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 June 30, 2019

or

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

For the transition period from _____ to _____

Commission File Number: 001-37894

FULGENT GENETICS, INC.

(exact name of registrant as specified in its charter)

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

(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 August 1, 2019, there were 18,421,792 outstanding shares of the registrant's common stock.

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PART I—FINANCIAL INFORMATION

Item 1. Financial Statements.

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

	June 30, 2019	December 31, 2018
Assets		
Current assets		
Cash and cash equivalents	$ 9,165	$ 6,736
Marketable securities	17,820	24,298
Trade accounts receivable, net of allowance for doubtful accounts of $585 and $590, as of June 30, 2019 and December 31, 2018, respectively	5,543	5,948
Other current assets	2,267	2,561
Total current assets	34,795	39,543
Marketable securities, long-term	11,697	6,386
Equity method investments	1,084	1,512
Fixed assets, net	5,937	6,446
Operating lease right-of-use asset	2,756	—
Other long-term assets	167	17
Total assets	$ 56,436	$ 53,904
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable	$ 1,175	$ 1,313
Accrued liabilities	1,333	1,425
Operating lease liabilities, short-term	401	—
Total current liabilities	2,909	2,738
Operating lease liabilities, long-term	2,385	—
Other long-term liabilities	—	14
Total liabilities	5,294	2,752
Commitments and contingencies (Note 8)		
Stockholders' equity		
Common stock, $0.0001 par value per share, 50,000 shares authorized, 18,393 and 18,172 shares issued and outstanding at June 30, 2019 and December 31, 2018, respectively	2	2
Preferred stock, $0.0001 par value per share, 1,000 shares authorized, no shares issued or outstanding at June 30, 2019 and December 31, 2018	—	—
Additional paid-in capital	115,532	114,203
Accumulated other comprehensive income (loss)	203	(35)
Accumulated deficit	(64,595)	(63,018)
Total stockholders' equity	51,142	51,152
Total liabilities and stockholders' equity	$ 56,436	$ 53,904

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 June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
Revenue	$ 8,424	$ 5,400	$ 13,794	$ 10,053
Cost of revenue	3,620	2,544	6,588	5,316
Gross profit	4,804	2,856	7,206	4,737
Operating expenses:				
Research and development	1,574	1,212	2,998	2,670
Selling and marketing	1,304	1,279	2,576	2,409
General and administrative	1,631	1,366	3,160	2,853
Total operating expenses	4,509	3,857	8,734	7,932
Operating income (loss)	295	(1,001)	(1,528)	(3,195)
Interest and other income, net	192	98	399	193
Income (loss) before income taxes and equity loss in investee	487	(903)	(1,129)	(3,002)
Provision for (benefit from) income taxes	7	(100)	20	(534)
Income (loss) before equity loss in investee	480	(803)	(1,149)	(2,468)
Equity loss in investee	(149)	(246)	(428)	(491)
Net income (loss)	$ 331	$ (1,049)	$ (1,577)	$ (2,959)
Net income (loss) per common share:				
Basic	$ 0.02	$ (0.06)	$ (0.09)	$ (0.17)
Diluted	$ 0.02	$ (0.06)	$ (0.09)	$ (0.17)
Weighted-average common shares:				
Basic	18,343	17,919	18,286	17,891
Diluted	19,021	17,919	18,286	17,891

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 June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
Net income (loss)	$ 331	$ (1,049)	$ (1,577)	$ (2,959)
Other comprehensive income (loss):				
Foreign currency translation gain (loss)	(14)	(43)	1	(21)
Net unrealized gain (loss) on marketable securities, net of tax	122	48	237	(17)
Comprehensive income (loss)	$ 439	$ (1,044)	$ (1,339)	$ (2,997)

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)	Accumulated Deficit	Total Equity
Balance at March 31, 2019	**18,286**	**$ 2**	**$ 114,790**	**$ 95**	**$ (64,926)**	**$ 49,961**
Equity-based compensation	—	—	737	—	—	737
Exercise of common stock options	15	—	5	—	—	5
Restricted stock awards	92	—	—	—	—	—
Other comprehensive gain, net	—	—	—	108	—	108
Net income	—	—	—	—	331	331
Balance at June 30, 2019	**18,393**	**$ 2**	**$ 115,532**	**$ 203**	**$ (64,595)**	**$ 51,142**

	Stockholders' Equity					
	Shares	Amount	Additional Paid-In Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Equity
Balance at March 31, 2018	**17,876**	**2**	**112,431**	**(87)**	**(59,321)**	**53,025**
Equity-based compensation	—	—	573	—	—	573
Exercise of common stock options	18	—	7	—	—	7
Restricted stock awards	69	—	—	—	—	—
Other comprehensive gain, net	—	—	—	5	—	5
Net loss	—	—	—	—	(1,049)	(1,049)
Balance at June 30, 2018	**17,963**	**2**	**113,011**	**$ (82)**	**$ (60,370)**	**$ 52,561**

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)	Accumulated Deficit	Total Equity
Balance at December 31, 2018	**18,172**	**$ 2**	**$ 114,203**	**$ (35)**	**$ (63,018)**	**$ 51,152**
Equity-based compensation	—	—	1,320	—	—	1,320
Exercise of common stock options	24	—	9	—	—	9
Restricted stock awards	197	—	—	—	—	—
Other comprehensive loss, net	—	—	—	238	—	238
Net loss	—	—	—	—	(1,577)	(1,577)
Balance at June 30, 2019	**18,393**	**$ 2**	**$ 115,532**	**$ 203**	**$ (64,595)**	**$ 51,142**

	Stockholders' Equity					
	Shares	Amount	Additional Paid-In Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Equity
Balance at December 31, 2017	**17,847**	**$ 2**	**$ 111,884**	**$ (44)**	**$ (57,664)**	**$ 54,178**
Equity-based compensation	—	—	1,118	—	—	1,118
Exercise of common stock options	23	—	9	—	—	9
Restricted stock awards	93	—	—	—	—	—
Cumulative effect of accounting change	—	—	—	—	327	327
Cumulative tax effect of accounting change	—	—	—	—	(74)	(74)
Other comprehensive income, net	—	—	—	(38)	—	(38)
Net loss	—	—	—	—	(2,959)	(2,959)
Balance at June 30, 2018	**17,963**	**$ 2**	**$ 113,011**	**$ (82)**	**$ (60,370)**	**$ 52,561**

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)

	Six Months Ended June 30,	
	2019	**2018**
Cash flow from operating activities:		
Net loss	$ (1,577)	$ (2,959)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities:		
Equity-based compensation	1,320	1,118
Depreciation	1,046	1,078
Noncash lease expense	201	—
Loss on disposal of fixed asset	11	55
Amortization of premium of marketable securities	44	160
Provision for bad debt	—	230
Deferred taxes	—	(535)
Equity loss in investee	428	491
Other	38	38
Changes in operating assets and liabilities:		
Accounts receivable	368	(990)
Other current and long-term assets	183	22
Accounts payable	(124)	(1,344)
Accrued liabilities	(20)	1,288
Operating lease liabilities	(188)	—
Net cash provided by (used in) operations	1,730	(1,348)
Cash flow from investing activities:		
Purchases of fixed assets	(633)	(1,152)
Purchase of marketable securities	(10,178)	(11,470)
Maturities of marketable securities	11,500	11,656
Purchase of equipment contributed to Equity Method Investee	—	(510)
Net cash (used in) provided by investing activities	689	(1,476)
Cash flow from financing activities:		
Proceeds from exercise of stock options	9	9
Net cash provided by financing activities	9	9
Effect of exchange rate changes on cash and cash equivalents	1	(21)
Net decrease in cash	2,429	(2,836)
Cash balance at beginning of period	6,736	6,490
Cash balance at end of period	$ 9,165	$ 3,654
Supplemental disclosures of cash flow information:		
Income taxes paid	$ 20	$ 1
Supplemental disclosures of non-cash investing and financing activities:		
Fixed assets included in accounts payable	$ 5	$ 1,011

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 ("U.S. GAAP"). These financial statements include the assets, liabilities, revenues and expenses of all wholly-owned subsidiaries and entities in which the Company has a controlling financial interest or is deemed to be the primary beneficiary. In determining whether the Company is the primary beneficiary of an entity, the Company applies a qualitative approach that determines whether it has both (1) the power to direct the economically significant activities of the entity and (2) the obligation to absorb losses of, or the right to receive benefits from, the entity that could potentially be significant to that entity. The Company uses the equity method to account for its investments in entities that it does not control, but in which it has the ability to exercise significant influence over operating and financial policies. All significant intercompany accounts and transactions are eliminated from the accompanying 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 growing technology company offering comprehensive genetic testing and providing physicians with clinically actionable diagnostic information they can use to improve the quality of patient care. The Company has developed a proprietary technology platform that allows us 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 our 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. 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 genetic 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, 2018, which are included in the Company's annual report on Form 10-K filed with the Securities and Exchange Commission on March 22, 2019 (the "2018 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, 2018 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 2018 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 2018 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 and disclosure of contingent 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. Actual results could differ from these estimates.

On an on-going basis, management evaluates its estimates, primarily those related to: (i) revenue recognition criteria, (ii) accounts receivable and allowances for doubtful accounts, (iii) the useful lives of fixed assets, (iv) estimates of tax liabilities and (v) 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 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 six months of 2019 and 2018. The Company and its subsidiaries that use the U.S. dollar as their functional currency remeasure monetary assets and liabilities at exchange rates in effect at the end of each period, and inventories, property and nonmonetary assets and liabilities at historical rates. Losses from these remeasurements were not significant in the first six months of 2019 and 2018.

Leases

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

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

Concentration of Customers

In certain periods, a small number of customers has accounted for a significant portion of the Company's revenue. In the three months ended June 30, 2019, after aggregating customers that are under common control or are affiliates, two customers contributed 32% and 15%, respectively, of our revenue for the period. In the six months ended June 30, 2019, after aggregating customers that are under common control or are affiliates, two customers contributed 27% and 10%, respectively, of our revenue for the period. In the three and six months ended June 30, 2018, after aggregating customers that are under common control or are affiliates, one customer contributed 13% of our revenue.

Revenue from Contracts with Customers

Disaggregation of Revenue

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

	Three months ended June 30,	
	2019	2018
	(in thousands)	
Genetic Testing Services by payor		
Institutional	$ 8,160	$ 4,782
Patient	143	156
Insurance	121	462
Total Revenue	$ 8,424	$ 5,400

	Six months ended June 30,	
	2019	2018
	(in thousands)	
Genetic Testing Services by payor		
Institutional	$ 13,279	$ 9,247
Patient	245	272
Insurance	270	534
Total Revenue	$ 13,794	$ 10,053

Contract Balances

Receivables from contracts with customers - As of June 30, 2019 and December 31, 2018, receivables from contracts with customers were approximately $5.5 million and $5.9 million, respectively, and are included within Trade accounts receivable on the Condensed Consolidated Balance Sheets.

Contracts assets and liabilities - As of June 30, 2019 and December 31, 2018, contract assets and liabilities from contracts with customers were not material.

Transaction Price Allocated to Future Performance Obligations

The Company does not have material future obligations associated with Genetic Testing Services that extend beyond one year.

Recent Accounting Pronouncements Adopted

ASU No. 2016-02

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

See Note 9, Leases, for further information.

ASU No. 2017-08

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

ASU No. 2018-02

In February 2018, the FASB issued ASU 2018-02 Income Statement - Reporting Comprehensive Income (ASC 220): Reclassification of Certain Tax Effects from Accumulated Other Comprehensive Income (AOCI), which gives entities the option to reclassify to retained earnings the tax effects resulting from the Tax Act related to items in Additional Other Comprehensive Income (AOCI) that the FASB refers to as having been “stranded” in AOCI. The guidance is effective for annual and interim periods beginning after December 15, 2018, and is applicable to the Company in fiscal year 2019; however, early adoption is permitted. The Company adopted ASU 2018-02 as of January 1, 2019 and elected not to reclassify the income tax effect of the Tax Act from AOCI to retained earnings. The adoption of ASU 2018-02 resulted in no impact to the Company's financial statements.

Recent Accounting Pronouncements

The Company evaluates all Accounting Standards Updates (ASUs) issued by the Financial Accounting Standards Board (FASB) for consideration of their applicability. ASUs not included in the Company’s disclosures were assessed and determined to be either not applicable or are not expected to have a material impact on its Condensed Consolidated Financial Statements.

ASU No. 2016-13

In June 2016, the FASB issued *ASU No. 2016-13, Financial Instruments-Credit Losses: Measurement of Credit Losses on Financial Instruments*. ASU No. 2016-13 replaces the incurred loss impairment methodology in current U.S. GAAP with a methodology that reflects expected credit losses. The update is intended to provide financial statement users with more decision-useful information about the expected credit losses on financial instruments and other commitments to extend credit held by a reporting entity at each reporting date. Entities will apply the standard's provisions as a cumulative-effect adjustment to retained earnings as of the beginning of the first reporting period in which the guidance is effective. In May 2019, the FASB issued *ASU 2019-05, Financial Instruments - Credit Losses (Topic 326): Targeted Transition Relief*. This update adds optional transition relief for entities to elect the fair value option for certain financial assets previously measured at amortized cost basis to increase comparability of similar financial assets. The standard will be effective for annual reporting periods beginning after December 15, 2019, including interim periods within those reporting periods. Early adoption is permitted. The Company has not yet evaluated the effect this ASU will have on its consolidated financial statements and related disclosures.

ASU No. 2018-15

In August 2018, the FASB issued *ASU No. 2018-15, Intangibles-Goodwill and Other-Internal-Use Software (Subtopic 350-40): Customer's Accounting for Implementation Costs Incurred in a Cloud Computing Arrangement That Is a Service Contract*, which provides new guidance on the accounting for implementation, set-up, and other upfront costs incurred in a hosted cloud computing arrangement. Under the new guidance, entities will apply the same criteria for capitalizing implementation costs as they would for an internal-use software license arrangement. This guidance is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2019, with early adoption permitted. This ASU can be adopted prospectively to eligible costs incurred on or after the date of adoption or retrospectively. The Company does not expect the adoption of the new guidance under the standard to materially affect its financial position or results of operations.

Note 3. Marketable Securities

The Company's marketable securities consisted of the following:

	June 30, 2019			
	Amortized Cost Basis	Unrealized Gains	Unrealized Losses	Aggregate Fair Value
	(in thousands)			
Marketable securities:				
Short-term				
Money market accounts	$ 3,722	—	—	$ 3,722
United States Treasury	999	—	—	999
U.S. government agency securities	797	1	—	798
Corporate debt securities	16,014	22	(13)	16,023
Less: Cash equivalents	(3,722)	—	—	(3,722)
Total short-term marketable securities	17,810	23	(13)	17,820
Corporate debt securities	11,561	136	—	11,697
Total long-term marketable securities	11,561	136	—	11,697
Total marketable securities	$ 29,371	$ 159	$ (13)	$ 29,517

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

Management determined that the gross unrealized losses of $13,000 on the Company's marketable securities as of June 30, 2019 were temporary in nature. Gross unrealized losses on the Company's marketable securities were $104,000 as of December 31, 2018. The Company currently does not intend to sell these securities prior to maturity and does not consider these investments to be other-than-temporarily impaired as of June 30, 2019.

Note 4. Fair Value Measurements

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

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

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

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

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

	June 30, 2019			
	Total	Level 1	Level 2	Level 3
	(in thousands)			
Marketable securities and cash equivalents:				
Corporate debt securities	$ 27,720	$ —	$ 27,720	$ —
United States Treasury	999	—	999	—
U.S. government agency securities	798	—	798	—
Money market accounts	3,722	3,722	—	—
Total marketable securities and cash equivalents	$ 33,239	$ 3,722	$ 29,517	$ —

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

The Company's Level 1 assets include money market instruments and are valued based upon observable market prices. Level 2 assets consist of United States Treasury, U.S. government agency securities, and corporate debt securities. Level 2 securities are valued based upon observable inputs that include reported trades, broker/dealer quotes, bids and offers. As of June 30, 2019, 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 six months of 2019.

Gross unrealized gains or losses for cash equivalents and marketable securities as of June 30, 2019 were not material. As of June 30, 2019, unrealized losses for securities in an unrealized loss position for more than 12 months were $13,000. During the three months ended June 30, 2019, the Company did not recognize other-than-temporary impairment losses related to its marketable securities.

Note 5. Fixed Assets

Major classes of fixed assets consisted of the following:

	Useful Lives	June 30, 2019	December 31, 2018
		(in thousands)	
Computer hardware	3 Years	$ 1,687	$ 1,579
Computer software	3 Years	530	495
Medical lab equipment	5 Years	8,136	8,136
Furniture and fixtures	5 Years	234	233
Leasehold improvements	Shorter of lease term or estimated useful life	802	802
Assets not yet placed in service		1,485	1,087
Total		12,874	12,332
Less: Accumulated depreciation		(6,937)	(5,886)
Property and equipment, net		$ 5,937	$ 6,446

Depreciation expense on fixed assets totaled $511,000 and $562,000 for the three months and $1.0 million and $1.1 million for the six months ended June 30, 2019 and 2018, respectively.

Note 6. Significant Balance Sheet Accounts

Other current assets consisted of the following:

	June 30, 2019	December 31, 2018
	(in thousands)	
Reagents	$ 405	$ 314
Prepaid expenses	1,024	706
Prepaid income taxes	609	1,251
Marketable securities interest receivable	196	220
Other receivable	33	70
Total	$ 2,267	$ 2,561

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

Note 7. Reporting Segment and Geographic Information

The Company views its operations and manages its business in one reporting segment. All long-lived assets were located in the United States during the first half of 2019 and 2018. Revenue by region was as follows:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
	(in thousands)		(in thousands)	
Revenue:				
United States	$ 6,686	$ 3,299	$ 10,300	$ 5,826
Foreign:				
Canada	516	1,070	1,054	2,040
Other Countries	1,222	1,031	2,440	2,187
Total	$ 8,424	$ 5,400	$ 13,794	$ 10,053

Note 8. Commitments and Contingencies

Operating Leases

See Note 9, Leases, for further information.

FF Gene Biotech

See Note 14 for a description of the Company's commitments related to its joint venture, FF Gene Biotech (as defined in Note 14).

Purchase Obligations

As of June 30, 2019, the Company had non-cancelable purchase obligations of $5.8 million for reagents, of which, $2.1 million is payable within twelve months, and $3.7 million is payable within the next twenty-four months.

Contingencies

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

Note 9. Leases

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

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

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

Rent expense was approximately $133,000 and $119,000 for the three months ended and $266,000 and $228,000 for the six months ended June 30, 2019 and 2018, respectively.

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

Our incremental borrowing rate was used to determine the present value of lease payments since our leases do not provide an implicit rate. The Company determined its incremental borrowing rate based on inquiries with our bank. The Company's lease agreements do not contain any residual value guarantees, material restrictive covenants, bargain purchase options or asset retirement obligations. Lease expense for our operating leases is recognized on a straight-line basis over the lease term. Our leases do not contain variable lease payments. The Company does not have any short-term leases and thus has excluded short-term costs from the table below. The Company did not enter into any new leases during the six months ended June 30, 2019.

The following was operating lease expense:

	Three months ended June 30, 2019	Six months ended June 30, 2019
Operating lease cost	$ 146	$ 292

Supplemental cash flow information related to leases was the following:

	Three months ended June 30, 2019	Six months ended June 30, 2019
Cash paid for amounts included in the measurement of lease liabilities	$ 116	$ 278
Operating cash flows from operating leases	$ 101	$ 201

Supplemental balance sheet information related to leases was the following:

	June 30, 2019
Weighted average remaining lease term - operating leases	6.1 years
Weighted average discount rate - operating leases	6.25%

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

	Operating Leases (in thousands)
Year Ending December 31,	
2019 (remaining 6 months)	$ 281
2020	559
2021	550
2022	558
2023	567
2024	330
Thereafter	532
Total lease payments	3,377
Less imputed interest	(591)
Total	$ 2,786

Future minimum payments under non-cancelable operating leases as of December 31, 2018 are as follows:

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

Note 10. Equity-Based Compensation

The Company has included equity-based compensation expense as part of cost of revenue and operating expenses in the accompanying condensed consolidated statements of operations as follows:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
	(in thousands)		(in thousands)	
Cost of revenue	$ 167	$ 151	$ 309	$ 275
Research and development	233	171	411	303
Selling and marketing	186	113	311	221
General and administrative	151	138	289	319
Total	$ 737	$ 573	$ 1,320	$ 1,118

Note 11. Income Taxes

Provision for income taxes consists of U.S. federal and state income taxes. A deferred tax liability is recognized for all taxable temporary differences, and a deferred tax asset is recognized for all deductible temporary differences, operating losses and tax credit carryforwards. A valuation allowance is provided when it is more likely than not that some portion or all of a deferred tax asset will not be realized.

In order to determine the Company's quarterly provision for income taxes, the Company used an estimated annual effective tax rate for the full fiscal year ending December 31, 2019, which is based on expected annual income and statutory tax rates in the various jurisdictions in which the Company operates, adjusted for discrete items recognized during the period. Certain significant or unusual items are separately recognized in the quarter during which they occur and can cause the effective tax rate to vary from quarter to quarter.

The Company's effective tax rate was 1% and -2% for the three and six months ended June 30, 2019, respectively, compared with 11% and 18% for the three and six months ended June 30, 2018, respectively. The change in effective tax rate for the three months and six months ended June 30, 2019, was primarily attributable to the full valuation allowance.

Note 12. Loss per Share

The following table presents the calculation of basic and diluted loss per share for the three and six months ended June 30, 2019 and 2018:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
	(in thousands, except per share data)			
Net income (loss)	$ 331	$ (1,049)	$ (1,577)	$ (2,959)
Weighted-average common shares—outstanding, basic	18,343	17,919	18,286	17,891
Weighted-average common shares—outstanding, diluted	19,021	17,919	18,286	17,891
Net income (loss) per common share, basic	$ 0.02	$ (0.06)	$ (0.09)	$ (0.17)
Net income (loss) per common share, diluted	$ 0.02	$ (0.06)	$ (0.09)	$ (0.17)

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
	(in thousands)			
Options	19	436	387	433
RSUs	358	1,055	1,093	961

The anti-dilutive shares described above were calculated using the treasury stock method. During the three months ended June 30, 2018 and the first six months ended June 30, 2019 and 2018, the Company had outstanding stock options and RSUs that were excluded from the weighted-average share calculation due to the Company's net loss position.

Note 13. Related Party

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

From time to time, the Company performs research testing services, on an arms-length basis, for the Foundation. The Company recognized $2,000 in revenue during the three and six months ended June 30, 2019 and zero for the three and six months ended June 30, 2018, as consideration for such services. Additionally, the Company subleased certain of its headquarters facilities to the Foundation. The Company recognized $8,000 and zero for the three months and $16,000 and $8,000 for the six months ended June 30, 2019 and 2018, respectively, as consideration for such sublease. As of June 30, 2019, and December 31, 2018, $2,000 and zero, respectively, was owed to the Company by the Foundation in connection with these relationships.

From time to time, the Company performs genetic sequencing services, on an arms-length basis, for the University. The Company recognized $9,000 and $7,000 for the three months ended and $22,000 and $16,000 for the six months ended June 30, 2019 and 2018, respectively, as consideration for such services. As of June 30, 2019, and December 31, 2018, $18,000 and $51,000, respectively, was owed to the Company by the University in connection with this relationship.

As more fully described in Note 14, in April 2017, the Company, through an affiliated company formed for the purpose of the relationship, entered into a cooperation agreement (the "JV Agreement") with Xilong Scientific Co., Ltd. ("Xilong Scientific") and Fuzhou Jinqiang Investment Partnership (LP) ("FJIP") to form a joint venture under the laws of the People's Republic of China ("PRC") called Fujian Fujun Gene Biotech Co., Ltd. ("FF Gene Biotech"). Xilong Scientific is an affiliate of Xi Long USA, Inc., a large stockholder of the Company that, as of June 30, 2019, owned 11% of the outstanding shares of the Company's common stock, and FJIP is owned by key management of FF Gene Biotech, including Dr. Han Lin Gao, the Chief Scientific Officer and a large stockholder of the Company and the owner of approximately 25% of FJIP.

Fulgent Pharma utilizes space in the facility at which our laboratory and corporate headquarters are located. Since the completion of the Pharma Split-Off, Fulgent Pharma reimburses us for the portion of the rent we pay that is attributable to the space it uses, which amounts are not significant. As of June 30, 2019, and December 31, 2018, $29,000 and $22,000, respectively, was due from Fulgent Pharma as a result of this arrangement, which is recorded in Other receivable in Other current assets in the accompanying condensed consolidated balance sheets.

Note 14. Equity Method Investments

In April 2017, the Company, through an affiliated company formed for the purpose of the relationship, entered into the JV Agreement with Xilong Scientific and FJIP to form FF Gene Biotech, a joint venture formed under the laws of the PRC to offer genetic testing services to customers in the PRC. Pursuant to the terms of the JV Agreement, the Company has agreed to contribute to FF Gene Biotech genetic sequencing and other equipment with a total cost of 60,000,000 renminbi ("RMB") over a five-year period for a 30% ownership interest in FF Gene Biotech, previously three-year per original agreement. Xilong Scientific has agreed to contribute to FF Gene Biotech 102,000,000 RMB over a five-year period for a 51% ownership interest in the FF Gene Biotech, previously three-year per original agreement. FJIP has agreed to contribute to FF Gene Biotech 19,000,000 RMB over a ten-year period for a 19% ownership interest in FF Gene Biotech, previously five-year per original agreement. 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 June 30, 2019, 40.3 million RMB (or approximately $5.9 million U.S. dollars) remains to be contributed to the investee under the terms of the JV agreement. To date, the Company has purchased and contributed equipment with an aggregate fair value of $3.0 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 its proportionate share of the losses of FF Gene Biotech in the three months ended June 30, 2019 in the accompanying condensed consolidated statements of operations, and recorded its contribution to date, net of its proportionate share in the accumulated losses of FF Gene Biotech, in the accompanying condensed consolidated balance sheet as of June 30, 2019.

The Company entered into a license agreement with FF Gene Biotech, pursuant to which it granted FF Gene Biotech a license to use certain of the Company’s clinical molecular diagnostic gene detection technology and related software and proprietary reference library of genetic information, along with any improvements on this technology that they may develop during the term of the license agreement. Under the license agreement, FF Gene Biotech will pay to the Company, on a quarterly basis, certain royalties based on the revenues of FF Gene Biotech. The license agreement expired on December 31, 2018. The Company earned $17,000 and $35,000 for royalties under the license agreement for the three and six months ended June 30, 2018, respectively.

In November 2017, FF Gene Biotech invested and formed a majority-owned subsidiary that focuses on sales and marketing for FF Gene Biotech.

Equity method investments as of June 30, 2019 and December 31, 2018 consisted of the following:

	June 30, 2019		December 31, 2018	
	Carrying Value	Ownership Percentage	Carrying Value	Ownership Percentage
	(in thousands)			
FF Gene Biotech	$ 1,084	30%	$ 1,512	30%
Total equity method investments	$ 1,084	30%	$ 1,512	30%

Summary Financial Information

Summary financial information for FF Gene Biotech is as follows:

	June 30, 2019	December 31, 2018
Consolidated Balance Sheets Data:	(in thousands)	
Current Assets	$ 2,367	$ 1,916
Non-Current Assets	3,892	4,068
Current Liabilities	4,318	2,415
Non-Current Liabilities	—	—
Minority Interest	207	—
Shareholders' Equity	1,734	3,569

	Six Months Ended June 30	
	2019	2018
Consolidated Statements of Operations Data:	(in thousands)	
Net Sales	$ 1,131	$ 349
Gross Profit	579	(1)
Net Loss	(1,423)	(1,637)
Share of loss from investments accounted for using the equity method (1)	(428)	(491)

(1) The Company's share of loss is based on pro-rated net loss beginning April 25, 2017, the date on which the Company entered into the JV Agreement.

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, or SEC, 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, 2018 filed with the SEC on March 22, 2019, or the 2018 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, and Section 21E of the Securities Exchange Act of 1934, as amended. Forward-looking statements are statements other than historical facts and relate to future events or circumstances or our future performance, and they are based on our current assumptions, expectations and beliefs concerning future developments and their potential effect on our business. The forward-looking statements in this discussion and analysis include statements about, among other things, our future financial and operating performance, our future cash flows and liquidity and our growth strategies, as well as anticipated trends in our business and industry. These forward-looking statements are subject to a number of risks and uncertainties, including, among others, those described under "Item 1A. Risk Factors" 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 growing technology company with an initial focus on offering comprehensive genetic testing to provide physicians with clinically actionable diagnostic information they can use to improve the quality of patient care. We have developed a proprietary technology platform that allows us to offer a broad and flexible test menu and continually expand and improve our proprietary genetic reference library, while maintaining accessible pricing, high accuracy and competitive turnaround times. We believe our test menu offers more genes for testing than our competitors in today's market, which enables us to provide expansive options for test customization and clinically actionable results.

Our existing customer base consists primarily of hospitals and medical institutions, which are typically frequent and high-volume users of genetic tests and which often pay us directly for our tests. We believe our relationships with these customers provide a meaningful opportunity for further growth, as we seek to deepen these relationships and drive increased ordering. We also believe our offering could be attractive to other types of customers, including individual physicians and other practitioners, regional medical networks, research institutions and other organizations, and we are building relationships in these new customer markets. Although we have devoted fewer overall resources to sales and marketing efforts than many of our competitors, we made material investments in our sales and marketing team and strategies, the global reach of our business and other aspects of our operations.

We offer tests at competitive prices averaging approximately $577 per billable test delivered in the first six months of 2019, and at a lower cost to us than many of our competitors, averaging approximately $276 per billable test delivered in the first six months of 2019. Our volume has grown rapidly since our commercial launch, with 16,369 and 23,899 billable tests delivered in the three and six months ended June 30, 2019, respectively, compared to 5,700 and 10,321 billable tests delivered in the three and six months ended June 30, 2018, respectively. An aggregate of over 83,100 billable tests were delivered to approximately 1,010 customers since launching our first commercial genetic tests in 2013 and through June 30, 2019. We have experienced compound quarterly growth of 22% in the number of billable tests delivered in our last eight completed fiscal quarters. We recorded revenue and net income of $8.4 million and $331,000, respectively, in the three months ended June 30, 2019, compared to revenue and net loss of $5.4 million and $1.0 million, respectively, in the three months ended June 30, 2018. We recorded revenue and net loss of $13.8 million and $1.6 million, respectively, in the six months ended June 30, 2019, compared to revenue and net loss of $10.1 million and $3.0 million, respectively, in the six months ended June 30, 2018. We achieved profitability in the first half of 2017 and the second quarter of 2019, but we have recorded losses in all other periods since our inception.

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 2018 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 2018 Annual Report.

	Three Months Ended June 30,		$	%	Six Months Ended June 30,		$	%
	2019	2018	Change	Change	2019	2018	Change	Change
Statement of Operations Data:	(dollars in thousands, except Other Operating Data)				(dollars in thousands, except Other Operating Data)			
Revenue	$ 8,424	$ 5,400	$ 3,024	56 %	$ 13,794	$ 10,053	$ 3,741	37 %
Cost of revenue	3,620	2,544	1,076	42 %	6,588	5,316	1,272	24 %
Gross profit	4,804	2,856	1,948	68 %	7,206	4,737	2,469	52 %
Operating expenses:								
Research and development	1,574	1,212	362	30 %	2,998	2,670	328	12 %
Selling and marketing	1,304	1,279	25	2 %	2,576	2,409	167	7 %
General and administrative	1,631	1,366	265	19 %	3,160	2,853	307	11 %
Total operating expenses	4,509	3,857	652	17 %	8,734	7,932	802	10 %
Operating income (loss)	295	(1,001)	1,296	(129) %	(1,528)	(3,195)	1,667	(52) %
Interest and other income, net	192	98	94	96 %	399	193	206	107 %
Income (loss) before income taxes and equity loss in investee	487	(903)	1,390	(154) %	(1,129)	(3,002)	1,873	(62) %
Provision for (benefit from) income taxes	7	(100)	107	(107) %	20	(534)	554	(104) %
Income (loss) before equity loss in investee	480	(803)	1,283	(160) %	(1,149)	(2,468)	1,319	(53) %
Equity loss in investee	(149)	(246)	97	(39) %	(428)	(491)	63	(13) %
Net income (loss)	$ 331	$ (1,049)	$ 1,380	(132) %	$ (1,577)	$ (2,959)	$ 1,382	(47) %
Other Operating Data:								
Billable tests delivered(1)	16,369	5,700		187 %	23,899	10,321		132 %
Average price per billable test delivered(2)	$ 515	$ 947		(46) %	$ 577	$ 974		(41) %
Cost per billable test delivered(3)	$ 221	$ 446		(50) %	$ 276	$ 515		(46) %

(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 $3.0 million, or 56%, from $5.4 million in the three months ended June 30, 2018 to $8.4 million in the three months ended June 30, 2019, and increased $3.7 million, or 37%, from $10.1 million in the six months ended June 30, 2018 to $13.8 million in the six months ended June 30, 2019. The increase in revenue between periods was primarily due to increase in the number of billable tests delivered, offset by a substantial decline in the average selling price per test.

The average price of the billable tests we delivered decreased from $947 in the three months ended June 30, 2018 to $515 in the three months ended June 30, 2019, and decreased from $974 in the six months ended June 30, 2018 to $577 in the six months ended June 30, 2019. This decrease was due to (i) lower price-points for the mix of tests we delivered in the six months ended June 30, 2019, (ii) the mix of customers ordering tests in these periods, which may order tests at different rates depending on the arrangements we have negotiated with them, and for which we may recognize different amounts of revenue at different times in the delivery and payment process based on the impact of our revenue recognition policy on, and differing collectability rates among, various customer groups, and (iii) our reduction of prices for certain of our tests due to general price degradation for genetic tests and other competitive factors during the six months ended June 30, 2019.

Revenue from non-U.S. sources decreased $363,000, or 17%, from $2.1 million in the three months ended June 30, 2018 to $1.7 million in the three months ended June 30, 2019, and decreased $733,000, or 17%, from $4.2 million in the six months ended June 30, 2018 to $3.5 million in the six months ended June 30, 2019. The decrease in revenue from non-U.S. sources between periods was primarily due to decreased sales to customers in Canada, which decreased by $554,000 and $986,000 in the three and six months ended June 30, 2019, respectively, partially offset by increased sales to customers in other countries, which increased by $191,000 and $253,000 in the three and six months ended June 30, 2019, respectively.

The number of billable tests we delivered increased 10,669, from 5,700 in the three months ended June 30, 2018 to 16,369 in the three months ended June 30, 2019, and increased 13,578, from 10,321 in the six months ended June 30, 2018 to 23,899 in the six months ended June 30, 2019. This increase was primarily attributable to the expansion of our test menu, an increase in sales to certain of our existing customers and an increase in sequencing as a service test orders, combined with growth in the genetic testing market and increased physician awareness and acceptance of genetic tests generally.

In the three months ended June 30, 2019, when customers who, to our knowledge, are under common control or otherwise affiliated with each other are aggregated, two groups of affiliated customers contributed 32% and 15% of our total revenue. In the six months ended June 30, 2019, when customers who, to our knowledge, are under common control or otherwise affiliated with each other are aggregated, two groups of affiliated customers contributed 27% and 10% of our total revenue.

Cost of Revenue

Cost of revenue increased $1.1 million, or 42%, from $2.5 million in the three months ended June 30, 2018 to $3.6 million in the three months ended June 30, 2019. The increase was primarily due to an increase of $823,000 in reagent and supply expenses related to increased billable tests delivered and $304,000 in personnel costs related to increased headcount.

Cost of revenue increased $1.3 million, or 24%, from $5.3 million in the six months ended June 30, 2018 to $6.6 million in the six months ended June 30, 2019. The increase was primarily due to an increase of $812,000 in reagent and supply expenses related to increased billable tests delivered and $491,000 in personnel costs related to increased headcount.

Cost per billable test delivered decreased $225, or 50%, from $446 in the three months ended June 30, 2018 to $221 in the three months ended June 30, 2019 as the increase in the number of billable tests we delivered was greater than the increase in our cost of revenue due to economies of scale related to the increased number of billable tests for the period. Cost per billable test delivered decreased $239, or 46%, from $515 in the six months ended June 30, 2018 to $276 in the six months ended June 30, 2019 as the increase in the number of billable tests we delivered was greater than the increase in our cost of revenue. The greater increase in the number of billable tests we delivered was primarily attributable to new customers. Our cost per billable test decreased in part due to our efforts to leverage our technology, such as engineered chemistry and competitive analytics powered by artificial intelligence and machine learning, for the increased number of billable tests during the three and six months ended June 30, 2019.

Our gross profit increased $1.9 million, from $2.9 million in the three months ended June 30, 2018 to $4.8 million in the three months ended June 30, 2019, and increased $2.5 million, from $4.7 million in the six months ended June 30, 2018 to $7.2 million in the six months ended June 30, 2019. Our gross profit as a percentage of revenue, or gross margin, increased from 52.9% to 57.0% between three months ended June 30, 2018 and 2019, and increased from 47.1% to 52.2% between six months ended June 30, 2018 and 2019, for the reasons described above.

Research and Development

Research and development expenses increased $362,000, or 30%, from $1.2 million in the three months ended June 30, 2018 to $1.6 million in the three months ended June 30, 2019. The increase was primarily due to an increase of $15,000 in reagent and supply expenses related to increase of consumables purchased in current period, increases of $180,000 in personnel costs and $62,000 in stock-based compensation expense related to increased headcount, and $74,000 in depreciation costs related to our increased efforts to maintain our technology advantage and expand our test menu.

Research and development expenses increased $328,000, or 12%, from $2.7 million in the six months ended June 30, 2018 to $3.0 million in the six months ended June 30, 2019. The increase was primarily due to increases of $317,000 in personnel costs and $107,000, in stock-based compensation expense related to increased headcount, and $143,000 in depreciation costs related to our increased efforts to maintain our technology advantage and expand our test menu, partially offset by decrease of $304,000 in reagent and supply expenses related to consumables purchased in the prior period that did not incur in the current period.

Selling and Marketing

Selling and marketing expenses increased $25,000, or 2% from $1.3 million in the three months ended June 30, 2018 to $1.3 million in the three months ended June 30, 2019. The increase was primarily due to an increase of $63,000 in personnel costs and $73,000 in stock-based compensation expense related to increased headcount, and $64,000 in consulting and outside labor expense related to the increase of outside labor for customer services in the current period, partially offset by a decrease of $149,000 in commission and fees related to the Company’s entry into certain strategic marketing agreements in the prior period that did not incur in the current period.

Selling and marketing expenses increased $167,000, or 7% from $2.4 million in the six months ended June 30, 2018 to $2.6 million in the six months ended June 30, 2019. The increase was primarily due to an increase of $56,000 in marketing materials cost related to increased billable tests delivered, and increase of $289,000 in personnel costs and $90,000 in stock-based compensation expense related to increased headcount, partially offset by a decrease of $180,000 in commission and fees related to the Company’s entry into certain strategic marketing agreements in the prior period that did not incur in the current period, and a decrease of $109,000 in marketing costs related to some marketing initiatives incurred in the prior period that did not incur in the current period.

General and Administrative

General and administrative expenses increased $265,000, or 19% from $1.4 million in the three months ended June 30, 2018 to $1.6 million in the three months ended June 30, 2019. The increase was primarily due to increases of $67,000 in personnel costs related to increased headcount, $74,000 in accounting fees, and $291,000 in legal and professional fees related to case settlement in current period, partially offset by a decrease of $186,000 in bad debt expense related to additional reserve for doubtful accounts in the prior period that did not incur in the current period.

General and administrative expenses increased $307,000, or 11% from $2.9 million in the three months ended June 30, 2018 to $3.2 million in the three months ended June 30, 2019. The increase was primarily due to increases of $135,000 in personnel costs related to increased headcount, $127,000 in accounting fees, and $330,000 in legal and professional fees related to case settlement in current period, partially offset by a decrease of $234,000 in bad debt expense related to additional reserve for doubtful accounts in the prior period that did not incur in the current period.

Interest and Other Income

Interest income was $204,000 and $133,000 in the three months ended June 30, 2019 and 2018, respectively, and $418,000 and $259,000 in the six months ended June 30, 2019 and 2018, respectively. This income related to interest received on various investments in marketable securities.

Other income was not significant in the three or six months ended June 30, 2019 and 2018. The primary component of other income in both periods was foreign currency valuation gains (losses).

Provision for (Benefit from) Income Taxes

Provision for (benefit from) income taxes were $7,000 and $20,000 for the three and six months ended June 30, 2019, respectively, and $(100,000) and $(534,000) for the three and six months ended June 30, 2018, respectively. The effective tax rate was 1% for the three months ended June 30, 2019 compared with 11% for the three months ended June 30, 2018. The effective tax rate was -2% for the six months ended June 30, 2019 compared with 18% for the six months ended June 30, 2018. The change in effective tax rate for the three and six months ended June 30, 2019, was primarily attributable to the full valuation allowance.

Equity Loss in Investee

Equity loss in investee was $149,000 and $246,000 in the three months ended June 30, 2019 and 2018, respectively, and $428,000 and $491,000 in the six months ended June 30, 2019 and 2018, respectively. Equity loss in investee relates to our 30% ownership interest in our joint venture, which we refer to as FF Gene Biotech.

Liquidity and Capital Resources

Liquidity and Sources of Cash

We had $6.7 million and $9.2 million in cash and cash equivalents and $30.7 million and $29.5 million in marketable securities, consisting of corporate bonds, as of December 31, 2018 and June 30, 2019, respectively.

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

Our primary uses of cash are to fund our operations as we continue to invest in and seek to grow our business. Cash used to fund operating expenses is impacted by the timing of our expense payments, as reflected in the changes in our outstanding accounts payable and accrued expenses. In addition, in connection with the establishment of FF Gene Biotech, we became obligated to contribute to FF Gene Biotech genetic sequencing and other equipment with a total cost of 60,000,000 renminbi, or RMB, over a five-year period, previously three-year per original agreement. To date, we have purchased and contributed to FF Gene Biotech equipment with an aggregate fair value of $3.0 million, of which, $510,000 and $2.5 million were contributed in 2018 and 2017, respectively, and as of June 30, 2019, 40.3 million RMB (or approximately $5.9 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 flows. In addition, although we have in the past made cash distributions for tax and other purposes to the equity holders of our predecessor, we do not expect to use our cash make these or any other types of distributions or dividends in the foreseeable future.

We believe our existing cash, along with cash from our operations and proceeds from our equity financings, will be sufficient to meet our anticipated cash requirements for at least the next 12 months. Much of the losses we have incurred 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 grows 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 in the next 12 months and in the longer term.

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

Cash Flows

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

	Six Months Ended June 30,	
	2019	2018
	(in thousands)	
Cash provided by (used in) operations	$ 1,730	$ (1,348)
Cash (used in) provided by investing activities	$ 689	$ (1,476)
Cash provided by financing activities	$ 9	$ 9

Operating Activities

Cash provided by operating activities in the six months ended June 30, 2019 was $1.7 million. The difference between net loss and cash provided by operating activities for the period was primarily due to the effects of $1.3 million in equity-based compensation expenses, $1.0 million in the depreciation of assets and $428,000 in equity loss in investee. Cash provided by operating activities increased between periods primarily due to a $368,000 decrease in accounts receivable mainly due to timing of collections from customers.

Cash used in operating activities in the six months ended June 30, 2018 was $1.3 million. The difference between net loss and cash used in operating activities for the period was primarily due to the effects of $1.1 million in equity-based compensation expenses and $1.1 million in the depreciation of assets, partially offset by $535,000 in deferred taxes. Cash used in operating activities decreased between periods primarily due to a $1.3 million decrease in accounts payable due to timing of payments, $990,000 increase in accounts receivable mainly due to timing of collections from customers, partially offset by the negative effect of a $1.3 million increase in accrued liabilities mainly related to payroll liabilities and deferred revenue.

Investing Activities

Cash provided by investing activities in the six months ended June 30, 2019 was $689,000, which primarily related to purchase of $10.2 million marketable securities, purchase of $633,000 fixed assets consisting mainly of computer hardware, and partially offset by maturity of $11.5 million marketable securities.

Cash used in investing activities in the six months ended June 30, 2018 was $1.5 million, which primarily related to purchase of $11.5 million marketable securities and purchase of $1.2 million fixed assets consisting mainly of medical laboratory equipment computer hardware and leasehold improvements, purchased equipment with a fair value of $510,000 contributed to FF Gene Biotech, partially offset by proceeds of $11.7 million related to maturities of marketable securities.

Financing Activities

Cash provided by financing activities in the six months ended June 30, 2019 and 2018 was minimal.

Critical Accounting Policies and Use of Estimates

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

Except as set forth below, there have been no significant changes to our critical accounting policies and estimates as described in the 2018 Annual Report.

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

The JOBS Act

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

Off-Balance Sheet Arrangements

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

Item 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 June 30, 2019. Based on this evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective as of June 30, 2019.

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 June 30, 2019 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.

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

Business and Strategy Risks

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

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

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

We have a history of losses. Although we achieved profitability in the first half of 2017 and the second quarter of 2019, we have recorded losses in all other periods since our inception. As a result, we may not be able to achieve profitability in any future period, and even if we can achieve profitability, we may not be able to sustain it. Further, we have generated limited revenue to date, and our historical revenue levels may not grow at historical rates or at all, and we may not be able to achieve or sustain profitability. We may incur additional losses in the future, particularly as we focus on investing in and growing our business and operations and experience related increases in expenses. Our prior losses and any future losses have had and will continue to have an adverse effect on our stockholders' equity and working capital, which could negatively impact our operations and your investment in our company. Any failure to sustain or grow our revenue levels and achieve or maintain profitability would negatively affect our business, financial condition, results of operations and cash flows, and could cause the market price of our common stock to decline.

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

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

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

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

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

The composition and concentration of our customer base can fluctuate from period to period, and in certain prior periods, a small number of customers accounted for a significant portion of our revenue. In particular, in the six months period ended June 30, 2019, when customers who, to our knowledge, are under common control or otherwise affiliated with each other are aggregated, two customers contributed 27% and 10%, respectively, of our total revenue. For these customers and generally, we do not have long-term purchase agreements with any of our customers, including any key customers, and, as a result, any or all of them could decide at any time to decrease, delay or discontinue their orders from us. Although we believe some of these fluctuations in customer demand may be attributable in part to the nature of our business, in which our customers can experience significant volatility in their genetic testing demand from period to period in the ordinary course of their operations, these demand fluctuations, particularly for 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 customers, may not continue in the amounts or at the rates as they have in the past, and such sales may never reach or exceed historical levels in any future period. The loss of any of our customers, or a reduction in orders or difficulties collecting payments for tests ordered by any of them, could significantly reduce our revenue and adversely affect our operating results.

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

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

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

- the genetic testing market generally, and particularly the market for next generation sequencing, or NGS, genetic tests, is relatively new and may not grow as predicted or may decline;
- our efforts to improve our existing tests and develop and launch new tests may be unsuccessful;
- we may not be able to convince additional hospitals and medical institutions or additional customer groups of the utility of our tests and their potential advantages over existing and new alternatives;
- our investments in our sales and marketing functions, including our efforts to increase and restructure our sales force and re-focus and expand our marketing initiatives and strategies, may fail;

- we may be unsuccessful in convincing customers of the benefits of our broad and customizable test menu;
- genetic testing is expensive and many existing and potential new customers may be sensitive to pricing, particularly if we are not able to maintain low prices relative to our competitors;
- potential new customers, particularly individual physicians and other practitioners, may not adopt our tests if coverage and adequate reimbursement are not available;
- negative publicity or regulatory investigations into the actions of companies in our industry could raise doubts about the legitimacy of diagnostic technologies generally, and could result in scrutiny of diagnostic activities by the U.S. Food and Drug Administration, or FDA, or other applicable government agencies; and
- our competitors could introduce new tests that cover more genes or that provide more accurate or reliable results.

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

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

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

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

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

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

acceptance and sales volume of our tests, which could prevent us from maintaining or increasing our revenue levels or achieving or sustaining profitability or could otherwise negatively affect our performance.

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

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

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

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

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

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

To increase the volume of tests we offer and deliver, we must invest in our infrastructure, including our testing capacity and information systems, enterprise software systems, customer service, billing and collections systems and processes and internal quality assurance programs. We will also need to invest in our workforce by hiring additional skilled personnel, including biostatisticians,

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

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

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

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

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

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

Coverage and reimbursement by a third-party payor may depend on a number of factors, including a payor's determination that a test is appropriate, medically necessary and cost-effective. Each payor makes its own decision as to whether to establish a policy or enter into a contract to cover our tests and the amount it will reimburse for each test, and any determination by a payor regarding coverage and amount of reimbursement for our tests would likely be made on an indication-by-indication basis. Even if a test has been approved for reimbursement, for any particular indication or in any particular jurisdiction, there is no guarantee this test will remain approved for reimbursement or that any similar or additional tests will be approved for reimbursement in the future. Moreover, there can be no assurance that any new tests we launch will be reimbursed or reimbursed at rates comparable to the rates of any previously reimbursed tests. In addition, the coding procedure used by all third-party payors with respect to establishing payment rates for various procedures, including our tests, is complex, does not currently adapt well to the genetic tests we perform and may not enable coverage and adequate reimbursement rates for our tests. If physicians fail to provide appropriate codes for desired tests, we may not be reimbursed our tests. Additionally, if we are not able to obtain sufficient clinical information in support of our tests, third-party payors

could designate our tests as experimental or investigational and decline to cover and reimburse our tests because of this designation. As a result of these factors, obtaining approvals from third-party payors to cover our tests and establishing adequate reimbursement levels is an unpredictable, challenging, time-consuming and costly process, and we may never be successful.

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

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

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

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

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

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

Our existing customer base includes international customers from a variety of geographic markets. In addition, we have established FF Gene Biotech to offer genetic testing to customers in the PRC. As part of our strategy, we aim to increase our volume of direct sales to international customers in a variety of markets by conducting targeted marketing outreach activities and, if opportunities arise, engaging distributors or establishing other types of arrangements, such as joint ventures or other relationships.

However, we may never be successful in achieving these objectives, and even if we are successful, these strategies may not result in meaningful or any increases in our customer base, test volumes or revenue.

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

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

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

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

based on our involvement in the joint venture's operations. The materialization of any of these risks related to FF Gene Biotech could materially harm our performance and prospects.

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

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

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

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

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

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

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

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

Billing for our tests is complex, time-consuming and expensive. Depending on the billing arrangement and applicable law, we bill various different parties for our tests, including customers directly in the case of our hospital and medical institution customers, as

well as Medicare, Medicaid, insurance companies and patients, all of which may have different billing requirements. We may face increased risk in our collection efforts due to the complexities of these billing requirements, including long collection cycles and lower collection rates, which could adversely affect our business, results of operations and financial condition.

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

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

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

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

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

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

financial information, conduct education and outreach activities and manage the administrative aspects of our operations, as described further below under "—We depend on our information technology systems, and any failure of these systems, due to hardware or software malfunctions, delays in operation, failures to implement new or enhanced systems or cybersecurity breaches, could harm our business." The occurrence of any of these risks could materially adversely affect our business.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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 potentially our 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, 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. Until the FDA finalizes its regulatory position regarding LDTs, however, or legislation is passed concerning regulation of LDTs, it is unknown how the FDA may regulate our tests in the future and what testing and data may be required to support any required clearance or approval.

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

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

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

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

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

In addition to CLIA requirements, we elect to participate in the accreditation program of the College of American Pathologists, or CAP. The Centers for Medicare & Medicaid Services, or CMS, has deemed CAP standards to be equally or more stringent than CLIA regulations and has approved CAP as a recognized accrediting organization. Inspection by CAP is performed in lieu of inspection by CMS for CAP-accredited laboratories. Because we are accredited by the CAP Laboratory Accreditation Program, we are deemed to also comply with CLIA. While not required to operate a CLIA-certified laboratory, many private insurers 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 at least as stringent as the CLIA regulations and establish standards for the operation of a clinical laboratory and performance of test services, including education and experience requirements for laboratory directors and personnel; physical requirements of a laboratory facility; equipment validations; and quality management practices. The laboratory director must maintain a Certificate of Qualification issued by New York's DOH in permitted categories. We are subject to on-site routine and complaint-driven inspections under both California and New York state laboratory laws and regulations. If we are found to be out of compliance with either California or New York requirements, the CA Department of Public Health or New York's DOH may suspend, restrict or revoke our license or laboratory permit, respectively (and, with respect to California, may exclude persons or entities from owning, operating or directing a laboratory for two years following such license revocation), assess civil monetary penalties, or impose specific corrective action plans, among other sanctions. Any such actions could materially and adversely affect our business by prohibiting or limiting our ability to offer testing.

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

Failure to comply with applicable clinical laboratory licensure requirements could result in a range of enforcement actions, including license suspension, limitation or revocation, directed plan of correction, onsite monitoring, civil monetary penalties, civil injunctive suits, criminal sanctions and exclusion from the Medicare and Medicaid programs, as well as significant adverse publicity. Any sanction imposed under CLIA, its implementing regulations or state or foreign laws or regulations governing clinical laboratory licensure, or our failure to renew our CLIA certificate or any other required local, state or foreign license or accreditation, could have

a material adverse effect on our business, financial condition and results of operations. In such case, even if we were able to bring our laboratory back into compliance, we could incur significant expenses and lose revenue while doing so.

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

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

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

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

In addition, the interpretation, application and interplay of consumer and health-related data protection laws in the United States, Europe and elsewhere are often uncertain, contradictory and in flux. As a result, it is possible that laws may be interpreted and applied in a manner that is inconsistent with our current practices. Moreover, these laws and their interpretations are constantly evolving and they may become more stringent over time. Complying with these laws or any new laws or interpretations of their application could involve significant time and substantial costs or require us to change our business practices and compliance procedures in a manner adverse to our business. We may not be able to obtain or maintain compliance with the diverse privacy and security requirements in all of the jurisdictions in which we currently or plan to do business, and failure to comply with any of these requirements could result in civil or criminal penalties, harm our reputation and materially adversely affect our business.

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

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

- the FDA's enforcement discretion with respect to LDTs;
- CLIA's and CAP's regulation of our laboratory activities;
- federal and state laws and standards affecting reimbursement by government payors, including certain coding requirements to obtain reimbursement and certain changes to the payment mechanism for clinical laboratory services resulting from the Protecting Access to Medicare Act of 2014, or PAMA;
- HIPAA and HITECH, which establish comprehensive federal standards with respect to the privacy and security of PHI, and requirements for the use of certain standardized electronic transactions with respect to transmission of such information, as well as similar laws protecting other types of personal information;

- state laws governing the maintenance of personally identifiable information of state residents, including medical information, and which impose varying breach notification requirements, some of which allow private rights of action by individuals for violations and also impose penalties for such violations;
- the federal Anti-Kickback Statute, which generally prohibits knowingly and willfully offering, paying, soliciting or receiving remuneration, directly or indirectly, in return for or to induce a person to refer to an individual any good, facility, item or service that is reimbursable under a federal health care program;
- the federal Stark Law, which generally prohibits a physician from making a referral for certain designated health services covered by the Medicare program, including laboratory and pathology services, if the physician or an immediate family member has a financial relationship with the entity providing the designated health services;
- the federal false claims laws, which generally impose liability on any person or entity that, among other things, knowingly presents, or causes to be presented, a false or fraudulent claim for payment to the federal government;
- the federal Civil Monetary Penalties Law, which generally prohibits, among other things, the offering or transfer of remuneration to a Medicare or Medicaid beneficiary if it is likely to influence the beneficiary's selection of a particular provider, practitioner or supplier of services reimbursable by Medicare or Medicaid;
- the Affordable Care Act, which, among other things, establishes a requirement for providers and suppliers to report and return any overpayments received from the Medicare and Medicaid programs;
- other federal and state fraud and abuse laws, such as anti-kickback laws, prohibitions on self-referral, fee-splitting restrictions, insurance fraud laws, anti-markup laws, prohibitions on the provision of tests at no or discounted cost to induce physician or patient adoption and false claims acts, some of which may extend to services reimbursable by any third-party payor, including private insurers;
- the federal Physician Sunshine Payment Act and various state laws on reporting relationships with health care providers and customers, which could be determined to apply to our LDTs;
- the prohibition on reassignment of Medicare claims;
- state laws that prohibit other specified healthcare practices, such as billing physicians for tests that they order, waiving coinsurance, copayments, deductibles and other amounts owed by patients, business corporations practicing medicine or employing or engaging physicians to practice medicine and billing a state Medicaid program at a price that is higher than what is charged to one or more other payors;
- the federal Foreign Corrupt Practices Act, or FCPA, and applicable foreign anti-bribery laws;
- federal, state and local regulations relating to the handling and disposal of regulated medical waste, hazardous waste and biohazardous waste and workplace safety for healthcare employees;
- laws and regulations relating to health and safety, labor and employment, public reporting, taxation and other areas applicable to businesses generally, all of which are subject to change, including, for example, the significant changes to the taxation of business entities were enacted in December 2017; and
- similar foreign laws and regulations that apply to us in the countries in which we operate or may operate in the future.

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.

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

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

The Affordable Care Act made a number of substantial changes to the way healthcare is financed both by governmental and private insurers. For example, the Affordable Care Act requires each medical device manufacturer to pay an excise tax on the medical devices it sells. The medical device tax has been suspended through 2019. It is unclear at this time when, or if, sales of our LDTs will trigger the medical device tax, and it is possible that this tax will apply to some or all of our existing tests or tests we may develop in the future. Additionally, the Affordable Care Act introduces mechanisms to reduce the per capita rate of growth in Medicare spending if expenditures exceed certain targets. Any such reductions could affect reimbursement payments for our tests. The Affordable Care Act also contains a number of other provisions, including provisions governing enrollment in federal and state healthcare programs, reimbursement matters and fraud and abuse, which we expect will impact our industry and our operations in ways that we cannot currently predict.

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

We cannot predict whether or when these or other recently enacted healthcare initiatives will be implemented at the federal or state level or how any such legislation or regulation may affect us. For instance, the payment reductions imposed by the Affordable Care Act and the changes to reimbursement amounts paid by Medicare for tests such as ours based on the procedure set forth in PAMA, could limit the prices we will be able to charge or the amount of available reimbursement for our tests, which would reduce our revenue. Additionally, these healthcare policy changes could be amended or additional healthcare initiatives could be implemented in the future. For instance, there is uncertainty regarding the continued effect or the Affordable Care Act in its current form following the results of the 2016 U.S. presidential election and in light of the policies of the current administration, which has threatened to repeal, replace or change the Affordable Care Act. Further, the impact on our business of the expansion of the federal and state governments' role in the U.S. healthcare industry generally, including the social, governmental and other pressures to reduce healthcare costs while expanding individual benefits, is uncertain. Any future changes or initiatives could have a materially adverse effect on our business, financial condition, results of operations and cash flows.

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

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

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

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

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

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

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

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

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

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

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

Intellectual Property Risks

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

We are required to maintain internal control over financial reporting and report any material weaknesses in these internal controls. Section 404 of the Sarbanes-Oxley Act requires that we evaluate and determine the effectiveness of our internal control over financial reporting and annually provide a management report on these internal controls. Although we have implemented systems, processes and controls and performed this evaluation as of the end of 2018, we will need to maintain and enhance them if and as we grow and, we may need to hire additional personnel and devote more resources to our financial reporting function in order to do so.

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

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

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

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

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

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

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

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 close to half of our outstanding voting equity. As a result, fewer shares are actively traded in the public market, which reduces the liquidity of our common stock. The lack of an active trading market could impair our stockholders' ability to sell their shares at the desired time or at a price considered reasonable. Further, an inactive trading market may impair our ability to raise capital by selling shares of our common stock in the future, and may impair our ability to enter into strategic relationships or acquire companies or technologies using shares of our common stock as consideration.

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

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

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

- actual or anticipated fluctuations in our operating results;
- competition from existing tests or new tests that may emerge, particularly if competitive factors in our industry, including prices for genetic testing, become more acute;
- failures to meet or exceed financial estimates and projections of the investment community or guidance we have provided to the public;
- issuance of new or updated research or reports by securities analysts or changed recommendations for our common stock;
- announcements by us or our competitors of significant acquisitions, investments, strategic relationships, joint ventures, collaborations or capital commitments;
- the timing and amount of our investments in our business and the market's perception of these investments and their impact on our prospects;
- actual or anticipated changes in laws or regulations applicable to our business or our tests;
- additions or departures of key management or other personnel;

- changes in coverage and reimbursement by current or potential payors;
- inability to obtain additional funding as and when needed on reasonable terms;
- disputes or other developments with respect to our or others' intellectual property rights;
- product liability claims or other litigation;
- sales of our common stock by us or our stockholders;
- general economic, political, industry and market conditions, including factors not directly related to our operating performance or the operating performance of our competitors, such as increased uncertainty in the U.S. regulatory environment for healthcare, trade and tax-related matters following the results of the 2016 U.S. presidential election;
- and the other risk factors discussed in this report.

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

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

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

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

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

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

To raise capital or for other strategic purposes, we may sell common stock, convertible securities or other equity securities in one or more transactions at prices and in a manner we determine from time to time. We also may issue common stock or grant other equity awards for compensatory purposes under our equity incentive plan. If we issue common stock, convertible securities or other equity securities, including equity awards under our equity incentive plan, our then-existing stockholders could be materially diluted by such issuances and, if we issue preferred stock, new investors could gain rights, preferences and privileges senior to the holders of our common stock, any of which could cause the price of our common stock to decline.

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

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

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

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

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

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

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

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

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

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

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

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

- any derivative action or proceeding brought on our behalf;
- any action asserting a claim of breach of a fiduciary duty owed by any of our directors, officers or other employees to us or to our stockholders;
- any action asserting a claim against us arising pursuant to any provision of the DGCL, our certificate of incorporation or our bylaws; and
- any action asserting a claim against us governed by the internal affairs doctrine.

Any person or entity purchasing or otherwise acquiring any interest in shares of our capital stock is deemed to have notice of and consented to this provision of our certificate of incorporation. This choice-of-forum provision may limit a stockholder's ability to bring a claim in a judicial forum it finds favorable for disputes with us or our directors, officers or other employees, which may discourage these lawsuits. Alternatively, if a court were to find this provision of our certificate of incorporation inapplicable to, or unenforceable in respect of, one or more of the specified types of actions or proceedings, we may incur additional costs associated with resolving these matters in other jurisdictions, which could adversely affect our business, financial condition or results of operations.

Item 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 $5.9 million of the net proceeds from the IPO, of which, $3.0 million was used for contributions to our joint venture, FF Gene Biotech, with $2.5 million made during the third quarter of 2017 and $510,000 made in the second quarter of 2018 in partial satisfaction of our contribution obligations under the cooperation agreement for the joint venture, and $2.9 million to fund the Company's operations. All other net proceeds from the IPO are invested in short-term, investment-grade, interest-bearing securities, such as money market accounts, certificates of deposit, commercial paper and guaranteed obligations of the U.S. government. There has been no material change in the planned use of proceeds from the IPO from that described in the Prospectus.

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§	Supplemental Agreement to Cooperation Agreement, dated April 10, 2019, by and among Fulgent Genetics, Inc., Shenzhen Fujin Gene Technology Co., Ltd., Xilong Science Co., Ltd. and Fuzhou Jinqiang Investment Partnership (Limited).	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.

§ Certain portions of this exhibit that are not material have been redacted pursuant to Item 601(b)(10)(iv) of Regulation S-K. A copy of the unredacted exhibit will be furnished to the SEC upon request.

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: August 9, 2019

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

Date: August 9, 2019

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

Exhibit 10.1

Certain identified information has been excluded from the exhibit because it is not material. Double asterisks denote omissions.

Supplemental Agreement to Cooperation Agreement

Party A: Shenzhen Fujin Gene Technology Co., Ltd.
Legal Address: Room 201, Building A, No. 1, Qianwan 1st Road, Qianhai Shenzhen-Hong Kong Cooperation Zone, Shenzhen (occupied in Shenzhen Qianhai Commerce Secretariat Co., Ltd.)
Legal Representative: Hanlin Gao
Unified Social Credit Code: [**]

Party B: Xilong Science Co., Ltd.
Legal Address: No. 1-3, Xilong Middle Street, Chaoshan Road, Shantou
Legal Representative: Weipeng Huang
Unified Social Credit Code: [**]

Party C: Fuzhou Jinqiang Investment Partnership (Limited)
Legal Address: 4F01A, 10# Plant, Zone C, No. 9, Maoling Road, Xindian Town, Jin'an District, Fuzhou, Fujian Province
Executive Partner: Xianshu Wei
Unified Social Credit Code: [**]

WHEREAS, Party A, Party B and Party C entered into the Partnership Agreement for the Joint Establishment of Fujian Fulgent Genetics Biotechnology Co., Ltd. in 2016, which stated that the three parties would jointly invest in the establishment of "Fujian Fulgent Genetics Biotechnology Co., Ltd." After friendly discussions among three parties, the parties now agree to adjust the capital contribution time of the parties set out in the above Partnership Agreement, specifically as follows:

Article 10 of the original agreement states that "Party A and Party B shall pay up the registered capitals subscribed by them and complete all capital contribution to the project company respectively within 3 years as of the date the Business License of the project company is issued; Party C shall pay up the registered capital it subscribed within 5 years as of the date the Business License of the project company is issued."

It is now modified as "Article 10 of the original agreement states that "Party A and Party B shall pay up the registered capitals subscribed by them and complete all capital contribution to the project company respectively within 5 years as of the date the Business License of the project company is issued; Party C shall pay up the registered capital it subscribed within 10 years as of the date the Business License of the project company is issued."

(The remainder of this page is intentionally left blank for signature)

(This page has no text and is a signature page of the Supplemental Agreement)

Party A: Shenzhen Fujin Gene Technology Co., Ltd. (sealed)

Legal Representative (or Authorized Representative): Hanlin Gao (signed)

Date: March 6, 2019

(This page has no text and is a signature page of the Supplemental Agreement)

Party C: Fuzhou Jinqiang Investment Partnership (Limited) (sealed)

Executive Partner: Xianshu Wei (signed)

Date: April 10, 2019

(This page has no text and is a signature page of the Supplemental Agreement)

Party B: Xilong Science Co., Ltd. (sealed)

Legal Representative (or Authorized Representative): Weipeng Huang (signed) Zou Junhui (signed)

Date:

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 June 30, 2019 of Fulgent Genetics, Inc.;

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

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

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

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated 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: August 9, 2019

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

Exhibit 31.2

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

I, Paul Kim, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2019 of Fulgent Genetics, Inc.;

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

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

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

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated 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: August 9, 2019

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 June 30, 2019 of Fulgent Genetics, Inc. (the "Company"), as filed with the Securities and Exchange Commission on the date hereof (the "Report"), each of the undersigned hereby certifies in his capacity as the specified officer of the Company, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that, to the best of his knowledge:

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

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

Date: August 9, 2019 By: /s/ Ming Hsieh
Ming Hsieh
President, **Chief Executive Officer**
(principal executive officer)

Date: August 9, 2019 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.