# 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 September 30, 2016**

**OR**

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

**For the transition period from _____ to _____**

**Commission File Number: 001-37894**

# FULGENT GENETICS, INC.

**(Exact Name of Registrant as Specified in its Charter)**

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

**(626) 350-0537**

**(Registrant's telephone number, including area code)**

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 and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted 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 and post such files). Yes ☒ No ☐

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

| | | | |
|---|---|---|---|
| Large accelerated filer | ☐ | Accelerated filer | ☐ |
| Non-accelerated filer | ☒ (Do not check if a small reporting company) | Small reporting company | ☐ |

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 November 14, 2016, the registrant had 17,676,256 shares of common stock, $0.0001 par value per share, outstanding.

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## PART I—FINANCIAL INFORMATION

**Item 1. Financial Statements.**

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

| | September 30, 2016 (Unaudited) | December 31, 2015 |
|---|---|---|
| **Assets** | | |
| Current assets | | |
| Cash | $ 8,205 | $ 489 |
| Trade accounts receivable, net of allowance for doubtful accounts of $48 and $75, respectively | 4,406 | 2,118 |
| Other current assets | 4,883 | 314 |
| Current assets of discontinued operations | | 9 |
| Total current assets | 17,494 | 2,930 |
| Fixed assets, net | 5,178 | 2,469 |
| Deferred tax asset | 86 | |
| Non-current assets of discontinued operations | | 433 |
| | 5,264 | 2,902 |
| Total assets | $ 22,758 | $ 5,832 |
| **Liabilities and Stockholders'/ Members' Equity** | | |
| Current liabilities | | |
| Accounts payable | $ 3,286 | $ 314 |
| Accrued liabilities | 471 | 199 |
| Other current liabilities | 1,253 | |
| Current liabilities of discontinued operations | | 173 |
| Total current liabilities | 5,010 | 686 |
| Deferred tax liability | 503 | |
| Total liabilities | 5,513 | 686 |
| Commitments and contingencies (Note 9) | | |
| Stockholders'/ Members' equity | | |
| Members' equity 56,000 Class D and 51,000 Class P preferred units authorized, issued and outstanding, 44,000 Class D and 49,000 Class P common units authorized and 34,000 Class D and 45,000 Class P common units issued and outstanding, at December 31, 2015 (Note 10) | | 58,306 |
| Common stock, $0.0001 par value per share, 200,000 shares authorized, 12,846 shares issued and outstanding at September 30, 2016 | 1 | |
| Preferred stock, $0.0001 par value per share, 1,000 shares authorized, no shares issued or outstanding at September 30, 2016 | | |
| Additional paid-in capital | 73,211 | |
| Accumulated deficit | (55,967) | (53,160) |
| Total Stockholders'/ Members'equity | 17,245 | 5,146 |
| Total liabilities and stockholders'/ members' equity | $ 22,758 | $ 5,832 |

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 and as noted)**
**(unaudited)**

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| | 2016 | 2015 | 2016 | 2015 |
| Revenue | $ 5,011 | $ 2,905 | $ 12,422 | $ 6,675 |
| Cost of revenue | 2,143 | 918 | 4,858 | 2,343 |
| Gross profit | 2,868 | 1,987 | 7,564 | 4,332 |
| Operating expenses: | | | | |
| Research and development | 1,523 | 311 | 2,739 | 782 |
| Selling and marketing | 893 | 280 | 1,671 | 757 |
| General and administrative | 1,147 | 216 | 3,494 | 461 |
| Total operating expenses | 3,563 | 807 | 7,904 | 2,000 |
| Operating income (loss) | (695) | 1,180 | (340) | 2,332 |
| Interest and other income (expense) | 5 | — | (5,444) | 20 |
| Income (loss) before income taxes | (690) | 1,180 | (5,784) | 2,352 |
| Provision for income taxes | 417 | — | 417 | — |
| Income (loss) from continuing operations | (1,107) | 1,180 | (6,201) | 2,352 |
| Income (loss) from discontinued operations | — | (821) | 41 | (2,121) |
| Net income (loss) | $ (1,107) | $ 359 | $ (6,160) | $ 231 |
| Basic and diluted income (loss) per common share: | | | | |
| Continuing operations—common stock | $ (0.44) | * | $ (1.17) | * |
| Continuing operations: | | | | |
| Weighted-average common shares—outstanding—basic and diluted | 12,846 | | 12,455 | |

*Basic and diluted income (loss) per common share was calculated prospectively from the date the Class D common units were issued in the October 2015 Recapitalization.

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

**FULGENT GENETICS, INC.**
**Consolidated Statements of Stockholders'/ Members' equity**
**(in thousands)**
**(unaudited)**

| | Members' Equity | | Stockholders' Equity | | Additional Paid-In | Accumulated | Total |
|---|---|---|---|---|---|---|---|
| | Units | Amount | Shares | Amount | Capital | Deficit | Equity |
| **Balance at December 31, 2015** | 186,000 | $ 58,306 | | | | $ (53,160) | $ 5,146 |
| Split-off of Pharma business | (96,000) | (12,390) | | | | 11,900 | (490) |
| Issuance of Class D-2 convertible preferred units (net of $185 issuance costs) | 15,395 | 32,452 | | | | | 32,452 |
| Repurchase and retirement of Class D-1 preferred units | (4,618) | (1,663) | | | | | (1,663) |
| Deemed dividend on retirement of Class D-1 preferred units | - | - | | | | (3,727) | (3,727) |
| Repurchase and retirement of Class D common units | (5,645) | (1,767) | | | | (4,820) | (6,587) |
| Equity-based compensation (Pre-Reorganization) | 2,500 | 2,978 | | | | | 2,978 |
| Distribution to Class D-1 preferred unitholder | - | (4,592) | | | | | (4,592) |
| Tax distribution to Class D common and preferred unitholders | | (1,253) | | | | | (1,253) |
| Reorganization (Note 1) | (97,632) | (72,071) | 12,846 | 1 | 72,070 | | - |
| Equity-based compensation (Post-Reorganization) | - | - | | | 1,141 | | 1,141 |
| Net loss | - | - | | | | (6,160) | (6,160) |
| **Balance at September 30, 2016** | - | $ - | 12,846 | $ 1 | $ 73,211 | $ (55,967) | $ 17,245 |

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)**

| | Nine Months Ended September 30, | |
|---|---|---|
| | **2016** | **2015** |
| **Cash flow from operating activities:** | | |
| Net income (loss) | $ (6,160) | $ 231 |
| Income (loss) from discontinued operations | 41 | (2,121) |
| Income (loss) from continuing operations | (6,201) | 2,352 |
| Adjustments to reconcile net income (loss) to net cash provided by (used in) operating activities: | | |
| Equity-based compensation | 4,119 | |
| Depreciation and amortization | 750 | 385 |
| Gain on disposal of fixed assets | | (20) |
| Provision for bad debt | (27) | 1 |
| Deferred income taxes | 417 | |
| Fair value adjustment recorded upon issuance of D-2 preferred units | 5,472 | |
| Changes in operating assets and liabilities: | | |
| Increase in accounts receivable | (2,261) | (1,276) |
| Increase in other current assets | (400) | (189) |
| Increase in accounts payable | 1,578 | 356 |
| (Decrease) increase in accrued liabilities | (265) | 36 |
| Cash provided by continuing operations | 3,182 | 1,645 |
| Cash used in discontinued operations | (31) | (2,079) |
| Net cash provided by (used in) operating activities | 3,151 | (434) |
| **Cash flow from investing activities:** | | |
| Proceeds from disposal of fixed assets | | 70 |
| Purchases of fixed assets | (3,379) | (1,875) |
| Cash used in continuing operations | (3,379) | (1,805) |
| Cash used in discontinued operations | | (125) |
| Net cash used in investing activities | (3,379) | (1,930) |
| **Cash flow from financing activities:** | | |
| Cash distributed in split-off of Pharma business | (159) | |
| Capital contributions | | 3,500 |
| Return of capital contribution | (4,592) | |
| Payment of initial public offering costs | (2,318) | |
| Proceeds from issuance of D-2 units | 27,165 | |
| Repurchase and retirement of Class D-1 preferred and Class D common units | (11,976) | |
| Issuance costs of Class D-2 preferred units | (185) | |
| Net cash provided by financing activities | 7,935 | 3,500 |
| **Net increase in cash** | 7,707 | 1,136 |
| **Cash balance at beginning of period** (including $9 and $0 at January 1, 2016 and 2015, respectively, from discontinued operations) | 498 | 172 |
| **Cash balance at end of period** (including $0 at September 30, 2016 and 2015 from discontinued operations) | $ 8,205 | $ 1,308 |
| **Supplemental cash flow information:** | | |
| Fixed assets included in accounts payable | $ 97 | $ 130 |
| Tax distribution to Class D common and preferred unitholders in Other current liabilities | $ 1,253 | |
| Deferred initial public offering costs included in accounts payable | $ 1,852 | |

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

## Note 1. Overview and Basis of Presentation

### *Nature of the Business*

Fulgent Genetics, Inc., together with its subsidiary (collectively referred to as the "Company," unless otherwise noted or the context otherwise requires), is a rapidly 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 overall quality of patient care. The Company has developed a proprietary technology platform that allows it to offer a broad and flexible test menu while maintaining accessible pricing, high accuracy and competitive turnaround times. The Company's current test menu offers single-gene tests and pre-established, multi-gene, disease-specific panels that collectively test for many genetic conditions, including various cancers, cardiovascular diseases and neurological disorders. The Company's existing customer base consists primarily of hospitals and medical institutions, which are frequent and high-volume users of genetic tests.

### *Background and Reorganization*

The Company was incorporated in the State of Delaware on May 13, 2016. On August 2, 2016, pursuant to the approval of the board of directors of the Company, the Company changed its name from Fulgent Diagnostics, Inc. to Fulgent Genetics, Inc. Prior to the Reorganization, as defined and described below, the Company had no material assets and had not conducted any activities other than those incidental to its incorporation and preparation for the initial public offering of its common stock. Following the ***Reorganization***, the Company is a holding company with no material assets other than 100% of the equity interests in Fulgent LLC, and Fulgent LLC is considered the Company's predecessor for accounting purposes and its financial statements for all periods prior to completion of the Reorganization constitute the Company's historical financial statements.

On September 30, 2016, the Company completed a reorganization pursuant to which Fulgent Therapeutics LLC, a California limited liability company (referred to, together with its former subsidiary unless otherwise noted or the context otherwise requires, as "Fulgent LLC"), became a wholly owned subsidiary of the Company (the "Reorganization"). For purposes of these notes and the accompanying condensed consolidated financial statements: (i) Fulgent LLC's operating agreement, as amended from time to time, is referred to as the "Operating Agreement;" (ii) Fulgent LLC's equity holders are referred to as "members;" (iii) Fulgent LLC's authorized, issued and outstanding equity interests prior to the Reorganization are referred to as "units" and consisted of Class D common units and Class D-1 and Class D-2 preferred units; (iv) certain of Fulgent LLC's Class D common units outstanding prior to the Reorganization constituted profits interests, which are a type of equity award containing a participation threshold (which is sometimes referred to as a "profits interest threshold") that entitled the recipient of the award to participate in the value of Fulgent LLC only to the extent it appreciated from and after the grant date of the award; and (v) prior to the Reorganization, Fulgent LLC was managed by its Manager, Ming Hsieh, who was also Fulgent LLC's controlling equity holder. In the Reorganization, each outstanding 7.6 units of Fulgent LLC were cancelled in exchange for one share of the Company's common stock, such that (i) all outstanding Class D common units of Fulgent LLC (including Class D common units that constitute profits interests) were cancelled in exchange for an aggregate of 4,060 shares of the Company's common stock; (ii) all outstanding Class D-1 preferred units of Fulgent LLC were cancelled in exchange for an aggregate of 6,761 shares of the Company's common stock; (iii) all outstanding Class D-2 preferred units were cancelled in exchange for an aggregate of 2,026 shares of the Company's common stock; (iv) all outstanding options to acquire common units of Fulgent LLC were cancelled in exchange for equivalent options to acquire up to an aggregate of 591,112 shares of the Company's common stock, and all such options became immediately exercisable to the extent vested; and (v) all outstanding restricted share units relating to common units of Fulgent LLC were cancelled in exchange for equivalent restricted stock units ("RSUs") relating to 65,789 shares of the Company's common stock. The Reorganization was accounted for as a common control transaction and no gain or loss was recorded.

***Initial Public Offering***

On October 4, 2016, the Company completed the initial public offering of its common stock (the “IPO”), in which it issued and sold an aggregate of 4,830 shares of common stock (including 630 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. The Company received net proceeds of approximately $36,258, after deducting underwriting discounts and commissions of $3,043 and other offering expenses paid or payable by the Company of approximately $4,169. The shares issued and sold in the IPO were registered under the Securities Act of 1933, as amended, on a registration statement on Form S-1 (File No. 333- 213469), as amended (the “Registration Statement,” and the final prospectus dated September 28, 2016 included in the Registration Statement, the “Prospectus”). The issuance of shares in the IPO occurred subsequent to September 30, 2016 and therefore is not reflected in the results of operations or financial position of the Company as set forth in these notes and the accompanying condensed consolidated financial statements.

***Unaudited Interim Financial Information***

The accompanying unaudited condensed consolidated financial statements include the accounts of the Company and its subsidiary. All intercompany accounts and transactions have been eliminated in consolidation. These interim condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America ("GAAP"). These financial statements have been prepared on the same basis as the audited consolidated financial statements for the fiscal year ended December 31, 2015 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. The accompanying condensed consolidated balance sheet as of December 31, 2015 has been derived from the audited financial statements at that date but does not include all of the disclosures required by 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 Company’s prospectus filed pursuant to Rule 424(b) under the Securities Act of 1933, as amended (the “Securities Act”), with the Securities and Exchange Commission on September 28, 2016 (the “Prospectus”).

***Discontinued Operations***

In April 2016, Fulgent LLC’s Operating Agreement was amended and restated to provide for the distribution of its wholly owned subsidiary, Fulgent Pharma LLC (“Fulgent Pharma”), in full redemption and cancellation of its former Class P preferred and common units (collectively, the “Class P units”). On April 4, 2016, the Company completed the split-off of Fulgent Pharma and the pharmaceutical business operated by Fulgent Pharma (the “Pharma business”) by redeeming all of the then-outstanding Class P units and distributing to each holder of Class P units substantially identical shares of Fulgent Pharma and causing Fulgent Pharma to assume all then-outstanding options to purchase Class P units. All Class P units were immediately cancelled upon redemption. The split-off of the Pharma business was a pro-rata distribution to all of the holders of Class P units, but did not involve the holders of Fulgent LLC’s Class D units. The Manager and controlling unitholder of Fulgent LLC prior to the Reorganization, Mr. Hsieh, is the Manager and controlling unitholder of Fulgent Pharma. Therefore, Fulgent LLC concluded that the split-off transaction should be accounted for as a common control transaction and the recorded amount of Fulgent Pharma’s net assets was transferred to the holders of Class P units and no gain or loss was recorded.

The split-off of the Pharma business is presented as discontinued operations in the accompanying condensed consolidated financial statements for all periods presented. Significant asset and liability categories of the Pharma business are disclosed on the accompanying condensed consolidated balance sheet. Significant assets and liabilities of the discontinued operations consist of fixed assets and accounts payable.

The major components of statements of operations data comprising the income (loss) on discontinued operations are as follows:

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| | 2016 | 2015 | 2016 | 2015 |
| Operating expenses: | | | | |
| Research and development | $ - | $ 732 | $ 350 | $ 1,220 |
| General and administrative | - | 89 | 9 | 900 |
| Total operating expenses | - | 821 | 359 | 2,120 |
| Operating Income (loss) | - | (821) | (359) | (2,120) |
| Interest and other income (expense) | - | - | 400 | (1) |
| Income (loss) | $ - | $ (821) | $ 41 | $ (2,121) |

**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 for the year ended December 31, 2015, which are included in the Prospectus. Except as described below, no such policies materially changed during the nine months ended September 30, 2016.

***Use of Estimates***

The preparation of consolidated financial statements in conformity with 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 reported 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 that management believes to be reasonable under the circumstances. Actual results could differ from these estimates.

Significant items subject to such estimates and assumptions include revenue recognition criteria, the fair value of equity-based awards, accounts receivable and allowances for doubtful accounts, the useful lives of fixed assets and estimates of tax liabilities.

***Reporting Segment and Geographic Information***

Reporting segments are identified as components of an enterprise about which separate discrete financial information is available for evaluation by the chief operating decision-maker in making decisions regarding resource allocation and assessing performance. The Company's chief operating decision maker is its CEO. The Company views its operations and manages its business in one reporting segment.

***Income Taxes***

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

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

Prior to the Reorganization, Fulgent LLC was organized as a limited liability company and its members elected to have Fulgent LLC treated as a partnership for income tax purposes. All taxable income or loss and tax credits generally were reflected in the personal income tax returns of the Fulgent LLC's members. Accordingly, no provision for federal and state income taxes was provided in the accompanying consolidated financial statements prior to the Reorganization. Pursuant to the Reorganization, the Company is a taxable entity. The change in tax status resulted in the recognition of a deferred tax asset in the amount of $86 and a deferred tax liability in the amount of $503 representing the initial temporary differences at the time of the change in status. The most significant components of the deferred tax asset and liability were the result of differences in book and tax depreciation and equity-based compensation.

***Recent Accounting Pronouncements***

In May 2014, the Financial Accounting Standards Board ("FASB") issued Accounting Standard Update ("ASU") No. 2014-09, *Revenue from Contracts with Customers*, which provides a single comprehensive model for entities to use in accounting for revenue arising from contracts with customers and will supersede most current revenue recognition guidance The FASB continues to address certain implementation issues and clarify certain core revenue recognition principles of ASU 2014-09. In July 2015, the FASB voted to delay the effective date of this standard such that ASU 2014-09, as amended, will be effective for the Company for annual and interim periods beginning after December 15, 2017. Early adoption of the standard is permitted for annual periods beginning after December 15, 2016. The guidance permits two implementation approaches, one requiring retrospective application of the new standard with restatement of prior years and one requiring prospective application of the new standard with disclosure of results under old standards. The Company is evaluating the effects of this standard on its financial position, results of operations and cash flows.

In January 2016, the FASB issued ASU No. 2016-01, Financial Instruments Overall (Subtopic 825-10): Recognition and Measurement of Financial Assets and Financial Liabilities ("ASU 2016-01"), which addresses certain aspects of recognition, measurement, presentation, and disclosure of financial instruments, including a provision that requires equity investments (except for investments accounted for under the equity method of accounting) to be measured at fair value, with changes in fair value recognized in current earnings. ASU 2016-01 is effective for the Company in the first quarter of 2018, with early adoption permitted. The Company is currently evaluating the effect that ASU 2016-01 will have on its consolidated financial statements and related disclosures.

In February 2016, the FASB issued ASU No. 2016-02, *Leases (Topic 842).* The update is aimed at making leasing activities more transparent and comparable, and requires substantially all leases be recognized by lessees on their balance sheet as a right-of-use asset and corresponding lease liability, including leases currently accounted for as operating leases. This guidance will become effective for interim and annual reporting periods beginning with the year ending December 31, 2019. Early adoption is permitted. The Company is currently evaluating the impact that the adoption of this guidance will have on its consolidated financial statements and related disclosures.

In August 2016, the FASB issued ASU No. 2016-15, Statement of Cash Flows. The standard clarifies the way certain cash receipts and cash payments are classified with the objective of reducing the existing diversity in practice. The standard is effective for fiscal years and interim periods beginning after December 15, 2017. Early adoption is permitted for all periods beginning after December 15, 2016. The Company is currently evaluating the impact of adopting this standard.

**Note 3. Income (Loss) per Share**

The income (loss) per share for the periods ended September 30, 2016 were computed as if the Reorganization, including the exchange of 1 share of common stock for every 7.6 Fulgent LLC unit had occurred on January 1, 2016. Income (loss) per share prior to the October 2015 Recapitalization is not presented. The following table presents the calculation of basic and diluted income (loss) per share for the three and nine months ended September 30, 2016:

| | Three Months Ended | | | Nine Months Ended | | |
|---|---|---|---|---|---|---|
| | Continuing Operations | Discontinued Operations | Total | Continuing Operations | Discontinued Operations | Total |
| Income (loss) | $ (1,107) | $ 0 | $ (1,107) | $ (6,201) | $ 41 | $ (6,160) |
| Deemed dividend on redemption of Class D-1 preferred unit | | | $ 0 | $ (3,727) | | $ (3,727) |
| Distribution to Class D-1 preferred unitholder | $ (4,592) | | $ (4,592) | $ (4,592) | | $ (4,592) |
| Income (loss) allocable to common shareholders | $ (5,699) | $ 0 | $ (5,699) | $ (14,520) | $ 41 | $ (14,479) |
| Income (loss) allocated to common shareholders | $ (5,699) | | | $ (14,520) | | |
| Income (loss) allocated to Class P common units | | | | | 18 | |
| Income (loss) allocated to Class P preferred units | | | | | 23 | |
| Weighted-average common shares—outstanding, basic and diluted | 12,846 | — | | 12,455 | — | |
| Weighted-average Class P common units outstanding, basic and diluted | — | — | | — | 13,522 | |
| Weighted-average Class P preferred units outstanding, basic and diluted | — | — | | — | 17,682 | |
| Income (loss) per common share from continuing operations, basic and diluted | $ (0.44) | — | | $ (1.17) | — | |
| Income per Class P common unit, basic and diluted | — | — | | — | — | |
| Income per Class P preferred unit, basic and diluted | — | — | | — | — | |

On April 4, 2016, Fulgent LLC completed the split-off of the Pharma business. The financial condition and results of the Pharma business are included in the accompanying condensed consolidated financial statements as discontinued operations for all periods presented, and the weighted -average Class P units related to the Pharma business were computed through the separation date of April 4, 2016.

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

| | Three Months Ended | | Nine Months Ended | |
|---|---|---|---|---|
| | Continuing Operations | Discontinued Operations | Continuing Operations | Discontinued Operations |
| Common share options | 591 | — | 591 | — |
| Common share restricted stock units | 66 | | 66 | |
| Class P common unit options | — | — | — | 1,810 |

The anti-dilutive shares disclosed above were calculated using the treasury stock method. During the three and nine month periods ended September 30, 2016, the Company had common share options and restricted units that were excluded from the weighted average share calculation for continuing operations due to the Company’s net loss positions. During the nine month period ended September 30, 2016, the Company had Class P common unit options that were excluded from the weighted average share calculation for discontinued operations as the shares were determined to be anti-dilutive using the treasury method.

**Note 4. Fixed Assets**

Major classes of fixed assets were as follows:

| | Useful Lives | September 30, 2016 | December 31, 2015 |
|---|---|---|---|
| Computer hardware | 3 Years | $ 1,003 | $ 601 |
| Computer software | 3 Years | 318 | 176 |
| Machinery and equipment | 5 Years | 177 | 210 |
| Medical lab equipment | 5 Years | 4,678 | 2,016 |
| General equipment | 3 Years | 59 | 59 |
| Furniture and fixtures | 5 Years | 86 | 51 |
| Leasehold improvements | Shorter of lease term or estimated useful life | 485 | 256 |
| Sub-Total | | $ 6,806 | $ 3,369 |
| Accumulated depreciation | | (1,628) | (900) |
| | | $ 5,178 | $ 2,469 |

Depreciation expense on fixed assets totaled $304 and $171 in the three months ended September 30, 2016 and 2015, respectively. Depreciation expense on fixed assets totaled $750 and $385 in the nine months ended September 30, 2016 and 2015, respectively.

**Note 5. Other Current Assets**

Other current assets consisted of the following:

| | September 30, 2016 | December 31, 2015 |
|---|---|---|
| Deferred initial public offering costs | $ 4,169 | $ — |
| Reagents | 525 | 212 |
| Prepaid expenses | 183 | 65 |
| Payroll tax refund | 6 | 37 |
| Total | $ 4,883 | $ 314 |

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

**Note 6. Other Current Liabilities**

The Company has accrued tax distributions of $1.3 million to the former LLC members as of September 30, 2016 based on the income tax liabilities of such former members attributable to Fulgent LLC’s 2016 net taxable income through the date of the Reorganization, as determined by the Manager in accordance with the Third Amended and Restated Operating Agreement for Fulgent LLC, and presented such in Other Current Liabilities on the accompanying condensed consolidated balance sheet.

**Note 7. Reporting Segment and Geographic Information**

The Company views its operations and manages its business in one reporting segment. All long-lived assets are located in the United States.

Revenue by region was as follows:

| | For the Three Months Ended September 30, | | For the Nine Months Ended September 30, | |
|---|---|---|---|---|
| | 2016 | 2015 | 2016 | 2015 |
| **Revenue:** | | | | |
| United States | $ 2,147 | $ 1,559 | $ 6,283 | $ 3,500 |
| Foreign: | | | | |
| Canada | 937 | 801 | 2,676 | 2,176 |
| China | 1,148 | | 1,148 | |
| Other Countries | 779 | 545 | 2,315 | 999 |
| | $ 5,011 | $ 2,905 | $ 12,422 | $ 6,675 |

**Note 8. Major Customers and Accounts Receivable**

The Company had a customer whose revenue individually represented 10% or more of the Company's total revenue, or whose accounts receivable balance individually represented 10% or more of the Company's total accounts receivable, as follows:

For the three months ended September 30, 2016 and 2015, one customer accounted for 23% and zero of revenue, respectively. For the nine months ended September 30, 2016 and 2015, the Company did not have a customer whose revenue individually represented 10% or more of the Company's total revenue.

At September 30, 2016, one customer accounted for 26% of the Company's total accounts receivable. At December 31, 2015, there were no customers that accounted for 10% or more of the Company's total accounts receivable.

**Note 9. Commitments and Contingencies**

***Operating Leases***

The Company has commitments under non-cancelable operating leases of varying terms and duration for its headquarters 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 ("CA DPH"). Rent expense for the three months ended September 30, 2016 and 2015 was $55 and $47, respectively. Rent expense for the nine months ended September 30, 2016 and 2015 was $179 and $115, respectively.

***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 10. Members' / Stockholders' Equity**

***Reorganization***

Upon completion of the Reorganization on September 30, 2016, all of Fulgent LLC's outstanding units were cancelled in exchange for shares of the Company's common stock, at a ratio of 7.6 units of Fulgent LLC cancelled for each one share of the Company's common stock.

The following is a summary of the units of Fulgent LLC that were cancelled in exchange for shares of the Company's common stock:

| | Pre-Reorganization |
|---|---|
| Class D-1 preferred units | 51,382 |
| Class D-2 preferred units | 15,395 |
| Class D common units | 2,500 |
| Class D common units — profit interests | 28,355 |
| | 97,632 |

The units set forth in the table above were cancelled in exchange for an aggregate of 12,846 shares of the Company's common stock. The members' equity balance of $72 million was reclassified into common stock and additional paid-in capital in the accompanying condensed consolidated balance sheet as of September 30, 2016.

***Certificate of Incorporation***

In accordance with the Company's certificate of incorporation, the Company is authorized to issue 200,000 shares of common stock, with a par value of $0.0001 per share, and 1,000 shares of preferred stock, with a par value of $0.0001 per share. Holders of the Company's common stock are entitled to one vote for each share held on all matters submitted to a vote of its stockholders. Holders of the Company's common stock have no cumulative voting rights. Further, as of September 30, 2016, holders of the Company's common stock have no preemptive, conversion, redemption or subscription rights and there are no sinking fund provisions applicable to the Company's common stock. Upon liquidation, dissolution or winding-up of the Company, holders of the Company's common stock are entitled to share ratably in all assets remaining after payment of all liabilities and the liquidation preferences of any outstanding shares of preferred stock. Subject to preferences that may be applicable to any outstanding shares of preferred stock, holders of the Company's common stock are entitled to receive dividends, if any, as may be declared from time to time by the Company's board of directors. As of September 30, 2016, there were no outstanding shares of preferred stock.

***Distributions***

The Company has accrued a tax distribution to Class D common and preferred unitholders as of September 30, 2016 in the amount of $1.3 million. The amount was based on income allocable to the LLC up to the Reorganization date. In addition, in September 2016, the Company distributed $4.6 million to Mr. Hsieh in his capacity as a member of Fulgent LLC as a return of capital contribution.

**Note 11. Equity-Based Compensation**

Equity-based compensation expense to employees is measured based on the fair value of the awards on the grant date and recognized in the Company's consolidated statements of operations over the period during which the employee is required to perform services in exchange for the award (generally the vesting period of the award). Compensation expense for awards with both a service and performance condition is recognized over the period required to achieve both conditions using the accelerated attribution method. The Company estimates the fair value of stock options using the Black-Scholes option valuation model. The Company measures the fair value of RSUs based on the fair value of the underlying shares on the date of grant. For awards of Fulgent LLC units subject to a profits interest threshold, the fair value is measured using the Black-Scholes option valuation model.

Prior to the Reorganization, the Company's employees and other service providers were granted awards under the Fulgent Therapeutics LLC Amended and Restated 2015 Equity Incentive Plan (the "2015 Plan"), which provided for the issuance of equity-based awards to eligible employees, directors and consultants. These awards generally consisted of options, restricted share units and units subject to a profits interest threshold. Options granted under the 2015 Plan typically vested over four years and expired 10 years from the date of grant, and were not exercisable, whether or not vested, until the earlier of a liquidity event or incorporation, each as defined in the 2015 Plan. Because the options were subject to both a service condition (as set forth in their vesting schedules) and a performance condition (the occurrence of a qualifying liquidity event or incorporation), no equity-based compensation expense was recognized for these options until the performance condition was deemed to have been satisfied. Restricted share units granted under the 2015 Plan typically vested over four years. Awards of units subject to profits interest thresholds were typically fully vested at the date of grant.

In connection with the Reorganization, the Company approved its 2016 Omnibus Incentive Plan (the "2016 Plan"), which provides for the issuance of up to an aggregate of 2,038 shares of the Company's common stock pursuant to awards granted to eligible

employees, directors and consultants. Terms regarding vesting period and contractual life of the 2016 Plan have not significantly changed from the terms of the 2015 Plan. Additionally, at the effective time of the Reorganization:

- The 2015 Plan was terminated and no additional awards will be granted thereunder.
- Each outstanding option to purchase 7.6 Class D common units of Fulgent LLC was cancelled in exchange for an equivalent option granted under the 2016 Plan to purchase one share of its common stock. The new options are subject to the same vesting schedule and other material terms and conditions as the cancelled options. The Reorganization was considered an incorporation pursuant to the terms of the 2015 Plan and the performance condition applicable to all options was deemed to have been satisfied. As a result, all of the options became immediately exercisable, to the extent vested, upon completion of the Reorganization. This satisfaction of the performance condition resulted in a cumulative stock-based compensation expense of $1,113 for the requisite service period, which the Company recorded during the period in which the Reorganization occurred. The remaining unrecognized stock-based compensation expense related to the options is being recorded over the remaining requisite vesting period of the awards using the accelerated attribution method.
- Each outstanding restricted share unit relating to 7.6 Class D common units of Fulgent LLC was cancelled in exchange for an equivalent RSU granted under the 2016 Plan relating to one share of its common stock. The new RSUs are subject to the same vesting schedule and other material terms and conditions as the cancelled restricted share units. Equity-based compensation expense for RSUs is recognized ratably over the requisite vesting period of the awards.
- Pursuant to the determination of the Manager of Fulgent LLC, the participation thresholds applicable to all Class D common units that constituted profits interests (i) were ignored and not applied in calculating the number of shares of the Company's common stock that were issued in exchange for such units in the Reorganization, and (ii) did not carry over to such shares of the Company's common stock. As a result, the holders of Fulgent LLC's Class D common units that constituted profits interests received shares of the Company's common stock in the Reorganization at the same ratio, 7.6-to-one, as the holders of Fulgent LLC's Class D common units that were not subject to profits interest thresholds. Ignoring all profits interest thresholds upon the modification of the Class D common units that constitute profits interests into shares of the Company's common stock resulted in a equity-based compensation expense of $1,353 that the Company recorded during the period in which the Reorganization occurred.

The following table summarizes the Company's equity-based compensation expense for the three and nine months ended September 30, 2016 in the accompanying condensed consolidated statements of operations:

| | For the Three Months Ended September 30, 2016 | For the Nine Months Ended September 30, 2016 |
|---|---|---|
| Cost of revenue | $ 586 | $ 586 |
| Research and development | 959 | 959 |
| Selling and marketing | 396 | 396 |
| General and administrative | 552 | 2,178 |
| Total | $ 2,493 | $ 4,119 |

***Award Activity***

*Option Awards*

The following table summarizes activity for options to acquire common shares in the nine months ended September 30, 2016:

| | Number of Shares Subject to Options | Weighted-Average Exercise Price Per Share | Weighted-Average Remaining Contractual Life (in years) | Aggregate Intrinsic Value |
|---|---|---|---|---|
| Outstanding as of December 31, 2015 | 274 | $ 0.38 | | $ 645 |
| Granted | 324 | $ 1.18 | | |
| Exercised | — | — | | |
| Forfeited/canceled | 7 | $ 0.38 | | |
| Outstanding as of September 30, 2016 | 591 | $ 0.82 | 9.3 | $ 5,034 |
| Exercisable at September 30, 2016 | 80 | $ 0.38 | 9.3 | 708 |

The number of shares subject to options and weighted average exercise price in the table above have been adjusted to show the effects of the Reorganization. The weighted-average grant date fair value of options to acquire common shares granted in the nine months ended September 30, 2016 was $6.98. As of September 30, 2016, the remaining unrecognized compensation expense of $2.0 million related to these options is expected to be recognized over a weighted-average period of 3.1 years.

*Share and Restricted Stock Unit Awards*

The following table shows grants of share awards and grants of restricted stock units during the nine months ended September 30, 2016:

| | Employee |
|---|---|
| Shares | 328,947 |
| Restricted Stock Units | 65,789 |

The common shares issued in the nine months ended September 30, 2016 were related to one award granted to an employee in January 2016, and recorded based on the estimated fair value of common shares on the grant date which resulted in equity-based compensation expense of $1.6 million. These shares were granted outside of the Plan, were immediately vested and are not subject to a profits interest threshold. The restricted stock units issued in the nine months ended September 30, 2016 are recorded based on the fair value of common shares on the grant date which resulted in equity-based compensation expense of $770 to be recognized over four years. As of September 30, 2016, $27 has been recognized and the remaining unrecognized compensation expense of $743 related to these restricted stock units is expected to be recognized over a weighted-average period of 3.9 years.

***Fair Value Assumptions***

*Option Awards to Employees*

The following table sets forth weighted-average assumptions used to estimate the fair value of options to acquire common shares granted to employees during the nine months ended September 30, 2016:

| | |
|---|---|
| Expected term (in years) | 6.1 |
| Risk-free interest rates | 1.4% |
| Dividend yield | 0 |
| Expected volatility | 95.6% |

These assumptions and estimates are as follows:

- *Expected Term.* The expected term represents the period that our equity-based awards are expected to be outstanding. We determine the expected term assumption based on the vesting terms, exercise terms and contractual terms of the options.
- *Risk-Free Interest Rate.* The Company determines the risk-free interest rate by using the equivalent to the expected term based on the U.S. Treasury yield curve in effect as of the date of grant.
- *Dividend Yield.* The assumed dividend yield is based on the Company’s expectation that it will not pay dividends in the foreseeable future, which is consistent with its history of not paying dividends.
- *Expected Volatility.* The Company does not have sufficient history to estimate the volatility of the price of its common stock or the expected term of its options. The Company calculates expected volatility based on historical volatility data of a representative group of companies that are publicly traded. The Company selected representative companies with comparable characteristics to it, including risk profiles and position within the industry, and with historical equity price information sufficient to meet the expected term of the equity-based awards. The Company computes the historical volatility of this selected group using the daily closing prices for the selected companies’ equity during the equivalent period of the calculated expected term of its equity-based awards. The Company will continue to use the representative group volatility information until the historical volatility of its equity is relevant to measure expected volatility for future option grants.
- *Forfeiture Rate.* The Company has early adopted Accounting Standards Update No. 2016-09, Stock Compensation (Topic 718); Improvements to Employee Share-Based Payment Accounting, and has elected to account for forfeitures as they occur.

*Option Awards to Non-Employees*

Equity-based compensation expense related to options granted to non-employees is recognized as the options are earned. The fair value of the options is more reliably measurable than the fair value of the services received.

The fair value of non-employee options is calculated at each reporting date, using the Black-Scholes option-pricing model, until the award vests or there is a substantial incentive for the non-employee not to perform the required services.

The following table sets forth the weighted-average assumptions used to estimate the fair value of options to acquire common shares granted to non-employees during the nine months ended September 30, 2016:

| | |
|---|---|
| Expected term (in years) | 10 |
| Risk-free interest rates | 1.6% |
| Dividend yield | 0 |
| Expected volatility | 96.9% |

**Note 12. Income Taxes**

Income tax expense consists of 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. Upon completion of the Reorganization, the Company converted from a pass-through entity for tax purposes to a taxable entity. The change in tax status resulted in the recognition of a deferred tax asset of $86 and a deferred tax liability of $503 for the initial temporary differences between book and tax, primarily from depreciation and equity-based compensation at the time of the change in status. No tax expense resulted as of the date of the Reorganization as it took place on the last day of quarter. Operational results attributed to that one day were deemed insignificant.

**Note 13. Subsequent Events**

***Initial Public Offering***

On October 4, 2016, the Company completed the IPO, in which it issued and sold an aggregate of 4,830 shares of common stock (including 630 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. The Company received net proceeds of approximately $36,258, after deducting underwriting discounts and commissions of $3,043 and other offering expenses paid or payable by the Company of approximately $4,169.

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

*On September 30, 2016, Fulgent Therapeutics LLC became a wholly owned subsidiary of Fulgent Genetics, Inc. in a transaction we refer to as the "Reorganization". As used in the following discussion and analysis and elsewhere in this report, unless the context otherwise requires, (i) the term "Fulgent LLC" refers to Fulgent Therapeutics LLC, (ii) the term "Fulgent Inc." refers to Fulgent Genetics, Inc. and (iii) the terms "Fulgent," the "company," "we," "us" and "our" refer, for periods prior to completion of the Reorganization, to Fulgent LLC and, for periods after completion of the Reorganization, to Fulgent Inc. and its consolidated subsidiary after giving effect to the Reorganization. Following the Reorganization, Fulgent Inc. is a holding company with no material assets other than 100% of the equity interests in its subsidiary, including Fulgent LLC, and Fulgent LLC is considered Fulgent Inc.'s predecessor for accounting purposes and its financial statements for all periods prior to completion of the Reorganization constitute Fulgent Inc.'s historical financial statements.*

*The following discussion and analysis of our financial condition and results of operations should be read together with the 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 the 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 registration statement on Form S-1 (File No. 333-213469), as amended, and the final prospectus dated September 28, 2016 included therein, or the Prospectus.*

**Forward Looking Statements**

The *statements in this* discussion and analysis *regarding expectations* of our *future performance, liquidity* and *capital resources and all other non-historical statements are forward-looking statements. These forward-looking statements are subject to numerous risks and uncertainties, including, among others,* the *risks and uncertainties described in "Risk Factors" in this report. Our actual* results *could differ materially from* the *results described in or implied by the* forward-looking statements *contained in this discussion and analysis.*

The following discussion and analysis *and other sections of this report contain forward-looking statements covered by the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. Forward-looking statements are statements other than historical facts and often address matters such as, for instance, our future financial and operating performance, future cash flows and liquidity, our strategies for growth and anticipated trends in our business and industry. These forward-looking statements* are based on the beliefs *and assumptions* of our management, *based on* information currently available *and expectations that we believe are reasonable. However, these statements are only predictions* and are subject to known and unknown risks, uncertainties and other factors that may cause our actual results to differ materially from those expressed or implied by *the* forward-looking statements. These risks, uncertainties, and other factors include, among others, those *discussed under* "Risk Factors" *in this report and in the Prospectus. Given these risks, uncertainties and other important factors, undue reliance should not be placed on these forward-looking statements. These forward-looking statements represent our estimates and assumptions only as of the date made, and we undertake no duty to update any of these forward-looking statements to conform to actual results or revised expectations except as otherwise required by law.*

**Overview**

We are a rapidly 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 overall quality of patient care. We have developed a proprietary technology platform that integrates sophisticated data comparison and suppression algorithms, adaptive learning software, advanced genetic diagnostics tools and integrated laboratory processes. This platform 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 current test menu includes more than 18,000 single-gene tests and approximately 250 pre-established, multi-gene, disease-specific panels that collectively test for more than 7,500 genetic conditions, including various cancers, cardiovascular diseases, neurological disorders and pediatric tests.

We have generated growing demand for our tests with relatively little marketing efforts to date, which we believe demonstrates the advantages of our offering compared to other available testing alternatives. We offer tests at competitive prices, averaging approximately $1,440 per billable test delivered in the nine months ended September 30, 2016, and at a lower cost to us than many of our competitors, totaling approximately $560 per billable test delivered in the nine months ended September 30, 2016. Our volume has grown rapidly since our commercial launch, with over 15,000 billable tests delivered to over 600 total customers as of September 30, 2016. We delivered 3,419 and 8,628 billable tests in the three and nine months ended September 30, 2016, respectively, compared to 2,052 and 4,814 billable tests delivered in the three and nine months ended September 30, 2015, respectively. We recorded revenue of $5 million and $12.4 million and a net loss of $1 million and $6.2 million in the three and nine months ended September 30, 2016, respectively.

## Factors Affecting Our Performance

### Market and Industry Trends

Genetic testing has experienced significant growth in recent years. As this trend continues, we believe genetic testing will become a more accepted part of standard medical care and the knowledge of a person's unique genetic makeup will begin to play a more important role in the practice of medicine. The advent of next generation sequencing, or NGS, technology, a relatively new genetic testing technique that enables millions of DNA fragments to be sequenced in parallel, has dramatically lowered the cost and improved the quality of genetic testing, contributing to increased adoption generally and increased volumes for our tests. According to GrandView Research, the size of the global NGS genetic testing market, which includes pre-sequencing, sequencing and data analysis, is estimated to be approximately $4.0 billion in 2016, including approximately $1.4 billion in the United States, and is expected to reach approximately $10.5 billion by 2022, including approximately $3.6 billion in the United States.

While adoption of genetic testing has increased in recent years, we believe widespread utilization has been limited in large part because of certain barriers to adoption that exist in today's market. Among these barriers are that genetic testing can be prohibitively expensive, only a limited number of genetic tests are currently reimbursable, certain genetic conditions cannot be diagnosed due to the limited scope of genetic analysis, genetic testing can be an inefficient process and the interpretation of genetic results can be cumbersome and time-consuming. We believe a significant market exists for a genetic testing option that provides broad genetic coverage and the flexibility to customize tests for individual patient needs, while maintaining accuracy and affordability, and we believe that the proprietary technology platform that we have developed will enable us to overcome many of these challenges facing our industry today.

#### *Number of Billable Tests Delivered*

Our performance is closely correlated with the number of tests for which we bill our customers, which we refer to as billable tests. The number of billable tests we deliver in a period depends on a number of factors, including the other factors affecting our performance discussed in this discussion and analysis. We believe the number of billable tests delivered in any period is an important indicator of the performance of our business. We have experienced compound quarterly growth of 20% in the number of billable tests delivered from the first quarter of 2015 through the third quarter of 2016.

#### *Mix of Customers*

Our existing customer base consists primarily of hospitals and medical institutions, which are frequent and high-volume users of genetic tests. We are focused on more deeply penetrating our relationships with existing customers to increase the volume of tests they order. In addition, we are seeking to grow our customer base by continuing to acquire new hospital and medical institution customers and expand into additional customer groups, such as individual physicians and other practitioners, as well as research institutions.

To this end, in 2016 to date, we have made efforts to diversify our customer base beyond hospitals by establishing a vendor code with a national clinical laboratory that orders our tests to fulfill some of the genetic testing orders it receives from certain U.S. government agencies, contracting with a regional hospital network within the U.S. Army to provide genetic tests for members and their families, and contracting with a healthcare services provider in the prenatal sector to provide proprietary carrier screening tests that we developed for this service provider. We have also pursued relationships with payors, including Medicare, some state Medicaid programs and third-party payors, in order to obtain coverage and reimbursement for our tests to make them accessible to more individual physicians. Other than our relationship with the hospital network within the U.S. Army, which involves a minimum commitment of approximately $400,000 of our tests annually over a three-year period, none of these relationships obligate any party to order our tests at any agreed volume or frequency, or at all. However, we believe our ability to establish these types of relationships and relationships with other new customers and achieve increased sales to existing customers are significant indicators of the potential for growth of our business.

We believe the key to further penetrating our existing customer base and expanding into new customer markets is to continue to focus on delivering a superior test menu while maintaining affordable prices. In order to offer our customers affordable price points, we continue to enhance our technology platform to develop tests that we can perform at a low internal cost. In addition, we believe an increased focus on sales and marketing will facilitate customer growth. To that end, we plan to invest in our sales and marketing function in the near-term, with the goal of more than doubling the size of our sales and marketing team in the next 12 months.

***Ability to Maintain Our Broad and Flexible Test Menu***

We believe the number of genes that we incorporate into our test menu provides a meaningful competitive advantage. We believe the breadth of genes in our portfolio allows us to provide more comprehensive genetic information and improves our variant detection rate, which can increase the clinical actionability of the data we produce. The breadth of genes in our portfolio also allows us to provide a flexible and customizable test menu for our customers. We believe that our ability to continue to offer more genes than our competitors could be a key contributor to the rate of growth of our business.

***Ability to Maintain Low Costs***

We have developed various proprietary technologies that improve our laboratory efficiency and reduce the costs we incur to perform our tests, including our proprietary gene probes, data algorithms, adaptive learning software and genetic reference library. This technology platform enables us to perform each test and deliver its results at a lower cost to us than many of our competitors, totaling approximately $560 per billable test delivered in the nine months ended September 30, 2016. This low cost per billable test allows us to maintain affordable pricing for our customers, averaging approximately $1,440 per billable test delivered in the nine months ended September 30, 2016, which we believe encourages repeat ordering from existing customers and attracts new customers. We believe this low internal cost is a key contributor to our ability to grow our business and drive profitability.

***Expansion into New Markets***

We intend to continue to expand our test menu to include more options and to cover more genes. For example, we intend to expand our offering of oncology, cardiology, pediatrics and prenatal test panels, which represent large genetic testing markets in which we believe our comprehensive and flexible tests will be competitive. For instance, we recently launched a new chromosomal test called CNV+ that is designed to use NGS technology to detect copy number variants with similar or improved results as compared to microarray-based genomic tests. In addition, we expect to offer somatic testing for certain cancers in the near future. We also believe there is a large potential for growth of genetic testing in many international markets due to the presence of high unmet diagnostic and predictive testing needs, rapidly rising healthcare expenditures and patient awareness of next generation sequencing technologies. We plan to engage distributors or establish other types of arrangements, such as joint ventures, in an effort to expand our presence and test volume in new geographic markets. To this end, we are working with Xi Long USA, Inc., or Xi Long, a stockholder of our company, to form a joint venture in China in which we expect to be a minority partner. Although the terms of this relationship have not yet been finalized and the joint venture has not yet been formed, we anticipate that this joint venture, if it proceeds, could afford us long-term opportunities to further address the genetic testing market in Asia. We believe expanding our test menu and our geographic presence will appeal to a broader base of potential customers and increase our revenue potential.

***Success Obtaining Reimbursement***

In today's market, third-party payors generally restrict the reimbursement of genetic testing to a limited subset of genetic tests and only for those patients that meet specific criteria. This lack of widespread favorable reimbursement policies has presented a challenge for genetic testing companies in building sustainable business models. As part of our strategy for growth, we intend to pursue coverage and reimbursement from third-party payors at a level adequate for us to achieve profitability with this payor group. To this end, in 2016 to date, we have contracted with a regional physician services organization and a national health insurance company to become an in-network provider and enrolled as a supplier with Medicare and approximately ten state Medicaid programs which means that we have agreed with these payors to provide certain of our tests at negotiated rates. Although this does not guarantee that we will receive reimbursement for our tests from these or any other payors at adequate levels, we believe our low cost per billable test will enhance our ability to compete effectively in the third-party payor market and our flexibility in establishing additional relationships with third-party payors. Our level of success in obtaining and maintaining adequate coverage and reimbursement from third-party payors for our testing services will, we believe, be a key factor in the rate of growth of our business over the long term.

***Equity-Based Compensation***

Our predecessor, Fulgent LLC granted an award of fully vested equity to our Chief Financial Officer, Paul Kim, upon his appointment in January 2016. The equity-based compensation expense associated with this award was $1.6 million recorded in full in the period in which the award was granted. As a result, there was a substantial increase in operating expenses in the quarter ended March 31, 2016. We do not intend to make additional awards of fully vested equity and, as a result, we do not expect that we will experience similar levels of stock-based compensation expense in future periods. Equity-based compensation is expected to be recorded over the requisite service period from the grant of restricted stock units as described in the 2016 Omnibus Incentive Plan.

During 2016, Fulgent LLC issued options that were not exercisable, whether or not vested, until the earlier of a liquidity event or an incorporation of Fulgent LLC, each as defined in Fulgent LLC's equity incentive plan under which the awards were granted. An incorporation was deemed to have occurred upon completion of the Reorganization on September 30, 2016, at which time the options became immediately exercisable, to the extent vested. As a result, no expense was recorded for these options prior to their exercisability, and an expense of $1.1 million was recorded for the completion of service related to these options as of the completion of the Reorganization on September 30, 2016. Generally, we record stock-based compensation expense for option awards over the requisite service period. The Company currently does not have any awards subject to performance conditions as of September 30, 2016.

During 2016, Fulgent LLC granted awards of units that constituted profits interests, which are a type of equity award containing a participation threshold (which we sometimes refer to as a "profits interest threshold") that entitled the recipient of the award to participate in the value of Fulgent LLC only to the extent it appreciated from and after the grant date of the award. Pursuant to the determination of the Manager of Fulgent LLC, the participation thresholds applicable to units that constituted profits interests (i) were ignored and not applied in calculating the number of shares of our common stock that were issued in exchange for such units in the Reorganization, and (ii) did not carry over to such shares of our common stock. As a result, the holders of Fulgent LLC's units that constituted profits interests received shares of our common stock in the Reorganization at the same ratio as the holders of Fulgent LLC's units that were not subject to such profits interest thresholds. Ignoring all profits interest thresholds upon the modification of the units that constituted profits interests into shares of our common stock resulted in a stock-based compensation expense of $1.4 million that we recorded in the period of the Reorganization.

***Xi Long Financing***

In May 2016, Fulgent LLC completed a transaction with Xi Long and certain members of Fulgent LLC. In this transaction, (i) Xi Long acquired 4,618,421 Class D-1 preferred units and 5,644,737 Class D common units from certain existing members of Fulgent LLC for an aggregate purchase price of approximately $12.0 million, which units were required to be redeemed by Fulgent LLC in exchange for its issuance to Xi Long of an equivalent number of Class D-2 preferred units, and (ii) Fulgent LLC sold an additional 5,131,579 Class D-2 preferred units to Xi Long for gross proceeds of approximately $15.2 million. Fulgent LLC incurred issuance costs of $185,000 for the transaction, resulting in net proceeds to Fulgent LLC of approximately $15.0 million. As a result of the transaction, Xi Long acquired an aggregate of 15,394,737 Class D-2 preferred units for an aggregate purchase price of approximately $27.2 million, even though, at issuance, the fair value of 15,394,737 Class D-2 preferred units as evidenced by Fulgent LLC's then most recent third-party valuation was approximately $32.6 million. The $5.5 million difference between the fair value of, and the aggregate consideration paid by Xi Long for, the Class D-2 preferred units issued in the transaction was not attributable to any stated rights or privileges. Rather Fulgent LLC, Xi Long and the members of Fulgent LLC that were party to the transaction determined to complete the transaction in line with their discussions, notwithstanding that the fair value of the Class D-2 preferred units as evidenced by Fulgent LLC's third-party valuation had increased from the time these discussions were initiated to the time the transaction was completed. The $5.5 million difference was determined to be a cost of completing the transaction with Xi Long and was recorded as an expense in the nine months ended September 30, 2016 in the accompanying condensed consolidated statement of operations which contributed to our net loss for the period.

**Business Risks and Uncertainties**

Our business and prospects are exposed to numerous risks and uncertainties. For more information, see "Risk Factors" in Part II, Item 1A of this report.

**Discontinued Operations**

Prior to April 4, 2016, Fulgent LLC conducted the following two lines of business: our existing business as described in this report, which Fulgent LLC conducted directly; and our former pharmaceutical business, or the Pharma Business, which was conducted through Fulgent LLC's former subsidiary, Fulgent Pharma LLC, or Fulgent Pharma. Prior to April 4, 2016, all of Fulgent LLC's authorized, issued and outstanding equity interests were separated into two series based on these two lines of business, such that holders of Fulgent LLC's Class D-1 preferred units and Class D voting and non-voting common units had economic rights based on the assets, income, earnings and profits and any liabilities, expenses, costs and charges of our existing business, and holders of Fulgent LLC's Class P preferred units and Class P voting and non-voting common units had economic rights based on the assets, income, earnings and profits and any liabilities, expenses, costs and charges of the Pharma Business. On April 4, 2016, Fulgent LLC separated the Pharma Business from our existing business in a transaction we refer to as the "Pharma Split-Off." To effect the Pharma Split-Off, Fulgent LLC redeemed each member's Class P preferred and common units, distributed to each such member substantially identical units of Fulgent Pharma and caused Fulgent Pharma to assume all then-outstanding options to acquire Class P common units.

The operating results of the Pharma Business have been reported as discontinued operations for all periods presented in the consolidated financial data included in this report. In the three months ended September 30, 2016 and 2015, we recorded an income (loss) from discontinued operations of zero and $(821,000), respectively. In the nine months ended September 30, 2016 and 2015, we recorded an income (loss) from discontinued operations of $41,000 and $(2.1) million, respectively.

**Reorganization**

On September 30, 2016, our predecessor Fulgent LLC became our wholly owned subsidiary upon completion of the Reorganization.

Prior to the Reorganization, among other things:

- Fulgent LLC's authorized, issued and outstanding equity interests, which we refer to as "units," consisted of voting and non-voting common units and two classes (Class D-1 and Class D-2) of preferred units convertible into Class D common units;
- Fulgent LLC's outstanding equity holders are referred to as "members;" and
- Fulgent Inc. did not conduct any activities other than activities incidental to its formation and preparation for our initial public offering.

Upon completion of the Reorganization, among other things:

- each outstanding 7.6 units of Fulgent LLC were cancelled in exchange for one share of our common stock, such that (i) all outstanding Class D common units of Fulgent LLC (including Class D common units that constituted profits interests) were cancelled in exchange for an aggregate of 4,059,900 shares of our common stock, (ii) all outstanding Class D-1 preferred units of Fulgent LLC were cancelled in exchange for an aggregate of 6,760,733 shares of our common stock and (iii) all outstanding Class D-2 preferred units were cancelled in exchange for an aggregate of 2,025,623 shares of our common stock;
- all outstanding options to acquire common units of Fulgent LLC were cancelled in exchange for equivalent options granted under our 2016 Omnibus Incentive Plan, or the 2016 Plan, to acquire up to an aggregate of 591,112 shares of our common stock, and all such options became immediately exercisable to the extent vested; and
- all outstanding restricted share units relating to common units of Fulgent LLC were cancelled in exchange for equivalent restricted stock units granted under the 2016 Plan relating to 65,789 shares of our common stock.

After completion of the Reorganization, we continue to exist as a holding company, with no material assets other than 100% of the equity interests of Fulgent LLC. In addition, we consolidate the financial results of Fulgent LLC, and the historical financial statements of Fulgent LLC are our historical financial statements.

## Financial Overview

### Revenue

We generate revenue from sales of our genetic tests. We recognize revenue upon delivery of a report to the ordering physician based on the established billing rate less contractual and other adjustments to arrive at the amount that we expect to collect. We generally bill directly to a hospital, medical institution or research institution customer or to a patient, a third-party payor or a combination of the patient and third-party payor.

### Cost of Revenue

Cost of revenue reflects the aggregate costs incurred in delivering test results and consists of: personnel costs, including salaries, employee benefit costs, bonuses and equity-based compensation expenses; costs of laboratory supplies; depreciation of laboratory equipment; amortization of leasehold improvements and allocated overhead, including rent and utilities. Costs associated with performing tests are recorded as tests are processed. We expect cost of revenue to generally increase as we increase the number of tests we deliver.

### Operating Expenses

Our operating expenses are classified into the following three categories: research and development; selling and marketing; and general and administrative. For each category, the largest component is personnel costs, which include salaries, employee benefit costs, bonuses and equity-based compensation expenses.

#### *Research and Development Expenses*

Research and development expenses represent costs incurred to develop our technology and future tests. These costs consist of personnel costs, laboratory supplies, consulting costs and allocated overhead, including rent and utilities. We expense all research and development costs in the periods in which they are incurred. We expect our research and development expenses will increase in absolute dollars in future periods as we continue to invest in research and development.

#### *Selling and Marketing Expenses*

Selling and marketing expenses consist of personnel costs, customer service expenses, direct marketing expenses, educational and promotional expenses, market research and analysis and allocated overhead, including rent and utilities. We expense all selling and marketing costs as incurred. We expect our selling and marketing costs will continue to increase in absolute dollars, primarily driven by our efforts to expand our sales and marketing team, increase our presence within and outside the United States and expand our brand awareness and customer base through targeted marketing initiatives.

#### *General and Administrative Expenses*

General and administrative expenses include executive, finance and accounting, legal and human resources functions. These expenses consist of personnel costs, audit and legal expenses, consulting costs and allocated overhead, including rent and utilities. We expense all general and administrative expenses as incurred. We expect our general and administrative expenses will increase as we scale our operations. We also expect to incur additional general and administrative expenses as a result of our initial public offering and operating as a public company, including expenses related to compliance with the rules and regulations of the Securities and Exchange Commission and the NASDAQ Stock Market, additional insurance expenses, investor relations activities and other administration and professional services.

### Provision for (Benefit from) Income Taxes

Provision for income taxes consists of U.S. federal and state income taxes. To date, we have no significant U.S. federal and state income taxes because of the status of our predecessor, Fulgent LLC, as a pass through entity for tax purposes prior to September 30, 2016.

We record a valuation allowance when it is more likely than not that some portion or all of a deferred tax asset will not be realized. In making such a determination, we consider all the available positive and negative evidence, including future reversals of existing taxable temporary differences, projected future taxable income, and ongoing prudent and feasible tax planning strategies, to assess the amount of the valuation allowance. When we establish or reduce the valuation allowance against the deferred tax assets, our provision for income taxes will increase or decrease, respectively, in the period in which such a determination is made.

## Results of Operations

### Comparison of Three Months Ended September 30, 2015 and 2016

The following table summarizes the results of our continuing operations for each of the periods indicated:

| (In thousands) | Three Months Ended September 30, | | | |
|---|---|---|---|---|
| | 2016 | 2015 | Dollar change | % Change |
| Revenue | $ 5,011 | $ 2,905 | $ 2,106 | 72% |
| Cost of revenue | 2,143 | 918 | 1,225 | 133% |
| Gross profit | 2,868 | 1,987 | 881 | 44% |
| Operating expenses: | | | | |
| Research and development | 1,523 | 311 | 1,212 | 390% |
| Selling and marketing | 893 | 280 | 613 | 219% |
| General and administrative | 1,147 | 216 | 931 | 431% |
| Total operating expenses | 3,563 | 807 | 2,756 | 342% |
| Operating income (loss) | (695) | 1,180 | (1,875) | (159)% |
| Interest and other income (expense) | 5 | — | 5 | * |
| Income (loss) before income taxes | (690) | 1,180 | (1,870) | (158)% |
| Provision for income taxes | 417 | — | 417 | * |
| Income (loss) from continuing operations | (1,107) | 1,180 | (2,287) | (194)% |
| **Other Operating Data:** | | | | |
| Billable tests | 3,419 | 2,052 | | 67% |

* Percentage not meaningful.

**Revenue**

Revenue increased $2.1 million, or 72%, from the three months ended September 30, 2015 to the three months ended September 30, 2016, primarily due to the increased number of billable tests delivered. The number of billable tests delivered increased from 2,052 in the three months ended September 30, 2015 to 3,419 in the same period in 2016. The increase in the number of billable tests delivered that positively impacted our revenue between periods was primarily attributable to the expansion of our test menu, including single-gene tests and multi-gene panels, and an increase in sales to our existing customers, combined with growth in the genetic testing market and increased physician awareness and acceptance of genetic tests. The average price of the billable tests we delivered remained relatively consistent between periods, but increased slightly from $1,420 in the three months ended September 30, 2015 to $1,470 in the three months ended September 30, 2016, largely due to our ability to offer more complex and customized tests. Revenue from non-U.S. and Canadian customers accounted for 38% and 19% of total revenue in the three months ended September 30, 2016 and 2015, respectively.

**Cost of Revenue**

Cost of revenue increased $1.2 million, or 133%, from the three months ended September 30, 2015 to the three months ended September 30, 2016. The increase was primarily due to increases of $586,000 in equity-based compensation, $251,000 in personnel costs related to increased headcount, $237,000 in reagents and supplies expenses, and $99,000 in depreciation. Our gross profit increased $881,000 between periods, primarily due to increased revenue, and our cost of revenue as a percent of revenue, or gross margin, decreased from 68% to 57% between periods, primarily due to the effects of equity-based compensation expense.

**Research and Development**

Research and development expenses increased $1.2 million, or 390%, from the three months ended September 30, 2015 to the three months ended September 30, 2016, primarily due to increases of $959,000 in equity-based compensation expense, $97,000 in reagents and supplies expenses, $77,000 in personnel costs related to increased headcount.

**Selling and Marketing**

Selling and marketing expenses increased $613,000, or 219%, from the three months ended September 30, 2015 to the three months ended September 30, 2016, primarily due to increases of $396,000 in equity-based compensation expense, $95,000 in consulting fees and $45,000 in travel expenses.

**General and Administrative**

General and administrative expenses increased $931,000, or 431%, from the three months ended September 30, 2015 to the three months ended September 30, 2016, primarily due to increases of $552,000 in equity-based compensation expense, $209,000 in accounting fees and $178,000 in personnel costs related to increased headcount.

**Provision for Income Taxes**

Provision for income taxes increased $417,000 from the three months ended September 30, 2015 to the three months ended September 30, 2016, primarily due to the conversion of the Company from a pass- through entity to a taxable entity. Prior to the Reorganization, Fulgent LLC was organized as a limited liability company and its members elected to have Fulgent LLC treated as a partnership for income tax purposes. All taxable income or loss and tax credits generally were reflected in the personal income tax returns of the Fulgent LLC's members. Accordingly, no provision for federal and state income taxes was provided in the accompanying consolidated financial statements prior to the Reorganization. Pursuant to the Reorganization, the Company is a taxable entity. The change in tax status resulted in the recognition of a deferred tax asset in the amount of $86,000 and a deferred tax liability in the amount of $503,000 representing the initial temporary differences at the time of the change in status. The most significant components of the deferred tax asset and liability were the result of differences in book and tax depreciation and equity-based compensation.

**Comparison of Nine Months Ended September 30, 2015 and 2016**

The following table summarizes the results of our continuing operations for each of the periods indicated:

| (In thousands) | Nine Months Ended September 30, | | | |
|---|---|---|---|---|
| | 2016 | 2015 | Dollar change | % Change |
| Revenue | $ 12,422 | $ 6,675 | $ 5,747 | 86% |
| Cost of revenue | 4,858 | 2,343 | 2,515 | 107% |
| Gross profit | 7,564 | 4,332 | 3,232 | 75% |
| Operating expenses: | | | | |
| Research and development | 2,739 | 782 | 1,957 | 250% |
| Selling and marketing | 1,671 | 757 | 914 | 121% |
| General and administrative | 3,494 | 461 | 3,033 | 658% |
| Total operating expenses | 7,904 | 2,000 | 5,904 | 295% |
| Operating income (loss) | (340) | 2,332 | (2,672) | (115)% |
| Interest and other income (expense) | (5,444) | 20 | (5,464) | * |
| Income (loss) before income taxes | (5,784) | 2,352 | (8,136) | (346)% |
| Provision for income taxes | 417 | — | 417 | * |
| Income (loss) from continuing operations | (6,201) | 2,352 | (8,553) | (364)% |
| **Other Operating Data:** | | | | |
| Billable tests | 8,628 | 4,814 | | 79% |

* Percentage not meaningful.

**Revenue**

Revenue increased $5.7 million, or 86%, from the nine months ended September 30, 2015 to the nine months ended September 30, 2016, primarily due to the increased number of billable tests delivered. The number of billable tests delivered increased from 4,814 in the nine months ended September 30, 2015 to 8,628 in the same period in 2016. The increase in the number of billable tests delivered that positively impacted our revenue was primarily attributable to the expansion of our test menu, including single-gene tests and multi-gene panels, and an increase in sales to our existing customers, combined with growth in the genetic testing market and increased physician awareness and acceptance of genetic tests. The average price of the billable tests we delivered remained relatively consistent between periods, but increased slightly from $1,400 in the nine months ended September 30, 2015 to $1,440 in the nine months ended September 30, 2016. Revenue from non-U.S. and Canadian customers accounted for 28% and 15% of total revenue in the nine months ended September 30, 2016 and 2015, respectively.

**Cost of Revenue**

Cost of revenue increased $2.5 million, or 107%, from the nine months ended September 30, 2015 to the nine months ended September 30, 2016. The increase was primarily due to increases of $777,000 in reagents and supplies expenses, $709,000 in personnel costs related to increased headcount, $586,000 in equity-based compensation, and $430,000 of facility and depreciation costs. Our gross profit increased $3.2 million between periods, primarily due to increased revenue, and our gross margin decreased from 65% to 61% between periods, primarily due to the effects of equity-based compensation expense.

**Research and Development**

Research and development expenses increased $2.0 million, or 250%, from the nine months ended September 30, 2015 to the nine months ended September 30, 2016, primarily due to increases of $959,000 increase equity-based compensation expense, $525,000 in personnel costs related to increased headcount, and $267,000 in reagents and supplies expenses.

**Selling and Marketing**

Selling and marketing expenses increased $914,000, or 121%, from the nine months ended September 30, 2015 to the nine months ended September 30, 2016, primarily due to increases of $396,000 in equity-compensation expense, $143,000 in travel expenses, $125,000 in personnel costs related to increased headcount, and $97,000 in consulting fees.

**General and Administrative**

General and administrative expenses increased $3 million, or 658%, from the nine months ended September 30, 2015 to the nine months ended September 30, 2016, primarily due to increases of $2.2 million in equity-based compensation expense, a $399,000 in personnel costs related to increased headcount and $384,000 in accounting fees.

**Interest and Other Income (Expense)**

Interest and other income (expense) was $(5.4) million for the nine months ended September 30, 2016, compared to income of $20,000 for the nine months ended September 30, 2015. The expense in the 2016 period related to the difference between the fair value and the effective issuance price of the Class D-2 preferred units we issued in the Xi Long financing in May 2016, which was determined to be a cost of completing the transaction with Xi Long and was recorded as an expense in the accompanying condensed consolidated statement of operations. Interest income was not significant in either the nine months ended September 30, 2016 or 2015.

**Provision for Income Taxes**

Provision for income taxes increased $417,000 from the nine months ended September 30, 2015 to the nine months ended September 30, 2016, primarily due to the conversion of the Company from a pass through entity to a taxable entity. Prior to the Reorganization, Fulgent LLC was organized as a limited liability company and its members elected to have Fulgent LLC treated as a partnership for income tax purposes. All taxable income or loss and tax credits generally were reflected in the personal income tax returns of the Fulgent LLC's members. Accordingly, no provision for federal and state income taxes was provided in the accompanying consolidated financial statements prior to the Reorganization. Pursuant to the Reorganization, the Company is a taxable entity. The change in tax status resulted in the recognition of a deferred tax asset in the amount of $86,000 and a deferred tax liability in the amount of $503,000 representing the initial temporary differences at the time of the change in status. The most significant components of the deferred tax asset and deferred tax liability were the result of differences in book and tax depreciation and equity-based compensation.

## Liquidity and Capital Resources

### Liquidity and Sources of Cash

As of September 30, 2016 and December 31, 2015, we had $8.2 million and $0.5 million of cash, respectively.

Since inception, our operations have been financed primarily by our founder, Ming Hsieh, and, in recent periods, by cash from our operations and equity financings. In May 2016, we closed the Xi Long financing for net proceeds to us of approximately $15.0 million, and in October 2016, we closed the initial public offering of our common stock, in which we issued an aggregate of 4,830,000 shares of our common stock and received net proceeds of approximately $36.3 million, after deducting underwriting discounts and commissions and offering expenses paid or payable by us.

Our primary uses of cash are to fund our operations as we continue to grow and invest in our business. Cash used to fund operating expenses is impacted by the timing of our payment of expenses, as reflected in the changes in our outstanding accounts payable and accrued expenses. In addition, in September 2016, we distributed $4.6 million to Mr. Hsieh in his capacity as a member of Fulgent LLC as a return of capital contribution, and in the fourth quarter of 2016, we expect to pay approximately $1.3 million in tax distributions to the former members of Fulgent LLC based on the income tax liabilities of such former members attributable to Fulgent LLC's 2016 net taxable income through the date of the Reorganization.

We believe that our existing cash, along with cash from our operations and proceeds from offering, will be sufficient to meet our anticipated cash requirements for at least the next 12 months. Much of the losses we incurred during the nine months ended September 30, 2016 are attributable to non-cash charges for equity-based compensation expense, as well as for other expense associated with the difference between the fair value and the effective issuance price of the units we issued to Xi Long in May 2016. Thus, in spite of the losses we recorded, cash provided by continuing operations has been positive since 2015 and has significantly contributed to our ability to meet our liquidity needs, including our ability to pay capital expenditures. Additionally, if our business continues to grow as we anticipate and we are able to achieve increased efficiencies and economies of scale in line with this growth, we expect that increased revenue will 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. As a result, we anticipate that cash from our operations will play a meaningful role in our ability to meet our liquidity requirements and pursue our business plan and strategies in the next 12 months and in the longer term.

However, our expectations regarding the cash to be provided by our operations and our cash needs in future periods could 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. Further, even if our liquidity expectations are correct, 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 equity securities 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 debt securities issued or borrowings, if available, could impose significant restrictions on our operations, such as limitations on our ability to incur additional debt or issue additional equity, limitations on our ability to acquire or license intellectual property rights and other operating restrictions that could adversely affect our ability to conduct our business, and would result in increased fixed payment obligations. In the event that 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 costs. If we are not able to secure additional funding 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 of these tests, programs or initiatives to our company. Any such outcome could significantly harm our business, performance and prospects.

**Cash Flows**

***Continuing Operations***

The following table summarizes cash flows from continuing operations for each of the periods indicated:

| | Nine Months Ended September 30, | |
|---|---|---|
| | 2016 | 2015 |
| | (in thousands) | |
| Cash provided by operating activities | $ 3,182 | $ 1,645 |
| Cash used in investing activities | (3,379) | (1,805) |

*Operating Activities*

Cash provided by operating activities in the nine months ended September 30, 2016 was $3.2 million. The difference between net loss and cash provided by operating activities for the period was primarily due to the effect of a $5.5 million of non-cash charge associated with the difference between the fair value and the effective issuance price of the units we issued to Xi Long, which was recorded as other expense, and the effect of $4 million of non-cash equity-based compensation charges. Cash provided by operating activities increased between periods primarily due to a $1.3 million increase in accounts payable and accrued liabilities, which resulted from increased revenue and purchases, offset by the negative effect of $2.3 million increase in accounts receivable from increased revenue. Cash provided by operating activities in the nine months ended September 30, 2015 was $1.6 million. The difference between net loss and cash provided by operating activities for the period was primarily due to $2.4 million of income from continuing operations, a $0.4 million increase in accounts payable, which resulted from increased revenue and purchases, offset by the negative effect of $1.3 million increase in accounts receivable from increased revenue.

*Investing Activities*

Cash used in investing activities in the nine months ended September 30, 2016 was $3.4 million, which was primarily related to purchases of fixed assets consisting mainly of medical laboratory equipment, computer hardware, software and leasehold improvements. Cash used in investing activities in the nine months ended September 30, 2015 was $1.8 million, which was primarily related to purchases of fixed assets consisting mainly of computer hardware and medical laboratory equipment.

*Discontinued Operations*

The following table summarizes cash flows from discontinued operations for each of the periods indicated:

| | Nine Months Ended September 30, | |
|---|---|---|
| | 2016 | 2015 |
| | (in thousands) | |
| Cash used in operating activities | $ (31) | $ (2,079) |
| Cash used in investing activities | — | (125) |

*Financing Activities*

Cash provided by financing activities in the nine months ended September 30, 2016 was $7.9 million, compared to cash provided by financing activities in the nine months ended September 30, 2015 of $3.5 million. All cash provided by financing activities in the nine months ended September 30, 2015 represents capital contributions received from Mr. Hsieh, and all cash provided by financing activities in the nine months ended September 30, 2016 represents net proceeds of approximately $15.0 million received from the issuance of Class D-2 preferred units to Xi Long, partially offset by $4.6 million return of capital contribution to Mr. Hsieh and $2.3 million of costs related to our initial public offering completed in October 2016.

### Critical Accounting Policies and Use of Estimates

The preparation of financial statements in accordance with generally accepted accounting principles in the United States of America, or U.S. GAAP, requires us to make a variety of decisions which affect reported amounts and related disclosures, including the selection of appropriate accounting principles and the assumptions on which to base accounting estimates. In reaching such decisions, we apply judgment based on our understanding and analysis of the relevant circumstances, including our historical experience and other assumptions. 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 the financial statements.

There have been no significant changes in the critical accounting policies and estimates as previously described in our Prospectus.

### Recent Accounting Pronouncements

The Jumpstart Our Business Startups Act of 2012, or the JOBS Act, permits an "emerging growth company" such as us to take advantage of an extended transition period for complying with new or revised accounting standards applicable to public companies. Thus, an emerging growth company can delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have irrevocably elected not to avail ourselves of this extended transition period and, as a result, we will be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies. See Note 2 to the condensed consolidated financial statements included in this report for a description of recent accounting pronouncements of new or revised accounting standards.

### 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 Securities and Exchange Commission, 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.

### Contractual Obligations and Other Commitments

There were no material changes in our commitments under contractual obligations, as disclosed in the Company's audited consolidated financial statements for the year ended December 31, 2015.

Our principal commitments consist of obligations under our operating leases for office space.

## Item 3. Quantitative and Qualitative Disclosures About Market Risk.

We are exposed to various market risks in the ordinary course of our business. We had cash of $8.2 million as of September 30, 2016, which consists of bank deposits. Such interest-bearing instruments carry a degree of risk; however, we have not been exposed to, nor do we anticipate being exposed to, material risks due to changes in interest rates. A hypothetical 10% change in interest rates during any of the periods presented in this report would not have had a material impact on our financial results.

Revenue from sales outside of the United States represented 49% of our revenue in the nine months ended September 30, 2016. Currently, our revenue-producing transactions are primarily denominated in U.S. dollars; however, as we continue to expand internationally, our results of operations and cash flows may increasingly become subject to fluctuations due to changes in foreign currency exchange rates. In periods when the U.S. dollar declines in value as compared to foreign currencies in which we incur expenses, our foreign-currency based expenses will increase when translated into U.S. dollars. In addition, future fluctuations in the value of the U.S. dollar may affect the price at which we sell our tests outside the United States. To date, our foreign currency risk has been minimal and we have not historically hedged our foreign currency risk, although we may consider doing so in the future.

**Item 4. Controls and Procedures.**

**Evaluation of Disclosure Controls and Procedures**

As required by Rule 13a-15(b) under the Securities Exchange Act of 1934, as amended, or Exchange Act, our management, under the supervision and with the participation of our Chief Executive Officer and Chief Financial Officer, has evaluated the effectiveness of the design and operation of our disclosure controls and procedures as of September 30, 2016. 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 rules and forms of the Securities and Exchange Commission, or the SEC. 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, as appropriate, to allow timely decisions regarding required disclosure. Based on the evaluation of our disclosure controls and procedures as of September 30, 2016, our Chief Executive Officer and Chief Financial Officer have concluded that, as of September 30, 2016, our disclosure controls and procedures were effective.

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.

**Changes in Internal Control over Financial Reporting**

There has been no change in our internal control over financial reporting during the quarter ended September 30, 2016, that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

## 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 currently subject, to any legal proceedings that, in the opinion of management, would have a material adverse 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. 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 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 analysis of 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 to maintain our competitive advantage. Our future success will depend 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 technological 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.

**We are an early-stage company with a limited operating history, which may 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 revenue growth may not continue or increase, we may not achieve profitability and, if we achieve profitability, we may not be able to sustain it. Our limited operating history makes it difficult to evaluate our current business and inhibits our ability to forecast our future operating results, including revenue, cash flows and movement toward profitability. For example, our gross profit during the last three months of 2015 was less than our gross profit in the preceding and subsequent four months. Our limited operating history makes it difficult to determine if these fluctuations reflect seasonality in our performance or are the result of other events. 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 other uncertainties described in this report. If our assumptions regarding these risks and uncertainties are incorrect or these risks and uncertainties change due to changes 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.

**We have a history of losses, and we may never be able to achieve or sustain profitability.**

We have a history of losses. For the year ended December 31, 2015 and the nine months ended September 30, 2016, we recorded a loss from continuing operations of $5.0 million and $6.2 million, respectively. To date, we have generated limited revenue, and we may never achieve revenue sufficient to offset our expenses and achieve or sustain profitability. In addition, we may continue to incur losses in the future, particularly as we focus on growing our business and operations and experience expected increases in expenses related to this growth. Our prior losses and any future losses have had and will continue to have an adverse effect on our stockholders' equity and working capital. Our failure to achieve and sustain profitability in the future 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.

**If we are not able to grow our customer base and increase demand for our tests from existing and new customers, our commercial success would be limited.**

To achieve our anticipated 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. For example, in 2016 to date, we have made efforts to diversify our customer base by establishing a vendor code with a national clinical laboratory that orders our tests to fulfill some of the genetic testing orders it receives from certain U.S. government agencies, contracting with a regional hospital network within the U.S. Army to provide genetic tests for members and their families, and contracting with a healthcare services provider in the prenatal sector to provide proprietary carrier screening tests that we developed for this service provider. We have also pursued relationships with payors, including Medicare, some state Medicaid programs and third-party payors, in order to obtain coverage and reimbursement for our tests to make them accessible to more individual physicians. Establishing these relationships means that we have agreed with the applicable payor, laboratory or other customer to provide certain of our tests at negotiated rates, but, except for our relationship with the hospital network within the U.S. Army, which involves a minimum commitment of approximately $400,000 of our tests annually over a three-year period, none of these relationships obligate any party to order our tests at any agreed volume or frequency, or at all. As a result, these relationships, or any similar relationships we may establish in the future, may not amount to meaningful increases in our customer base, the number of billable tests we deliver or our total revenue, or improve our ability to achieve profitability. We may not succeed in facilitating the clinical acceptance and adoption of our tests needed to achieve the increased volumes and customer growth we expect. Because detailed genetic data from tests such as ours have only recently become available at relatively affordable prices, the pace and degree of market acceptance and adoption of these tests is uncertain.

We may fail to expand our customer base and grow our volume of tests delivered 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, such as individual physicians, other practitioners and research institutions, of the utility of our tests and their potential advantages over existing and new alternatives;
- our efforts to increase our sales force and expand our marketing efforts may fail;
- we may be unsuccessful in demonstrating 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 within our industry could raise doubts about the legitimacy of diagnostics 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 at the same or a lower price than ours.

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 anticipated growth in billable tests and our results of operations would be adversely impacted.

**We face intense competition, which is likely to intensify further as existing competitors devote additional resources to, and new participants enter, the market, and if we cannot compete successfully, we may be unable to increase our revenue or achieve or grow profitability.**

With the development of NGS, the clinical genetic testing market has become increasingly competitive, and we expect this competition to further intensify in the future. We face competition from a variety of sources, including, among others:

- dozens of companies focused on molecular genetic testing services, including specialty and reference laboratories that offer traditional single-gene and multi-gene tests, such as Ambry Genetics, Inc.; Counsyl Inc.; Foundation Medicine, Inc.; GeneDx, a subsidiary of OPKO Health, Inc.; Invitae Corporation; Myriad Genetics, Inc.; and Pathway Genomics Corporation, as well as other commercial and academic laboratories; and
- established and emerging healthcare, information technology and service companies that may develop and sell competitive tests, which may include informatics, analysis, integrated genetic tools and services for health and wellness.

Additionally, participants in closely related markets, such as prenatal testing and clinical trial or companion diagnostic testing, could converge on offerings that are competitive with the type of tests we perform. Instances where potential competitors are aligned with key suppliers or are themselves suppliers could provide such 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, greater brand recognition and 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, devote greater resources to the development, promotion and sale of their tests, devote more resources to and obtain more favorable results from third-party payors regarding coverage and reimbursement for their offerings, adopt more aggressive pricing policies for their tests, secure supplies from vendors on more favorable terms or devote substantially more resources to infrastructure and systems development. 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 pricing pressures, which could harm our sales or ability to gain market share and achieve 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 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, we may be unable to increase market acceptance and sales volume of our tests, which could prevent us from increasing our revenue or achieving or growing profitability.

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

To increase the volume of tests that 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, in the near term. We will also need to invest in 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 only one such laboratory director with all of the required licenses, Dr. Han Lin Gao, who conducts this review and approval for each test we deliver. We are in the process of licensing additional laboratory directors to assist Dr. Gao, and we may need to hire more laboratory directors in the future to further scale our business. If we fail to hire additional qualified personnel 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 as our volumes increase, and any need to obtain an additional facility or replace our existing facility with a larger one would involve significant challenges.

The time and resources required to implement new systems, to add and train additional skilled personnel and to acquire or expand 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 we may not be able to do.

**We have limited experience marketing and selling our tests and our commercial success will depend in part upon our ability to grow our sales and marketing team and generate sales using this relatively small internal and developing team.**

We have limited experience marketing and selling our tests, which we began selling in 2013. We may not be able to market or sell our existing tests or any future tests we may develop in order to drive demand sufficient to support our planned growth. We currently sell our tests in the United States through a small internal sales force and outside the United States through one internal sales person and we have historically relied significantly on organic growth and word-of-mouth among our customers to generate interest in our tests. Our ability to maintain and grow sales volume in the future will depend in large part upon our ability to develop and substantially expand our sales team and to increase the scope of our marketing efforts. We intend to aggressively build our sales and marketing team in the near term in order to pursue expansion of our customer base and growth in the volume of tests ordered, with the goal of more than doubling the size of our sales and marketing team in the next 12 months. This expansion will involve significant time and expense. Additionally, we may not be able to attract and hire the qualified personnel we need to grow our sales and marketing team as quickly as we intend for various reasons, including intense competition in our industry for qualified personnel. Even if we are able to further develop our sales and marketing team, we have limited experience managing a sales and marketing team and it may not be successful in growing our customer base or increasing penetration into our existing customers.

In addition, our future sales will depend in large part upon our ability to expand our brand awareness, laterally grow our customer base and vertically penetrate our relationships with existing customers by educating the medical community, including existing and potential future customers, about the benefits and the full scale of our offering. We also intend to obtain publication of scientific and medical results in peer-reviewed journals and make presentations at leading industry conferences. We have limited experience with this type of activity and we may not be successful in implementing these initiatives. If we are not able to drive sufficient levels of revenue using our sales and marketing strategies to support our planned growth, our business and results of operations would be negatively affected. 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 as a result of such designation.

We also intend to increase our focus on growing our international sales and customer base. Outside the United States, we use and intend to continue to use one internal sales person, and we may also engage distributors or establish other types of arrangements, such as joint ventures, to assist with sales, logistics, education and customer support in the future. To this end, we are working with Xi Long USA, Inc., or Xi Long, a stockholder of our company, to form a joint venture in China in which we expect to be a minority partner. We anticipate that this joint venture, if it proceeds, could expand our long-term opportunities to address the genetic testing market in Asia; however, the terms of this relationship have not yet been finalized and no joint venture has been formed, and we may never be successful in forming this joint venture or realizing any of the benefits we anticipate from the joint venture. We believe identifying, qualifying and engaging distributors or other partners with local industry experience and knowledge will be necessary to effectively market and sell our tests outside the United States. We may not be successful in finding, attracting and retaining qualified distributors or other partners or we may not be able to enter into arrangements covering desired territories on favorable terms. Sales practices utilized by distributors or other 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 are not successful outside the United States, we may not achieve significant market acceptance for our tests in international markets, which could materially and adversely impact our business operations.

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

Our business depends upon 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 those 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, a substantial amount of 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. A product liability or professional liability 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. 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. Additionally, 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.

**Our ability to achieve profitability depends upon our ability to collect payment for the tests we deliver to hospitals and medical institutions, which we may not be able to do successfully.**

We are currently, and since our inception have been, focused on providing our tests to hospitals and medical institutions. These customers are typically able to 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 perform is subject to a number of risks, many of which are not within our control, including risks of 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 was decreased, these customers may slow, or stop altogether, their purchasing of our tests.

**If third-party payors do not provide coverage and adequate reimbursement for our tests, our commercial success 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 success is dependent upon 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 our 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 delay in or decreased likelihood of our collection of 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 upon our success in achieving 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 a test, and seeking a determination by a payor to cover our tests and the amount it will reimburse for our tests would likely be made on an indication-by-indication basis. 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. As a result, 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 with a regional physician services organization and a national health insurance company to become an in-network provider. We have also enrolled as a supplier in the Medicare program and in approximately nine state Medicaid programs, but we have not obtained any coverage, pricing or reimbursement approvals from payors in any countries outside of the United States. 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 to order our tests or guarantee that we will receive reimbursement for our tests from these or any other payors at adequate levels. Thus, these payor relationships, or any similar relationships we may establish in the future, may not result in acceptable levels of reimbursement for our tests or meaningful 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. We believe it may take several years to achieve coverage and adequate contracted reimbursement with third-party payors. However, we cannot predict whether, under what circumstances, or at what payment levels payors will cover and reimburse for our tests. If we fail to establish and maintain broad coverage and reimbursement for our tests, our ability to generate increased revenue and grow our test volume and customer base could be limited and our future prospects and our business could suffer.

**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 is inoperable for even a short period of time could result in the loss of customers or harm to our reputation. Although we maintain insurance for damage to our property and the 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 locate additional laboratory space as our business grows, 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 partners seek to procure laboratory space outside the United States as we seek to expand our international operations. If we are unable to obtain or are delayed in obtaining new laboratory space as needed, we may not be able to provide existing tests or develop and launch new tests, which could result in harm to our business, reputation, financial condition and results of operations.

**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 lead patients to refuse to use or physicians to be reluctant to order genetic tests, 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, either of which could have an adverse effect on our business, financial condition and results of operations.

**We rely on a limited number of suppliers and, in some cases, a sole supplier, for some of our laboratory instruments and materials and we may not be able to find replacements or immediately transition to alternative suppliers if necessary.**

We rely on a limited number of suppliers, or, in the case of Illumina, Inc., a sole supplier, for certain laboratory substances used in the chemical reactions incorporated into our processes, which we refer to as reagents, as well as for the sequencers and various other equipment and materials that we use in our laboratory operations. 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 or fail to provide us with sufficient quantities of materials that meet our specifications. Our laboratory operations would be interrupted if we encounter delays or difficulties in securing these reagents, sequencers or other equipment or materials or if we need a substitute for any of our suppliers and are not able to locate and make arrangements with an acceptable substitute. Any such interruption could significantly affect our business, financial condition, results of operations and reputation. We rely on Illumina as the sole supplier of the next generation sequencers and associated reagents we use to perform our genetic tests and as the sole provider of maintenance and repair services for these sequencers. Any disruption in Illumina's operations could impact our supply chain and laboratory operations as well as our ability to conduct our tests.

We believe there are only a few other manufacturers that are currently capable of supplying and servicing the equipment necessary for our laboratory operations, including sequencers and various associated reagents. Transitioning to a new supplier 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. In the case of obtaining an alternative supplier for Illumina, replacement sequencers and associated reagents 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 in securing, reconfiguring or revalidating the equipment and reagents we require for our tests, our business, financial condition, results of operations and reputation would be adversely affected.

**We plan to rely on a third-party for certain portions of our billing and collection processing, which is complex and time-consuming, and any delay in transmitting and collecting claims could have an adverse effect on our future revenue.**

We have engaged a third-party service provider for certain claims processing, billing and collection functions. Billing for our tests is complex, time-consuming and expensive. Depending on the billing arrangement and applicable law, we plan to bill various payors, 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, 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.

Even though we have engaged a third party to assist with some of these billing and collections functions, we will still need to make significant efforts and expend significant resources to develop systems and procedures to handle these aspects of our business, which will become increasingly important as we focus on 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 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, it could have an adverse effect on our revenue and our business.

**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, many of which are based in Canada. Approximately $6.1 million and $3.2 million of our revenue came from non-U.S. customers in the nine months ended September 30, 2016 and 2015, respectively, and of this, approximately $2.7 million and $2.2 million in the respective periods came from customers located in Canada. Our business strategy includes plans to increase this volume in the near term, from customers in Canada and other geographic markets, including potentially Asia and Europe. To this end, we have started to receive revenues from tests ordered by customers in China and we are pursuing a joint venture relationship with Xi Long in order to further pursue our opportunities in this market, although this relationship has not yet been, and may never be, finalized or successful. We may also enter into new geographic markets and increase our presence in existing foreign markets by engaging distributors or joining with other partners to conduct physician outreach activities and develop and expand payor relationships outside of the United States.

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

- multiple, conflicting and evolving laws and regulations, such as privacy regulations, tax laws, employment laws, regulatory requirements and other government approvals, permits and licenses;
- logistics and regulations associated with shipping blood or other tissue specimens, including export and import restrictions, infrastructure conditions and transportation delays;
- limits on our ability to penetrate international markets if we do not conduct our tests locally, including local legal and regulatory requirements that would force us to build additional laboratories or engage in joint ventures or other business partnerships in order to offer our tests in certain countries;
- failure by us or any distributors or other partners we may engage in the future to obtain regulatory approvals for the use of our tests in various countries;
- complexities and difficulties in obtaining protection for and enforcing our intellectual property;
- 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, the impact of local and regional financial conditions on demand and payment for our tests and exposure to foreign currency exchange rate fluctuations;

- natural disasters, political and economic instability, including wars, terrorism, and political unrest, outbreak of disease, boycotts, curtailment of trade and other business restrictions; and
- regulatory and compliance risks that relate to prohibiting bribery and maintaining accurate information and control over activities that may fall within the purview of the anti-bribery provisions of the U.S. Foreign Corrupt Practices Act, or FCPA, or the United Kingdom's Bribery Act of 2010.

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.

**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 upon our ability to continue to expand our test offering and develop and sell new tests. For instance, we recently launched a new chromosomal test called CNV+ that is designed to use NGS technology to detect copy number variants with similar or improved results as compared to microarray-based genomic tests. We expect these tests will target customers that are already using microarray-based testing; however, these tests may not be accepted as a replacement for microarray-based tests and they may not be adopted by these customers or at all. In addition, we expect to offer somatic testing for certain cancers in the near future. We may not be successful in launching or marketing these or any other new tests we may develop or, 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 and further develop and 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 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 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 and sell new tests could negatively impact our ability to attract and retain customers and our revenue and prospects.

**Actual or attempted security breaches, loss of data and 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 and a third-party billing and collections provider that we have engaged generate, collect and store sensitive data, including protected health information, or PHI, personally identifiable information, intellectual property and proprietary information and other business-critical information, such as research and development data, commercial information and 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, inappropriate disclosure, unauthorized modification and inability to adequately implement protective controls.

The secure processing, storage, maintenance and transmission of this critical 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 designed to protect sensitive information from unauthorized access, use or disclosure, our information technology and infrastructure and that of our third-party billing and collections provider 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 and state 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 business, any of which could 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 upon the skills, experience and performance of our executive management team and others in key leadership positions, especially Ming Hsieh, our founder and Chief Executive Officer, and Dr. Gao, our Chief Scientific Officer and Lab 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 delivering 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 that 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 a long-term retention agreement 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 effectively.**

Our performance, including our research and development programs and laboratory operations, largely depends upon 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 plan due to high levels of competition for these personnel among our competitors, other life science businesses, universities and public and private research institutions. In addition, our compensation arrangements may not be successful in attracting new employees and retaining and motivating our existing employees. If we are not able to attract and retain the necessary personnel to accomplish our business objectives, we may experience constraints that could adversely affect our ability to expand our business and support our clinical laboratory operations and our sales and marketing and research and development efforts, which would negatively affect our prospects for future growth and success.

**Our inability to obtain additional capital in the future 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 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 equity securities 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 debt securities issued or borrowings, if available, could impose significant restrictions on our operations, such as limitations on our ability to incur additional debt or issue additional equity, limitations on our ability to acquire or license intellectual property rights and other operating restrictions that could adversely affect our ability to conduct our business, and would result in increased fixed payment obligations. In the event that 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 costs. If we are not able to secure additional funding 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 of these tests, programs or initiatives to our company. 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 that 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 strategic relationships, including partnerships with pharmaceutical companies to further develop our pharmacogenomics opportunities. 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 business, 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 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 partnerships with pharmaceutical companies, our ability to establish and maintain these partnerships could be challenging due to several factors, including competition with other genetic testing companies and internal and external constraints placed on pharmaceutical 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 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 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 "—Our inability to obtain additional capital when needed and on acceptable terms in the future may limit our ability to execute our business plan." Further, additional funds may not be available when needed, on acceptable terms or at all. We may also seek to fund these transactions with issuances of our capital stock, even if the price of our common stock is low or volatile, which would involve risks associated with capital-raising equity offerings, including dilution to existing stockholders and the possible decline of the market price of our common stock. Any inability to fund acquisitions, investments or strategic relationships could cause us to forfeit opportunities that we believe to be promising or valuable, which could harm our prospects.

**We depend on our information technology systems and any failure of these systems 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 expansive 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, our report production systems and our billing and reimbursement, research and development, scientific and medical data analysis and general administrative activities, including our financial controls and reporting functions. In addition, our third-party service providers depend upon technology and telecommunications systems in order to provide the contracted services for us. In connection with becoming a public company, we expect to expand and strengthen a number of enterprise software systems that affect a broad range of business processes and functions, including for example, systems handling human resources, financial and other disclosure controls and reporting, customer relationship management, regulatory compliance, security controls and other infrastructure operations.

Information technology and telecommunications systems are vulnerable to damage from a variety of sources, including telecommunications or network failures, malicious human acts and natural disasters. Moreover, despite network security and back-up measures, some of our servers are potentially vulnerable to 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, failures or significant downtime of these systems or those used by our third-party service providers could prevent us from conducting tests, preparing and providing reports to customers, billing payors, handling 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. Any disruption or loss of information technology or telecommunications systems on which critical aspects of our operations depend could have an adverse effect on our business.

**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. Specimens are typically received within days for analysis at our Temple City, California laboratory. Disruptions in delivery service, whether due to labor disruptions, bad weather, natural disaster, 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

**We conduct business in a heavily regulated industry, and any changes in applicable laws, regulations or the enforcement discretion of the FDA, or violations of laws or regulations by us, could adversely affect our business, prospects, results of operations or financial condition.**

The diagnostics industry is highly regulated, and the regulatory environment in which we operate could change significantly and adversely in the future. In particular, 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, which are defined to include, among other things, in vitro diagnostic products, or IVDs, used for clinical purposes. The tests that we offer are IVDs. 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 IVDs, are safe and effective for their intended uses, the FDA has historically exercised its enforcement discretion and not enforced applicable provisions of the FDC Act and regulations with respect to laboratory developed tests, or LDTs, which are a subset of IVDs that are intended for clinical use and designed, manufactured and used within a single laboratory. We believe our tests fall within the definition of an LDT. As a result, we believe our diagnostic tests are not currently subject to the FDA's enforcement of its medical device regulations and the applicable FDC Act provisions.

Even though we commercialize our tests as LDTs, our tests may in the future become subject to more onerous regulation by the FDA. For example, 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, pursuant to the Food and Drug Administration Safety and Innovation Act of 2012, or FDASIA, the FDA notified Congress on July 31, 2014 that the FDA intended to issue in 60 days a draft guidance entitled "Framework for Regulatory Oversight of Laboratory Developed Tests (LDTs)," or the Framework Guidance, and a separate draft guidance entitled "FDA Notification and Medical Device Reporting for Laboratory Developed Tests (LDTs)," or the Notification Guidance. On October 3, 2014, the FDA issued the anticipated Framework Guidance and Notification Guidance. The Framework Guidance states that the FDA intends to modify its policy of enforcement discretion with respect to LDTs in a risk-based manner consistent with the existing classification of medical devices. Thus, the FDA plans to begin to enforce its medical device requirements, including premarket submission requirements, for LDTs that have historically been marketed without FDA premarket review and oversight. The FDA states its intention in the Framework Guidance to require registration or listing and adverse event reporting six months after the Framework Guidance is finalized and to publish general LDT classification guidance within 24 months of the date on which the Framework Guidance is finalized. According to the Framework Guidance, the FDA intends to enforce premarket review requirements in a risk-based, phased-in manner, starting with the highest risk LDTs beginning 12 months after the Framework Guidance is finalized, followed by other high risk LDTs in the next four years, and then moderate risk LDTs in the four years after that. Generally, for each category of LDTs, the FDA intends to continue exercising enforcement discretion pending the FDA's review and consideration of the premarket submissions for devices that are already in use at the time—so long as premarket submissions are timely made. However, for certain categories of the highest risk LDTs (specifically, (i) LDTs with the same intended use as a cleared or approved companion diagnostic; (ii) LDTs with the same intended use as an FDA-approved Class III medical device; and (iii) certain LDTs for determining the safety or efficacy of blood or blood products), the FDA intends to begin enforcing premarket review requirements immediately upon publication of the finalized Framework Guidance for all new LDTs in those categories.

If and when the Framework Guidance and Notification Guidance are finalized, or if the FDA disagrees with our assessment that our tests fall within the definition of an LDT, we could for the first time be subject to enforcement of regulatory requirements such as registration and listing requirements, medical device reporting requirements and quality control requirements. Any new FDA enforcement policies affecting LDTs may result in increased regulatory burdens on our ability to continue marketing our tests and to develop and introduce new tests in the future. Additionally, if and when the FDA begins to actively enforce its premarket submission regulations with respect to LDTs generally or our tests in particular, we may be required to obtain premarket clearance for our tests under Section 510(k) of the FDC Act or approval of a premarket approval application, or PMA. If the FDA disagrees that our tests fall within the definition of an LDT, we may be required to cease marketing our tests until we obtain premarket clearance or premarket approval of our tests. However, the Framework Guidance states that, in the interest of ensuring continuity in the testing market and avoiding disruption of access to tests marketed as LDTs that do not meet the FDA's definition of LDTs, the FDA intends to apply the same risk-based framework described in the Framework Guidance to any IVD that is offered as an LDT by a laboratory certified under the Clinical Laboratory Improvement Amendments of 1988, or CLIA. Thus, there is a possibility that we would be able to continue selling our tests pending premarket clearance or approval even if the FDA determines they are not LDTs.

The premarket review process may involve, among other things, successfully completing clinical trials. If we are required to conduct premarket clinical trials, whether using prospectively acquired samples or archival samples, delays in the commencement or completion of clinical testing could significantly increase our development costs, delay introduction of any future tests and interrupt sales of our current tests. Many of the factors that may cause or lead to a delay in the commencement or completion of clinical trials may also ultimately lead to delay or denial of regulatory clearance or approval. The commencement of clinical trials may be delayed due to insufficient patient enrollment, which is a function of many factors, including the size of the patient population, the nature of the protocol, the proximity of patients to clinical sites and the eligibility criteria for the clinical trial. The process for submitting a 510(k) premarket notification and receiving FDA clearance usually takes from three to 12 months, but it can take significantly longer and clearance is never guaranteed. The process for submitting and obtaining FDA approval of a PMA generally takes from one to three years or even longer and approval is not guaranteed. PMA approval typically requires extensive clinical data and can be significantly longer, more expensive and more uncertain than the 510(k) clearance process. Despite the time, effort and expense expended, there can be no assurance that a particular device ultimately will be cleared or approved by the FDA through either the 510(k) clearance process or the PMA process on a timely basis, or at all.

Additionally, the FDA has recently solicited public input and published two draft guidance documents relating to FDA oversight of NGS-based tests. The two draft guidance documents on NGS-based tests describe the FDA's current thinking and proposed approach regarding the possible use of FDA-recognized standards to support analytical validity, and public human genetic variant databases to support clinical validity, of these tests. While it appears that the FDA is striving to provide a flexible pathway to device clearance or approval for manufacturers seeking to market NGS-based tests, it is unknown how the FDA may regulate such tests in the future and what testing and data may be required to support such clearance or approval. If premarket review is required for some or all of our tests and the FDA requires more extensive testing, such as clinical trials, for example, we could experience significantly increased development costs and delay.

Moreover, there can be no assurance that any cleared or approved labeling claims will be consistent with our current claims or adequate to support continued adoption of and reimbursement for our tests. If premarket review is required for some or all of our tests, the FDA could require that we stop selling our tests pending clearance or approval and conduct clinical testing prior to making submissions to FDA to obtain premarket clearance or approval. If our diagnostic tests are allowed to remain on the market but there is uncertainty about their legal status, if we are required by the FDA to label them 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 tests, or from tests which we may develop.

In addition, while we qualify all materials used in our products in accordance with CLIA regulations and guidelines, the FDA could promulgate regulations or guidance documents impacting our ability to purchase materials necessary for the performance of our products. Should any of the reagents we obtain from suppliers and use in our products be 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.

The FDA enforces its medical device requirements by various means, including inspection and market surveillance. If the FDA finds a violation, it can institute a wide variety of enforcement actions, ranging from an Untitled Letter or Warning Letter to more severe sanctions such as: fines, injunctions and civil penalties; recall or seizure of products; operating restrictions, partial suspension or total shutdown of production; and criminal prosecution.

While we believe we are currently in material compliance with applicable laws and regulations as historically enforced by the FDA, the FDA may not agree with our determination, and any determination that we have violated these laws and regulations, or a public announcement that we are being investigated for possible violations, could adversely affect our business, prospects, results of operations or financial condition.

Legislative proposals addressing the FDA's oversight of LDTs have been introduced by Congress in the past and we expect that new legislative proposals may be introduced from time to time in the future. The likelihood that Congress will pass such legislation and the extent to which such legislation may affect the FDA's ability to enforce its medical device regulations with respect to certain LDTs is difficult to predict at this time. If the FDA ultimately begins to enforce its medical device requirements with respect to LDTs, our tests may be subject to additional regulatory requirements imposed by the FDA, the nature and extent of which would depend upon applicable final guidance or regulation by the FDA or instruction by Congress. If the FDA imposes significant changes to the regulation of LDTs it could reduce our revenue or increase our costs and adversely affect our business, prospects, results of operations or financial condition. 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.

Any new FDA enforcement policies affecting LDTs or new legislation, regulations or guidance may result in increased regulatory burdens on our ability to continue marketing our products and to develop and introduce new products in the future, which could reduce our revenue or increase our costs and adversely affect our business, prospects, results of operations or financial condition.

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

We are subject to CLIA, a federal law that established quality standards for all laboratory testing and is intended to ensure the accuracy, reliability and timeliness of patient results. CLIA regulates all facilities that perform laboratory testing on specimens derived from humans for the purpose of providing information for the diagnosis, prevention or treatment of disease or the impairment or assessment of health. 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 healthcare 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. Our CLIA certification was last renewed October 23, 2015.

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. We also maintain out-of-state laboratory licenses to perform testing on specimens from Florida, Maryland and Pennsylvania. In addition to having a laboratory license in New York, our laboratory is required to obtain approval on a test-specific basis by the New York State Department of Health before specific testing is performed on samples from New York. Because our license application is still pending in New York, we are currently prohibited from performing these tests on samples from New York until our license is approved. Other 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 of 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 in and while doing so.

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 and 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 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 1996, or HIPAA, the federal Health Information Technology for Economic and Clinical Health Act, or HITECH, and similar state laws.

The HIPAA privacy, security, and breach notification regulations establish a uniform federal "floor," but do not supersede state laws that are more stringent or provide individuals with greater rights with respect to the privacy or security of, and access to, their records containing PHI or insofar as such state laws apply to personal information that is broader in scope than PHI as defined under HIPAA. Massachusetts, for example, has a state law that protects the privacy and security of personal information of Massachusetts residents.

Numerous other state, federal and foreign laws, including consumer protection laws and regulations, govern the collection, dissemination, use, access to, confidentiality and security of patient health information. In addition, Congress and some states are considering new laws and regulations that further protect the privacy and security of medical records or medical information. With the recent increase in publicity regarding data breaches resulting in improper dissemination of consumer information, many states have passed laws regulating the actions that a business must take if it experiences a data breach, such as prompt disclosure to affected customers. Generally, these laws are limited to electronic data and make some exemptions for smaller breaches. Congress has also been considering similar federal legislation relating to data breaches. 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 this 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 include civil monetary penalties of up to $1.5 million per violation of the same requirement per calendar year. A single breach incident can result in violations of multiple requirements, resulting in potential penalties in excess of $1.5 million. Additionally, a person who knowingly obtains or discloses individually identifiable health information in violation of HIPAA may face a criminal penalty of up to $50,000 and up to one year of imprisonment. These criminal penalties increase if the wrongful conduct involves false pretenses or the intent to sell, transfer or use identifiable health information for commercial advantage, personal gain or malicious harm.

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. For example, a new General Data Protection Regulation, or GDPR, and Cybersecurity Directive have been enacted in the European Union and will come into full effect in May 2018. These texts will introduce many changes to privacy and security in the European Union, including stricter rules on consent and security duties for critical industries, including for the health sector. The interpretation of some rules is still unclear, and some requirements may be completed by national legislation. This makes it difficult to assess the impact of these new data protection laws on our business at this time. More generally, foreign laws and interpretations governing data privacy and security are constantly evolving and it is possible that laws may be interpreted and applied in a manner that is inconsistent with our current practices, in which case we could be subject to government-imposed fines or orders requiring that we change our practices. These fines can be very high. For instance, the GDPR introduces fines of up to approximately $22 million or 4% of a group's worldwide annual turnover for certain infringements. In addition, privacy regulations differ widely from country to country. Complying with these various 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.

**Complying with 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 operations are subject to extensive federal, state, local and foreign laws and regulations, all of which are subject to change. These laws and regulations currently include, among others:

- the FDA's enforcement discretion with respect to LDTs and its expressed intention to begin enforcing the medical device requirements with respect to LDTs in a risk-based manner;
- 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, which establishes 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;
- amendments to HIPAA under HITECH, which strengthen and expand HIPAA privacy and security compliance requirements, increase penalties for violators, expand vicarious liability, extend enforcement authority to state attorneys general and impose requirements for breach notification;
- 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 prohibits knowingly and willfully offering, paying, soliciting or receiving remuneration, directly or indirectly, overtly or covertly, in cash or in kind, in return for or to induce a person to refer an individual, or to purchase, lease, order, arrange for, or recommend purchasing, leasing or ordering, any good, facility, item or service that is reimbursable, in whole or in part, under a federal healthcare program. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. A violation of the federal Anti-Kickback Statute can serve as a basis for liability under federal false claims law (as described below);
- the federal Stark Law, which 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, and prohibits that entity from billing or presenting a claim for the designated health services furnished pursuant to the prohibited referral, unless an exception applies. If a referring physician does not meet the requirements of a Stark Law exception, then the physician is prohibited from making Medicare and Medicaid referrals to the laboratory and any such referrals will result in overpayments to the laboratory and subject the laboratory to the Stark Law's penalties;
- the federal false claims laws, which 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. Actions under the federal False Claims Act may be brought by the Attorney General or as a qui tam action by a private individual in the name of the government. Violations of the federal False Claims Act can result in significant monetary penalties and treble damages. The federal government has used the False Claims Act, and the accompanying threat of significant liability, in its investigation and prosecution of biotechnology companies, including clinical diagnostic laboratories, throughout the country, for example, in connection with their sales and marketing practices. The government has obtained multi-million and multi-billion dollar settlements under the False Claims Act in addition to individual criminal convictions under applicable criminal statutes. Given the significant size of actual and potential settlements, it is expected that the government will continue to devote substantial resources to investigating healthcare providers' and manufacturers' compliance with applicable fraud and abuse laws;
- the federal Civil Monetary Penalties Law, which prohibits, among other things, the offering or transfer of remuneration to a Medicare or state healthcare program beneficiary if the person knows or should know it is likely to influence the beneficiary's selection of a particular provider, practitioner or supplier of services reimbursable by Medicare or a state healthcare program, unless an exception applies, and imposes penalties against any person or entity that, among other things, is determined to have presented or caused to be presented a claim to a federal health program that the person knows or should know is for an item or service that was not provided as claimed or for a claim that is false or fraudulent;
- the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, collectively referred to as the "Affordable Care Act," which established a requirement for providers and suppliers to report and return any overpayments received from government payors under the Medicare and Medicaid programs within 60 days of identification. Failure to identify and return such overpayments exposes the provider or supplier to liability under federal false claims laws;
- federal criminal statutes under HIPAA that prohibit, among other things, defrauding healthcare programs, willfully obstructing a criminal investigation of a healthcare offense and falsifying or concealing a material fact or making any materially false statements in connection with the payment for healthcare benefits, items or services. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- 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 healthcare providers and customers, which are applicable to certain manufacturers of covered products, such as kits that require FDA approval or clearance, and could be determined to apply to our LDTs;
- the prohibition on reassignment of Medicare claims, which, subject to certain exceptions, precludes the reassignment of Medicare claims to any other party;
- state laws that prohibit other specified practices, such as billing physicians for testing 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 FCPA's prohibition of, among other things, making improper payments to foreign or non-U.S. government officials for the purpose of obtaining or retaining business or securing any other improper advantage;
- 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; and
- similar foreign laws and regulations that apply to us in the countries in which we operate or may operate in the future.

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 and our policies and procedures. Our compliance is also subject to review by applicable government agencies. The growth of our business and our planned expansion outside of the United States and our use of consultants and commercial partners may increase the potential of violating these laws or our internal policies and procedures. 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 the courts, and their provisions are thus open to a variety of interpretations. 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 be in compliance 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, distributors, consultants and commercial partners, are found to be in violation of any of these laws and regulations, we may be subject to any applicable penalty 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 the foregoing consequences could seriously harm our business and our financial results.

**Healthcare policy changes, including recently enacted 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 a sales tax equal to 2.3% of the price for which such manufacturer sells its medical devices. The medical device tax has been suspended for 2016 and 2017, but is scheduled to return beginning in 2018. It is unclear at this time when, or if, the provision of our LDTs will trigger the medical device tax if the FDA ends its policy of general enforcement discretion and regulates certain LDTs as medical devices, 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 establishes an Independent Payment Advisory Board, or IPAB, to propose reductions to payments in order to reduce the per capita rate of growth in Medicare spending if expenditures exceed certain targets. The expenditure targets for IPAB proposals have not been exceeded at this time, and it is unclear when such targets may be exceeded in the future, when any IPAB-proposed reductions to payments could take effect and how any such reductions would 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 report to CMS, beginning in 2017 and every three years thereafter (or annually for "advanced diagnostic laboratory tests"), 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. We do not believe that our tests meet the current definition of advanced diagnostic laboratory tests, and therefore we believe we will be required to report private payor rates for our tests every three years. As required under PAMA, CMS will use the rates and volumes reported by

laboratories to develop Medicare payment rates for laboratory tests equal to the volume-weighted median of the private payor payment rates for the tests. On June 23, 2016, CMS published the final rule implementing the reporting and rate-setting requirements under PAMA. The impact of the new payment system on rates for our tests, including any current or future clinical diagnostic laboratory tests or advanced diagnostic laboratory tests we may develop, is not clear at this time.

We cannot predict whether these or other recently enacted or future 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, as well as the expansion of the federal and state governments' role in the U.S. healthcare industry generally and the social, governmental and other pressures to reduce healthcare costs while expanding individual benefits, could limit the prices we will be able to charge or the amount of available reimbursement for our tests, which would reduce our revenue and have a materially adverse effect on our business, financial condition, results of operations and cash flows.

**If we use hazardous materials in a manner that causes contamination or injury, we could be liable for resulting damages.**

Our activities require the use of regulated medical waste, hazardous waste and biohazardous waste, including chemicals, biological agents and compounds, blood and other tissue specimens. We cannot eliminate the risk of accidental contamination or injury to employees or third parties from the use, storage, handling or disposal of these materials. In the event of contamination or injury, we could be held liable for any resulting damages, and any liability could exceed our resources or any applicable insurance coverage we may have secured. Additionally, we are subject on an ongoing basis to federal, state and local laws and regulations governing the use, storage, handling and disposal of these materials and specified waste products. Although we typically use outside vendors to dispose of such waste that are licensed or otherwise qualified to handle and dispose of the waste, applicable laws and regulations may hold us liable for damages and fines as a result of others' actions should contamination of the environment or individual exposure to hazardous substances occur. The cost of compliance with these laws and regulations could become significant and our failure to comply could result in substantial fines or other consequences, either of which could negatively affect our operating results and significantly harm our reputation.

**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. 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. If we engage independent distributors or other partners to assist with sales of our tests internationally, we will need to exercise a high degree of vigilance in maintaining, implementing and enforcing our policy against participation in corrupt activity, as these distributors or other partners could be deemed to be our agents and we could be held responsible for their actions. We also may be subject to similar anti-bribery laws in the jurisdictions in which we operate, such as the United Kingdom's Bribery Act of 2010, which prohibits commercial bribery and the acceptance of bribes, and makes it a crime for companies subject to its jurisdiction to fail to prevent bribery. These laws are complex and far-reaching in nature and, as a result, 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 some business outside of the United States, and we plan to increase our international operations in the future. These operations could involve dealings with governments and state-owned entities, such as government hospitals, outside of the United States. In addition, we may engage third-party intermediaries, such as representatives, contractors, partners, and agents, to promote and sell our products and solutions abroad and to obtain necessary permits, licenses, and other regulatory approvals. We or our third-party intermediaries may have direct or indirect interactions with foreign officials, which expose us to risks under the FCPA and other anti-corruption laws. Other U.S. companies in the medical device and pharmaceutical fields have faced substantial fines and criminal penalties for violating the FCPA. We have instituted policies, procedures, and internal controls reasonably designed to promote compliance with the FCPA and other anti-corruption laws. We could be held liable for the corrupt or other illegal activities of our employees and intermediaries, even if we do not explicitly authorize or have actual knowledge of such activities, and our employees or third-party intermediaries may not comply with our policies, procedures, or applicable anti-corruption laws. 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 could result in a material adverse effect on our business, prospects, financial condition, or results of operations. We could also incur severe penalties, including criminal and civil penalties, disgorgement, and other remedial measures, as well as reputational harm.

**Our services present the potential for embezzlement, identity theft or other similar illegal behavior by our employees, consultants 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 or commercial partners takes, converts or misuses such funds, documents or data, we could be liable for damages, and our business reputation could be damaged or destroyed.

## Intellectual Property Risks

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

We currently rely upon 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 similar methods and have aggregated and are expected to continue to aggregate similar libraries of genetic testing information, our success will depend upon our ability to develop proprietary methods and libraries and to defend any advantages afforded to us by such methods and libraries relative to our competitors. If we do not protect our intellectual property 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 that our proprietary technologies are effectively maintained as trade secrets. We expect to rely primarily upon trade secret and proprietary know-how protection for our confidential and proprietary information and we have taken security measures to protect this information. These measures, however, may not provide adequate protection for our trade secrets, know-how or other confidential information. Among other things, we seek to protect our trade secrets and other confidential information by entering into confidentiality agreements with employees, consultants and other third parties. These confidentiality agreements may not sufficiently safeguard our trade secrets and confidential information and may not provide adequate remedies in the event of unauthorized use or disclosure of such information. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret can 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 to be 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 could prevent us from selling our tests.**

Our commercial success will depend in part upon our ability to avoid infringement of patents and other proprietary rights owned by third parties, including the intellectual property rights of competitors. There are numerous U.S. and foreign patents and pending patent applications and other intellectual property rights that cover technologies relevant to genetic testing and that are owned by third parties. 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 patent applications that, if issued, could be asserted against us. As a result, our existing or future operations may be found or alleged to infringe existing or future patents or other intellectual property rights of others. As we continue to sell our existing tests, 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 successful entry into new markets.

If a patent infringement or misappropriation of intellectual property suit were 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 suit while it is pending. Additionally, defense of these claims, regardless of merit, could cause us to incur substantial expenses, be a substantial diversion of our management and other employee resources and significantly harm our reputation. In the event of a successful claim of infringement against us, we may be forced to pay substantial damages, including treble damages and attorneys' fees if we are 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 monetary expenditure. Further, 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. 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 recently been decided by the Supreme Court. 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 technology 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, these patents 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 these patents. Whether based on patents issued prior to 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 against us, which are 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 could 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 unclear.

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 stop the misappropriation of our intellectual property rights. Moreover, changes in the law and legal decisions by courts in foreign countries could affect our ability to obtain adequate protection for our technology and the enforcement of intellectual property rights. As a result, our efforts to protect and enforce our intellectual property rights in foreign countries may ultimately prove to be inadequate, in which case our ability to grow our business and our revenue and prospects 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, biometric solution or genetic testing, diagnostic or other healthcare companies, including our competitors or potential competitors. 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, including trade secrets or other proprietary information, of a former employer or other third-party. 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 technology and other parties' intellectual property. Litigation may be necessary to defend against these claims. If we fail in defending 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.

## Public Company Risks

**We will incur increased costs and demands as a result of compliance with laws and regulations applicable to public companies.**

As a public company, we will experience significant additional demands that we did not experience as a private company. For example, the Sarbanes-Oxley Act of 2002, as amended, or Sarbanes-Oxley Act, and related and other rules implemented by the SEC and The NASDAQ Stock Market LLC, or NASDAQ, impose a number of requirements on public companies, including with respect to corporate governance practices. For instance, as a result of becoming a public company, a majority of our directors are required to be independent and we are required to maintain audit and compensation committees comprised solely of independent directors, maintain a variety of corporate governance policies, adopt and maintain policies regarding internal controls and disclosure controls and procedures and prepare reports on internal controls over financial reporting. Until completion of the Reorganization, we operated without a board of directors under the direction of the Manager of Fulgent LLC, Mr. Hsieh. Further, the SEC and other regulators have continued to adopt new rules and regulations and make additional changes to existing regulations that require our compliance, including pursuant to the Dodd-Frank Wall Street Reform and Consumer Protection Act, or Dodd-Frank Act, which was enacted in July 2010. There are significant corporate governance and executive compensation-related disclosure provisions in the Dodd-Frank Act that require the SEC to adopt additional rules and regulations in these areas.

Moreover, the rules and regulations applicable to public companies will substantially increase our legal, accounting and financial compliance costs. For instance, we will need to hire additional personnel for, and devote more resources to, our financial reporting function. Additionally, if we continue to grow as anticipated, we will need to implement new and more sophisticated financial and accounting systems and adopt additional procedures for financial reporting in order to meet our obligations as a public company. Any transition of accounting systems can be expensive and can result in delays in our ability to process and report transactions in a timely manner. Our management and other personnel will need to devote a substantial amount of attention to maintaining our compliance with these obligations, which could be time-consuming and expensive. If these requirements divert the attention of our management and personnel from other aspects of our business or if they require substantial costs that we cannot afford, they could have a material adverse effect on our business, financial condition and results of operations. We also expect that, as a public company, it will be more expensive for us to attract and compensate qualified directors and officers and obtain adequate director and officer liability insurance.

**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.**

As a public company, we are required to maintain internal control over financial reporting and to report any material weaknesses in such 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, beginning with our annual report for the year ended December 31, 2017, provide a management report on our internal control over financial reporting. If we have a material weakness in our internal control over financial reporting, we may not detect errors on a timely basis and our financial statements may be materially misstated. We have only started to implement the systems and processes necessary to perform the evaluation needed to comply with Section 404 of the Sarbanes-Oxley Act. We will need to maintain and enhance these systems, processes and controls 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.

During the process of evaluating our internal controls, if we identify one or more material weaknesses, our management will be unable to conclude that our internal control over financial reporting is effective. Moreover, when we are no longer an emerging growth company, our independent registered public accounting firm will be required to issue an attestation report on the effectiveness of our internal control over financial reporting. Even if our management concludes that our internal control over financial reporting is effective, our independent registered public accounting firm may conclude that there are material weaknesses with respect to our internal controls or the level at which our internal controls are documented, designed, implemented or reviewed.

If we are unable to conclude that our internal control over financial reporting is effective or, when we are no longer an emerging growth company, our auditors were to express an adverse opinion on the effectiveness of our internal control over financial reporting 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.**

As a result of becoming a public company, we are now subject to the periodic reporting and other requirements of the Exchange Act. As a result, 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.

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

We are an emerging growth company, as defined under the Jumpstart Our Business Startups Act of 2012, or the JOBS Act. We will remain an emerging growth company until December 31, 2021, unless our gross revenue exceeds $1.0 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 million as of the last business day of the second fiscal quarter of any fiscal year before that date. As an emerging growth company, we are eligible for certain exemptions from various reporting requirements applicable to certain other public companies, including exemption from the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act, reduced financial statement and other financial disclosures in registration statements we file, reduced disclosure obligations regarding executive compensation and exemption from the requirements of holding a nonbinding advisory vote on executive compensation and obtaining stockholder approval of any golden parachute payments not previously approved. Even after we no longer qualify as an emerging growth company, we may still qualify as a “smaller reporting company,” which would allow us to take advantage of many of the same exemptions from disclosure requirements, including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act and having reduced disclosure obligations regarding executive compensation. We have relied on many of these exemptions to date and investors may find our common stock less attractive if we choose to continue to rely on any of 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 also delay adopting new or revised accounting standards until such time as those standards apply to private companies. We have irrevocably elected not to avail ourselves of this exemption and, as a result, will be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies.

## Common Stock Risks

**An active, liquid trading market for our common stock may never develop, which could make it difficult for you to sell your shares of our common stock.**

Prior to the completion of our initial public offering on October 4, 2016, no public market for shares of our common stock existed. An active trading market for our shares may never develop or, if developed, may not be sustained. Further, Mr. Hsieh, our founder and Chief Executive Officer, beneficially owns approximately 43.9% of our outstanding voting equity as of the completion of our initial public offering. As a result, fewer shares are actively traded in the public market, which reduces the liquidity of the market for our common stock. The lack of an active trading market could impair your ability to sell your shares at the time you wish to sell them or at a price you consider reasonable. Further, an inactive trading market may impair our ability to raise capital in the future by selling shares of our common stock 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 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 shares since the completion of our initial public offering on October 4, 2016. Other factors that may contribute to this volatility may include, among others:

- actual or anticipated fluctuations in our operating results;
- competition from existing tests or new tests that may emerge;
- announcements by us or our competitors of significant acquisitions, investments, strategic partnerships, joint ventures, collaborations or capital commitments;
- failure to meet or exceed financial estimates and projections of the investment community or that we provide to the public;
- issuance of new or updated research or reports by securities analysts or changed recommendations for our common stock;
- the timing and amount of our investments in the growth of our business;
- disputes or other developments with respect to our or others’ intellectual property rights;
- actual or anticipated changes in regulatory oversight of our business;
- changes in laws or regulations applicable to 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;
- product liability claims or other litigation;
- sales of our common stock by us or our stockholders in the future;
- general economic, industry and market conditions, including factors unrelated to our operating performance or the operating performance of our competitors; and
- the other risk factors discussed in this report.

In addition, the stock market in general, and the market for stock of companies in the life sciences and technology industries in particular, has experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of specific companies. 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.**

As of November 14, 2016, our executive officers, directors, holders of 5% or more of our outstanding voting equity and their respective affiliates beneficially owned approximately 65.4% of our outstanding voting equity and Mr. Hsieh, our founder and Chief Executive Officer, beneficially owns approximately 43.9% 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 for our common stock that you may feel are in your best interest as one of our stockholders, as the interests of these stockholders may not coincide with your interests or the interests of other stockholders and they may act in a manner that advances their best interests and not necessarily those of all 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. These sales, or the perception in the market that such sales are pending or could occur, could reduce the market price of our common stock. As of November 14, 2016, we had 17,676,256 outstanding shares of common stock. Of these shares, approximately 3,830,000 shares of our common stock are freely tradable without restriction in the public market. The remaining outstanding shares of our common stock are restricted from sale until March 27, 2017 pursuant to the terms certain lock-up agreements entered into in connection with our initial public offering and/or are held by our “affiliates,” as that term is defined in the Securities Act, and constitute restricted securities under the Securities Act. Generally, restricted securities may not be sold in the public market unless the sale is registered under the Securities Act or an exemption from registration is available.

Moreover, Xi Long, which holds an aggregate of 2,025,623 shares of our common stock, 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 following May 16, 2019. We have also registered the shares of our common stock that we may issue under our 2016 Omnibus Incentive Plan, or the 2016 Plan, totaling 591,112 shares subject to options outstanding as of September 30, 2016 and 1,447,368 additional shares reserved for issuance under the 2016 Plan. As a result, these shares will be freely tradable in the public market upon issuance, subject to volume and manner of sale limitations applicable to affiliates and any other legal and contractual limitations.

**Future issuances of our common stock or rights to purchase our common stock, including pursuant to our equity incentive plans, 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 in the future, 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. If we sell common stock, convertible securities or other equity securities, our then-existing stockholders could be materially diluted by such issuances and new investors could gain rights, preferences and privileges senior to the holders of our common stock, 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 future earnings for the development, operation and expansion of our business. As a result, other than tax distributions we expect to pay to the former members of Fulgent LLC, we do not anticipate declaring or paying any cash dividends or other distributions for the foreseeable future. Further, if we were to enter into a credit facility or issue debt securities or preferred equity securities in the future, we may be 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 future 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.**

If a trading market for our common stock develops, that trading market will be influenced to some extent by the research and reports that industry or securities analysts publish about us or our business. We have only recently obtained research coverage by securities and industry analysts. 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 significantly 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 the stockholders of our company 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 the 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 the 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 may discourage, delay or prevent a change in control of our company. Section 203 imposes certain restrictions on mergers, business combinations and other transactions between us and holders of 15% or more of our common stock.

**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 on the part of our stockholders. Our board of directors will also have the power, without stockholder approval, to set the terms of any series of preferred stock that may be issued, including voting rights, dividend rights, preferences over our common stock with respect to dividends or in the event of a dissolution, liquidation or winding up and other terms. In the event that we issue preferred stock in the future that has preferences over our common stock with respect to payment of dividends or upon our 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 or 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 favorable judicial forum 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; or
- 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 shall be 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 that it finds favorable for disputes with us or our directors, officers or other employees, which may discourage such lawsuits against us and our directors, officers and other employees. Alternatively, if a court were to find these provisions 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 such 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.**

**Unregistered Sales of Equity Securities**

On September 30, 2016, Fulgent Inc. issued an aggregate of 12,846,256 shares of its common stock in the Reorganization. These issuances were exempt from the registration requirements of the Securities Act in reliance upon Section 4(a)(2) thereof because they did not involve any public offering of securities based on the following facts: no underwriters, underwriting discounts or commissions were involved in the transactions; no general solicitation was used; the recipients of the securities represented their intention to acquire the securities for investment only and not with a view to or for sale in connection with any distribution thereof and had adequate access through their relationship with us to information about us; and all of the securities were issued as restricted securities for purposes of the Securities Act.

During the quarter ended September 30, 2016, Fulgent LLC issued options to acquire an aggregate of 45,000 Class D non-voting common units subject to an exercise price of $1.62 per unit, which, upon completion of the Reorganization, became options to acquire an aggregate of 5,920 shares of our common stock subject to an exercise price of $12.31 per share. These issuances were all exempt from the registration requirements of the Securities Act in reliance upon Rule 701 thereunder because the securities were issued under written compensatory plans intended to comply with Rule 701 and the recipients of these securities were bona fide service providers to us at the time of grant.

During the quarter ended September 30, 2016, Fulgent LLC issued restricted share units relating to an aggregate of 500,000 Class D non-voting common units, which upon completion of the Reorganization, became restricted stock units relating to an aggregate of 65,789 shares of our common stock. These securities were issued to a member of our management team in consideration of his service for our company. This issuance was exempt from the registration requirements of the Securities Act in reliance upon Section 4(a)(2) thereof because it did not involve any public offering of securities based on the following facts: no underwriters, underwriting discounts or commissions were involved in the transaction; no general solicitation was used; the recipient of the securities represented his intention to acquire the securities for investment only and not with a view to or for sale in connection with any distribution thereof and had adequate access through his relationship with us to information about us; and all of the securities were issued as restricted securities for purposes of the Securities Act.

**Use of Proceeds**

On September 28, 2016, our registration statement on Form S-1 (File No. 333-213469), as amended, or the Registration Statement, including the final prospectus dated September 28, 2016, or the Prospectus, relating to the initial public offering, or IPO, of our common stock, was declared effective by the SEC. The IPO was completed on October 4, 2016, and 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 and for gross proceeds of $43.5 million. We received net proceeds from the IPO of approximately $36.3 million, after deducting underwriting discounts and commissions of approximately $3 million and offering expenses paid or payable by us of approximately $4.2 million. None of the expenses associated with the IPO have been paid to directors, officers, persons owning 10% or more of any class of equity securities or to their associates or to any of our affiliates. The managing underwriters of the offering were Credit Suisse Securities (USA) LLC and Piper Jaffray & Co.

The 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 follows the signature page to this report and is incorporated herein by reference.

**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: November 14, 2016

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

Date: November 14, 2016

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

## Exhibit Index

| Exhibit Number | Description |
|---|---|
| 2.1 | Agreement and Plan of Merger, dated September 16, 2016, by and among the registrant, Fulgent MergerSub, LLC and Fulgent Therapeutics LLC (incorporated by reference to **Exhibit** 2.1 to Amendment No. 1 to the registrant's Registration Statement on Form S-1 (File No. 333-213912) filed with the SEC on September 19, 2016). |
| 10.1# | 2016 Omnibus Incentive Plan of the registrant (incorporated by reference to Exhibit 10.6 to Amendment No. 2 to the registrant's Registration Statement on Form S-1 (File No. 333-213912) filed with the SEC on September 26, 2016).. |
| 10.2# | Form of Notice of Stock Option Award and Stock Option Award Agreement under the 2016 Omnibus Incentive Plan of the registrant (incorporated by reference to Exhibit 10.7 to the registrant's Registration Statement on Form S-1 (File No. 333-213912) filed with the SEC on September 2, 2016). |
| 10.3# | Form of Notice of Restricted Stock Unit Award and Restricted Stock Unit Agreement under the 2016 Omnibus Incentive Plan of the registrant (incorporated by reference to Exhibit 10.8 to the registrant's Registration Statement on Form S-1 (File No. 333-213912) filed with the SEC on September 2, 2016). |
| 10.4# | Form of Option Substitution Award under the 2016 Omnibus Incentive Plan of the registrant (incorporated by reference to Exhibit 10.9 to the registrant's Registration Statement on Form S-1 (File No. 333-213912) filed with the SEC on September 2, 2016). |
| 10.5# | Form of Notice of Restricted Stock Unit Substitution Award and Restricted Stock Unit Agreement under the 2016 Omnibus Incentive Plan of the registrant (incorporated by reference to Exhibit 10.10 to the registrant's Registration Statement on Form S-1 (File No. 333-213912) filed with the SEC on September 2, 2016). |
| 10.6# | Severance Agreement, dated July 7, 2016, by and among Fulgent Therapeutics LLC, the registrant and Ming Hsieh (incorporated by reference to Exhibit 10.14 to the registrant's Registration Statement on Form S-1 (File No. 333-213912) filed with the SEC on September 2, 2016). |
| 10.7# | Severance Agreement, dated July 7, 2016, by and among Fulgent Therapeutics LLC, the registrant and Paul Kim (incorporated by reference to Exhibit 10.15 to the registrant's Registration Statement on Form S-1 (File No. 333-213912) filed with the SEC on September 2, 2016). |
| 10.8# | Severance Agreement, dated July 7, 2016, by and among Fulgent Therapeutics LLC, the registrant and Han Lin Gao (incorporated by reference to Exhibit 10.16 to the registrant's Registration Statement on Form S-1 (File No. 333-213912) filed with the SEC on September 2, 2016). |
| 10.9 | Form of Fourth Amended and Restated Operating Agreement of Fulgent Therapeutics LLC (included as an exhibit to Exhibit 2.1, incorporated by reference to Exhibit 2.1 to Amendment No. 1 to the registrant's Registration Statement on Form S-1 (File No. 333-213912) filed with the SEC on September 19, 2016). |
| 10.10 | Commercial Lease, dated August 1, 2016, by and between E & E Plaza LLC and Fulgent Therapeutics LLC (incorporated by reference to Exhibit 10.19 to the registrant's Registration Statement on Form S-1 (File No. 333-213912) filed with the SEC on September 2, 2016). |
| 10.11# | Director Compensation Program of the registrant, effective as of September 28, 2016 (incorporated by reference to Exhibit 10.1 to Amendment No. 1 to the registrant's Registration Statement on Form S-1 (File No. 333-213912) filed with the SEC on September 19, 2016). |
| 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. |
| 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. |
| 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. |
| 101.INS* | XBRL Instance Document |
| 101.SCH* | XBRL Taxonomy Extension Schema Document |
| 101.CAL* | XBRL Taxonomy Extension Calculation Linkbase Document |
| 101.DEF* | XBRL Taxonomy Extension Definition Linkbase Document |
| 101.LAB* | XBRL Taxonomy Extension Label Linkbase Document |
| 101.PRE* | XBRL Taxonomy Extension Presentation Linkbase Document |

* Filed herewith.

** Furnished herewith.

# Management contract or compensatory plan, contract or arrangement.

**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 September 30, 2016 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 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) 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

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

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

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

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

Date: November 14, 2016

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 September 30, 2016 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 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) 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

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

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

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

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

Date: November 14, 2016

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 September 30, 2016 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: November 14, 2016 By: /s/ Ming Hsieh
Ming Hsieh
President, **Chief Executive Officer**
(principal executive officer)

Date: November 14, 2016 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.