receive reimbursement in cash for his or her reasonable out-of-pocket costs and travel expenses incurred in connection with attendance at meetings of the Board and the committees of the Board (the "Committees") of which such Director is a member, which reimbursement shall be paid by the Company within thirty (30) days after the Company's receipt of a Director's request for reimbursement and reasonable evidence of such costs and expenses

2. Each Director that is not an employee of the Company or any of its affiliates (each, a "Non-Employee Director") shall receive the following annual cash retainer fees (collectively, the "Cash Retainer Fees") based on his or her service as a Director, Chair of a Committee and/or member of a Committee:

		Cash Retainer Fee Amount(1)
Annual Director Cash Retainer Fee:		
Each Non-Employee Director	$	35,000
Annual Committee Chair Cash Retainer Fees:(2)		
Audit Committee Chair	$	15,000
Compensation Committee Chair	$	10,000
Nominating Committee Chair	$	6,000
Annual Committee Member Cash Retainer Fees:(2)		
Audit Committee Member	$	7,500
Compensation Committee Member	$	5,000
Nominating Committee Member	$	3,000

(1) Directors, Committee Chairs and Committee members receive pro-rated amounts of all applicable Cash Retainer Fees for any partial year of service in any such position.

(2) Cash Retainer Fees for Committee Chair and Committee member positions are in addition to the Cash Retainer Fee for service as a Director.

All Cash Retainer Fees earned by a Non-Employee Director for service as a director during a fiscal year shall be paid by the Company bi-annually, within thirty (30) days after the end of the second and fourth fiscal quarters of such fiscal year.

B. Equity Compensation.

1. Subject to the approval of the administrator under the applicable Plan (as defined below), on the date of his or her election or appointment as a Director, each Non-Employee Director shall be granted the following equity award or awards (such award or awards, the "Initial Award"): (i) a non-qualified stock option award to acquire up to a number of shares of the Company's common stock equal to the applicable Available Amount (as defined below); (ii) a restricted stock unit award relating to a number of shares of the Company's common stock equal to the product obtained by multiplying (a) the applicable Available Amount, by (b) 0.4; or (iii) a non-qualified stock option award and a restricted stock unit award to acquire or relating to, as applicable, a number of shares of the Company's common stock such that the sum of (a) the number of shares of the Company's common stock subject to the non-qualified stock option award, and (b) the quotient obtained by dividing (1) the number of shares of the Company's common stock subject to the restricted stock unit award, by (2) 0.4, is equal to the applicable Available Amount.

2. Subject to the approval of the administrator under the applicable Plan, on the date of each Annual Meeting of the Stockholders of the Company, each Non-Employee Director that is serving as such immediately prior to and immediately after the applicable Annual Meeting of the Stockholders shall be granted the following equity award or awards (such award or awards, the "Annual Award"): (i) a non-qualified stock option award to acquire up to a number of shares of the Company's common stock equal to the applicable Available Amount; (ii) a restricted stock unit award relating to a number of shares of the Company's common stock equal to the product obtained by multiplying (a) the applicable Available Amount, by (b) 0.4; or (iii) a non-qualified stock option award and a restricted stock unit award to acquire or relating to, as applicable, a number of shares of the Company's common stock such that the sum of (a) the number of shares of the Company's common stock subject to the non-qualified stock option award, and (b) the quotient obtained by dividing (1) the number of shares of the Company's common stock subject to the restricted stock unit award, by (2) 0.4, is equal to the applicable Available Amount.

3. In addition to the Initial Award and the Annual Award, directors shall be eligible to receive such additional equity awards in such amounts and on such dates and subject to such terms as the Board and/or any appropriate Committees may approve.

4. For purposes of this Program, the "Available Amount" for all Initial Awards and Annual Awards shall be as follows:

	Available Amount
Initial Award	20,000
Annual Award	5,000

5. All Initial Awards and Annual Awards (referred to collectively as the "Awards") shall be granted under and subject to the Company's 2016 Omnibus Incentive Plan or such other comparable equity incentive plan of the Company that is then in effect (such applicable plan, the "Plan") and shall be subject to the following terms: (i) each Award that is a non-qualified stock option shall expire after 10 years; (ii) each Initial Award shall commence vesting on the date of the appointment or election of the applicable Non-Employee Director, and each Annual Award shall commence vesting on the date of the applicable Annual Meeting of Stockholders of the Company; (iii) each Award shall vest as follows: one-quarter of the total shares of the Company's common stock subject to the Award shall vest one year after the vesting commencement date of the Award and 1/16th of the total shares of the Company's common stock subject to the Award shall vest at the end of every three-month period thereafter, subject to the applicable Non-Employee Director's continued service for the Company on each such vesting date; and (iii) each Award shall be subject to all other terms set forth in the applicable form of award agreement under the Plan that has been approved by the Board.

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 Quarterly Report on Form 10-Q for the quarterly period ended March 31, 2021 of Fulgent Genetics, Inc.;

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

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

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

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiary, 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

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: May 7, 2021

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

7Exhibit 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 Quarterly Report on Form 10-Q for the quarterly period ended March 31, 2021 of Fulgent Genetics, Inc.;

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

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

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

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiary, 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

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: May 7, 2021

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 Quarterly Report on Form 10-Q for the quarterly period ended March 31, 2021 of Fulgent Genetics, Inc. (the "Company"), as filed with the Securities and Exchange Commission on the date hereof (the "Report"), each of the undersigned hereby certifies in his capacity as the specified officer of the Company, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that, to the best of his knowledge:

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

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

Date: May 7, 2021 By: /s/ Ming Hsieh

Ming Hsieh
President, **Chief Executive Officer**
(principal executive officer)

Date: May 7, 2021 By: /s/ Paul Kim

Paul Kim
Chief Financial Officer
(principal financial and accounting officer)

This certification accompanies the Quarterly Report on Form 10-Q 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 Form 10-Q), irrespective of any general incorporation language contained in such filing.