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, 2019

OR

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

For the transition period from _____ to _____

Commission File Number: 001-38943

Personalis, Inc.

(Exact Name of Registrant as Specified in its Charter)

Delaware	**27-5411038**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
1330 O'Brien Drive **Menlo Park, California 94025**	**94025**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (650) 752-1300

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value $0.0001	PSNL	The Nasdaq Global Market

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

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

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

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

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

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

As of November 8, 2019, the registrant had 31,233,959 shares of common stock, $0.0001 par value per share, outstanding.

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SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. All statements other than statements of historical facts contained in this Quarterly Report on Form 10-Q, including statements regarding our future results of operations or financial condition, business strategy and plans, and objectives of management for future operations, are forward-looking statements. In some cases, you can identify forward-looking statements because they contain words such as "anticipate," "believe," "contemplate," "continue," "could," "estimate," "expect," "hope," "intend," "may," "might," "objective," "ongoing," "plan," "potential," "predict," "project," "should," "target," "will," or "would" or the negative of these words or other similar terms or expressions. These forward-looking statements include, but are not limited to, statements concerning the following:

- the evolution of cancer therapies and market adoption of our services;
- estimates of our total addressable market, future revenue, expenses, capital requirements, and our needs for additional financing;
- our ability to compete effectively with existing competitors and new market entrants;
- our ability to scale our infrastructure;
- our ability to manage and grow our business by expanding our sales to existing customers or introducing our products to new customers;
- expectations regarding our relationship with the U.S. Department of Veterans Affairs' Million Veteran Program;
- our ability to establish and maintain intellectual property protection for our products or avoid claims of infringement;
- potential effects of extensive government regulation;
- our ability to hire and retain key personnel;
- our ability to obtain financing in future offerings;
- the volatility of the trading price of our common stock;
- our belief that approval of personalized cancer therapies by the Food and Drug Administration may drive benefits to our business; and
- our expectation regarding the time during which we will be an emerging growth company under the JOBS Act.

Actual events or results may differ from those expressed in forward-looking statements. As such, you should not rely on forward-looking statements as predictions of future events. We have based the forward-looking statements contained in this Quarterly Report on Form 10-Q primarily on our current expectations and projections about future events and trends that we believe may affect our business, financial condition, operating results, prospects, strategy, and financial needs. The outcome of the events described in these forward-looking statements is subject to risks, uncertainties, assumptions, and other factors described in the section titled "Risk Factors" and elsewhere in this Quarterly Report on Form 10-Q. Moreover, we operate in a highly competitive and rapidly changing environment. New risks and uncertainties emerge from time to time, and it is not possible for us to predict all risks and uncertainties that could have an impact on the forward-looking statements contained in this Quarterly Report on Form 10-Q. The results, events and circumstances reflected in the forward-looking statements may not be achieved or occur, and actual results, events or circumstances could differ materially from those described in the forward-looking statements.

In addition, statements that "we believe" and similar statements reflect our beliefs and opinions on the relevant subject. These statements are based on information available to us as of the date of this Quarterly Report on Form 10-Q. While we believe that such information provides a reasonable basis for these statements, such information may be limited or incomplete. Our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all relevant information. These statements are inherently uncertain, and investors are cautioned not to unduly rely on these statements.

The forward-looking statements made in this Quarterly Report on Form 10-Q relate only to events as of the date on which the statements are made. We undertake no obligation to update any forward-looking statements made in this Quarterly Report on Form 10-Q to reflect events or circumstances after the date of this Quarterly Report on Form 10-Q or to reflect new information, actual results, revised expectations, or the occurrence of unanticipated events, except as required by law. We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements, and you should not place undue reliance on our forward-looking statements.

Unless the context otherwise requires, references in this Quarterly Report on Form 10-Q to the "company," "Personalis," "we," "us" and "our" refer to Personalis, Inc.

PART I—FINANCIAL INFORMATION

Item 1. Financial Statements

PERSONALIS, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS (unaudited)
(in thousands, except share and per share data)

	September 30, 2019	December 31, 2018
Assets		
Current assets		
Cash and cash equivalents	$ 87,013	$ 19,744
Short-term investments	40,263	—
Accounts receivable, net	4,445	4,457
Inventory and other deferred costs	4,604	3,432
Prepaid expenses and other current assets	3,973	1,926
Total current assets	140,298	29,559
Property and equipment, net	15,215	11,452
Operating lease right-of-use assets	2,154	—
Other long-term assets	2,024	659
Total assets	$ 159,691	$ 41,670
Liabilities, Redeemable Convertible Preferred Stock, and Stockholders' Equity (Deficit)		
Current liabilities		
Accounts payable	$ 7,764	$ 6,565
Accrued and other current liabilities	5,899	3,392
Contract liabilities	33,726	42,897
Short-term debt	—	4,996
Total current liabilities	47,389	57,850
Redeemable convertible preferred stock warrant liability	—	683
Other long-term liabilities	910	121
Total liabilities	48,299	58,654
Commitments and Contingencies (Note 12)		
Redeemable convertible preferred stock	—	89,404
Stockholders' equity (deficit)		
Common stock, $0.0001 par value — 200,000,000 shares authorized and 31,142,643 shares issued and outstanding as of September 30, 2019; 102,700,000 shares authorized and 3,085,307 shares issued and outstanding as of December 31, 2018	3	1
Additional paid-in-capital	245,362	9,131
Accumulated other comprehensive loss	(29)	(15)
Accumulated deficit	(133,944)	(115,505)
Total stockholders' equity (deficit)	111,392	(106,388)
Total liabilities, redeemable convertible preferred stock, and stockholders' equity (deficit)	$ 159,691	$ 41,670

See accompanying notes to condensed consolidated financial statements.

PERSONALIS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS (unaudited)
(in thousands, except share and per share data)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Revenues	$ 17,153	$ 11,654	$ 47,053	$ 24,617
Costs and expenses				
Costs of revenues	11,524	7,173	31,538	17,641
Research and development	5,303	3,574	15,045	10,023
Selling, general and administrative	6,056	2,658	15,692	7,575
Total costs and expenses	22,883	13,405	62,275	35,239
Loss from operations	(5,730)	(1,751)	(15,222)	(10,622)
Interest income	756	83	1,040	215
Interest expense	(204)	(455)	(1,133)	(1,650)
Loss on debt extinguishment	(1,704)	(1,336)	(1,704)	(4,658)
Other (expense) income, net	(2)	(180)	(1,415)	389
Loss before income taxes	(6,884)	(3,639)	(18,434)	(16,326)
Provision for income taxes	(1)	(2)	(5)	(5)
Net loss	$ (6,885)	$ (3,641)	$ (18,439)	$ (16,331)
Net loss per share, basic and diluted	$ (0.22)	$ (1.19)	$ (1.35)	$ (5.33)
Weighted-average shares outstanding, basic and diluted	31,133,683	3,065,256	13,613,444	3,062,464

See accompanying notes to condensed consolidated financial statements.

PERSONALIS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS (unaudited)
(in thousands)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Net loss	$ (6,885)	$ (3,641)	$ (18,439)	$ (16,331)
Other comprehensive loss				
Foreign currency translation adjustment	(2)	(1)	(2)	(3)
Change in unrealized loss on available-for-sale debt securities	(12)	—	(12)	—
Comprehensive loss	$ (6,899)	$ (3,642)	$ (18,453)	$ (16,334)

See accompanying notes to condensed consolidated financial statements.

PERSONALIS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF REDEEMABLE CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY (DEFICIT) (unaudited)
(in thousands)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Redeemable convertible preferred stock				
Total redeemable convertible preferred stock, beginning balances	$ —	$ 75,995	$ 89,404	$ 75,995
Conversion of redeemable convertible preferred stock to common stock	—	—	(89,404)	—
Convertible Notes conversion on September 20, 2018 (see Note 6), net of issuance cost	—	13,409	—	13,409
Total redeemable convertible preferred stock, ending balances	$ —	$ 89,404	$ —	$ 89,404
Stockholders' equity (deficit)				
Common stock and additional paid-in capital:				
Beginning balances	$ 244,092	$ 7,523	$ 9,132	$ 3,026
Equity component credited to additional paid-in capital upon Convertible Notes modification on May 31, 2018 and August 20, 2018 (see Note 6)	—	800	—	4,690
Conversion of Series A, B and C redeemable convertible preferred stock to common stock	—	—	89,404	—
Proceeds from initial public offering, net of expenses	(197)	—	139,828	—
Conversion of redeemable convertible preferred stock warrants to common stock warrants	—	—	2,086	
Proceeds from exercise of common stock warrant	—	—	8	—
Issuance of common stock warrants	—	—	572	—
Proceeds from exercise of stock options	68	12	678	36
Stock-based compensation	1,402	341	3,657	924
Ending balances	245,365	8,676	245,365	8,676
Accumulated other comprehensive loss:				
Beginning balances	(15)	(12)	(15)	(10)
Foreign currency translation adjustment	(2)	(1)	(2)	(3)
Unrealized loss on available-for-sale debt securities	(12)	—	(12)	—
Ending balances	(29)	(13)	(29)	(13)
Accumulated deficit:				
Beginning balances	(127,059)	(108,309)	(115,505)	(95,619)
Net loss	(6,885)	(3,641)	(18,439)	(16,331)
Ending balances	(133,944)	(111,950)	(133,944)	(111,950)
Total stockholders' equity (deficit), ending balances	$ 111,392	$ (103,287)	$ 111,392	$ (103,287)

See accompanying notes to condensed consolidated financial statements.

PERSONALIS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS (unaudited)
(in thousands)

	Nine Months Ended September 30,	
	2019	**2018**
Cash flows from operating activities:		
Net loss	$ (18,439)	$ (16,331)
Adjustments to reconcile net loss to net cash (used in) provided by operating activities		
Depreciation and amortization	3,382	2,050
Noncash lease expense	673	—
Stock-based compensation expense	3,657	924
Loss on debt extinguishment	1,704	4,658
Change in fair value of convertible preferred stock warrant liability	1,403	166
Change in fair value of compound derivative instrument	—	(574)
Accretion of noncash interest and debt reduction	156	1,137
Other	73	(4)
Changes in operating assets and liabilities		
Accounts receivable	(75)	(1,160)
Inventories and other deferred costs	(1,173)	(1,878)
Prepaid expenses and other assets	(3,410)	(818)
Accounts payable	474	773
Accrued and other current liabilities	1,076	542
Contract liabilities	(9,170)	12,955
Other long-term liabilities	(805)	(71)
Net cash (used in) provided by operating activities	(20,474)	2,369
Cash flows from investing activities:		
Purchase of available-for-sale debt securities	(40,262)	—
Purchase of property and equipment	(6,469)	(7,181)
Net cash used in investing activities	(46,731)	(7,181)
Cash flows from financing activities:		
Proceeds from initial public offering, net of underwriting discounts and commissions	144,025	—
Payment of costs related to initial public offering	(3,950)	—
Proceeds from borrowings	20,000	—
Payment of costs related to issuance of Series C redeemable convertible preferred stock	—	(18)
Payments of borrowing costs	(490)	—
Repayments under borrowing arrangements	(25,000)	(645)
Debt extinguishment costs	(794)	—
Proceeds from exercise of common stock warrants	8	—
Proceeds from exercise of stock options	678	34
Net cash provided by (used in) financing activities	134,477	(629)
Effect of exchange rates on cash flows and cash equivalents	(3)	(1)
Net increase (decrease) in cash and cash equivalents	67,269	(5,442)
Cash and cash equivalents, beginning of period	19,744	22,617
Cash and cash equivalents, end of period	$ 87,013	$ 17,175

See accompanying notes to condensed consolidated financial statements.

Note 1. Company and Nature of Business

Description of Business

Personalis, Inc. (the "Company") was incorporated in Delaware on February 21, 2011, and began operations in September 2011. The Company formed a wholly owned subsidiary, Personalis (UK) Ltd., in August 2013. The Company is a growing cancer genomics company transforming the development of next-generation therapies by providing more comprehensive molecular data about each patient's cancer and immune response. The Company operates and manages its business as one reportable operating segment, which is the sale of sequencing and data analysis services.

Significant Risks and Uncertainties

The Company has incurred net operating losses and negative cash flows from operations every year. As of September 30, 2019, the Company had an accumulated deficit of $133.9 million.

In June 2019, the Company completed an initial public offering ("IPO") of its common stock and raised proceeds of $139.8 million, after deducting underwriting discounts, commissions and offering expenses. Management believes that these proceeds combined with existing sources of liquidity will be sufficient to fund operations for at least one year from the issuance of these unaudited condensed consolidated financial statements. However, there can be no assurance that additional financing will not be required or that the Company will be successful in raising additional capital on terms that are acceptable to the Company.

If the Company requires but is unable to obtain additional funding, the Company could be required to modify, delay, or abandon some of its planned future expansion or expenditures or reduce some of its ongoing operating costs, which could harm its business, operating results, financial condition, and ability to achieve its intended business objectives.

Approval of Amended and Restated Certificate of Incorporation

An amended and restated certificate of incorporation, which authorized 200,000,000 shares of common stock and 10,000,000 shares of preferred stock became effective in June 2019 in connection with the closing of the Company's IPO. As of September 30, 2019 no shares of preferred stock are outstanding.

Note 2. Summary of Significant Accounting Policies

Basis of Presentation

The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America ("U.S. GAAP") and the applicable rules and regulations of the Securities and Exchange Commission ("SEC") regarding interim reporting. Certain information and note disclosures normally included in the financial statements prepared in accordance with U.S. GAAP have been condensed or omitted pursuant to such rules and regulations. As such, the information included in this Quarterly Report on Form 10-Q should be read in conjunction with the consolidated financial statements and accompanying notes included in the Company's final prospectus filed with the SEC pursuant to Rule 424(b) under the Securities Act of 1933, as amended, on June 20, 2019 (the "Prospectus").

The condensed consolidated balance sheet as of December 31, 2018 included herein was derived from the audited financial statements as of that date, but does not include all disclosures, including notes required by U.S. GAAP.

The condensed consolidated financial statements include the accounts of Personalis, Inc. and its wholly owned subsidiary, Personalis (UK) Ltd. All intercompany balances and transactions have been eliminated.

The accompanying condensed consolidated financial statements reflect all normal recurring adjustments that are necessary to present fairly the results for the interim periods presented. Interim results are not necessarily indicative of the results for the full year ending December 31, 2019.

Use of Estimates

The preparation of condensed consolidated financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, and disclosure of contingent assets and liabilities, at the date of the condensed consolidated financial statements and the reported amounts of revenues and expense during the reporting period. The estimates include, but are not limited to, useful lives assigned to long-lived assets, the valuation of common and convertible redeemable preferred stock and related warrants and options, the valuation of the compound derivative instrument, the valuation of stock-based awards, and provisions for income taxes and contingencies. Actual results could differ from these estimates, and such differences could be material to the Company's condensed consolidated financial position and results of operations.

Reverse Stock Split

On June 4, 2019, the Company filed an amendment to the Company's amended and restated certificate of incorporation to effect a reverse split of shares of the Company's common stock and redeemable convertible preferred stock on a four-for-one basis (the "Reverse Stock Split"). The par value of the common stock and redeemable convertible preferred stock was not adjusted as a result of the Reverse Stock Split. All references to common stock, options to purchase common stock, share data, per share data, redeemable convertible preferred stock and related information contained in these consolidated financial statements have been retrospectively adjusted to reflect the effect of the Reverse Stock Split for all periods presented.

Initial Public Offering

On June 20, 2019, the Company completed an IPO in which it issued and sold 9,109,725 shares of its common stock at a public offering price of $17.00 per share. The Company received net proceeds of $139.8 million after deducting underwriting discounts, commissions and offering expenses. Offering expenses were $4.2 million and consisted of fees and expenses incurred in connection with the sale of the Company's common stock in the IPO, including legal, accounting, printing, and other IPO-related costs. During the nine months ended September 30, 2019, $3.9 million of the offering expenses were paid.

A warrant to purchase 188,643 shares of our common stock was exercised prior to completion of the IPO. In addition, in connection with the IPO, all shares of the Company's then-outstanding redeemable convertible preferred stock were automatically converted into 18,474,703 shares of the Company's common stock, and all then-outstanding warrants to purchase the Company's convertible preferred stock were automatically converted into warrants to purchase 84,585 shares of the Company's common stock.

Concentration of Credit Risk and Other Risks and Uncertainties

The Company is subject to credit risk from its portfolio of cash and cash equivalents. The Company's cash and cash equivalents are deposited with high-quality financial institutions. Deposits at these institutions may, at times, exceed federally insured limits. Management believes these financial institutions are financially sound and, accordingly, that minimal credit risk exists. The Company has not experienced any losses on its deposits of cash and cash equivalents.

The Company also invests in investment-grade debt instruments and has policy limits for the amount it can invest in any one type of security, except for securities issued or guaranteed by the U.S. government. The goals of the Company's investment policy are as follows: preservation of principal; liquidity of investments sufficient to meet cash flow requirements; avoidance of inappropriate concentration and credit risk; competitive after-tax rate of returns; and fiduciary control of cash and investments. Under its investment policy, the Company limits the amounts invested in such securities by credit rating, maturity, investment type, and issuer. As a result, management believes that these financial instruments do not expose the Company to any significant concentrations of credit risk.

The Company purchases various reagents and sequencing materials from sole source suppliers. Any extended interruption in the supply of these materials could result in the Company's inability to secure sufficient materials to conduct business and meet customer demand.

The Company routinely assesses the creditworthiness of its customers and does not require collateral. The Company has not experienced any material losses related to receivables from individual customers, or groups of customers. The Company maintains an allowance for doubtful accounts, which was $0.1 million and zero as of September 30, 2019 and December 31, 2018, respectively. During the three and nine months ended September 30, 2019, bad debt expense was $0.1 million. The Company had no bad debt expense in 2018.

Significant customers are those that represent more than 10% of the Company's total revenues or accounts receivable balance at each respective condensed consolidated balance sheet date. For each significant customer, revenue as a percentage of total revenues and accounts receivable as a percentage of total accounts receivable are as follows:

	Revenue (unaudited)		Revenue (unaudited)		Accounts Receivable	
	Three Months Ended September 30		Nine Months Ended September 30		September 30, 2019	December 31, 2018
	2019	2018	2019	2018	(unaudited)	
VA MVP	75%	56%	63%	51%	49%	*
Merck & Co., Inc.	*	18%	*	16%	*	10%
Pfizer Inc.	11%	10%	17%	*	22%	33%
Customer D	*	*	*	*	*	17%
Customer E	*	*	*	*	*	10%

* Less than 10% of revenue or accounts receivable

Revenue Recognition

The Company applies the revenue recognition guidance in accordance with Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") Topic 606, Revenue from Contracts with Customers ("Topic 606").

Revenue Recognition

The revenue guidance provides a five-step framework through which revenue is recognized when control of promised goods or services is transferred to a customer at an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. To determine revenue recognition for arrangements that the Company concludes are within the scope of the new revenue recognition standard, management performs the following five steps: (i) identifies the contract(s) with a customer; (ii) identifies the performance obligations in the contract(s); (iii) determines the transaction price, including whether there are any constraints on variable consideration; (iv) allocates the transaction price to the performance obligations; and (v) recognizes revenue when (or as) the Company satisfies a performance obligation. At contract inception, once a contract is determined to be within the scope of the new revenue standard, the Company assesses whether individual goods or services promised within each contract are distinct and, therefore, represent separate performance obligation.

The Company derives revenues from sequencing and data analysis services to support the development of personalized cancer vaccines and other next-generation cancer immunotherapies. The Company's contracts are in the form of a combination of signed agreements, statements of work, and/or purchase orders. Under ASC Topic 606, the Company accounts for a contract with a customer when there is approval and commitment from both parties, the rights of the parties are identified, payment terms are identified, the contract has commercial substance, and it is probable that the Company will collect substantially all of the consideration to which it will be entitled.

The sequencing and data analysis services are the only distinct services that meet the definition of a performance obligation and are accounted for as one performance obligation under ASC Topic 606. The Company recognizes revenue from such services at the point in time when control of the test results is transferred to the customer. The Company has elected to exclude all sales and value added taxes from the measurement of the transaction price. Sequencing and data analysis services are based on a fixed price per test.

Payment terms and conditions vary by contract and customer. The Company's standard payment terms are less than 90 days from the invoice date. In instances where the timing of the Company's revenue recognition differs from the timing of its invoicing, the Company does not assess whether a contract has a significant financing component if the expectation at contract inception is such that the period between payment by the customer and the transfer of the promised services to the customer will be one year or less. After assessing each of its revenue-generating arrangements to determine whether a significant financing component exists, the Company concluded that a significant financing component does not exist in any of its arrangements. The primary purpose of the Company's invoicing terms is to provide customers with simplified and predictable ways of purchasing the Company's services and to provide payment protection for the Company.

Practical Expedients and Exemptions

As a practical expedient, the Company recognizes the incremental costs of obtaining contracts, such as sales commissions, as an expense when incurred since the amortization period of the asset the Company otherwise would have recognized is one year or less. Sales commissions are recorded within selling, general, and administrative expenses in the consolidated statements of operations.

Costs of Revenues

The Company's costs of revenues primarily consist of production materials, personnel costs (e.g., salaries, bonuses, benefit, and stock-based compensation), cost of expensed equipment, consumables and laboratory supplies, information technology ("IT") and facility costs, and depreciation and service maintenance contracts on capitalized equipment.

Cash and Cash Equivalents

Cash equivalents consist of highly liquid investments with maturities at the time of purchase of three months or less. Cash equivalents include bank demand deposits and money market accounts that invest primarily in cash, U.S. Treasury bills, notes, and other obligations issued or guaranteed as to principal and interest by the U.S. Government, its agencies or instrumentalities, and repurchase agreements secured by such obligations or cash. Cash equivalents also include commercial paper, which are marketable debt securities recorded at fair value and accounted for in the same manner as other marketable debt securities described below.

Short-term Investments

The Company's investments in marketable debt securities are classified as available-for-sale and recorded at fair value. Investments with original maturities of greater than three months and remaining maturities of less than one year are classified as short-term investments. Investments with maturities beyond one year may be classified as short-term based on their highly liquid nature and because such marketable securities represent the investment of cash that is available for current operations. Short-term investments primarily consist of U.S. agency bonds, commercial paper, corporate bonds, and U.S. treasuries.

Unrealized gains and losses are included in accumulated other comprehensive loss in stockholders' equity (deficit). Any discount or premium arising at purchase is accreted or amortized to interest income or expense. Realized gains and losses and declines in fair value, if any, judged to be other than temporary are reported in other (expense) income, net. When securities are sold, any associated unrealized gain or loss initially recorded as a separate component of stockholders' equity (deficit) is reclassified out of stockholders' equity (deficit) on a specific-identification basis and recorded in earnings for the period.

The Company periodically evaluates whether declines in fair values of its investments below their book value are other-than-temporary. This evaluation consists of several qualitative and quantitative factors regarding the severity and duration of the unrealized loss as well as the Company's ability and intent to hold the marketable security until a forecasted recovery occurs. Factors considered include quoted market prices, recent financial results and operating trends, implied values from any recent transactions or offers of investee securities, credit quality of debt instrument issuers, other publicly available information that may affect the value of the marketable security, duration and severity of the decline in value, and management's strategy and intentions for holding the marketable security. To date, the Company has not recorded any impairment charges on its marketable securities related to other-than-temporary declines in market value.

Fair Value Measurements

Financial assets and liabilities are recorded at fair value. Fair value is defined as the price that would be received to sell an asset or paid to transfer a liability (an exit price) in an orderly transaction between market participants at the reporting date. The hierarchy below lists three levels of fair value based on the extent to which inputs used in measuring fair value are observable in the market. Observable inputs reflect market data obtained from independent sources while unobservable inputs reflect market assumptions made by the reporting entity.

The three-level hierarchy for the inputs to valuation techniques used to measure fair value is briefly summarized as follows:

Level 1 — Unadjusted quoted prices in active markets that are accessible to the reporting entity at the measurement date for identical assets and liabilities.

Level 2 — Inputs other than quoted prices in active markets for identical assets and liabilities that are observable either directly or indirectly for substantially the full term of the asset or liability. Level 2 inputs include the following:

- Quoted prices for similar assets and liabilities in active markets.
- Quoted prices for identical or similar assets or liabilities in markets that are not active.
- Observable inputs other than quoted prices that are used in the valuation of the asset or liabilities (e.g., interest rate and yield curve quotes at commonly quoted intervals).
- Inputs that are derived principally from or are corroborated by observable market data by correlation or other means.

Level 3 — Unobservable inputs for the assets or liabilities (i.e., supported by little or no market activity). Level 3 inputs include management's own assumptions about the assumptions that market participants would use in pricing the asset or liability (including assumptions about risk).

This hierarchy requires the Company to use observable market data, when available, and to minimize the use of unobservable inputs when determining fair value.

Inventory and Other Deferred Costs

Inventories, consisting of supplies used in the Company's genomic analysis contracts, are valued at the lower of cost or net realizable value. Cost is determined using actual costs, on a first-in, first-out basis.

Other deferred costs relate to work in process for costs incurred on genomic analysis contracts that have not been completed or recognized as revenues. Other deferred costs represent materials used in sequencing services, labor, and overhead allocations.

Net Loss per Share Attributable to Common Stockholders

Basic net loss per common share is calculated by dividing the net loss attributable to common stockholders by the weighted-average number of shares of common stock outstanding during the period, without consideration of potentially dilutive securities. Diluted net loss per share is computed by dividing the net loss attributable to common stockholders by the weighted-average number of shares of common stock and potentially dilutive securities outstanding for the period. For purposes of the diluted net loss per share calculation, the redeemable convertible preferred stock, convertible preferred stock warrants, common stock warrants, common stock subject to repurchase, and stock options are considered to be potentially dilutive securities. Basic and diluted net loss attributable to common stockholders per share is presented in conformity with the two-class method required for participating securities as the redeemable convertible preferred stock is considered a participating security. The Company's participating securities do not have a contractual obligation to share in the Company's losses. As such, the net loss is attributed entirely to common stockholders. Because the Company has reported a net loss for the reporting periods presented, the diluted net loss per common share is the same as basic net loss per common share for those periods.

Recent Accounting Pronouncements

Recently Adopted Accounting Pronouncements

In May 2014, the FASB issued Accounting Standard Update ("ASU") No. 2014-09, Revenue from Contracts with Customers (Topic 606) ("ASU No. 2014-09"). Subsequently, the FASB also issued ASU No. 2015-14, Revenue from Contracts with Customers (Topic 606), which adjusted the effective date of ASU No. 2014-09; ASU No. 2016-08, Revenue from Contracts with Customers (Topic 606): Principal versus Agent Considerations (Reporting Revenue Gross versus Net), which amends the principal-versus-agent implementation guidance and illustrations in ASU No. 2014-09; ASU No. 2016-10, Revenue from Contracts with Customers (Topic 606): Identifying Performance Obligations and Licensing, which clarifies identifying performance obligation and licensing implementation guidance and illustrations in ASU No. 2014-09; and ASU No. 2016-12, Revenue from Contracts with Customers (Topic 606): Narrow-Scope Improvements and Practical Expedients, which addresses implementation issues and is intended to reduce the cost and complexity of applying the new revenue standard in ASU No. 2014-09 (collectively, the "Revenue ASUs").

The Revenue ASUs provide an accounting standard for a single comprehensive model for use in accounting for revenues arising from contracts with customers and supersedes most current revenue recognition guidance. The accounting standard is effective for interim and annual periods beginning after December 15, 2017. The guidance permits two methods of adoption: retrospectively to each prior reporting period presented (the full retrospective method), or retrospectively with the cumulative effect of initially applying the guidance recognized at the date of initial application (the modified retrospective method). The Company performed a detailed review of its revenue agreements and assessed the differences in accounting for such contracts under this guidance compared with previous revenue accounting standards. On January 1, 2017, the Company early adopted ASU No. 2014-09 using the full retrospective method. The adoption of this standard did not have a material impact on the Company's consolidated financial statements. Results for all periods presented are under ASC Topic 606.

In June 2018, the FASB issued ASU No. 2018-07, Improvements to Nonemployee Share-Based Payment Accounting ("ASU No. 2018-07"). ASU No. 2018-07 simplifies the accounting for share-based payments to nonemployees by aligning it with the accounting for share-based payments to employees, with certain exceptions. For all entities, the amendments are effective for annual periods beginning after December 15, 2019, and interim periods within annual periods beginning after December 15, 2020. Early adoption is permitted for any entity in any interim or annual period for which consolidated financial statements have not been issued or made available for issuance, but not before an entity adopts ASC Topic 606. The Company early adopted this guidance on January 1, 2017, which did not result in a material impact on its consolidated financial statements and related disclosures.

In February 2016, the FASB issued ASU No. 2016-02, Leases (Topic 842) ("ASU No. 2016-02"). In July 2018, the FASB issued ASU No. 2018-10, Codification Improvements to Topic 842, Leases, which provides clarification to ASU 2016-02. These ASUs (collectively, the "new lease standard") require an entity to recognize a lease liability and a right-of-use ("ROU") asset on the balance sheet for leases with lease terms of more than twelve months. Lessor accounting is largely unchanged, while lessees will no longer be provided with a source of off-balance sheet financing. This guidance is effective for fiscal years beginning after December 15, 2018, including interim periods within those fiscal years. In July 2018, the FASB issued ASU No. 2018-11, Leases (Topic 842) — Targeted Improvements, which allows entities to elect a modified retrospective transition method where entities may continue to apply the existing lease guidance during the comparative periods and apply the new lease requirements through a cumulative effect adjustment in the period of adoptions rather than in the earliest period presented.

On January 1, 2019, the Company adopted ASU No. 2016-02, and its associated amendments using the modified retrospective transition method by applying the new standard to all leases existing at the date of initial application and not restating comparative periods. There was no cumulative-effect adjustment recorded to retained earnings upon adoption. Under the standard, a lessee is required to recognize a lease liability and ROU asset for all leases. The new guidance also modified the classification criteria and requires additional disclosures to enable users of financial statements to understand the amount, timing, and uncertainty of cash flows arising from leases. Consistent with current guidance, a lessee's recognition, measurement, and presentation of expenses and cash flows arising from a lease continues to depend primarily on its classification. The Company elected the package of practical expedients permitted under the transition guidance, which allowed the Company to carryforward its historical lease classification, its assessment as to whether a contract was or contains a lease, and its initial direct costs for any leases that existed prior to January 1, 2019. The Company also elected the practical expedient not to separate lease and non-lease components. In addition, the Company elected the short-term lease exception as a practical expedient.

At the date of adoption, the Company derecognized a deferred rent liability in the amount of $0.3 million, and recognized a ROU asset and respective lease liability in the amount of $1.7 million and $2.0 million, respectively. As of September 30, 2019, lease liabilities in the amount of $1.4 million and $0.9 million are included in "Accrued and other current liabilities" and "Other long-term liabilities," respectively.

New Accounting Pronouncements Not Yet Adopted

In June 2016, the FASB issued ASU 2016-13, Financial Instruments - Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments, which amends the impairment model by requiring entities to use a forward-looking approach based on expected losses to estimate credit losses on certain types of financial instruments, including trade receivables and available-for-sale debt securities. The guidance is effective for the Company beginning in the first quarter of 2020. The Company is currently evaluating the impact of the new guidance on its condensed consolidated financial statements and related disclosures.

JOBS Act Accounting Election

The Company is an emerging growth company, as defined in the Jumpstart Our Business Startups Act (the "JOBS Act"). Under the JOBS Act, emerging growth companies can delay adopting new or revised accounting standards issued subsequent to the enactment of the JOBS Act until such time as those standards apply to private companies. The Company has irrevocably elected not to avail itself of this exemption from new or revised accounting standards, and therefore, the Company will be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies.

Note 3. Revenues

The following table presents the Company's revenues disaggregated by customer type (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
VA MVP	$ 12,912	$ 6,520	$ 29,791	$ 12,472
All other customers	4,241	5,134	17,262	12,145
Total	$ 17,153	$ 11,654	$ 47,053	$ 24,617

Revenues from countries outside of the United States, based on the billing addresses of customers, represented 1% and 2% of the Company's revenues for the three months ended September 30, 2019 and 2018, respectively, and 1% and 3% for the nine months ended September 30, 2019 and 2018, respectively.

Contract Assets and Liabilities

The Company had no contract assets as of September 30, 2019 and December 31, 2018, respectively.

The Company's contract liabilities consist of customer deposits in excess of revenues recognized and are presented as current liabilities in the condensed consolidated balance sheets.

The balance of contract liabilities was $33.7 million and $42.9 million as of September 30, 2019 and December 31, 2018, respectively. Revenues recognized for the three months ended September 30, 2019 and 2018 that were included in the contract liability balance at the beginning of each reporting period were $10.7 million and $4.8 million, respectively. Revenues recognized for the nine months ended September 30, 2019 and 2018 that were included in the contract liability balance at the beginning of each reporting period were $25.2 million and $6.3 million, respectively.

Revenues allocated to remaining performance obligations represent contracted revenues that have not yet been recognized ("contracted not recognized revenues"), which include VA MVP contract liabilities and amounts that will be invoiced and recognized as revenues in future periods. Contracted not recognized revenues were $82.5 million as of September 30, 2019, which we expect to recognize as revenues over the next 18 months.

Note 4. Balance Sheet Details

Inventory and other deferred costs consist of the following (in thousands):

	September 30, 2019	December 31, 2018
Raw materials	$ 1,969	$ 2,134
Other deferred costs	2,635	1,298
Total inventory and other deferred costs	$ 4,604	$ 3,432

Property and equipment. Depreciation and amortization expense for the three months ended September 30, 2019 and 2018 was $1.2 million and $0.9 million, respectively, and for the nine months ended September 30, 2019 and 2018 was $3.4 million and $2.1 million, respectively. Accumulated depreciation and amortization was $8.6 million and $5.2 million as of September 30, 2019 and December 31, 2018, respectively.

Accrued and other current liabilities consist of the following (in thousands):

	September 30, 2019	December 31, 2018
Accrued compensation	$ 3,052	$ 2,843
Operating lease right-of-use liabilities	1,421	—
Accrued taxes	431	181
Accrued liabilities	352	59
Accrued interest	—	207
Deferred rent	—	99
Other current liabilities	643	3
Total accrued and other current liabilities	$ 5,899	$ 3,392

Note 5. Fair Value Measurements

The following tables show the Company's financial assets and liabilities measured at fair value on a recurring basis and the level of inputs used in such measurements as of September 30, 2019 and December 31, 2018 (in thousands):

	As of September 30, 2019				
	Adjusted Cost	Unrealized Gains	Unrealized Losses	Fair Value	Fair Value Level
Assets					
Cash and cash equivalents					
Money market funds	$ 45,013	$ —	$ —	$ 45,013	Level 1
Commercial paper	39,762	—	(4)	39,758	Level 2
Short-term investments					
Commercial paper	7,164	—	(1)	7,163	Level 2
U.S. government securities	2,012	—	—	2,012	Level 1
Corporate debt securities	4,804	1	—	4,805	Level 2
U.S. agency securities	26,291	2	(10)	26,283	Level 2
Total assets measured at fair value	$ 125,046	$ 3	$ (15)	$ 125,034	

	As of December 31, 2018				
	Adjusted Cost	Unrealized Gains	Unrealized Losses	Fair Value	Fair Value Level
Assets					
Cash and cash equivalents					
Money market funds	$ 18,142	$ —	$ —	$ 18,142	Level 1
Total assets measured at fair value	$ 18,142	$ —	$ —	$ 18,142	
Liabilities					
Long-term liabilities					
Convertible preferred stock warrants liability				$ 683	Level 3
Total liabilities measured at fair value				$ 683	

There have been no realized gains or losses on sales of marketable securities for the periods presented. The Company began investing in marketable debt securities during the current quarter and, therefore, no security has been in an unrealized loss position for 12 months or greater. The Company determined that it did have the ability and intent to hold all marketable securities that have been in a continuous loss position until maturity or recovery. As of September 30, 2019, the Company does not consider any of its marketable debt securities to be other than temporarily impaired.

The Company's marketable debt securities at September 30, 2019 have maturities due in one year or less, except for debt securities with an aggregate cost basis and fair value of $3.9 million that have maturities ranging from 13 to 15 months.

The Black-Scholes option-pricing model was used to estimate the fair value of the convertible preferred stock warrants at the date of issuance and at each subsequent consolidated balance sheet date. The fair value of the convertible preferred stock warrants was also estimated at the time of conversion to common stock warrants (see Note 10). Under this option-pricing model, convertible preferred stock warrants were valued by creating a series of call options with exercise prices based on the liquidation preferences and conversion terms of each equity class. The values of the redeemable convertible preferred stock and common stock are inferred by analyzing these options.

The fair value of each convertible preferred stock warrant was estimated using theBlack-Scholes option-pricing model with the assumptions described below. Upon conversion to common stock warrants in the second quarterof 2019 (see Note 10), no further fair value measurements were made. Therefore, there is no activity with respect to periods after the second quarter of 2019. For the periods indicated the Company has limited historical volatility information available, and the expected volatility was based on actual volatility for comparable public companies projected over the expected terms of the warrants. The Company didnot apply a forfeiture rate to the warrants as there is not enough historical information available to estimate such a rate. The risk-free interest rate was based on the U.S. Treasury yield curve over the expected term of the warrants.

	Six Months Ended June 30, 2019	Year Ended December 31, 2018
Expected term (in years)	5.01 - 5.26	5.17 - 7.00
Volatility	57.20% - 57.24%	55.56% - 56.42%
Risk-free interest rate	1.75%	2.58% - 3.01%
Dividend yield	0%	0%

The fair value of the compound derivative instrument was estimated at the date of inception in June 2017 and at each subsequent consolidated balance sheet date using a hybrid method that combines probability-weighted and with-or-without methods using unobservable inputs, which are classified as Level 3 within the fair value hierarchy. The primary inputs for this approach included the probability of achieving various settlement scenarios that provide the lenders the right or the obligation to receive cash or a variable number of shares upon the completion of a capital transaction. The probability assumptions related to estimating various settlement scenarios as of December 31, 2017 and 2018, and the inception date ranged between 0.2% and 70%, and a discount rate of 35.1% was applied to estimated future cash flows. After the initial measurement, changes in the fair value of this compound derivative were recorded in other income (expense), net.

The following table sets forth a summary of the changes in the fair value of the Company's Level 3 financial instruments (in thousands):

	Warrant Liability	Derivative Asset	Derivative Liability
Balance — December 31, 2017	$ 292	$ —	$ 671
Initial fair value of derivative asset	—	623	—
Change in fair value	391	(97)	(671)
Elimination as a result of debt extinguishment	—	(526)	—
Balance — December 31, 2018	683	—	—
Change in fair value	1,403	—	—
Reclassification of warrant liability to additional paid in capital on conversion	(2,086)		
Balance — September 30, 2019	$ —	$ —	$ —

Note 6. Borrowings

Amounts outstanding under the Company's financing arrangements consisted of the following (in thousands):

	December 31, 2018
Credit agreement	
Revolving Loan	$ 5,000
Total principal payments due	5,000
Less reduction in carrying value	(4)
Total amounts outstanding	4,996
Less: Current portion	(4,996)
Long-Term portion	$ —

Term Loan

In September 2014, the Company entered into a loan and security agreement with Silicon Valley Bank to borrow up to $3.0 million under an equipment loan to be secured with the equipment financed (the "Term Loan"). On October 3, 2014, the Company borrowed $2.4 million under the Term Loan. The Term Loan required 12 interest-only payments, followed by 36 equal monthly installments of principal, plus interest, which began on October 3, 2015.

In connection with the Term Loan, the Company issued to the bank a warrant exercisable for ten years from the date of grant to purchase 22,489 shares of the Company's Series B redeemable convertible preferred stock at an exercise price of $4.60 per share (see Note 10).

The estimated fair value of the warrants upon draw down of $0.1 million was based on the Black-Scholes option-pricing model. The Company recorded the fair value of the warrant at issuance as a reduction in the debt-carrying value and as a warrant liability. The debt-carrying value reduction was accreted using the effective interest method as additional interest expense over the contractual period of four years for the Term Loan.

On September 30, 2018, the Term Loan was repaid in full.

Revolving Loan

In June 2017, the Company entered into a $10.0 million revolving loan and security agreement (the "Revolving Loan") with TriplePoint Capital LLC ("TriplePoint"). Borrowings under the Revolving Loan bear an interest rate of prime, plus 6.75%. The Revolving Loan also has a 5.5% end of term loan payment on the highest outstanding principal amount. The Revolving Loan requires monthly interest-only payments until the maturity date. The Revolving Loan's original maturity date was December 31, 2018, and in December 2018 the maturity date was further extended until March 22, 2019. Upon determining that the change in cash flows between the previous and current credit facility was not greater than 10%, the Company accounted for the transaction as a debt modification.

As of December 31, 2018, the Company's outstanding principal under the Revolving Loan was $5.0 million and $5.0 million was available to borrow.

In connection with the Revolving Loan, the Company issued to TriplePoint a warrant to purchase up to 62,096 shares of the Company's Series C redeemable convertible preferred stock at an exercise price of $8.052 per share (see Note 10).

The estimated fair value of the warrant upon draw down of $0.1 million was based on the Black-Scholes option-pricing model. The Company recorded the fair value of the warrant at issuance as a reduction in the debt-carrying value and as a warrant liability. The debt-carrying value reduction was accreted using the effective interest method as additional interest expense over the contractual period of 1.5 years for the Revolving Loan.

The Revolving Loan had an effective interest rate of 19.22% per year. The Revolving Loan interest expense for the three and nine months ended September 30, 2018 was $0.2 million and $0.7 million, respectively. Interest expense for the three and nine months ended September 30, 2019 was not significant.

The Company accrued $0.2 million as of December 31, 2018 related to accretion of final payment due at maturity per the agreement using the effective interest rate method.

On March 22, 2019, this Revolving Loan was repaid in full.

Growth Capital Loan

On March 22, 2019, the Company entered into a growth capital loan (the "Growth Capital Loan") with TriplePoint to provide for a $20.0 million growth capital loan facility and as of June 30, 2019, had drawn down the full $20.0 million available under the facility. The Company used $5.3 million of the Growth Capital Loan to repay, in its entirety, all amounts outstanding under the Revolving Loan. Borrowings under the Growth Capital Loan bore interest at a floating rate of prime rate plus 5.00% for borrowings up to $15.0 million and the prime rate plus 6.50% for borrowing greater than $15.0 million. Under the agreement, the Company was required to make monthly interest-only payments through April 1, 2020 and was required to make 36 equal monthly payments of principal, plus accrued interest, from April 1, 2020 through March 1, 2023, when all unpaid principal and interest was to become due and payable. The agreement allowed voluntarily prepayment of all, but not part, of the outstanding principal at any time prior to the maturity date, subject to a prepayment fee of 1.00% of the outstanding balance if prepaid in months one through 12 of the loan term. In addition to the final payment, the Company paid an amount equal to 2.75% of each principal amount drawn under this growth capital loan facility.

In connection with the Growth Capital Loan, the Company issued a warrant to purchase 65,502 shares of common stock to TriplePoint at an exercise price of $9.16 per share. The Company recorded the issuance-date fair value of the warrant of $0.6 million and fees paid to TriplePoint of $0.3 million as a debt discount, which was amortized over the term of the Growth Capital Loan using the effective interest rate method.

Upon issuance, the Growth Capital Loan had an effective interest rate of 15.23% per year. Interest expense for the three and nine months ended September 30, 2019 was $0.3 million and $1.0 million, respectively.

On August 14, 2019 the Company paid off the Growth Capital Loan in its entirety. In connection with this debt repayment, the Company recorded a $1.7 million loss on extinguishment of debt in the consolidated statements of operations.

Convertible Notes

On June 29, 2017, the Company entered into a convertible promissory note agreement with certain existing redeemable convertible preferred stockholders and third parties (collectively, the "Investors") for the issuance of convertible promissory notes with a face value of $12.2 million (the "Convertible Notes"). Under the terms of the Convertible Notes agreement, the Convertible Notes bear interest of 8.00% per annum, with a maturity date of June 28, 2018. In the event that the Company issued and sold shares of its equity securities (the "Equity Securities") to Investors on or before the maturity date in an equity financing with total proceeds to the Company of not less than $10 million (including the conversion of the Convertible Notes or other convertible securities issued for capital raising purposes) (a "Qualified Financing"), then the outstanding principal amount of the Convertible Notes and any unpaid accrued interest would have automatically converted in whole without any further action by the holder into such Equity Securities sold in the Qualified Financing at a conversion price equal to the price paid per share for Equity Securities by the Investors in the Qualified Financing multiplied by 0.8. If the Company consummated a change of control while the Convertible Notes remained outstanding, the Company would have repaid the holders in cash an amount equal to 150% of the outstanding principal amount of the Convertible Notes, plus any unpaid accrued interest on the original principal. The Convertible Notes had customary events of default.

Certain conversion and redemption features of the Convertible Notes met the requirements for separate accounting and were accounted for as a single, compound derivative instrument. The compound derivative instrument was recorded at fair value at inception and was subject to remeasurement to fair value at each consolidated balance sheet date, with any changes in fair value recognized in the consolidated statements of operations as other income (expense). The estimated fair value of the compound derivative instrument was $0.5 million at issuance and was recorded as a reduction in the carrying value of the Convertible Notes and as a single compound derivative liability. The Convertible Notes carrying value reduction was accreted using the effective interest method as interest expense over the Convertible Notes contractual period of one year. The Convertible Notes had an effective interest rate of 12.69% per year.

On May 31, 2018, the original maturity date for the Convertible Notes was extended to June 28, 2019 (previously June 28, 2018). The maturity date extension was deemed substantial and was accounted for as a debt extinguishment under ASC 470, *Debt*. In connection with the debt extinguishment on May 31, 2018, the fair value of the Convertible Notes was allocated between the carrying amount of the Convertible Notes and accrued interested of $13.1 million, a compound derivative asset of $0.6 million, and an equity component of $3.9 million, which was credited to additional paid-in capital within the consolidated statements of redeemable convertible preferred stock and stockholders' equity (deficit). A $3.3 million loss on debt extinguishment was also recorded in the consolidated statements of operations. The new carrying value of the Convertible Notes was accreted using the effective interest method as interest expense over the new contractual period of 1.1 years.

On August 20, 2018, the maturity date for the Convertible Notes was changed to September 20, 2018 (previously June 28, 2019). The term change was deemed substantial and was accounted for as a debt extinguishment under ASC 470. In connection with the debt extinguishment on August 20, 2018, the fair value of the Convertible Notes was allocated between the new carrying amount of the Convertible Notes and accrued interest of $13.4 million, and an equity component of $0.8 million, which resulted in an additional credit to additional paid-in capital. Upon modification, the compound derivative asset was eliminated. A $0.8 million loss on debt extinguishment was also recorded in the consolidated statements of operations. The new carrying value of Convertible Notes was accreted using the effective interest method as interest expense over the new contractual period of one month.

On September 20, 2018, upon the maturity of the Convertible Notes, the carrying amount, including accrued interest of $13.4 million was converted into 1,667,997 shares of the Company's Series C redeemable convertible preferred stock at a conversion price equal to $8.052 per share. No gain or loss was recorded on the conversion.

Interest expense on the Convertible Notes for the three and nine months ended September 30, 2018 was $0.2 million and $0.9 million, respectively.

Note 7. Leases

Operating Lease Obligations

In February 2015, the Company entered into a noncancelable operating lease for approximately 31,280 square feet of space used for its current laboratory and office space. The lease expires on November 30, 2020 and includes an option to extend the term for a period of three years immediately following the expiration of the term with rent payments equal to then current fair market rental for the space.

For the 2018 periods presented, the Company recognized rent expense on a straight-line basis over the noncancelable lease term. The Company's rent expense was $0.2 million and $0.7 million for the three and nine months ended September 30, 2018, respectively.

In August 2019, the Company entered into a noncancelable operating lease for a co-located data center space. The lease expires on September 1, 2022 and includes an option to extend the term for a period of three years immediately following the expiration of the term with rent payments to be negotiated upon such a renewal.

The Company adopted ASC 842 as of January 1, 2019. In determining the present value of lease payments, the Company uses its incremental borrowing rate based on the information available at the lease commencement date if the rate implicit in the lease is not readily determinable. At the date of adoption of ASC 842, the Company determined the amounts of lease liability using a discount rate of 8.0%, which represents the Company's incremental borrowing rate. The Company determines its incremental borrowing rate for lease liability using its current borrowing rate, adjusted for various factors including level of collateralization and term. With respect to the lease for co-located data center space, the Company determined the amounts of lease liability using a discount rate of 6.6%, and the Company recognized a $1.1 million operating lease right-of-use asset and lease liability on the lease commencement date in September 2019. The optional renewal periods for both leases were not recognized as part of the right-of-use asset or lease liability as a result of the renewal option assessment at the lease commencement dates.

Operating lease cost for the three and nine months ended September 30, 2019 was $0.3 million and $0.8 million, respectively. Cash paid for operating lease liabilities, included in cash flow from operating activities in the Condensed Consolidated Statement of Cash Flows was $0.8 million for the nine months period ended September 30, 2019. As of September 30, 2019, the weighted average remaining lease term for the operating leases was 2.0 years and the weighted average incremental borrowing rate was 7.3%.

Future minimum lease payments at December 31, 2018 under the noncancelable operating lease were as follows (in thousands):

	Amount
2019	$ 1,091
2020	1,030
Total future minimum lease payments	$ 2,121

Future minimum lease payments at September 30, 2019 under noncancelable operating leases were as follows (in thousands):

	Amount
2019 (remaining three months)	$ 369
2020	1,408
2021	403
2022	319
Total future minimum lease payments	2,499
Less: Imputed interest	(168)
Present value of future minimum lease payments	2,331
Less: Current portion of operating lease liability	(1,421)
Operating lease liabilities - noncurrent	$ 910

Note 8. Redeemable Convertible Preferred Stock

Series A redeemable convertible preferred stock, Series B redeemable convertible preferred stock and Series C redeemable convertible preferred stock (collectively the "Redeemable Convertible Preferred Stock") outstanding consisted of the following as of December 31, 2018 and as of immediately prior to the automatic conversion of the Redeemable Convertible Preferred Stock into common stock:

	December 31, 2018			
	Shares Authorized	Shares Issued and Outstanding	Aggregate Liquidation Preference	Net Carrying Value
			(in thousands)	
Series A	31,250,000	7,812,497	$ 20,500	$ 20,261
Series B	19,288,150	4,799,548	22,078	22,047
Series C	24,700,000	5,862,697	47,206	47,096
Total redeemable convertible preferred stock	75,238,150	18,474,742	$ 89,784	$ 89,404

Immediately prior to the closing of the Company's IPO, all shares of the Company's then-outstanding Redeemable Convertible Preferred Stock, as shown in the table above, automatically converted on a one-for-one basis into an aggregate of 18,474,703 shares of common stock. The Reverse Stock Split was effected on a holder-by-holder basis with no fractional shares issued, which resulted in 39 fewer shares of common stock issued as compared to the amounts shown in the above table.

Note 9. Stock-Based Compensation

2011 Equity Incentive Plan and 2019 Equity Incentive Plan

In 2011, the Company established its 2011 Equity Incentive Plan (the "2011 Plan") that provided for the granting of stock options to employees and nonemployees of the Company. Under the 2011 Plan, the Company had the ability to issue incentive stock options ("ISOs"), nonstatutory stock options ("NSOs"), stock appreciation rights, restricted stock awards, and restricted stock unit awards. Options under the 2011 Plan could be granted for periods of up to 10 years. The ISOs could be granted at a price per share not less than the fair value at the date of grant. The exercise price of an ISO granted to a 10% stockholder was not less than 110% of the estimated fair value of the shares on the date of grant, as determined by the board of directors (the "Board"). Options granted to new hires generally vested over a four-year period, with 25% vesting at the end of one year and the remaining vesting monthly thereafter; options granted as merit awards generally vested monthly over a four-year period.

For stock option grants issued prior to December 31, 2015, the Company allowed employees to exercise options granted under the 2011 Plan prior to vesting (early exercise of stock options). The unvested shares are subject to the Company's repurchase rights at the original purchase price. Initially, the proceeds were recorded as an accrued liability from the early exercise of stock options and reclassified to common stock as the Company's repurchase rights lapse. There were 262 and 78 unvested shares subject to the Company's repurchase rights as of December 31, 2018 and September 30, 2019, respectively.

The Company's Board adopted and the Company's stockholders approved the Company's 2019 Equity Incentive Plan (the "2019 Plan") in May 2019 and June 2019, respectively. The 2019 Plan became effective in June 2019 in connection with the Company's IPO, and no further grants will be made under the 2011 Plan. Shares reserved and remaining available for issuance under the 2011 Plan were added to the 2019 Plan reserve upon its effectiveness.

The 2019 Plan provides for the grant of ISOs, NSOs, stock appreciation rights, restricted stock awards, restricted stock unit awards, performance-based stock awards, and other forms of equity compensation. Additionally, the 2019 Plan provides for the grant of performance cash awards. ISOs may be granted only to the Company's employees and to any of the Company's parent or subsidiary corporation's employees. All other awards may be granted to employees, including officers, and to non-employee directors and consultants of the Company and any of the Company's affiliates. The exercise price of a stock option generally cannot be less than 100% of the fair market value of our common stock on the date of grant. Options under the 2019 Plan may be granted for periods of up to 10 years.

At December 31, 2018 there were 4,647,839 shares of common stock available for issuance under the 2011 Plan. At September 30, 2019 there were 4,508,463 shares of common stock available for issuance under the 2011 Plan and 2,758,017 available for issuance under the 2019 Plan.

Stock Option Activity

A summary of the Company's stock option activity under the 2011 Plan and 2019 Plan for the nine months ended September 30, 2019 is as follows:

	Outstanding Options			
(in thousands, except share and per share data)	Number of Shares	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value
Balance—December 31, 2018	4,110,130	$ 3.16	6.94	$ 24,716
Options granted	897,913	11.95		—
Options exercised	(265,230)	2.55		—
Options cancelled	(64,637)	6.34		—
Balance—September 30, 2019	4,678,176	$ 4.83	6.79	$ 46,163

The aggregate intrinsic value of unexercised stock options is calculated as the difference between the closing price of the Company's common stock of $14.68 on September 30, 2019 (the last trading day of the quarter) and the exercise prices of the underlying stock options. Out-of-the money stock options are excluded from the aggregate intrinsic value.

The weighted-average grant date fair value of options granted was $8.81 and $4.44 per share for the three months ended September 30, 2019 and 2018, respectively, and $8.19 and $3.44 per share for the nine months ended September 30, 2019 and 2018, respectively. As of September 30, 2019, the unrecognized stock-based compensation of unvested options was $10.2 million, which is expected to be recognized over a weighted-average period of 3.0 years.

Valuation of Stock Options

The Company estimated the fair value of stock options using the Black-Scholes option-pricing model. The fair value of stock options is recognized on a straight-line basis over the requisite service periods of the awards.

The fair value of stock options was estimated using the following weighted-average assumptions:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Expected term (in years)	6.00 - 6.08	1.50 - 5.98	5.00 - 6.87	1.50 - 5.99
Volatility	62.28 - 63.08%	52.19 - 56.20%	56.20 - 63.08%	52.19 - 56.20%
Risk-free interest rate	1.53 - 1.73%	2.62 - 2.87%	1.53 - 2.52%	2.62 - 2.88%
Dividend yield	0%	0%	0%	0%

Expected Term. The expected term is calculated using the simplified method, which is available if there is insufficient historical data about exercise patterns and post-vesting employment termination behavior. The simplified method is based on the vesting period and the contractual term for each grant, or for each vesting tranche for awards with graded vesting. The midpoint of the vesting date and the maximum contractual expiration date is used as the expected term under this method. For awards with multiple vesting tranches, the times from grant until the midpoints for each of the tranches may be averaged to provide an overall expected term.

Expected Volatility. The Company used an average historical stock price volatility of a peer group of publicly traded companies to be representative of its expected future stock price volatility, as the Company did not have sufficient trading history for its common stock. For purposes of identifying these peer companies, the Company considered the industry, stage of development, size, and financial leverage of potential comparable companies. For each grant, the Company measured historical volatility over a period equivalent to the expected term.

Risk-Free Interest Rate. The risk-free interest rate is based on the implied yield currently available on U.S. Treasury zero-coupon issues with remaining terms equivalent to the expected term of a stock award.

Expected Dividend Rate. The Company has not paid and does not anticipate paying any dividends in the near future. Accordingly, the Company has estimated the dividend yield to be zero.

2019 Employee Stock Purchase Plan

In May 2019, the Board adopted the 2019 Employee Stock Purchase Plan (the "ESPP"), which was approved by the Company's stockholders in June 2019. A total of 250,000 shares of common stock are initially reserved for issuance under the ESPP. The number of shares may be increased in accordance with the terms of the ESPP.

Subject to any plan limitations, the ESPP allows eligible employees to contribute, normally through payroll deductions, up to 15% of their earnings for the purchase of the Company's common stock at a discounted price per share. The price at which common stock is purchased under the ESPP is equal to 85% of the fair market value of the Company's common stock on the first or last day of the offering period, whichever is lower. Except for the initial offering period, the ESPP provides for separate six-month offering periods beginning on May 1 and November 1 of each year. The initial offering period runs from June 20, 2019 through October 31, 2019.

During the nine months ended September 30, 2019, no shares of common stock were purchased under the ESPP. The total compensation expense related to the ESPP for the three and nine months ended September 30, 2019 was $0.2 million. The following assumptions were used to calculate the stock-based compensation for each stock purchase right granted under the ESPP: a weighted-average expected life of 0.37 years; expected volatility of 59.1%; a risk-free interest rate of 2.1%; and a zero dividend yield.

Stock-based Compensation Expense

The following is a summary of stock-based compensation expense by function (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Costs of revenues	$ 149	$ 53	$ 339	$ 116
Research and development	290	121	647	288
Selling, general, and administrative	963	167	2,671	520
Total stock-based compensation expense	$ 1,402	$ 341	$ 3,657	$ 924

During the three months ended September 30, 2019, no shares with performance conditions vested. During the nine months ended September 30, 2019, 67,418 shares with performance conditions vested. The awards were subject to two vesting criteria: (i) a time-based service criterion, and (ii) a performance criterion of an initial public offering, which were met in connection with our June 20, 2019 IPO. The Company recognized $0.3 million of stock-based compensation expense for all such awards. During the three and nine months ended September 30, 2018, no shares with performance conditions vested and no stock-based compensation expense was recognized related to shares with performance conditions.

Note 10. Redeemable Convertible Preferred Stock Warrants

In September 2014, in connection with the Term Loan (see Note 6), the Company issued a warrant to purchase 22,489 shares of its Series B redeemable convertible preferred stock at an exercise price of $4.60 per share. The estimated fair value of the Series B convertible preferred stock warrant on the date of issuance of $0.1 million was recorded as a debt reduction. As of the issuance date, the fair value of the Series B convertible preferred stock warrant was calculated using the Black-Scholes option-pricing model and was based on a contractual term of ten years, a risk-free interest rate of 2.52%, expected volatility of 66.53%, and 0% expected dividend yield.

In June 2017, as additional consideration for the Revolving Loan (see Note 6), the Company issued a warrant to purchase up to 62,096 shares of its Series C redeemable convertible preferred stock at an exercise price of $8.052, subject to certain adjustments, such as any stock splits, stock dividends, recapitalizations, reclassifications, combinations, or similar transactions. The remaining term of the Series C convertible preferred stock warrant is seven years from June 28, 2017.

The estimated fair value of the Series C convertible preferred stock warrant on the date of issuance of $0.1 million was recorded as a debt reduction. As of the issuance date, the fair value of the Series C convertible preferred stock warrant was calculated using the Black-Scholes option-pricing model and was based on a contractual term of seven years, a risk-free interest rate of 1.97%, expected volatility of 64.33%, and 0% expected dividend yield.

At initial recognition, the convertible preferred stock warrants were recorded at their estimated fair values and were subject to remeasurement at each consolidated balance sheet date, with changes in fair value recognized as a component of net income. As of December 31, 2018, the fair values of the convertible preferred stock warrants were calculated to be $0.7 million.

Immediately prior to the closing of the Company's IPO, the redeemable convertible preferred stock warrants automatically converted to common stock warrants, and were reclassified as common stock warrants. As a result of the automatic conversion of the redeemable convertible preferred stock warrants to common stock warrants, the Company revalued the redeemable convertible preferred stock warrants as of the completion of the IPO and reclassified the outstanding preferred stock warrant liability balance to additional paid-in capital with no further remeasurements as the common stock warrants are now deemed permanent equity. The fair value transferred to additional paid-in capital was $2.1 million.

Subsequent to the conversion to a common stock warrant and before the end of the Company's second quarter ended June 30, 2019, the common stock warrant for 22,489 shares was exercised. As a result, the Company issued 19,069 shares of common stock as the contract allows a net share settlement. As of September 30, 2019, the common stock warrant for 62,096 shares was still outstanding.

Note 11. Common Stock Warrants

In connection with the sale of Series A redeemable convertible preferred stock in August 2011, the Company issued a warrant to purchase 188,643 shares of common stock to an investor who purchased Series A redeemable convertible preferred stock in August 2011 at an exercise price of $0.04 per share. The Company recorded the issuance-date fair value of the warrant of $0.1 million in equity as the warrant met all criteria for equity classification. The common stock warrant was exercised in June 2019 prior to the Company's IPO and is no longer outstanding as of September 30, 2019.

In connection with the Growth Capital Loan agreement (see Note 6), the Company issued a warrant to purchase 65,502 shares of common stock to the lender at an exercise price of $9.16 per share. The Company recorded the issuance-date fair value of the warrant of $0.6 million in equity as the warrant met all criteria for equity classification. The warrant is still outstanding as of September 30, 2019.

Note 12. Commitments and Contingencies

Contingencies

The Company is subject to claims and assessments from time to time in the ordinary course of business. Accruals for litigation and contingencies are reflected in the consolidated financial statements based on management's assessment, including the advice of legal counsel, of the expected outcome of litigation or other dispute resolution proceedings and/or the expected resolution of contingencies. Liabilities for estimated losses are accrued if the potential losses from any claims or legal proceedings are considered probable and the amounts can be reasonably estimated. Significant judgment is required in both the determination of probability of loss and the determination as to whether the amount can be reasonably estimated. Accruals are based only on information available at the time of the assessment due to the uncertain nature of such matters. As additional information becomes available, management reassesses potential liabilities related to pending claims and litigation and may revise its previous estimates, which could materially affect the Company's consolidated results of operations in a given period. As of December 31, 2018 and September 30, 2019, the Company was not involved in any material legal proceedings.

Indemnification

In the normal course of business, the Company enters into contracts and agreements that contain a variety of representations and warranties and provide for general indemnifications. The Company's exposure under these agreements is unknown because it involves claims that may be made against the Company in the future, but that have not yet been made. To date, the Company has not paid any claims or been required to defend any action related to its indemnification obligations. However, the Company may record charges in the future as a result of these indemnification obligations.

Note 13. Net Loss per Share Attributable to Common Stockholders

Basic net loss per share is computed by dividing the net loss by the weighted-average number of common shares outstanding for the period. Because the Company reported a net loss for the three and nine months ended September 30, 2019 and 2018, the number of shares used to calculate diluted net loss per common share is the same as the number of shares used to calculate basic net loss per common share for those periods presented because the potentially dilutive shares would have been antidilutive if included in the calculation.

The following table sets forth the computation of basic and diluted net loss per share attributable to common stockholders (in thousands, except share and per share data):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Numerator:				
Net loss attributable to common stockholders	$ (6,885)	$ (3,641)	$ (18,439)	$ (16,331)
Denominator:				
Weighted-average shares outstanding	31,134,009	3,065,386	13,614,087	3,063,418
Less weighted-average shares subject to repurchase	(326)	(130)	(643)	(954)
Weighted-average shares outstanding used in computing net loss per share attributable to common stockholders — basic and diluted	31,133,683	3,065,256	13,613,444	3,062,464
Net loss per share attributable to common stockholders — basic and diluted	$ (0.22)	$ (1.19)	$ (1.35)	$ (5.33)

The following outstanding shares of potentially dilutive securities were excluded from the computation of diluted net loss per share attributable to common stockholders for the periods presented because including them would have been antidilutive:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Redeemable convertible preferred stock	—	18,474,742	—	18,474,742
Common stock warrants	127,598	188,643	127,598	188,643
Series B preferred stock warrant	—	22,489	—	22,489
Series C preferred stock warrant	—	31,048	—	31,048
Options to purchase common stock	4,678,176	3,423,123	4,678,176	3,423,123
Unvested early exercised common stock options	78	—	78	—
Employee stock purchase plan	55,110	—	55,110	—
Total	4,860,962	22,140,045	4,860,962	22,140,045

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

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our condensed consolidated financial statements and the related notes and other financial information included elsewhere in this Quarterly Report on Form 10-Q and our final prospectus filed with the Securities and Exchange Commission (the "SEC") pursuant to Rule 424(b) under the Securities Act of 1933, as amended, on June 20, 2019 (the "Prospectus"). In addition to historical consolidated financial information, the following discussion contains forward-looking statements that reflect our plans, estimates, and beliefs. Our actual results could differ materially from those discussed in the forward-looking statements. You should review the sections titled "Special Note Regarding Forward-Looking Statements" for a discussion of forward-looking statements and in Part II, Item 1A, "Risk Factors" for a discussion of factors that could cause actual results to differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis and elsewhere in this Quarterly Report on Form 10-Q and in our Prospectus.

This Quarterly Report on Form 10-Q contains statistical data and estimates that we obtained from industry publications and reports. These publications typically indicate that they have obtained their information from sources they believe to be reliable, but do not guarantee the accuracy and completeness of their information. Some data contained in this Quarterly Report on Form 10-Q is also based on our internal estimates.

Overview

We are a growing cancer genomics company transforming the development of next-generation therapies by providing more comprehensive molecular data about each patient's cancer and immune response. We designed our NeXT Platform to adapt to the complex and evolving understanding of cancer, providing our biopharmaceutical customers with information on all of the approximately 20,000 human genes, together with the immune system, in contrast to many cancer panels that cover roughly 50 to 500 genes. We are also developing a complementary liquid biopsy assay that analyzes all human genes versus the more narrowly focused liquid biopsy assays that are currently available. By combining technological innovation, operational scale, and regulatory differentiation, our NeXT Platform is designed to help our customers obtain new insights into the mechanisms of response and resistance to therapy as well as new potential therapeutic targets. Our platform enhances the ability of biopharmaceutical companies to unlock the potential of conducting translational research in the clinic rather than with pre-clinical animal models or cancer cell lines. We are also planning to release a diagnostic based on our NeXT Platform that we envision being used initially by biopharmaceutical customers and clinical collaborators. Since inception, we have provided our services to more than 47 biopharmaceutical customers, including several of the largest pharmaceutical companies in the world.

We have focused on human genome sequencing since our inception in 2011. In 2013, we introduced our patented ACE Exome technology, providing enhanced and more complete coverage over all of the approximately 20,000 human genes. The superior performance of ACE Exome technology compared to other exomes was described in Genome Medicine and Nature Review publications.

In November 2016, we launched our ACE ImmunoID product, the first generation of our immuno-oncology genomics platform that combined our ACE exome and transcriptome technology with analytics to provide a more comprehensive tumor profiling solution for biopharma customers conducting cancer clinical trials and translational research. With ACE ImmunoID for Personalized Cancer Therapy, we further enhanced the platform for personalized cancer therapy customers with additional neoantigen analytics, improved turnaround times, and access to a Device Master File that we filed with the U.S. Food and Drug Administration. With the ACE ImmunoID for Biomarkers, we extended the platform further with ImmunogenomicsID, a broad immunogenomics biomarker analysis engine. In November 2018, we announced ImmunoID NeXT, our universal cancer immunogenomics platform, which is the first technology to enable comprehensive analysis of both a tumor and its immune microenvironment from a single sample and provides utility across immuno-oncology, targeted, and personalized therapies. We are currently commercializing ImmunoID NeXT.

In parallel with the work described above, we also developed multiple clinical diagnostic tests. Clinical diagnostic testing has remained a small portion of our business, primarily because we have elected not to expend the time and resources necessary to secure third-party reimbursement, choosing instead to pursue more immediate revenue opportunities. Nevertheless, it has helped us to develop important capabilities that do not depend on third-party reimbursement. In June 2015, we launched our ACE CancerPlus Test based on a 1,400-gene panel. We plan to build on this experience in 2019 by introducing a clinical diagnostic test based on our ImmunoID NeXT Platform, which will include all of the approximately 20,000 human genes and will be targeted initially to biopharmaceutical customers.

In parallel with the development of our platform technology, we have also provided DNA sequencing and analysis services under contract with the U.S. Department of Veterans Affairs (the "VA") Million Veteran Program (the "VA MVP"), beginning in 2012. This relationship with the VA MVP has enabled us to innovate, scale our operational infrastructure, and achieve greater efficiencies in our lab. Our customers include large-cap pharmaceutical companies, emerging biotechnology companies, universities, non-profit medical research institutes, and government entities. In September 2019, we announced receipt of a new $38.1 million task order from the VA MVP.

Results of Operations

The following sets forth, for the periods presented, certain unaudited condensed consolidated statements of operations information (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Revenues	$ 17,153	$ 11,654	$ 47,053	$ 24,617
Costs and expenses				
Costs of revenues	11,524	7,173	31,538	17,641
Research and development	5,303	3,574	15,045	10,023
Selling, general and administrative	6,056	2,658	15,692	7,575
Total costs and expenses	22,883	13,405	62,275	35,239
Loss from operations	(5,730)	(1,751)	(15,222)	(10,622)
Interest income	756	83	1,040	215
Interest expense	(204)	(455)	(1,133)	(1,650)
Loss on debt extinguishment	(1,704)	(1,336)	(1,704)	(4,658)
Other (expense) income, net	(2)	(180)	(1,415)	389
Loss before income taxes	(6,884)	(3,639)	(18,434)	(16,326)
Provision for income taxes	(1)	(2)	(5)	(5)
Net loss	$ (6,885)	$ (3,641)	$ (18,439)	$ (16,331)
Net loss per share, basic and diluted	$ (0.22)	$ (1.19)	$ (1.35)	$ (5.33)
Weighted-average shares outstanding, basic and diluted	31,133,683	3,065,256	13,613,444	3,062,464

Third Quarter 2019 Financial Results

Revenues

Comparison of the Three Months Ended September 30, 2019 and 2018

Revenues were $17.2 million for the three months ended September 30, 2019 compared to $11.7 million for the three months ended September 30, 2018, an increase of $5.5 million, or 47%. This increase was primarily due to an increase in revenues from the VA MVP, which increased $6.4 million, or 98%, and was partially offset by a decrease of $0.9 million in revenues from all other customers, when compared to the three months ended September 30, 2018. The increase in revenues from the VA MVP was driven by an increase in the volume of samples we tested in the three months ended September 30, 2019, partially offset by lower prices per sample. The decrease in revenues from all other customers in the third quarter of 2019 was primarily driven by the receipt of relatively large orders from pharmaceutical customers in early 2018 that were fulfilled beginning around the second quarter of 2018 through the second quarter of 2019.

Comparison of the Nine Months Ended September 30, 2019 and 2018

Revenues were $47.0 million for the nine months ended September 30, 2019 compared to $24.6 million for the nine months ended September 30, 2018, an increase of $22.5 million, or 91%. This increase was primarily due to an increase in revenues from the VA MVP, which increased $17.3 million, or 139%, when compared to the nine months ended September 30, 2018. Revenues from all other customers increased $5.1 million, or 42%, when compared to the nine months ended September 30, 2018. The increase in revenues from the VA MVP was driven by an increase in the volume of samples we tested in the period, partially offset by lower prices per sample. The increase in revenues from all other customers was primarily due to an increase in the volume of samples we tested in relation to the sequencing and data analysis services we provided to our customers.

Costs of Revenues

Comparison of the Three Months Ended September 30, 2019 and 2018

Costs of revenues were $11.5 million for the three months ended September 30, 2019 compared to $7.2 million for the three months ended September 30, 2018, an increase of $4.3 million, or 60%. This increase was primarily due to the increase in revenues discussed above. The cost components related to the increase in costs of revenues were an increase in production materials of $3.0 million, an increase related to personnel costs including salaries, bonuses, benefits, and stock-based compensation expenses of $0.5 million, an increase in depreciation, service maintenance on capitalized equipment, and the cost of expensed equipment of $0.4 million, an increase in the consumption cost of consumables and laboratory supplies of $0.2 million, and an increase in IT and facility costs of $0.2 million.

Comparison of the Nine Months Ended September 30, 2019 and 2018

Costs of revenues were $31.5 million for the nine months ended September 30, 2019 compared to $17.6 million for the nine months ended September 30, 2018, an increase of $13.9 million, or 79%. This increase was primarily due to the increase in revenues discussed above. The cost components related to the increase in costs of revenues were an increase in production materials of $9.2 million, an increase related to personnel costs including salaries, bonuses, benefits, and stock-based compensation expenses of $1.8 million, an increase in depreciation, service maintenance on capitalized equipment, and the cost of expensed equipment of $1.5 million, an increase in the consumption cost of consumables and laboratory supplies of $0.7 million, and an increase in IT and facility costs of $0.7 million.

Research and Development Expenses

Comparison of the Three Months Ended September 30, 2019 and 2018

Research and development expenses were $5.3 million for the three months ended September 30, 2019 compared to $3.6 million for the three months ended September 30, 2018, an increase of $1.7 million, or 47%. This was primarily due to increased development activities for new product offerings, lab and automation development costs, and IT and facility costs. Research and development expenses increased due to an increase of $0.9 million in personnel-related expenses, including salaries, bonuses, benefits, and stock-based compensation expenses, a $0.6 million increase in laboratory and automation supplies consumed and equipment, and $0.2 million increase in other costs.

Comparison of the Nine Months Ended September 30, 2019 and 2018

Research and development expenses were $15.0 million for the nine months ended September 30, 2019 compared to $10.0 million for the nine months ended September 30, 2018, an increase of $5.0 million, or 50%. This was primarily due to increased development activities for new product offerings, lab and automation development costs, and IT and facility costs. Research and development expenses increased due to an increase of $2.5 million in personnel-related expenses, including salaries, bonuses, benefits, and stock-based compensation expenses, a $1.6 million increase in laboratory and automation supplies consumed, a $0.8 million increase in depreciation, service maintenance on capitalized equipment, and cost of expensed equipment, and $0.1 million increase in other costs.

Selling, General, and Administrative Expenses

Comparison of the Three Months Ended September 30, 2019 and 2018

Selling, general, and administrative expenses were $6.1 million for the three months ended September 30, 2019 compared to $2.7 million for the three months ended September 30, 2018, an increase of $3.4 million, or 126%. Selling, general, and administrative expenses increased due to a $2.0 million increase in personnel-related expenses including salaries, bonuses, benefits, and stock-based compensation expenses primarily related to increased headcount, a $1.1 million increase in professional services primarily related to public company-related costs, and a $0.3 million increase in other costs.

Comparison of the Nine Months Ended September 30, 2019 and 2018

Selling, general, and administrative expenses were $15.7 million for the nine months ended September 30, 2019 compared to $7.6 million for the nine months ended September 30, 2018, an increase of $8.1 million, or 107%. Selling, general, and administrative expenses increased due to a $5.0 million increase in personnel-related expenses including salaries, bonuses, benefits, and stock-based compensation expenses primarily related to increased headcount, a $2.4 million increase in professional services primarily related to public company-related costs, and a $0.7 million increase in other costs.

Other (Expense) Income, Net

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
	(in thousands)			
Changes in fair values of warrants for Series B and Series C convertible preferred stock	$ —	$ (166)	$ (1,403)	$ (166)
Changes in fair value of the compound derivative instrument	—	—	—	574
Other	(2)	(14)	(12)	(19)
Total other (expense) income, net	$ (2)	$ (180)	$ (1,415)	$ 389

Comparison of the Three Months Ended September 30, 2019 and 2018

Our other expenses, net for the three months ended September 30, 2019 was not significant, compared to other expenses, net of $0.2 million for the three months ended September 30, 2018. Other expenses, net in the three months ended September 30, 2018 was primarily comprised of a $0.2 million increase in the fair values of warrants for Series B and Series C redeemable convertible preferred stock.

Comparison of the Nine Months Ended September 30, 2019 and 2018

We had other expenses, net of $1.4 million for the nine months ended September 30, 2019, compared to other income, net of $0.4 million for the nine months ended September 30, 2018. Other expenses, net in the nine months ended September 30, 2019 were primarily comprised of a $1.4 million increase in the fair values of warrants for Series B and Series C redeemable convertible preferred stock. Other income, net in the nine months ended September 30, 2018 was primarily comprised of a $0.6 million decrease in fair value of the compound derivative instrument, partially offset by a $0.2 million increase in the fair values of warrants for Series B and Series C redeemable convertible preferred stock.

Liquidity and Capital Resources

Sources of Liquidity

From our inception through September 30, 2019, we have funded our operations primarily from the issuance of redeemable convertible preferred stock, cash from operations, debt financing, and proceeds from our initial public offering ("IPO"). On March 22, 2019, we received $20.0 million in gross cash proceeds from a growth capital loan described below. On June 24, 2019, we closed our IPO, whereby we sold 9,109,725 shares of common stock at a price of $17.00 per share. The shares began trading on the Nasdaq Global Market on June 20, 2019. The net proceeds received by us from the IPO were $144.0 million, net of underwriting discounts and commissions. We incurred $4.2 million in costs directly related to the offering, $3.9 million of which was paid during the nine months ended September 30, 2019. As of September 30, 2019, we had cash and cash equivalents and marketable securities in the amount of $127.3 million.

We anticipate that our current cash and cash equivalents and marketable securities, together with cash provided by operating activities are sufficient to fund our near-term capital and operating needs for at least the next 12 months.

Term Loan

In September 2014, we entered into a loan and security agreement with a bank to borrow up to $3.0 million under an equipment loan secured by the equipment financed (the "Term Loan"). On October 3, 2014, we borrowed $2.4 million under the Term Loan. The Term Loan required 12 interest-only payments, followed by 36 equal monthly installments of principal, plus interest, which began on October 3, 2015.

In connection with the Term Loan, we issued a warrant exercisable for ten years to purchase 22,489 shares of our Series B redeemable convertible preferred stock at an exercise price of $4.60 per share. The warrant was exercised in full during our second quarter of 2019 and is no longer outstanding.

On September 30, 2018, the Term Loan was repaid in full.

Revolving Loan

In June 2017, we entered into a $10.0 million revolving loan and security agreement (the "Revolving Loan") with TriplePoint Capital LLC ("TriplePoint"). Borrowings under the Revolving Loan had an interest rate of prime, plus 6.75%. The Revolving Loan also had a 5.5% end of term loan payment on the highest outstanding principal amount. The Revolving Loan required monthly interest-only payments until the maturity date. The Revolving Loan's original maturity date was December 31, 2018, and in December 2018, the maturity date was further extended until March 22, 2019. The maturity date of the extension of the Revolving Loan was not deemed substantial; therefore, we accounted for the transaction as a debt modification.

As of December 31, 2018, our outstanding principal under the Revolving Loan was $5.0 million and $5.0 million was available to borrow.

In connection with the Revolving Loan, we issued a warrant to purchase up to 62,096 shares of our Series C redeemable convertible preferred stock at an exercise price of $8.052 per share, which was still outstanding as of September 30, 2019.

The Revolving Loan had an effective interest rate of 19.22% per year. The Revolving Loan interest expense for the three and nine months ended September 30, 2018 was $0.2 million and $0.7 million, respectively. Interest expense for the three and nine months ended September 30, 2019 was not significant.

In March 2019, we entered into an amendment to the Revolving Loan with TriplePoint that provided for a $20.0 million growth capital loan facility (the "Growth Capital Loan"). In March 2019, we used $5.3 million of the Growth Capital Loan to repay all amounts owing in respect of the Revolving Loan.

Growth Capital Loan

On March 22, 2019, we entered into the Growth Capital Loan with TriplePoint to provide for a $20.0 million growth capital loan facility and as of June 30, 2019, had drawn down the full $20.0 million available under the facility. We used $5.3 million of the Growth Capital Loan to repay, in its entirety, all amounts outstanding under the Revolving Loan. Borrowings under the Growth Capital Loan bore interest at a floating rate of prime rate plus 5.00% for borrowings up to $15.0 million and the prime rate plus 6.50% for borrowings greater than $15.0 million. Under the agreement, we were required to make monthly interest-only payments through April 1, 2020 and were required to make 36 equal monthly payments of principal, plus accrued interest, from April 1, 2020 through March 1, 2023, when all unpaid principal and interest was to become due and payable. The agreement allowed us to voluntarily prepay all, but not part, of the outstanding principal at any time prior to the maturity date, subject to a prepayment fee of 1.00% of the outstanding balance, if prepaid in months one through 12 of the loan term. In addition to the final payment, we paid an amount equal to 2.75% of each principal amount drawn under this Growth Capital Loan.

In connection with the Growth Capital Loan, we issued a warrant to purchase 65,502 shares of common stock to the lender at an exercise price of $9.16 per share. We recorded the issuance-date fair value of the warrant of $0.6 million and fees paid to the lender of $0.3 million as a debt discount, which was amortized over the term of the Growth Capital Loan using the effective interest rate method.

Upon issuance, the Growth Capital Loan had an effective interest rate of 15.23% per year. Interest expense for the three and nine months ended September 30, 2019 was $0.3 million and $1.0 million, respectively.

On August 14, 2019, we paid off the Growth Capital Loan in its entirety. In connection with this debt repayment, we recognized a $1.7 million loss on debt extinguishment in our consolidated statements of operations. The warrant to purchase 65,502 shares of our common stock remains outstanding as of September 30, 2019.

Convertible Notes

On June 29, 2017, we entered into a convertible promissory note agreement with certain existing redeemable convertible preferred stockholders and third parties (collectively, the "Investors") for the issuance of convertible promissory notes with a face value of $12.2 million (the "Convertible Notes"). Under the terms of the Convertible Notes agreement, the Convertible Notes bear interest of 8.00% per annum, with a maturity date of June 28, 2018. In the event that we issued and sold shares of its equity securities (the "Equity Securities") to Investors on or before the maturity date in an equity financing with total proceeds to us of not less than $10 million (including the conversion of the Convertible Notes or other convertible securities issued for capital raising purposes) (a "Qualified Financing"), then the outstanding principal amount of the Convertible Notes and any unpaid accrued interest would have automatically converted in whole without any further action by the holder into such Equity Securities sold in the Qualified Financing at a conversion price equal to the price paid per share for Equity Securities by the Investors in the Qualified Financing multiplied by 0.8. If we consummated a change of control while the Convertible Notes remained outstanding, we would have repaid the holders in cash an amount equal to 150% of the outstanding principal amount of the Convertible Notes, plus any unpaid accrued interest on the original principal. The Convertible Notes had customary events of default.

Certain conversion and redemption features of the Convertible Notes met the requirements for separate accounting and were accounted for as a single, compound derivative instrument. The compound derivative instrument was recorded at fair value at inception and was subject to remeasurement to fair value at each consolidated balance sheet date, with any changes in fair value recognized in the consolidated statements of operations. The estimated fair value of the compound derivative instrument at issuance was recorded as a reduction in the carrying value of the Convertible Notes and as a single compound derivative liability. The Convertible Notes carrying value reduction was accreted using the effective interest method as interest expense over the Convertible Notes contractual period of one year. The Convertible Notes had an effective interest rate of 12.69% per year.

On May 31, 2018, the original maturity date for the Convertible Notes was extended to June 28, 2019 (previously June 28, 2018). The maturity date extension was deemed substantial and was accounted for as a debt extinguishment under Accounting Standards Codification ("ASC") Topic 470, *Debt* ("ASC 470"). In connection with the debt extinguishment on May 31, 2018, the fair value of the Convertible Notes was allocated between the carrying amount of the Convertible Notes and accrued interest of $13.1 million, a compound derivative asset of $0.6 million, and an equity component of $3.9 million, which was credited to additional paid-in capital within the consolidated statements of redeemable convertible preferred stock and stockholders' equity (deficit). The transaction also resulted in a $3.3 million loss recorded as debt extinguishment in our consolidated statements of operations. The new carrying value of the Convertible Notes was accreted using the effective interest method as interest expense over the new contractual period of 1.1 years.

On August 20, 2018, the maturity date for the Convertible Notes was changed to September 20, 2018 (previously June 28, 2019). The term change was deemed substantial and was accounted for as a debt extinguishment under ASC 470. In connection with the debt extinguishment on August 20, 2018, the fair value of the Convertible Notes was allocated between the new carrying amount of the Convertible Notes and accrued interest of $13.4 million, and an equity component of $0.8 million, which resulted in an additional credit to additional paid-in capital. Upon modification, the compound derivative asset was eliminated. The transaction also resulted in a $0.8 million loss recorded as debt extinguishment in our consolidated statements of operations. The new carrying value of the Convertible Notes was accreted using the effective interest method as interest expense over the new contractual period of one month.

On September 20, 2018, upon the maturity of the Convertible Notes, the carrying amount, including accrued interest of $13.4 million was converted into 1,667,997 shares of our Series C redeemable convertible preferred stock at a conversion price equal to $8.052 per share. No gain or loss was recorded on the conversion.

Interest expense on the Convertible Notes for the three and nine months ended September 30, 2018 was $0.2 million and $0.9 million, respectively.

Summary Consolidated Statements of Cash Flows

The following table sets forth the primary sources and uses of cash and cash equivalents for each of the periods presented below:

	Nine Months Ended September 30,	
	2019	**2018**
	(in thousands)	
Net cash (used in) provided by operating activities	$ (20,474)	$ 2,369
Net cash used in investing activities	(46,731)	(7,181)
Net cash provided by (used in) financing activities	134,477	(629)

Net Cash (Used in) Provided by Operating Activities

Net cash used in operating activities during the nine months ended September 30, 2019 was $20.5 million, which resulted from a net loss of $18.4 million and net change in our operating assets and liabilities of $13.1 million, partially offset by non-cash charges of $11.0 million. The net change in our operating assets and liabilities was primarily the result of a $9.2 million decrease in contract liabilities related to customer prepayments, a $3.4 million increase in prepaid expenses and other assets, a $1.2 million increase in inventory and other deferred costs, and a $0.8 million decrease in other long-term liabilities, partially offset by a $1.6 million increase in accounts payable and accrued liabilities. Non-cash charges primarily consisted of $3.7 million of stock-based compensation expense, $3.4 million of depreciation and amortization expense, a $1.7 million loss on debt extinguishment, $1.4 million of change in fair value of convertible preferred stock warrant liability, $0.7 million noncash lease expense, and $0.1 million change in accretion of noncash interest and debt reduction.

Net cash provided by operating activities during the nine months ended September 30, 2018 was $2.4 million, which resulted from a net loss of $16.3 million, offset by a net change in our operating assets and liabilities of $10.3 million and non-cash charges of $8.4 million. The net change in our operating assets and liabilities was primarily the result of a $12.9 million increase in contract liabilities related to customer prepayments, a $1.3 million increase in accounts payable and accrued liabilities to support inventory, and general expenses, partially offset by a $1.9 million increase in inventory and other deferred costs, a $1.2 million increase in accounts receivables related to increases in revenue, and a $0.8 million increase in prepaid expenses and other assets. Non-cash charges primarily consisted of a $4.7 million loss on debt extinguishment, $2.1 million of depreciation and amortization expense, $1.1 million of accretion of noncash interest and debt reduction, and $0.9 million of stock-based compensation expense, partially offset by $0.4 million of change in fair value of compound derivative instrument and convertible preferred stock warrant liability.

Net Cash Used in Investing Activities

Net cash used in investing activities for the nine months ended September 30, 2019 was $46.7 million, which consisted of $40.2 million purchases of available-for-sale debt securities and $6.5 million purchases of property and equipment used for our sequencing and data analysis services and facility expansion to support expanded operations.

Net cash used in investing activities for the nine months ended September 30, 2018 was $7.2 million, which was primarily related to the acquisition of property and equipment used for our sequencing and data analysis services and facility expansion to support expanded operations.

Net Cash Provided by (Used in) Financing Activities

Net cash provided by financing activities was $134.5 million for the nine months ended September 30, 2019, which primarily consisted of $144.0 million proceeds from our IPO, net of the underwriting discount of $10.8 million, $20.0 million borrowings under the Growth Capital Loan, and $0.7 million from proceeds of exercise of stock options, partially offset by $25.0 million in debt repayments, $3.9 million in payment of costs related to our IPO, $0.8 million in debt extinguishment costs, and $0.5 million in borrowing costs.

Net cash used in financing activities was $0.6 million for the nine months ended September 30, 2018, which primarily consisted of borrowing costs.

Critical Accounting Policies and Estimates

Our condensed consolidated financial statements are prepared in accordance with U.S. GAAP. The preparation of these condensed consolidated financial statements requires us to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenues, costs and expenses, and related disclosures. Our estimates are based on our historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

An accounting policy is deemed to be critical if it requires an accounting estimate to be made based on assumptions about matters that are highly uncertain at the time the estimate is made, if different estimates reasonably could have been used, or if changes in the estimate that are reasonably possible could materially impact the financial statements. We believe that the assumptions and estimates associated with revenue recognition, the valuation of common stock warrants and convertible preferred stock warrants, convertible instruments, common stock valuations, stock-based compensation, and income taxes have the greatest potential impact on our condensed consolidated financial statements. Therefore, we consider these to be our critical accounting policies and estimates.

There have been no material changes to our critical accounting policies and estimates as compared to the critical accounting policies and estimates described in our Prospectus.

On January 1, 2019, we adopted Accounting Standards Update No. 2016-02, Leases (Topic 842) (ASU 2016-02), as amended, which supersedes the lease accounting guidance under Topic 840, and generally requires lessees to recognize operating and financing lease liabilities and corresponding right-of-use (ROU) assets on the balance sheet and to provide enhanced disclosures surrounding the amount, timing and uncertainty of cash flows arising from leasing arrangements. We adopted the new guidance using the modified retrospective transition approach by applying the new standard to all leases existing at the date of initial application and not restating comparative periods. The most significant impact was the recognition of ROU assets and lease liabilities for operating leases. See Note 2 — Summary of Significant Accounting Policies and Note 7 — Leases in the notes to the condensed consolidated financial statements included in this Quarterly Report on Form 10-Q for additional information regarding the adoption.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

Interest Rate Sensitivity

The market risk inherent in our financial instruments and in our financial position represents the potential loss arising from adverse changes in interest rates or exchange rates.

As of September 30, 2019, we had cash and cash equivalents of $87.0 million, consisting of cash held in bank accounts and money market funds denominated in U.S. dollars. Cash equivalents also include $39.8 million of commercial paper, which are highly liquid marketable debt securities with maturities at the time of purchase of three months or less. As of September 30, 2019, we had short-term marketable debt securities of $40.3 million, consisting of U.S. agency bonds, commercial paper, corporate bonds, and U.S. treasuries. Our primary exposure to market risk is interest income sensitivity, which is affected by changes in the general level of the interest rates in the United States. As of September 30, 2019, a hypothetical 100 basis point increase in interest rates would have resulted in an approximate $0.3 million decline of the fair value of our marketable debt securities. This estimate is based on a sensitivity model that measures market value changes when changes in interest rates occur. A 100 basis point change in interest rates would not have a material effect on the fair market value of our cash and cash equivalents, exclusive of the marketable debt securities.

Foreign Currency Risk

The majority of our revenues is generated in the United States. As of September 30, 2019, we had generated an insignificant amount of revenues denominated in foreign currencies. As we expand our presence in the international market, our results of operations and cash flows are expected to increasingly be subject to fluctuations due to changes in foreign currency exchange rates and may be adversely affected in the future due to changes in foreign exchange rates.

Item 4. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

Management has conducted an evaluation of the effectiveness of our disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), as of the end of the period covered by this Quarterly Report on Form 10-Q. Disclosure controls and procedures are designed to ensure that information required to be disclosed in reports filed or submitted under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified by the SEC rules and forms and that such information is accumulated and communicated to management, including our principal executive officer and principal financial officer, to ensure timely decisions regarding required disclosures. In connection with preparation of our financial statements for the years ended December 31, 2017 and 2018, management identified a material weakness in our internal controls due to a lack of sufficient full-time accounting staff with requisite experience and deep technical accounting knowledge to (i) identify and resolve complex accounting issues under U.S. GAAP and (ii) allow for appropriate segregation of duties. As a result, our principal executive officer and principal financial officer concluded that, as of December 31, 2018, our disclosure controls and procedures were ineffective. Upon identification of the material weaknesses and under the direction of our principal executive officer and principal financial officer, we developed a comprehensive plan to remediate the material weaknesses.

As of September 30, 2019, and as described under Status of Remediation of Material Weakness in Internal Control Over Financial Reporting below, all of the material weaknesses were not fully remediated. As a result, our principal executive officer and principal financial officer concluded that, as of September 30, 2019, our disclosure controls and procedures were not effective. Notwithstanding the aforementioned material weaknesses and failure of disclosure controls, our management has taken additional steps to assure there is appropriate disclosure in this report and has concluded that the financial statements included in this report fairly present, in all material respects, our financial condition for the periods presented in conformity with U.S. GAAP.

Status of Remediation of Material Weakness in Internal Control Over Financial Reporting

We have been and are actively engaged in the implementation of remediation efforts to address the material weaknesses in our internal control over financial reporting as of December 31, 2018. As part of our remediation plan to address the material weakness identified above, we hired a new Chief Financial Officer in March 2019 and four additional accounting resources in the second and third quarters of 2019, including two Certified Public Accountants with the specific technical accounting and financial reporting experience necessary for a public company. Management believes that these additional resources will provide an appropriate remediation of the material weakness; however, the effectiveness of the controls have not been fully tested by management.

We will continue to assess the adequacy of our accounting personnel and resources, and will add additional personnel, as well as adjust our resources, as necessary, commensurate with any increase in the size and complexity of our business.

Changes in Internal Control Over Financial Reporting

There were no changes in our internal control over financial reporting during the third quarter of 2019, which were identified in connection with management's evaluation required by paragraph (d) of Rules 13a-15 and 15d-15 under the Exchange Act, that have materially affected, or are 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 become involved in legal proceedings or be subject to claims arising in the ordinary course of our business. We are not presently a party to any legal proceedings that in the opinion of our management, if determined unfavorably to us, would have a material adverse effect on our business, financial condition, operating results or cash flows. Regardless of the outcome, litigation can, among other things, be time consuming and expensive to resolve, and divert management resources.

Item 1A. Risk Factors.

Our operations and financial results are subject to various risks and uncertainties including those described below. You should consider carefully the risks and uncertainties described below, in addition to other information contained in this Quarterly Report on Form 10-Q, including our unaudited condensed consolidated financial statements and related notes. The risks and uncertainties described below are not the only ones we face. Additional risks and uncertainties that we are unaware of, or that we currently believe are not material, may also become important factors that adversely affect our business. If any of the following risks or others not specified below materialize, our business, financial condition and results of operations could be materially and adversely affected. In that case, the trading price of our common stock could decline.

Risks Related to Our Business and Strategy

We have a history of losses, and as our costs increase, we expect to incur significant losses for the foreseeable future and may not be able to generate sufficient revenues to achieve or sustain profitability.

We have incurred net losses since our inception. For the nine months ended September 30, 2019 and 2018, we had net losses of $18.4 million and $16.3 million, respectively. As of September 30, 2019, we had an accumulated deficit of $133.9 million. To date, we have not generated sufficient revenues to achieve profitability, and we may never achieve or sustain profitability. In addition, we expect to continue to incur net losses for the foreseeable future, and we expect our accumulated deficit to continue to increase as we focus on scaling our business and operations. Our efforts to sustain and grow our business may be more costly than we expect, and we may not be able to increase our revenues sufficiently to offset our higher operating expenses. Our prior losses and expected 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 unable to increase sales of our current services or successfully develop and commercialize other services or products, our revenues will be insufficient for us to achieve profitability.

We currently derive substantially all of our revenues from sales of our services. We began offering our services through our Clinical Laboratory Improvement Amendments of 1988 ("CLIA")-certified, College of American Pathologists ("CAP")-accredited, and state-licensed laboratory in 2013. We are in varying stages of research and development for other services and products that we may offer. If we are unable to increase sales of our existing services or successfully develop and commercialize other services and products, we will not generate sufficient revenues to become profitable.

Certain of our customers prepay us for a portion of the services that they expect to order from us in the future and we may be required to refund some or all of those prepayments if a customer cancels its contract with us or reduces the level of services that it expects to receive.

Certain of our customers prepay us for a portion of the services that they expect to order from us before they place purchase orders and we deliver those services. In some cases, this prepayment can be substantial and may be paid months or a year or more in advance of these customers providing samples to us and before our delivery of the services to which some or all of the deposit relates. As of September 30, 2019, we had approximately $33.7 million in customer deposits, including $31.2 million from one customer. However, as of that date, we had $87.0 million of cash and cash equivalents. We are generally not required by our contracts to retain these deposits in cash or otherwise and we have generally used these deposits to make capital expenditures and fund our operations. If a customer that has prepaid us for future services cancels its contract with us or reduces the level of services that it expects to receive, we would generally be required to repay that customer's deposit with little or no notice. We may not have the cash or other available resources to satisfy that repayment obligation. Even if we are able to satisfy the repayment obligation from available resources, we may need to seek additional sources of capital to fund our operations, which funding may not be available when needed or on acceptable terms. In either of those circumstances, our business, financial condition, results of operations, and reputation would be materially and adversely affected. Furthermore, in the future, customers may elect not to prepay us for our services in which case we would have to find other sources of funding for our capital expenditures and operations, which would be costly relative to the aforementioned cost-free customer deposit funding and which may not be available when needed or on acceptable terms.

If we are unable to execute our sales and marketing strategy for our services and are unable to gain sufficient acceptance in the maket, we may be unable to generate sufficient revenues to sustain our business.

We are a growing genomics company and have engaged in targeted sales and marketing activities for our services. Although we have had revenues from sales of our services since 2013, our services may never gain significant acceptance in the marketplace and therefore may never generate substantial revenues or permit us to become profitable. We will need to further establish and grow the market for our services through the expansion of our current relationships and development of new relationships with biopharmaceutical customers. Gaining acceptance in medical communities can be supported by, among other things, publications in leading peer-reviewed journals of results from studies using our services. The process of publication in leading medical journals is subject to a peer review process and peer reviewers may not consider the results of our studies sufficiently novel or worthy of publication. Failure to have our studies published in peer-reviewed journals would limit the adoption of our services.

Our ability to successfully market our services that we have developed, and may develop in the future, will depend on numerous factors, including:

- our ability to demonstrate the utility and value of our services to our customers;
- the success of our sales force;
- whether biopharmaceutical companies accept that our services are sufficiently sensitive and specific;
- our ability to convince biopharmaceutical companies of the utility of the comprehensiveness of our services and of testing patients at multiple time points;
- our ability to continue to fund sales and marketing activities;
- whether our services are considered superior to those of our competitors;
- any negative publicity regarding our or our competitors' services resulting from defects or errors;
- our success obtaining and maintaining patent and trade secret protection for our services and technologies; and
- our success enforcing and defending intellectual property rights and claims.

Failure to achieve broad market acceptance of our services would materially harm our business, financial condition, and results of operations.

If we cannot compete successfully with our competitors, we may be unable to increase or sustain our revenues or achieve and sustain profitability.

Our principal competition comes from commercial and academic organizations using established and new laboratory tests to produce information that is similar to the information that we generate for our customers. These commercial and academic organizations may not utilize our services or may not believe them to be superior to those tests that they currently use or others that are developed. Further, it may be difficult to convince our customers to use our comprehensive test rather than simpler panels provided by our competitors. For example, the information that we provide may be more challenging or require additional resources for our customers to interpret than the information provided by our competitors' less comprehensive assays.

Some of our present and potential competitors, including Guardant Health, Inc., Foundation Medicine, Inc., which was acquired by Roche Holdings, Inc. in July 2018, Roche Molecular Systems, Inc., NanoString Technologies, Inc., Personal Genome Diagnostics, Inc., Adaptive Biotechnologies Corporation, and NeoGenomics, Inc., may have widespread brand recognition and substantially greater financial and technical resources and development, production capacities, and marketing capabilities than we do. They may be able to devote greater resources to the development, promotion, and sale of their products and services than we do or sell their products and services at prices designed to win significant levels of market share. In addition, competitors may be acquired by, receive investments from, or enter into other commercial relationships with larger, well-established, and well-financed companies. Others may develop lower-priced, less complex products and services that pharmaceutical companies could view as functionally equivalent to our current or planned future services, which could force us to lower the price of our services and impact our operating margins and our ability to achieve and maintain profitability. In addition, companies or governments that control access to genetic testing and related services through umbrella contracts or regional preferences could promote our competitors or prevent us from performing certain services. In addition, technological innovations that result in the creation of enhanced products or diagnostic tools that are more sensitive or specific than ours may enable other clinical laboratories, hospitals, physicians, or medical providers to provide specialized products or services similar to ours in a more patient-friendly, efficient, or cost-effective manner than is currently possible. If we cannot compete successfully against current or future competitors, we may be unable to ensure or increase market acceptance and sales of our current or planned future services, which could prevent us from increasing or sustaining our revenues or achieving or sustaining profitability.

We expect that biopharmaceutical companies will increasingly focus attention and resources on the targeted and personalized cancer diagnostic sector as the potential and prevalence of molecularly targeted oncology therapies approved by the U.S. Food and Drug Administration (the "FDA") along with companion diagnostics increases. For example, the FDA has approved several such targeted oncology therapies that use companion diagnostics, including the anaplastic lymphoma kinase FISH test from Abbott Laboratories, Inc. for use with Xalkori® from Pfizer Inc., the BRAF kinase V600 mutation test from Roche Molecular Systems, Inc. for use with Zelboraf® from Daiichi-Sankyo/Genentech/Roche, and the BRAF kinase V600 mutation test from bioMerieux for use with Tafinlar® from GlaxoSmithKline. Since companion diagnostic tests are part of FDA labeling, non-FDA cleared tests, such as the ones we currently offer as part of our services, would be considered an off-label use and this may limit our access to this market segment.

Additionally, projects related to cancer diagnostics and particularly genomics have received increased government funding, both in the United States and internationally. As more information regarding cancer genomics becomes available to the public, we anticipate that more products aimed at identifying targeted treatment options will be developed and that these products may compete with our services. In addition, competitors may develop their own versions of our current or planned future services in countries where we did not apply for or receive patents and compete with us in those countries, including encouraging the use of their products or services by biopharmaceutical companies in other countries.

Our inability to raise additional capital on acceptable terms in the future may limit our ability to continue to operate our business and further expand our operations.

We expect capital expenditures and operating expenses to increase over the next several years as we continue to operate our business and expand our infrastructure, commercial operations, and research and development activities. Additionally, if we decide to grow our business by developing in vitro diagnostic tests, our capital expenditures and operating expenses would significantly increase. We may seek to raise additional capital through equity offerings, debt financings, collaborations, or licensing arrangements. Additional funding may not be available to us on acceptable terms, or at all.

The various ways we could raise additional capital carry potential risks. If we raise funds by issuing equity securities, dilution to our stockholders would result. Any equity securities issued may also provide for rights, preferences, or privileges senior to those of holders of our common stock. In addition, the issuance of additional equity securities by us, or the possibility of such issuance, may cause the market price of our common stock to decline. If we raise funds by issuing debt securities, those debt securities would have rights, preferences, and privileges senior to those of holders of our common stock. The terms of debt securities issued or borrowings pursuant to a credit agreement, if available, could impose significant restrictions on our operations. The incurrence of additional indebtedness or the issuance of certain equity securities could result in increased fixed payment obligations and could also result in restrictive covenants, 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. In the event that we enter into collaborations or licensing arrangements to raise capital, we may be required to accept unfavorable terms. These agreements may require that we relinquish or license to a third party on unfavorable terms our rights to tests we otherwise would seek to develop or commercialize ourselves, or reserve certain opportunities for future potential arrangements when we might be able to achieve more favorable terms.

If we are not able to secure additional funding when needed, we may have to delay, reduce the scope of or eliminate one or more research and development programs or sales and marketing initiatives. In addition, we may have to work with a partner on one or more aspects of our tests or market development programs, which could lower the economic value of those tests or programs to us. While we believe our existing cash and cash equivalents will be sufficient to meet our anticipated cash requirements for at least the next 12 months, we cannot assure you that we will generate sufficient revenues from commercial sales to adequately fund our operating needs or achieve or sustain profitability.

We will need to invest in our infrastructure in advance of increased demand for our services, and our failure to accurately forecast demand would have a negative impact on our business and our ability to achieve and sustain profitability.

In order to execute our business model, we need to invest in scaling our infrastructure, including hiring additional personnel, expanding our internal quality assurance program, and expanding laboratory capacity. We will also need to purchase additional equipment, some of which can take several months or more to procure, setup, and validate, and increase our software and computing capacity to meet increased demand. There is no assurance that any of these increases in scale, expansion of personnel, equipment, software, and computing capacities, or process enhancements will be successfully implemented, or that we will have adequate space in our laboratory facility to accommodate such required expansion. We expect that much of this growth will be in advance of increased demand for our services. Our current and projected future expense levels are to a large extent fixed and are largely based on our current investment plans and our estimates of future test volume. As a result, if revenues do not meet our expectations we may not be able to promptly adjust or reduce our spending to levels commensurate with our revenues. If we fail to generate demand commensurate with our infrastructure growth or if we fail to scale our infrastructure sufficiently in advance of demand to successfully meet such demand, our business, prospects, financial condition, and results of operations could be adversely affected.

As we commercialize additional services orproducts, we may need to incorporate new equipment, implement new technology systems and laboratory processes, or hire new personnel with different qualifications. Failure to manage this growth or transition could result in turnaround time delays, higher costs, declining service and/or product quality, deteriorating customer service, and slower responses to competitive challenges. A failure in any one of these areas could make it difficult for us to meet market expectations for our services, and could damage our reputation and the prospects for our business.

We have substantial customer concentration, with a limited number of customers accounting for a substantial portion of our 2019 revenues and accounts receivable.

Like other genomics profiling companies that sell to the pharmaceutical industry, we have customer concentration. We currently derive a significant portion of our revenues from the U.S. Department of Veterans Affairs (the "VA") Million Veteran Program (the "VA MVP"), which accounted for 75% and 63% of our revenues in the three months and nine months ended September 30, 2019, respectively. Our top five customers, including the VA MVP, accounted for93% and 92% of our revenues for the three months and nine months ended September 30, 2019, respectively. There are inherent risks whenever a large percentage of revenues are concentrated with a limited number of customers. It is not possible for us to predict the future level of demand for our services that will be generated by these customers. In addition, revenues from our larger customers have historically fluctuated and may continue to fluctuate based on the commencement and completion of clinical trials or other projects, the timing of which may be affected by market conditions or other facts, some of which may be outside of our control. Further, while we have long-term contractual arrangements with certain of our customers, these customers are not required to purchase a minimum number of analyses. If any of these customers suspend or terminate clinical trials, receive less funding, experience declining or delayed sales, or otherwise chose to reduce or eliminate their use of our services, we could be pressured to reduce the prices we charge for our services which would have an adverse effect on our margins and financial position, and which would likely negatively affect our revenues and results of operations. In particular, if the VA MVP terminates our services for convenience, which it is permitted to do, such termination would have a material adverse effect on our revenues, cash position, and results of operations. Further, if our largest customers were to cease using or stop payment for our services, it would have a material adverse effect on our accounts receivable, increasing our credit risk. The failure of these customers to pay their balances, or any customer to pay future outstanding balances, would result in an operating expense and reduce our cash flows.

We currently derive a substantial portion of our revenues from DNA sequencing and data analysis services that we provide to our largest customer, the VA MVP. If the VA MVP's demand for and/or funding for our DNA sequencing and data analysis services is substantially reduced, our business, financial condition, operating results, and cash flows would be materially harmed.

We derive a substantial portion of our current and expected future revenues from sales of our DNA sequencing and data analysis services to the VA MVP. In September 2017, we entered into a one-year contract with three one-year option renewal periods with the VA for the VA MVP, pursuant to which we received orders from the VA MVP in September 2017, 2018, and 2019.

The VA MVP's orders for DNA sequencing and data analysis services are subject to the availability of funding, enrollment of veterans in the VA MVP study, and the VA MVP's continued demand for our services. We have no certainty that funding will be made available for our services. If the priorities of the VA, the VA MVP, or the U.S. government change, funding for our services may be limited or not available, and our business, financial condition, and operating results and cash flows would be materially harmed. The success of our business and our future operating results are significantly dependent on the VA MVP's receipt of funding for use of our services and the terms of our sales to the VA MVP, including the price per sample, the number of samples and the timing of the VA MVP's deliveries of samples.

If we cannot maintain our current customer relationships, or fail to acquire new customers, our revenue prospects will be reduced. Many of our customers are biopharmaceutical companies engaged in clinical trials of new drug candidates, which are expensive, can take many years to complete, and their outcome is inherently uncertain.

Our customers other than the VA MVP are primarily biopharmaceutical companies that use our services to support clinical trials. Our future success is substantially dependent on our ability to maintain our customer relationships and to establish new ones. Many factors have the potential to impact our customer relations, including the type of support our customers and potential customers require and our ability to deliver it, our customers' satisfaction with our services, and other factors that may be beyond our control. Furthermore, our customers may decide to decrease or discontinue their use of our services due to changes in research and product development plans, failures in their clinical trials, financial constraints, or utilization of internal testing resources or tests performed by other parties, or other circumstances outside of our control.

We engage in conversations with customers regarding potential commercial opportunities on an ongoing basis in the event that one of these customers' drug candidates is approved. There is no assurance that any of these conversations will result in a commercial agreement, or if an agreement is reached, that the resulting relationship will be successful or that clinical studies conducted as part of the engagement will produce successful outcomes. Speculation in the industry about our existing or potential relationships with biopharmaceutical companies could be a catalyst for adverse speculation about us, our services, and our technology, which can adversely affect our reputation and our business. In addition, the termination of these relationships could result in a temporary or permanent loss of revenue.

Our customers' clinical trials are expensive, can take many years to complete, and their outcome is inherently uncertain. Failure can occur at any time during the clinical trial process. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through pre-clinical studies and early clinical trials. Many of the biopharmaceutical companies that are our customers do not have products approved for commercial sale and are not profitable. These customers must continue to raise capital in order to continue their development programs and to potentially continue as our customers. If our customers' clinical trials fail or they are unable to raise sufficient capital to continue investing in their clinical programs, our revenues from these customers may decrease or cease entirely, and our business may be harmed. Furthermore, even if these customers have a drug approved for commercial sale, they may not choose to use our services as a companion diagnostic with their drug, thereby limiting our potential revenues.

The size of the potential future market for our services is an estimate and may be smaller than we believe.

Our estimate of the potential future market for our services is based on a number of internal and third-party estimates. While we believe these factors have historically provided and will continue to provide us with effective tools in estimating the total market for our services, these estimates may not be correct and the conditions supporting our estimates may change at any time, thereby reducing the predictive accuracy of these underlying factors. As a result, our estimates of the total addressable market for our services may prove to be incorrect. If the actual number of patients who would benefit from our services and the total addressable market for our services is smaller than we have estimated, our future growth could be adversely impacted.

We rely on a limited number of suppliers, or 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 should we need to do so.

We rely on a limited number of suppliers for sequencers and other equipment and materials that we use in our laboratory operations. For example, we rely on Illumina, Inc. ("Illumina") as the sole supplier of sequencers and various associated reagents, and as the sole provider of maintenance and repair services for these sequencers. Our master subcontractor agreement with Illumina is set to expire in August 2021, and our various pricing agreements with Illumina are set to expire on various dates up to December 2022. Any disruption in Illumina's operations, or our inability to negotiate an extension to our agreements with Illumina on acceptable terms, or at all, could impact our supply chain and laboratory operations and our ability to conduct our business and generate revenue. Our suppliers could cease supplying these materials, reagents, and equipment at any time, or fail to provide us with sufficient quantities of materials or materials that meet our specifications. Our laboratory operations could be interrupted if we encounter delays or difficulties in securing equipment, materials, reagents, or sequencers, or if we cannot obtain an acceptable substitute. Any such interruption could significantly affect our business, financial condition, results of operations, and reputation.

We believe that there are only a few manufacturers other than Illumina that are currently capable of supplying and servicing the equipment necessary for our laboratory operations, including sequencers and various associated reagents. The use of equipment or materials provided by these replacement suppliers would require us to alter our laboratory operations. Transitioning to a new supplier would be time-consuming and expensive, may result in interruptions in our laboratory operations, could affect the performance specifications of our laboratory operations, or could require that we revalidate our tests. We cannot assure you that we will be able to secure alternative equipment, reagents, and other materials, and bring such equipment, reagents, and materials on line and revalidate them without experiencing interruptions in our workflow. If we encounter delays or difficulties in securing, reconfiguring, or revalidating the equipment and reagents we require for our services, our business, financial condition, results of operations, and reputation could be adversely affected.

In addition, the Device Master File that we have filed with the FDA, which is focused on the technology, quality management, and validation of our platform, specifically on its use for the development of personalized immunotherapies, is predicated on our use of specified equipment and processes, including Illumina sequencers and related equipment. The detailed information in the Device Master File is not shared with our customers, but with our permission they can reference our FDA file number in their Investigational New Drug filings with the FDA. If we were required to transition to a new supplier of sequencers or certain other equipment or processes in our laboratory, our Device Master File would need to be replaced or updated, and until such time as that occurred, customers for which we deliver services after the transition would not be able to reference our Device Master File, which would cause us to lose a competitive advantage.

If our sole laboratory facility becomes damaged or inoperable, or we are required to vacate the facility, our ability to sell and provide our services and pursue our research and development efforts may be jeopardized.

We currently derive our revenues from our genomic analysis conducted in our laboratory. We do not have any clinical reference laboratory facilities other than our facility in Menlo Park, California. Our facilities and equipment could be harmed or rendered inoperable by natural or man-made disasters, including fires, earthquakes, flooding, and power outages, which may render it difficult or impossible for us to sell or perform our services for some period of time. Northern California has recently experienced serious fires and the San Francisco Bay Area is considered to lie in an area with earthquake risk. The inability to sell or to perform our diagnostic and other services, or the backlog of samples that could develop if our facility is inoperable for even a short period of time, may result in the loss of customers or harm to our reputation or relationships with scientific or clinical collaborators, and we may be unable to regain those customers or repair our reputation or such relationships in the future. Furthermore, our facilities and the equipment we use to perform our services and our research and development work could be costly and time-consuming to repair or replace.

Additionally, a key component of our research and development process involves using biological samples as the basis for the development of our services. In some cases, these samples are difficult to obtain. If the parts of our laboratory facility where we store these biological samples were damaged or compromised, our ability to pursue our research and development projects, as well as our reputation, could be jeopardized. We carry insurance for damage to our property and the disruption of our business, but 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 our laboratory became inoperable, we would likely not be able to license or transfer our technology to another facility with the necessary qualifications, including state licensure and CLIA certification, under the scope of which our current and our planned future services could be performed. Even if we find a facility with such qualifications to perform our services, it may not be available to us on commercially reasonable terms.

Our internal information technology systems, or those of our third-party vendors, contractors, or consultants, may fail or suffer security breaches, loss or leakage of data, and other disruptions, which could result in a material disruption of our services, compromise sensitive information related to our business, or prevent us from accessing critical information, potentially exposing us to liability or otherwise adversely affecting our business.

We are increasingly dependent upon information technology systems, infrastructure, and data to operate our business. In the ordinary course of business, we collect, store, and transmit confidential information (including but not limited to intellectual property, proprietary business information, and personal information). It is critical that we do so in a secure manner to maintain the confidentiality and integrity of such confidential information. We also have outsourced elements of our operations to third parties, and as a result we manage a number of third-party vendors and other contractors and consultants who have access to our confidential information.

Despite the implementation of security measures, given the size and complexity of our internal information technology systems and those of our third-party vendors and other contractors and consultants, and the increasing amounts of confidential information that they maintain, our such information technology systems are potentially vulnerable to breakdown or other damage or interruption from service interruptions, system malfunction, natural disasters, terrorism, war, and telecommunication and electrical failures, as well as security breaches from inadvertent or intentional actions by our employees, third-party vendors, contractors, consultants, business partners, and/or other third parties, or from cyber-attacks by malicious third parties (including the deployment of harmful malware, ransomware, denial-of-service attacks, social engineering, and other means to affect service reliability and threaten the confidentiality, integrity, and availability of information), which may compromise our system infrastructure, or that of our third-party vendors and other contractors and consultants, or lead to data leakage. The risk of a security breach or disruption, particularly through cyber-attacks or cyber intrusion, including by computer hackers, foreign governments, and cyber terrorists, has generally increased as the number, intensity, and sophistication of attempted attacks and intrusions from around the world have increased. We may not be able to anticipate all types of security threats, and we may not be able to implement preventive measures effective against all such security threats. The techniques used by cyber criminals change frequently, may not be recognized until launched, and can originate from a wide variety of sources, including outside groups such as external service providers, organized crime affiliates, terrorist organizations, or hostile foreign governments or agencies. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or those of our third-party vendors and other contractors and consultants, or inappropriate disclosure of confidential or proprietary information, we could incur liability and reputational damage and the further development and commercialization of our services could be delayed. The costs related to significant security breaches or disruptions could be material and exceed the limits of the cybersecurity insurance we maintain against such risks. If the information technology systems of our third-party vendors and other contractors and consultants become subject to disruptions or security breaches, we may have insufficient recourse against such third parties and we may have to expend significant resources to mitigate the impact of such an event, and to develop and implement protections to prevent future events of this nature from occurring.

While we have not experienced any such system failure, accident, or security breach to date and believe that our data protection efforts and our investment in information technology reduce the likelihood of such incidents in the future, we cannot assure you that our data protection efforts and our investment in information technology will prevent significant breakdowns, data leakages, breaches in our systems, or those of our third-party vendors and other contractors and consultants, or other cyber incidents that could have a material adverse effect upon our reputation, business, operations, or financial condition. For example, if such an event were to occur and cause interruptions in our operations, or those of our third-party vendors and other contractors and consultants, it could result in a material disruption of our programs and the development of our services and technologies could be delayed. Furthermore, significant disruptions of our internal information technology systems or those of our third-party vendors and other contractors and consultants, or security breaches could result in the loss, misappropriation, and/or unauthorized access, use, or disclosure of, or the prevention of access to, confidential information (including trade secrets or other intellectual property, proprietary business information, and personal information), which could result in financial, legal, business, and reputational harm to us. For example, any such event that leads to unauthorized access, use, or disclosure of personal information, including personal information regarding our customers or employees, could harm our reputation directly, compel us to comply with federal and/or state breach notification laws and foreign law equivalents, subject us to mandatory corrective action, and otherwise subject us to liability under laws and regulations that protect the privacy and security of personal information, which could result in significant legal and financial exposure and reputational damages that could potentially have an adverse effect on our business.

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

In the ordinary course of our business, we collect and store sensitive data, including protected health information ("PHI"), personally identifiable information ("PII"), credit card and other financial information, intellectual property, and proprietary business information owned or controlled by ourselves or our customers, payors, and other parties. We manage and maintain our applications and data utilizing a combination of on-site systems and cloud-based data centers. We utilize external security and infrastructure vendors to manage parts of our data centers. We also communicate sensitive data, including patient data, electronically, and through relationships with multiple third-party vendors and their subcontractors. These applications and data encompass a wide variety of business-critical information, including research and development information, patient data, commercial information, and business and financial information. We face a number of risks relative to protecting this critical information, including loss of access risk, inappropriate use or disclosure, inappropriate modification, and the risk of our being unable to adequately monitor, audit, and modify our controls over our critical information. This risk extends to the third-party vendors and subcontractors we use to manage this sensitive data.

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 such information. Although we take measures to protect sensitive data from unauthorized access, use or disclosure, our information technology and infrastructure may be vulnerable to attacks by hackers or viruses or breached due to employee error, malfeasance, or other malicious or inadvertent disruptions. Any such breach or interruption could compromise our networks and the information stored there could be accessed by unauthorized parties, manipulated, publicly disclosed, lost, or stolen. Any such access, breach, or other loss of information could result in legal claims or proceedings, liability under federal or state laws that protect the privacy of personal information, such as the Health Insurance Portability and Accountability Act of 1996 ("HIPAA") and the Health Information Technology for Economic and Clinical Health Act ("HITECH"), and regulatory penalties. Notice of breaches must be made to affected individuals, the Secretary of the Department of Health and Human Services ("HHS"), and for extensive breaches, notice may need to be made to the media or state attorneys general. Such a notice could harm our reputation and our ability to compete. Although we have implemented security measures and a formal, dedicated enterprise security program to prevent unauthorized access to patient data, such data is currently accessible through multiple channels, and there is no guarantee we can protect our data from breach. Unauthorized access, loss, or dissemination could also damage our reputation or disrupt our operations, including our ability to conduct our analyses, deliver test results, process claims and appeals, provide customer assistance, conduct research and development activities, collect, process, and prepare company financial information, provide information about our tests and other patient and physician education and outreach efforts through our website, and manage the administrative aspects of our business.

Penalties for violations of these laws vary. For instance, penalties for failure to comply with a requirement of HIPAA and HITECH vary significantly, and include significant civil monetary penalties and, in certain circumstances, criminal penalties with fines up to $250,000 per violation and/or imprisonment. In addition, numerous breach incidents could lead to possible penalties in excess of $1.68 million. 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 imprisonment. The 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.

Further, various states, such as California and Massachusetts, have implemented similar privacy laws and regulations, such as the California Confidentiality of Medical Information Act, that impose restrictive requirements regulating the use and disclosure of health information and other personally identifiable information. These laws and regulations are not necessarily preempted by HIPAA, particularly if a state affords greater protection to individuals than HIPAA. Where state laws are more protective, we have to comply with the stricter provisions. In addition to fines and penalties imposed upon violators, some of these state laws also afford private rights of action to individuals who believe their personal information has been misused. California's patient privacy laws, for example, provide for penalties of up to $250,000 and permit injured parties to sue for damages. The interplay of federal and state laws may be subject to varying interpretations by courts and government agencies, creating complex compliance issues for us and data we receive, use and share, potentially exposing us to additional expense, adverse publicity and liability. Further, as regulatory focus on privacy issues continues to increase and laws and regulations concerning the protection of personal information expand and become more complex, these potential risks to our business could intensify. Changes in laws or regulations associated with the enhanced protection of certain types of sensitive data, such as PHI or PII, for the treatment of genetic data, along with increased customer demands for enhanced data security infrastructure, could greatly increase our cost of providing our services, decrease demand for our services, reduce our revenues and/or subject us to additional liabilities.

In addition, the interpretation and application of consumer, health-related and data protection laws, especially with respect to genetic samples and data, in the United States, the European Union (the "EU"), and elsewhere are often uncertain, contradictory and in flux. For example, the EU-wide General Data Protection Regulation (EU) 2016/679 ("GDPR") became applicable on May 25, 2018, replacing data protection laws issued by of each EU member state based on the Directive 95/46/EC (the "Directive"). Unlike the Directive, which needed to be transposed at a national level, the GDPR text is directly applicable in each EU member state, resulting in a more uniform application of data privacy laws across the EU. The GDPR imposes onerous accountability obligations requiring data controllers and processors to maintain a record of their data processing and policies. It requires data controllers to implement more stringent operational requirements for processors and controllers of personal data, including, for example, transparent and expanded disclosure to data subjects (in a concise, intelligible and easily accessible form) about how their personal information is to be used, imposes limitations on retention of information, increases requirements pertaining to health data and pseudonymized (i.e., key-coded) data, introduces mandatory data breach notification requirements, and sets higher standards for data controllers to demonstrate that they have obtained valid consent for certain data processing activities. Fines for non-compliance with the GDPR will be significant—the greater of €20 million or 4% of global turnover. The GDPR provides that EU member states may introduce further conditions, including limitations, to make their own further laws and regulations limiting the processing of genetic, biometric, or health data, which could limit our ability to collect, use and share European data, or could cause our compliance costs to increase, ultimately having an adverse impact on our business, and harm our business and financial condition. It is possible that these laws may be interpreted and applied in a manner that is inconsistent with our practices. If so, this could result in government-imposed fines or orders requiring that we change our practices, which could adversely affect our business. Further, the United Kingdom's vote in favor of exiting the EU, often referred to as Brexit, and ongoing developments in the United Kingdom regarding the timing and conditions of Brexit have created uncertainty with regard to data protection regulation in the United Kingdom. In particular, it is unclear when Brexit may occur, if at all, and whether the United Kingdom will enact data protection legislation equivalent to the GDPR and how data transfers to and from the United Kingdom will be regulated.

Compliance with U.S. and international data protection laws and regulations could cause us to incur substantial costs or require us to change our business practices and compliance procedures in a manner adverse to our business. Moreover, complying with these various laws could require us to take on more onerous obligations in our contracts, restrict our ability to collect, use and disclose data, or in some cases, impact our ability to operate in certain jurisdictions. We rely on our customers to obtain valid and appropriate consents from data subjects whose genetic samples and data we process on such customers' behalf. Given that we do not obtain direct consent from such data subjects and we do not audit our customers to ensure that they have obtained the necessary consents required by law, the failure of our customers to obtain consents that are in compliance with applicable law could result in our own non-compliance with privacy laws. Such failure to comply with U.S. and international data protection laws and regulations could result in government enforcement actions (which could include civil or criminal penalties), private litigation and/or adverse publicity and could negatively affect our operating results and business. Claims that we have violated individuals' privacy rights, failed to comply with data protection laws, or breached our contractual obligations, even if we are not found liable, could be expensive and time consuming to defend, could result in adverse publicity and could have a material adverse effect on our business, financial condition and results of operations.

Our success depends on our ability to provide reliable, high-quality genomic data and analyses and to rapidly evolve to meet our customers' needs.

Errors, including if our tests fail to accurately detect gene variants, or mistakes, including if we fail to or incompletely or incorrectly identify the significance of gene variants, could have a significant adverse impact on our business. We classify variants in accordance with guidelines that are subject to change and subject to our interpretation. There can also be flaws in the databases, third-party tools, algorithms we use, and in the software that handles automated parts of our classification protocol. If we receive poor quality or degraded samples, our tests may be unable to accurately detect gene variants or we may fail to or incompletely or incorrectly identify the significance of gene variants, which could have a significant adverse impact on our business.

Inaccurate results or misunderstandings of, or inappropriate reliance on, the information we provide to our customers could lead to, or be associated with, side effects or adverse events in patients who use our tests, including treatment-related death, and could lead to termination of our services or claims against us. A product liability or professional liability claim could result in substantial damages and be costly and time-consuming for us to defend.

Although we maintain liability insurance, including for errors and omissions and professional liability, we cannot assure you that our insurance would be sufficient to 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, including an errors and omissions liability claim, brought against us, with or without merit, could increase our insurance rates or prevent us from securing insurance coverage in the future. Additionally, any liability lawsuit could cause injury to our reputation or cause us to suspend sales of our tests or cause a suspension of our license to operate. The occurrence of any of these events could have an adverse effect on our business, reputation, and results of operations.

If we cannot develop services and products to keep pace with rapid advances in technology, medicine, and science, or if we experience delays in developing such services and products, our operating results and competitive position could be harmed.

In recent years, there have been numerous advances in technologies relating to the diagnosis and treatment of cancer. Several new cancer drugs have been approved, and a number of new drugs are in pre-clinical and clinical development. There have also been advances in methods used to identify patients likely to benefit from these drugs based on analysis of biomarkers. We must continuously develop new services and products, enhance any existing services, and avoid delays in such developments and enhancements to keep pace with evolving technologies on a timely and cost-effective basis. Our current services and our planned future services and products (such as our planned liquid biopsy test) could become obsolete unless we continually innovate and expand them to demonstrate benefit in the diagnosis, monitoring, or prognosis of patients with cancer. New cancer therapies typically have only a few years of clinical data associated with them, and much of that data may not be disclosed by the pharmaceutical company that conducted the clinical trials. This could limit our ability to develop services and products based on, for example, biomarker analysis related to the appearance or development of resistance to those therapies. If we cannot adequately demonstrate the clinical utility of our services and our planned future services and products to new treatments, sales of our services could decline, which would have a material adverse effect on our business, financial condition, and results of operations.

We are researching and developing improvements to our tests and test features on a continuous basis, but we may not be able to make these improvements on a timely basis, and even if we do, we may not realize the benefits of these efforts in our financial results.

To remain competitive, we must continually research and develop improvements to our tests or test features. However, we cannot assure you that we will be able to develop and commercialize the improvements to our tests or test features on a timely basis. Our competitors may develop and commercialize competing or alternative tests and improvements faster than we are able to do so. In addition, we must expend significant time and funds in order to conduct research and development, further develop and scale our laboratory processes, and further develop and scale our infrastructure. We may never realize a return on investment on this effort and expense, especially if our improvements fail to perform as expected. If we are not able to realize the benefits of our efforts to improve our tests or test features, it could have an adverse effect on our business, financial condition, and results of operations.

Personalized cancer therapies represent new therapeutic approaches that could result in heightened regulatory scrutiny, delays in clinical development, or delays in or inability to achieve regulatory approval, commercialization, or payor coverage, any of which could adversely affect our business.

We currently work with certain companies developing personalized cancer therapies, and our future success will in part depend on our personalized cancer customers obtaining regulatory approval for and commercializing their product candidate. Because personalized cancer therapies represent a new approach to immunotherapy for the treatment of cancer and other diseases, developing and commercializing personalized cancer therapies is subject to a number of challenges.

Actual or perceived safety issues, including adoption of new therapeutics or novel approaches to treatment, may adversely influence the willingness of subjects to participate in clinical studies, or if approved by applicable regulatory authorities, of physicians to subscribe to the novel treatment mechanics. The FDA or other applicable regulatory authorities may ask for specific post-market requirements, and additional information regarding benefits or risks of our services may emerge at any time prior to or after regulatory approval.

Physicians, hospitals, and third-party payors often are slow to adopt new products, technologies, and treatment practices that require additional upfront costs and training. Physicians may not be willing to undergo training to adopt personalized cancer therapies, may decide that such therapies are too complex to adopt without appropriate training or not cost-efficient, and may choose not to administer these therapies. Based on these and other factors, hospitals and payors may decide that the benefits of personalized cancer therapies do not or will not outweigh their costs.

The loss of key members of our executive management team could adversely affect our business.

Our success in implementing our business strategy depends largely on the skills, experience, and performance of key members of our executive management team and others in key management positions, including John West, our Chief Executive Officer, Richard Chen, our Chief Scientific Officer, Clinton Musil, our Chief Business Officer, and Aaron Tachibana, our Chief Financial Officer. The collective efforts of each of these persons and others working with them as a team are critical to us as we continue to develop our technologies, services, products, and research and development programs. As a result of the difficulty in locating qualified new management, the loss or incapacity of existing members of our executive management team could adversely affect our operations. If we were to lose one or more of these key employees, we could experience difficulties in finding qualified successors, competing effectively, developing our technologies, and implementing our business strategy. Each member of our executive management team has an employment agreement; however, the existence of an employment agreement does not guarantee retention of members of our executive management team, and we may not be able to retain those individuals. We do not maintain "key person" life insurance on any of our employees.

In addition, we rely on collaborators, consultants, and advisors, including scientific and clinical advisors, to assist us in formulating our research and development and commercialization strategy. Our collaborators, consultants, and advisors are generally employed by employers other than us and may have commitments under agreements with other entities that may limit their availability to us.

The loss of a key employee, the failure of a key employee to perform in his or her current position, or our inability to attract and retain skilled employees could result in our inability to continue to grow our business or to implement our business strategy.

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

Our performance, including our research and development programs and laboratory operations, largely depends on our continuing ability to identify, hire, develop, motivate, and retain highly skilled personnel for all areas of our organization. Competition in our industry for qualified employees is intense, and we may not be able to attract or retain qualified personnel in the future, including bioinformatic scientists, bioinformatic engineers, software engineers, statisticians, variant curators, clinical laboratory scientists, and genetic counselors, due to the competition for qualified personnel among life science businesses, technology companies, as well as universities and public and private research institutions, particularly in the San Francisco Bay Area. All of our U.S. employees are at-will, which means that either we or the employee may terminate their employment at any time. In addition, our compensation arrangements, such as our equity award programs, may not always be successful in attracting new employees and retaining and motivating our existing employees for reasons that may include movements in our stock price. 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 scale our business and support our research and development efforts and our laboratory operations. We believe that our corporate culture fosters innovation, creativity, and teamwork. However, as our organization grows, we may find it increasingly difficult to maintain the beneficial aspects of our corporate culture. This could negatively impact our ability to retain and attract employees and our future success.

We may not be able to manage our future growth effectively, which could make it difficult to execute our business strategy.

Our expected future growth could create a strain on our organizational, administrative, and operational infrastructure, including laboratory operations, quality control, customer service, marketing and sales, and management. We may not be able to maintain the quality of or expected turnaround times for our tests, or satisfy customer demand as our test volume grows. Our ability to manage our growth properly will require us to continue to improve our operational, financial, and management controls, as well as our reporting systems and procedures. As a result of our growth, our operating costs may escalate even faster than planned, and some of our internal systems may need to be enhanced or replaced. If we are unable to manage our growth effectively, it may be difficult for us to execute our business strategy and our business could be harmed.

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, including our laboratory information management system, our bioinformatics analytical software systems, our database of information relating to genetic variations and their role in disease process, our clinical report systems, our billing systems, our business intelligence systems, our logistics and customer relationship systems, our customer-facing web-based software, our customer reporting, and our family history and risk assessment tools. We have installed, and expect to expand, a number of enterprise software systems that affect a broad range of business processes and functional areas, including, for example, systems handling human resources, financial reporting and controls, customer relationship management, regulatory compliance, and other infrastructure operations.

Although we invest substantially in the backup/restore, high-availability architecture, monitoring and reporting, documentation and preventive security controls of our systems, all information technology and telecommunications systems are vulnerable to damage from a variety of sources, including telecommunications or network failures, malicious or inadvertent human acts and natural disasters. Our servers are potentially vulnerable to physical or electronic break-ins, employee errors, computer viruses and similar disruptive problems. Despite the precautionary measures we have taken to prevent unanticipated problems that could affect our information technology and telecommunications systems, failures or significant downtime of our information technology or telecommunications systems or those used by our third-party service providers could prevent us from conducting tests, preparing and providing reports to our customers, billing customers, collecting revenue, handling inquiries from our customers, conducting research and development activities, and managing the administrative aspects of our business. For example, in the first quarter of 2018, we experienced downtime in our information technology systems in connection with the adoption of certain new information technology, and our results of operations in the first and second quarters of 2018 were adversely affected as a result. 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.

Additionally, we have internally developed, and expect to continue to invest in and expand, proprietary informatics and software systems that are designed to manage the unique aspects and challenges of our genomics laboratory and on which we depend. Any disruption of failure of our internally developed informatics and software systems could have an adverse effect on our business.

Our employees may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements, which could cause significant liability for us and harm our reputation.

We are exposed to the risk of employee fraud or other misconduct, including intentional failures to comply with government regulations, including federal and state healthcare fraud and abuse laws and regulations, to misuse information, including patient information, and to report financial information or data accurately or disclose unauthorized activities to us. Such misconduct could also involve the improper use of information obtained in the course of clinical studies, which could result in regulatory sanctions and cause serious harm to our reputation. We have a code of conduct and ethics for our directors, officers and employees, but it is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business and results of operations, including the imposition of significant administrative, civil and criminal penalties, damages, fines, imprisonment, exclusion from government healthcare programs, contractual damages, refunding of payments received by us, reputational harm, additional reporting, or oversight obligations if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with the law and curtailment or restructuring of our operations. Whether or not we are successful in defending against such actions or investigations, we could incur substantial costs, including legal fees, and divert the attention of management in defending ourselves against any of these claims or investigations.

We may acquire businesses or assets, form joint ventures, or make investments in other companies or technologies 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, as well as technology licensing arrangements. We may also pursue strategic alliances that leverage our core technology and industry experience to expand our offerings or distribution, or make investments in other companies. As an organization, we have limited experience with respect to acquisitions as well as the formation of strategic alliances and joint ventures. We may not identify or complete these transactions in a timely manner, on a cost-effective basis, or at all, and we may not realize the anticipated benefits of any acquisition, technology license, strategic alliance, joint venture or investment. In addition, we may not be able to find suitable partners or acquisition candidates, and we may not be able to complete such transactions on favorable terms, if at all. Any future acquisitions by us also could result in significant write-offs or the incurrence of debt and contingent liabilities, any of which could harm our operating results. If we make any acquisitions in the future, we may not be able to integrate these acquisitions successfully into our existing business, and we could assume unknown or contingent liabilities. Integration of an acquired company or business also may require management resources that otherwise would be available for ongoing development of our existing business.

To finance any acquisitions or investments, we may choose to raise additional funds. The various ways wecould raise additional funds carry potential risks. See "—Our inability to raise additional capital on acceptable terms in the future may limit our ability to continue to operate our business and further expand our operations." If the price of our commonstock is low or volatile, we may not be able to acquire other companies using stock as consideration. Alternatively, it may be necessary for us to raise additional funds for these activities through public or private financings. Additional funds may not be available on terms that are favorable to us, or at all.

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. 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 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.

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 concerns regarding privacy and the appropriate uses of the resulting information. Governmental authorities have, through the Genetic Information Nondisclosure Act, and could further, 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. Ethical and social concerns may also influence governmental authorities to deny or delay the issuance of patents for technology relevant to our business. Similarly, these concerns may lead patients to refuse to use, or clinicians to be reluctant to order, genetic tests even if permissible. These and other ethical, legal, and social concerns may limit market acceptance of our tests or reduce the potential markets for our tests, either of which could have an adverse effect on our business, financial condition, or results of operations.

The December 2017 tax reform law could adversely affect our business and financial condition.

On December 22, 2017, President Trump signed into law comprehensive tax legislation (the "Tax Cuts and Jobs Act") that significantly revised the Internal Revenue Code of 1986, as amended (the "Code"). The Tax Cuts and Jobs Act, among other things, contained significant changes to corporate taxation, including reduction of the corporate tax rate from a top marginal rate of 35% to a flat rate of 21%, limitation of the tax deduction for interest expense to 30% of adjusted taxable income (except for certain small businesses), limitation of the deduction for net operating losses incurred after 2017 to 80% of current year taxable income and elimination of net operating loss carrybacks, one-time taxation of offshore earnings at reduced rates regardless of whether they are repatriated, elimination of U.S. tax on foreign earnings (subject to certain important exceptions), immediate deductions for certain new investments instead of deductions for depreciation expense over time, and modifying or repealing many business deductions and credits. Notwithstanding the reduction in the corporate income tax rate, the overall impact of the Tax Cuts and Jobs Act is uncertain and our business and financial condition could be adversely affected. In addition, it is uncertain if and to what extent various states will conform to the Tax Cuts and Jobs Act. The impact of this tax reform on holders of our common stock is also uncertain and could be adverse. We urge our stockholders to consult with their legal and tax advisors with respect to this legislation and the potential tax consequences of investing in or holding our common stock.

Our effective tax rate may fluctuate, and we may incur obligations in tax jurisdictions in excess of accrued amounts.

We are subject to taxation in numerous U.S. states and territories. As a result, our effective tax rate is derived from a combination of applicable tax rates in the various places that we operate. In preparing our financial statements, we estimate the amount of tax that will become payable in each of such places. Nevertheless, our effective tax rate may be different than experienced in the past due to numerous factors, including passage of the Tax Cuts and Jobs Act, changes in the mix of our profitability from state to state, the results of examinations and audits of our tax filings, our inability to secure or sustain acceptable agreements with tax authorities, changes in accounting for income taxes and changes in tax laws. Any of these factors could cause us to experience an effective tax rate significantly different from previous periods or our current expectations and may result in tax obligations in excess of amounts accrued in our financial statements.

Risks Related to Government Regulation

Our tests may be subject to regulatory action if regulatory agencies determine that our tests do not appropriately comply with statutory and regulatory requirements enforced by the U.S. Food and Drug Administration, and/or CLIA requirements for quality laboratory testing.

The laws and regulations governing the marketing of clinical laboratory tests are extremely complex and in many instances there are no significant regulatory or judicial interpretations of these laws and regulations. The Federal Food, Drug and Cosmetic Act (the "FDC Act") defines a medical device to include any instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent or other similar or related article, including a component, part, or accessory, intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment or prevention of disease, in man or other animals. Some of our tests may be considered by the FDA to be in vitro diagnostic products that are subject to regulation as medical devices. 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 are safe and effective for their intended uses, the FDA has generally exercised its enforcement discretion and not enforced applicable regulations with respect to laboratory developed tests ("LDTs"), which are a subset of in vitro diagnostic devices that are intended for clinical use and designed, manufactured, and used entirely within a single laboratory. We currently market our tests as LDTs and, therefore, we believe that they are not currently subject to the FDA's enforcement of its medical device regulations and the applicable FDC Act provisions. Despite the FDA's historic enforcement discretion policy with respect to LDTs, in November 2017, the FDA finalized a classification order setting out the regulatory requirements that apply to certain genetic health risk tests and revised a separate classification order exempting certain carrier screening tests from FDA premarket clearance and approval requirements when certain regulatory requirements are met. None of our tests comply with these classification orders because we market our tests as LDTs that are subject to the FDA's policy of enforcement discretion. However, the FDA may find that our tests do not fall within the definition of an LDT, and may determine that our tests are subject to the FDA's enforcement of its medical device regulations, including the recent classification orders, and the applicable FDC Act provisions. While we believe that we are currently in material compliance with applicable laws and regulations, we cannot assure you that the FDA or other regulatory agencies would agree with our determination, and a determination that we have violated these laws, or a public announcement that we are being investigated for possible violations of these laws, could adversely affect our business, prospects, results of operations or financial condition. If the FDA determines that our tests are subject to enforcement as medical devices, we could be subject to enforcement action, including administrative and judicial sanctions, and additional regulatory controls and submissions for our tests, all of which could be burdensome. See "—Failure to comply with federal, state, and foreign laboratory licensing requirements and the applicable requirements of the FDA or any other regulatory authority, could cause us to lose the ability to perform our tests, experience disruptions to our business or become subject to administrative or judicial sanctions."

Moreover, LDTs may in the future become subject to more onerous regulation by the FDA. A significant change in any of the laws, regulations, or policies may require us to change our business model in order to maintain regulatory compliance. At various times since 2006, the FDA has issued documents outlining its intent to require varying levels of FDA oversight of many types of LDTs. In October 2014, the FDA issued two non-binding draft guidance documents that set forth a proposed risk-based regulatory framework that would apply varying levels of FDA oversight to LDTs. The FDA indicated that it did not intend to implement its proposed framework until the draft guidance documents are finalized. The FDA was expected to finalize its proposal for the oversight of LDTs before the end of 2016, but in November 2016, the FDA announced that it would halt finalizing of the guidance documents and continue to work with stakeholders, the incoming administration, and Congress on the approach to LDT regulation. This announcement was followed by the issuance of an information discussion paper on January 13, 2017, in which the FDA outlined a substantially revised "possible approach" to the oversight of LDTs. The discussion paper explicitly states that it is not a final version of the 2014 draft guidance and that it is not enforceable and does not represent the FDA's "formal position." It is unclear at this time if or when the FDA will finalize its plans to end enforcement discretion for LDTs, and even then, whether the new regulatory requirements are expected to be phased-in over time. However, the FDA may decide to regulate certain LDTs on a case-by-case basis at any time, which could result in delay or additional expense in offering our tests and tests that we may develop in the future.

Legislative proposals addressing oversight of genetic testing and LDTs have been introduced in previous Congresses, and we expect that new legislative proposals will be introduced from time to time in the future. We cannot provide any assurance that FDA regulation, including pre-market review, will not be required in the future for our tests, whether through finalization of guidance issued by the FDA, new enforcement policies adopted by the FDA or new legislation enacted by Congress. It is possible that legislation will be enacted into law or guidance could be issued by the FDA that may result in increased regulatory burdens for us to continue to offer our tests or to develop and introduce new tests. This legislative and regulatory uncertainty exposes us to the possibility of enforcement action or additional regulatory controls and submissions for our tests, both of which could be burdensome. We cannot be certain that the FDA will not enact rules or guidance documents that could impact our ability to purchase certain materials necessary for the performance of our tests, such as products labeled for research use only. Should any of the reagents obtained by us from suppliers and used in conducting our tests be affected by future regulatory actions, our business could be adversely affected by those actions, including increasing the cost of testing or delaying, limiting, or prohibiting the purchase of reagents necessary to perform testing.

Additionally, the Centers for Medicare & Medicaid Services ("CMS"), and certain state agencies regulate the performance of LDTs (as authorized under CLIA and state law, respectively). Our tests are developed in compliance with CLIA requirements. However, if our laboratory fails to comply with the prescribed quality requirements for laboratory testing or other requirements for CLIA, we could lose CLIA certification. That in turn would impact our ability to operate our laboratory and provide results to our customers, which could negatively impact our business operations.

If the FDA determines that our services are subject to enforcement as medical devices, we could incur substantial costs and time delays associated with satisfying statutory and regulatory requirements such as pre-market clearance or approval and we could incur additional expense in offering our tests and tests that we may develop in the future.

If the FDA determines that our tests and associated software do not fall within the definition of an LDT, or there are regulatory or legislative changes, we may be required to obtain premarket clearance for our tests and associated software under Section 510(k) of the FDC Act or approval of a premarket approval application ("PMA"). We would also be subject to ongoing regulatory requirements such as registration and listing requirements, medical device reporting requirements, and quality control requirements. If our tests are considered medical devices not subject to enforcement discretion, the regulatory requirements to which our tests are subject would depend on the FDA's classification of our tests. The FDA has issued regulations classifying over 1,700 different generic types of medical devices into one of three regulatory control categories (Class I, Class II, or Class III) depending on the degree of regulation that the FDA finds necessary to provide reasonable assurance of their safety and effectiveness. The class into which a device is placed determines the requirements that a medical device manufacturer must meet both pre- and post-market.

Generally, Class I devices do not require premarket authorization, but are subject to a comprehensive set of regulatory authorities referred to as general controls. Class II devices, in addition to general controls, generally require special controls and premarket clearance through the submission of a section 510(k) premarket notification. Class III devices are subject to general controls and special controls, and also require premarket approval prior to commercial distribution, which is a more rigorous process than premarket clearance. Under the FDC Act, a device that is first marketed after May 28, 1976 is by default a Class III device requiring premarket approval unless it is within a type of generic device class that has been classified as Class I or Class II. Even if a device falls under an existing Class II, non-exempt, device classification, the product must also be shown to be "substantially equivalent" to a legally marketed predicate device through submission of a section 510(k) premarket notification. If after reviewing a firm's 510(k) premarket notification, the FDA determines that a device is not substantially equivalent to a legally marketed predicate device, the new device is classified into Class III, requiring premarket approval. It is possible for a manufacturer to obtain a Class I or Class II designation without an appropriate predicate by submitting a *de novo* request for reclassification.

The process for submitting a 510(k) premarket notification and receiving FDA clearance usually takes from three to twelve months, but it can take significantly longer and clearance is never guaranteed. The process for submitting and obtaining FDA approval of a PMA is much more costly, lengthy, and uncertain. It 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.

If our tests are considered medical devices not subject to enforcement discretion, one classification regulation that could be relevant to one or more of our tests is a recently finalized classification for genetic health risk ("GHR") assessment tests. On April 6, 2017, in response to a *de novo* request for reclassification submitted by another company, the FDA issued an order classifying genetic tests known as genetic health risk assessment systems ("GHR tests") as Class II devices subject to premarket notification and specified special controls requirements. On November 7, 2017, the FDA codified this classification at 21 C.F.R. § 866.5950. If our tests are considered medical devices that are not subject to enforcement discretion and one or more of our tests is considered to fall under the 21 C.F.R. § 866.5950 classification regulation for GHR tests, or under another Class II classification that is subject to a premarket notification requirement, we would be required to obtain marketing clearance for such tests. Further, if considered to fall under the 21 C.F.R. § 866.5950 classification for GHR tests, our tests would be required to adhere to specified special controls, such as labeling and testing specifications and information about the test to be posted on the manufacturer's website. Although the FDA has also issued a proposal for a simplified path to market GHR tests that would amend the classification regulation at 21 C.F.R. § 886.5950 such that manufacturers would only be subject to a one-time marketing review to ensure that they meet the applicable FDA requirements prior to selling GHR tests in the market, the FDA has yet to finalize this proposal, and we do not know if and when finalization will occur. Even if the FDA finalizes the proposed limited exemption for GHR tests, if any of our current or pipeline tests are not considered by the FDA to be GHR tests or do not qualify for the limited exemption (if and when finalized), or if any of our tests fall under a different non-exempt classification or are unclassified, we could be required to obtain 510(k) clearance or approval of a PMA for such test in the future.

If premarket review of our tests is required, the premarket review process may involve, among other things, successfully completing additional 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 product development costs, delay commercialization of any future products, and interrupt sales of our current products. 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 concerns around genetic testing, the nature of the protocol, the proximity of patients to clinical sites, and the eligibility criteria for the clinical trial.

If we are required to conduct clinical trials, we and any third-party contractors we engage would be required to comply with good clinical practices ("GCPs"), which are regulations and guidelines enforced by the FDA, for products in clinical development. The FDA enforces these GCPs through periodic inspections of trial sponsors, principal investigators, and trial sites. If we or any third-party contractor fails to comply with applicable GCPs, the clinical data generated in clinical trials may be deemed unreliable and the FDA may require us to perform additional clinical trials before clearing or approving our marketing applications. A failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory clearance or approval process. In addition, if these parties do not successfully carry out their contractual duties or obligations or meet expected deadlines, or if the quality, completeness or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols or for other reasons, our clinical trials may have to be extended, delayed or terminated. Many of these factors would be beyond our control. We may not be able to enter into replacement arrangements without undue delays or considerable expenditures. If there are delays in testing or approvals as a result of the failure to perform by third parties, our research and development costs would increase, and we may not be able to obtain regulatory clearance or approval for our tests. In addition, we may not be able to establish or maintain relationships with these parties on favorable terms, if at all. Each of these outcomes would harm our ability to market our tests or to achieve or sustain profitability.

The FDA requires medical device manufacturers to comply with, among other things, current good manufacturing practices for medical devices, set forth in the Quality System Regulation at 21 C.F.R. Part 820, which requires manufacturers to follow elaborate design, testing, control, documentation, and other quality assurance procedures during the manufacturing process; the medical device reporting regulation, which requires that manufacturers report to the FDA if their device or a similar device they market may have caused or contributed to a death or serious injury or malfunctioned in a way that would likely cause or contribute to a death or serious injury if it were to recur; labeling regulations, including the FDA's general prohibition against promoting products for unapproved or "off-label" uses; the reports of corrections and removals regulation, which requires manufacturers to report to the FDA if a device correction or removal was initiated to reduce a risk to health posed by the device or to remedy a violation of the FDC Act caused by the device which may present a risk to health; and the establishment registration and device listing regulation.

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 our products. If premarket review is required for some or all of our products, the FDA may require that we stop selling our products pending clearance or approval, which would negatively impact our business. Even if our products are allowed to remain on the market prior to clearance or approval, demand for our products may decline if there is uncertainty about our products, if we are required to label our products as investigational by the FDA, or if the FDA limits the labeling claims we are permitted to make for our products. As a result, we could experience significantly increased development costs and a delay in generating additional revenues from our services, or from other services or products now in development.

In addition, any clearance or approval we obtain for our products may contain requirements for costly post-market testing and surveillance to monitor the safety or efficacy of the product. The FDA has broad post-market enforcement powers, and if unanticipated problems with our products arise, or if we or our suppliers fail to comply with regulatory requirements following FDA clearance or approval, we may become subject to enforcement actions such as:

- restrictions on manufacturing processes;
- restrictions on product marketing;
- warning letters;
- withdrawal or recall of products from the market;
- refusal to approve pending PMAs, 510(k)s, or supplements to approved PMAs or cleared 510(k)s that we submit;
- fines, restitution, or disgorgement of profits or revenue;
- suspension or withdrawal of regulatory clearances or approvals;
- limitation on, or refusal to permit, import or export of our products;
- product seizures;
- injunctions; or
- imposition of civil or criminal penalties.

Moreover, the FDA strictly regulates the promotional claims that may be made about medical devices. In particular, a medical device may not be promoted for uses that are not approved by the FDA as reflected in the device's approved labeling. However, companies may share truthful and not misleading information that is otherwise consistent with the product's FDA approved labeling. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant civil, criminal, and administrative penalties.

Failure to comply with federal, state, and foreign laboratory licensing requirements and the applicable requirements of the FDA or any other regulatory authority, could cause us to lose the ability to perform our tests, experience disruptions to our business, or become subject to administrative or judicial sanctions.

We are subject to CLIA, a federal law that regulates clinical laboratories that perform testing on specimens derived from humans for the purpose of providing information for the diagnosis, prevention, or treatment of disease. CLIA regulations establish specific standards with respect to personnel qualifications, facility administration, proficiency testing, quality control, quality assurance, and inspections. We have a current CLIA certificate to conduct our tests at our laboratory in Menlo Park, California. To renew this certificate, we are subject to survey and inspection every two years. Moreover, CLIA inspectors may make random inspections of our clinical reference laboratory.

We are also required to maintain a license to conduct testing in California. California laws establish standards for day-to-day operation of our clinical reference laboratory in Menlo Park, including the training and skills required of personnel and quality control. Several other states in which we operate also require that we hold licenses to test specimens from patients in those states, under certain circumstances. For example, our clinical reference laboratory is required to be licensed on a product-specific basis by New York as an out-of-state laboratory, and our products, as LDTs, must be approved by the New York State Department of Health (the "NYDOH") on a product-by-product basis before they are offered in New York. We are subject to periodic inspection by the NYDOH and are required to demonstrate ongoing compliance with NYDOH regulations and standards. To the extent NYDOH identified any non-compliance and we are unable to implement satisfactory corrective actions to remedy such non-compliance, the State of New York could withdraw approval for our tests. Additionally, states such as Maryland, Pennsylvania, and Rhode Island may also require us to maintain out-of-state licenses. Other states may have similar requirements or may adopt similar requirements in the future. Although we have obtained licenses from states where we believe we are required to be licensed, we may become aware of other states that require out-of-state laboratories to obtain licensure in order to accept specimens from the state, and it is possible that other states currently have such requirements or will have such requirements in the future. We may also be subject to regulation in foreign jurisdictions as we seek to expand international utilization of our tests or such jurisdictions adopt new licensure requirements, which may require review of our tests in order to offer them or may have other limitations such as restrictions on the transport of human blood necessary for us to perform our tests that may limit our ability to make our tests available outside of the United States. Complying with licensure requirements in new jurisdictions may be expensive and/or time-consuming, may subject us to significant and unanticipated delays, or may be in conflict with other applicable requirements.

Failure to comply with applicable clinical laboratory licensure requirements may result in a range of enforcement actions, including license suspension, limitation, or revocation, directed plan of action, onsite monitoring, civil monetary penalties, and criminal sanctions 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, a state or foreign license or accreditation, could have a material adverse effect on our business, financial condition and results of operations. Even if we were able to bring our laboratory back into compliance, we could incur significant expenses and potentially lose revenues in doing so.

Although we market our tests as LDTs that are currently subject to the FDA's exercise of enforcement discretion, if we fail to operate within the conditions of that exercise of enforcement discretion, or if any of our products otherwise fail to comply with FDA regulatory requirements as enforced, we would be subject to the applicable requirements of the FDC Act and the FDA's implementing regulations. The FDA is empowered to impose sanctions for violations of the FDC Act and the FDA's implementing regulations, including warning letters, civil and criminal penalties, injunctions, product seizure or recall, import bans, restrictions on the conduct of our operations and total or partial suspension of production. Any of the aforementioned sanctions could cause reputational damage, undermine our ability to maintain and increase our revenues, and harm our business, financial condition, and results of operations. In particular, if we or the FDA discover that any of our products have defects that call into question the accuracy of their results, we may be required to undertake a retest of all results and analyses provided during the period relevant to the defect, or recall the affected products. The direct costs incurred in connection with such a recall in terms of management time, administrative, and legal expenses and lost revenue, together with the indirect costs to our reputation could harm our business, financial condition and results of operations, and our ability to execute our business strategy. While we believe that we are currently in material compliance with applicable laws and regulations as currently enforced, the FDA or other regulatory agencies may not agree, and a determination that we have violated these laws or a public announcement that we are being investigated for possible violations of these laws could adversely affect our business, financial condition, results of operations, and prospects.

Complying with numerous statutes and regulations pertaining to our business is an expensive and time-consuming process, and any failure to comply could result in substantial penalties.

Our operations may be subject to other 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 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 such 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. In addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the false claims statutes;

- the federal Stark physician self-referral 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. Failure to refund amounts received as a result of a prohibited referral on a timely basis may constitute a false or fraudulent claim under the False Claims Act;

- the "Anti-Markup Rule" and similar state and similar state laws, among other things, prohibits a physician or supplier billing the Medicare program from marking up the price of a purchased diagnostic service performed by another laboratory or supplier that does not "share a practice" with the billing physician or supplier. Penalties may apply to the billing physician or supplier if Medicare or another payer is billed at a rate that exceeds the performing laboratory's charges to the billing physician or supplier, and the performing laboratory could be at risk under false claims laws, described below, for causing the submission of a false claim;

- the federal civil and criminal false claims laws, including the False Claims Act, 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. These laws can apply to entities that provide information on coverage, coding, and reimbursement of their products and assistance with obtaining reimbursement to persons who bill payors. Private individuals can bring False Claims Act "qui tam" actions, on behalf of the government and such individuals, commonly known as "whistleblowers," may share in amounts paid by the entity to the government in fines or settlement;

- 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;

- the federal Physician Payments Sunshine Act, which requires certain manufacturers of drugs, biologicals, and medical devices or supplies that require premarket approval by or notification to the FDA, and for which payment is available under Medicare, Medicaid, or the Children's Health Insurance Program ("CHIP") to report annually to CMS information related to (i) payments and other transfers of value to physicians and teaching hospitals, and (ii) ownership and investment interests held by physicians and their immediate family members;

- the HIPAA fraud and abuse provisions, which created federal civil and criminal statutes 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;

- the Eliminating Kickbacks in Recovery Act of 2018 ("EKRA"), which prohibits payments for referrals to recovery homes, clinical treatment facilities, and laboratories. EKRA's reach extends beyond federal health care programs to include private insurance (i.e., it is an "all payer" statute);

- other federal and state fraud and abuse laws, such as anti-kickback laws, prohibitions on self-referral, fee-splitting restrictions, insurance fraud laws, prohibitions on the provision of tests at no or discounted cost to induce physician or patient adoption, and false claims acts, which may extend to services reimbursable by any payer, including private insurers;

- 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; billing a state Medicaid program at a price that is higher than what is charged to one or more other payors employing, exercising control over, licensed professionals in violation of state laws prohibiting corporate practice of medicine and other professions, and prohibitions against the splitting of professional fees with licensed professionals; and

- similar foreign laws and regulations that apply to us in the countries in which we operate or may operate in the future.

As a clinical laboratory, our business practices may face additional scrutiny from government regulatory agencies such as the Department of Justice, the HHS Office of Inspector General (the "OIG") and CMS. Certain arrangements between clinical laboratories and referring physicians have been identified in fraud alerts issued by the OIG as implicating the Anti-Kickback Statute. The OIG has stated that it is particularly concerned about these types of arrangements because the choice of laboratory, as well as the decision to order laboratory tests, typically are made or strongly influenced by the physician, with little or no input from patients. Moreover, the provision of payments or other items of value by a clinical laboratory to a referral source could be prohibited under the Stark Law unless the arrangement meets all criteria of an applicable exception. The government has been active in enforcement of these laws as they apply to clinical laboratories.

The growth of our business and our expansion outside of the United States may increase the potential of violating these laws or our internal policies and procedures. The risk of our being found in violation of these or other laws and regulations is further increased by the fact that many have not been fully interpreted by the regulatory authorities or the courts, and their provisions are open to a variety of interpretations. 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 and reputational harm and divert our management's attention from the operation of our business. If our operations 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 significant administrative, civil and criminal penalties, damages, fines, imprisonment, exclusion from participation in federal healthcare programs, refunding of payments received by us, integrity oversight and reporting obligations, and curtailment or cessation of our operations. Any of the foregoing consequences could seriously harm our business and our financial results.

If we decide to grow our business by developing in vitro diagnostic tests, we may be subject to reimbursement challenges.

The coverage and reimbursement status of newly approved or cleared laboratory tests is uncertain. If we develop in vitro diagnostic tests and decide to seek reimbursement, and if such tests are inadequately covered by insurance and ineligible for such reimbursement, this could limit our ability to market any such future tests. The commercial success of future products in both domestic and international markets may depend in part on the availability of coverage and adequate reimbursement from third-party payors, including government payors, such as the Medicare and Medicaid programs, managed care organizations, and other third-party payors. The government and other third-party payors are increasingly attempting to contain health care costs by limiting both insurance coverage and the level of reimbursement for new diagnostic tests. As a result, they may not cover or provide adequate payment for any future in vitro diagnostic tests that we develop. These payors may conclude that our products are less safe, less effective, or less cost-effective than existing or later-introduced products. These payors may also conclude that the overall cost of using one of our tests exceeds the overall cost of using a competing test, and third-party payors may not approve any future in vitro diagnostic tests we develop for insurance coverage and adequate reimbursement.

We could be adversely affected by violations of the Foreign Corrupt Practices Act of 1977, as amended (the "FCPA"), and other worldwide anti-bribery laws.

We are subject to the FCPA, which prohibits companies and their intermediaries from making payments in violation of law to non-U.S. government officials for the purpose of obtaining or retaining business or securing any other improper advantage. Other U.S. companies in the medical device and pharmaceutical fields have faced criminal penalties under the FCPA for allowing their agents to deviate from appropriate practices in doing business with these individuals. We are also subject to similar anti-bribery laws in the jurisdictions in which we operate, including the United Kingdom's Bribery Act of 2010, which also prohibits commercial bribery and makes it a crime for companies to fail to prevent bribery. These laws are complex and far-reaching in nature, and, as a result, we cannot assure you that we would not be required in the future to alter one or more of our practices to be in compliance with these laws or any changes in these laws or the interpretation thereof. 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.

Expansion into international markets would subject us to increased regulatory oversight and regulatory, economic, social and political uncertainties, which could cause a material adverse effect on our business, financial position, and results of operations.

We may in the future expand our business and operations into international jurisdictions in which we have limited operating experience, including with respect to seeking regulatory approvals and marketing and selling products and services. If we expand internationally, our operations in these jurisdictions may be adversely affected by general economic conditions and economic and fiscal policy, including changes in exchange rates and controls, interest rates and taxation policies, increased government regulation, social stability, and political, economic or diplomatic developments in the future. Certain jurisdictions have, from time to time, experienced instances of civil unrest and hostilities, both internally and with neighboring countries. Rioting, military activity, terrorist attacks, or armed hostilities could cause our operations in such jurisdictions to be adversely affected or suspended. We generally do not have insurance for losses and interruptions caused by terrorist attacks, military conflicts and wars. In addition, anti-bribery and anti-corruption laws may conflict with some local customs and practices in foreign jurisdictions. Our international operations may subject us to heightened scrutiny under the FCPA, the UK Bribery Act and similar anti-bribery laws, and could subject us to liability under such laws despite our best efforts to comply with such laws. As a result of our policy to comply with the FCPA, the UK Bribery Act and similar anti-bribery laws, we may be at a competitive disadvantage to competitors that are not subject to, or do not comply with, such laws. Further, notwithstanding our compliance programs, there can be no assurances that our policies will prevent our employees or agents from violating these laws or protect us from any such violations. Additionally, we cannot predict the nature, scope or impact of any future regulatory requirements that may apply to our international operations or how foreign governments will interpret existing or new laws. Alleged, perceived, or actual violations of any such existing or future laws by us or due to the acts of others, may result in criminal or civil sanctions, including contract cancellations or debarment, and damage to our reputation, any of which could have a material adverse effect on our business.

Changes in health care policy could increase our costs, decrease our revenues, and impact sales of and reimbursement for our tests.

In March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act (the "ACA"), became law. This law substantially changed the way health care is financed by both commercial payers and government payers, and significantly impacts our industry. The ACA contains a number of provisions that are expected to impact the business and operations of our customers, some of which in ways we cannot currently predict, including those governing enrollment in state and federal health care programs, reimbursement changes, and fraud and abuse, which will impact existing state and federal health care programs and will result in the development of new programs.

Among other things, the ACA:

- imposed an annual excise tax of 2.3% on any entity that manufactures or imports medical devices offered for sale in the United States, with limited exceptions, although the effective rate paid may be lower. Under the Consolidated Appropriations Act of 2016, the excise tax was suspended through December 31, 2017, and under the continuing resolution on appropriations for fiscal year 2018, signed by President Trump on January 22, 2018, was further suspended through December 31, 2019;

- expanded eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to additional individuals and by adding new mandatory eligibility categories for individuals with income at or below 133% of the federal poverty level, thereby potentially increasing manufacturers' Medicaid rebate liability;

- established a new Patient-Centered Outcomes Research Institute to oversee and identify priorities in comparative clinical efficacy research in an effort to coordinate and develop such research; and

- established a Center for Medicare & Medicaid Innovation at CMS to test innovative payment and service delivery models to lower Medicare and Medicaid spending.

Some of the provisions of the ACA have yet to be implemented, and there have been judicial and Congressional challenges to certain aspects of the ACA, as well as recent efforts by the Trump administration to repeal or replace certain aspects of the ACA. Since January 2017, President Trump has signed two Executive Orders and other directives to delay the implementation of certain requirements of the ACA. Concurrently, Congress has considered legislation that would repeal or repeal and replace all or part of the ACA. While Congress has not passed comprehensive repeal legislation, it has enacted laws that modify certain provisions of the ACA such as removing penalties, starting January 1, 2019, for not complying with the ACA's individual mandate to carry health insurance and delaying the implementation of certain ACA-mandated fees including, without limitation, the medical device excise tax. On December 14, 2018, a Texas U.S. District Court Judge ruled that the ACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress as part of the Tax Cuts and Jobs Act. While the Texas U.S. District Court Judge, as well as the Trump administration and CMS, have stated that the ruling will have no immediate effect pending appeal of the decision, it is unclear how this decision, subsequent appeals, and other efforts to repeal and replace the ACA will impact the ACA and our business. Additional legislation may be enacted that further amends, or repeals, the ACA, which could result in lower numbers of insured individuals, reduced coverage for insured individuals and adversely affect our and our customers' business.

In addition, other legislative changes have been proposed and adopted since the Affordable Care Act was enacted. On August 2, 2011, the Budget Control Act of 2011 was signed into law, which, among other things, reduced Medicare payments to providers by 2% per fiscal year, effective on April 1, 2013 and, due to subsequent legislative amendments to the statute, will remain in effect through 2027 unless additional Congressional action is taken. On January 2, 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, reduced Medicare payments to several providers, including hospitals, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. The Medicare Access and CHIP Reauthorization Act of 2015, enacted on April 16, 2015 ("MACRA"), repealed the formula by which Medicare made annual payment adjustments to physicians and replaced the former formula with fixed annual updates and a new system of incentive payments beginning in 2019 that are based on various performance measures and physicians' participation in alternative payment models such as accountable care organizations.

In April 2014, Congress passed the Protecting Access to Medicare Act of 2014 ("PAMA"), which included substantial changes to the way in which clinical laboratory services are paid under Medicare. Under PAMA, laboratories that receive the majority of their Medicare revenues from payments made under the Medicare Clinical Laboratory Fee Schedule, or the Physician Fee Schedule are required to report to CMS, beginning in 2017 and every three years thereafter (or annually for "advanced diagnostic laboratory tests"), private payer payment rates and volumes for their tests. CMS will use this data to calculate a weighted median payment rate for each test, which will be used to establish revised Medicare reimbursement rates for the tests. Laboratories that fail to report the required payment information may be subject to substantial civil monetary penalties. It is unclear what impact new quality and payment programs, such as MACRA, or new pricing structures, such as those adopted under PAMA, may have on our business, financial condition, results of operations, or cash flows.

We anticipate there will continue to be proposals by legislators at both the federal and state levels, regulators and private payers to reduce costs while expanding individual healthcare benefits. Certain of these changes could impose additional limitations on the prices we will be able to charge for our tests, the coverage of or the amounts of reimbursement available for our tests from payers, including commercial payers and government payers.

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

Our activities currently require the use of hazardous chemicals and biological material. We cannot eliminate the risk of an accidental environmental release or injury to employees or third parties from the use, storage, handling, or disposal of these materials. In the event of an environmental release 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. 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. The cost of maintaining compliance with these laws and regulations may become significant and our failure to comply may result in substantial fines or other consequences, and either could negatively affect our operating results.

Risks Related to Our Intellectual Property

Litigation or other proceedings or third-party claims of intellectual property infringement, misappropriation or other violations may require us to spend significant time and money, and could in the future prevent us from selling our tests or impact our stock price, any of which could have a material adverse effect.

Our commercial success will depend in part on our avoiding infringement of patents and infringement, misappropriation or other violations of other proprietary rights of third parties, including for example the intellectual property of competitors. There is extensive intellectual property litigation involving the biotechnology and pharmaceutical industries and genetic sequencing technology. Our activities may be subject to claims that we infringe or otherwise violate patents owned or controlled by third parties. Numerous U.S. and foreign patents and pending patent applications exist in the genetic testing market and are owned by third parties. We cannot assure you that our operations do not, or will not in the future, infringe existing or future patents. For example, we are aware of several third-party issued U.S. patents and pending patent applications with claims relating to genetic sequencing technology and methodology that may be asserted against us and may be construed to encompass our products and services, including ACE ImmunoID and ImmunoID NeXT technology. In order to avoid infringing these third-party patents, we may find it necessary to or prudent to initiate invalidity proceedings against such patents or to obtain licenses from such third-party intellectual property holders. If we are not able to invalidate such patents or obtain or maintain a license on commercially reasonable terms and such third parties assert infringement claims against us, we may be prevented from exploiting our technology and our business, financial condition, results of operations, and prospects may be materially and adversely affected. We may also be unaware of patents that a third party, including for example a competitor in the genetic testing market, might assert are infringed by our business. There may also be patent applications that, if issued as patents, could be asserted against us. Patent applications in the United States and elsewhere are typically published approximately 18 months after the earliest filing for which priority is claimed, with such earliest filing date being commonly referred to as the priority date. Certain U.S. patent applications that will not be filed outside the United States can remain confidential until patents issue. Therefore, patent applications covering our products, services, or technologies could have been filed by third parties without our knowledge. Additionally, pending patent applications that have been published can, subject to certain limitations, be later amended in a manner that could cover our products, services, technologies, and their use. The scope of a patent claim is determined by an interpretation of the law, the written disclosure in a patent and the patent's prosecution history and can involve other factors such as expert opinion. Our interpretation of the relevance or the scope of claims in a patent or a pending application may be incorrect, which may negatively impact our ability to market our products and services. Further, we may incorrectly determine that our technologies, products, or services are not covered by a third-party patent or may incorrectly predict whether a third party's pending patent application will issue with claims of relevant scope. Our determination of the expiration date of any patent in the United States or abroad that we consider relevant may be incorrect, which may negatively impact our ability to develop and market our products or services.

Third-party intellectual property right holders may also actively bring infringement or other intellectual property-related claims against us, even if we have received patent protection for our technologies, products, and services. Regardless of the merit of third parties claims against us for infringement, misappropriation or violations of their intellectual property rights, such third parties may seek and obtain injunctive or other equitable relief, which could effectively block our ability to perform our tests. Further, if a patent infringement suit were brought against us, we could be forced to stop or delay our development or sales of any tests or other activities that are the subject of such suit. Defense of these claims, even if such claims are resolved in our favor, could cause us to incur substantial expenses and be a substantial diversion of our employee resources even if we are ultimately successful. Any adverse ruling or perception of an adverse ruling in defending ourselves could have a material adverse impact on our cash position and stock price. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing, or distribution activities. We may not have sufficient financial or other resources to conduct such litigation or proceedings adequately. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources and more mature and developed intellectual property portfolios.

As we continue to commercialize our tests in their current or an updated form, launch different and expanded tests and enter new markets, other competitors might claim that our tests infringe, misappropriate or violate their intellectual property rights as part of business strategies designed to impede our successful commercialization and entry into new markets. If such a suit were brought, regardless of merit, there is no assurance that a court would find in our favor on questions of infringement, validity, enforceability or priority. Even if we are successful in defending against such suit, we could incur substantial costs and diversion of the attention of our management and technical personnel in defending ourselves against such claims. A court of competent jurisdiction could hold that third-party patents asserted against us are valid, enforceable, and infringed, which could materially and adversely affect our ability to commercialize any products, services or technologies we may develop and any other technologies covered by the asserted third-party patents and any adverse ruling or perception of an adverse ruling in defending ourselves could have a material adverse impact on our cash position and stock price. If we are found to infringe, misappropriate or otherwise violate a third party's intellectual property rights, and we are unsuccessful in demonstrating that such rights are invalid or unenforceable, we may be required to pay substantial damages, including treble damages and attorneys' fees for willful infringement; obtain one or more licenses from third parties in order to continue developing and marketing our products and technology, which may not be available on commercially reasonable terms (if at all) or may be non-exclusive, thereby giving our competitors and other third parties access to the same technologies licensed to us; pay substantial royalties and other fees; and redesign any infringing tests or other activities, which may be impossible or require substantial time and monetary expenditure, or be prohibited from commercializing certain tests, all of which could have a material adverse effect on our business, financial condition, results of operations, and prospects.

Where we collaborate with third parties in the development of technology, our collaborators may not properly maintain or defend our intellectual property rights or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our intellectual property or proprietary information. Further, collaborators may infringe the intellectual property rights of third parties, which may expose us to litigation and potential liability. Also, we may be obligated under our agreements with our collaborators, licensors, suppliers and others to indemnify and hold them harmless for damages arising from intellectual property infringement by us.

If we cannot license rights to use technologies on reasonable terms, we may not be able to commercialize new products in the future.

In the future, we may identify additional third-party intellectual property we may need to license in order to engage in our business, including to develop or commercialize new products or services. However, such licenses may not be available on acceptable terms or at all. Even if such licenses are available, we may be required to pay the licensor substantial royalties based on sales of our products and services. Such royalties are a component of the cost of our products or services and may affect the margins on our products and services. In addition, such licenses may be nonexclusive, which could give our competitors access to the same intellectual property licensed to us. If we are unable to enter into the necessary licenses on acceptable terms or at all, if any necessary licenses are subsequently terminated, if our licensors fail to abide by the terms of the licenses, if our licensors fail to prevent infringement by third parties, or if the licensed patents or other rights are found to be invalid or unenforceable, our business, financial condition, results of operations, and prospects could be materially and adversely affected.

If licenses to third-party intellectual property rights are or become required for us to engage in our business, the rights may be non-exclusive, which could give our competitors access to the same technology or intellectual property rights licensed to us. Moreover, we could encounter delays in the introduction of tests while we attempt to develop alternatives. Defense of any lawsuit or failure to obtain any of these licenses on favorable terms could prevent us from commercializing tests, which could materially affect our ability to grow and thus adversely affect our business and financial condition.

Developments or uncertainty in the patent statute, patent case law or U.S. Patent and Trademark Office ("USPTO"), rules and regulations may impact the validity, scope or enforceability of our patent rights, thereby impairing our ability to protect our products.

Our patent rights, their associated costs, and the enforcement or defense of such patent rights may be affected by developments or uncertainty in the patent statute, patent case law or USPTO rules and regulations.

There are a number of recent changes to the patent laws that may have a significant impact on our ability to protect our technology and enforce our intellectual property rights. For example, the Leahy-Smith America Invents Act (the "AIA") enacted within the last several years involves significant changes in patent legislation. These include provisions that affect the way patent applications will be prosecuted and may also affect patent litigation. As an example, assuming that other requirements for patentability are met, prior to March 2013, in the United States, the first to invent the claimed invention was entitled to the patent, while outside the United States, the first to file a patent application was entitled to the patent. On or after March 16, 2013, under the AIA, the United States transitioned to a first inventor to file system in which, assuming that other requirements for patentability are met, means that the party that is first to file in the United States generally is awarded the patent rights, regardless of whether such party invented the claimed invention first.

The AIA also includes a number of significant changes that affect the way patent applications will be prosecuted and also may affect patent litigation. These include allowing third party submission of prior art to the USPTO during patent prosecution and additional procedures to attack the validity of a patent by USPTO administered post-grant proceedings, including post-grant review, *inter partes* review, and derivation proceedings. Because of a lower evidentiary standard in USPTO proceedings compared to the evidentiary standard in United States federal courts necessary to invalidate a patent claim, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action. Accordingly, a third party may attempt to use the USPTO procedures to invalidate our patent claims that would not have been invalidated if first challenged by the third party as a defendant in a district court action. The AIA and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business, financial condition, results of operations, and prospects.

Further, the standards applied by the USPTO and foreign patent offices in granting patents are not always applied uniformly or predictably. For example, there is no uniform worldwide policy regarding patentable subject matter or the scope of claims allowable in biotechnology patents. As such, we do not know the degree of future protection that we will have on our technologies, products, and services. While we will endeavor to try to protect our technologies, products, and services with intellectual property rights such as patents, as appropriate, the process of obtaining patents is time-consuming, expensive, and sometimes unpredictable.

In addition, the patent position of companies engaged in the development and commercialization of diagnostic tests is particularly uncertain. Various courts, including the Supreme Court have rendered decisions that affect the scope of patentability of certain inventions or discoveries relating to certain diagnostic tests and related methods. These decisions state, among other things, that a patent claim that recites an abstract idea, natural phenomenon or law of nature (for example, the relationship between particular genetic variants and cancer) are not themselves patentable. Precisely what constitutes a law of nature or abstract idea is uncertain, and it is possible that certain aspects of genetic diagnostics tests would be considered natural laws. Accordingly, the evolving case law in the United States may adversely affect our ability to obtain patents and may facilitate third-party challenges to any owned or licensed patents. The laws of some foreign countries do not protect intellectual property rights to the same extent as the laws of the United States, and we may encounter difficulties in protecting and defending such rights in foreign jurisdictions. The legal systems of many other countries do not favor the enforcement of patents and other intellectual property protection, particularly those relating to biotechnology, which could make it difficult for us to stop the infringement of our patents in such countries. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial cost and divert our efforts and attention from other aspects of our business.

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

Patents have a limited lifespan. In the United States, the natural expiration of a patent is generally 20 years after its first effective non-provisional filing date. Although various extensions may be available, the life of a patent, and the protection it affords, is limited. Even if patents covering our technologies, products, and services are obtained, once the patent life has expired, we may be open to competition from competitive products. Our issued patents will expire on dates ranging from 2033 to 2037, subject to any patent extensions that may be available for such patents. If patents are issued on our pending patent applications, the resulting patents are projected to expire on dates ranging from 2033 to 2038. In addition, although upon issuance in the United States a patent's life can be increased based on certain delays caused by the USPTO, this increase can be reduced or eliminated based on certain delays caused by the patent applicant during patent prosecution. If we do not have sufficient patent life to protect our technologies, products and services, our competitive position, business, financial condition, results of operations, and prospects will be adversely affected.

If we are not able to obtain and enforce patent protection for any products we develop and for our technologies, or if the scope of patent protection obtained is not sufficiently broad, our competitors and other third parties could develop and commercialize products and technology similar or identical to ours, and our ability to successfully commercialize our products, services, and technologies may be adversely affected.

We have applied, and we intend to continue applying, for patents covering such aspects of our technologies as we deem appropriate. However, the patent process is expensive, time consuming and complex, and we may not be able to apply for patents on certain aspects of our services, products, and other technologies in a timely fashion, at a reasonable cost, in all jurisdictions or at all, and any potential patent coverage we obtain may not be sufficient to prevent substantial competition.

Moreover, the patent position of biotechnology companies can be highly uncertain because it involves complex legal and factual questions for which important legal principles remain unresolved. No consistent policy regarding the breadth of claims allowed in such companies' patents has emerged to date in the United States or elsewhere. Courts frequently render opinions in the biotechnology field that may affect the patentability of certain inventions or discoveries, including opinions that may affect the patentability of methods for analyzing nucleic acid sequences.

Others may independently develop similar or alternative technologies or design around technologies for which we may not be able to obtain patent protection. In addition, any patent applications we file may be challenged and may not result in issued patents or may be invalidated, rendered unenforceable or narrowed in scope after they are issued, and there is no guarantee any of our issued patents include or will include claims that are sufficiently broad to cover our products, services and other technologies or to provide meaningful protection from our competitors. Consequently, we do not know whether any of our platform advances, products, services, and other technologies will be protectable or remain protected by valid and enforceable patents. Our competitors or other third parties may be able to circumvent our patents by developing similar or alternative technologies or products in a non-infringing manner.

Even if they are unchallenged, our patents and patent applications may not adequately protect our intellectual property, provide exclusivity for our technologies, products, and services, or prevent others from designing around our claims. Any finding that our patents or applications are invalid, unpatentable, or unenforceable could harm our ability to prevent others from practicing the related technology, and a finding that others have inventorship or ownership rights to our patents and applications could require us to obtain certain rights to practice related technologies, which may not be available on favorable terms, if at all. If we initiate lawsuits to protect or enforce our patents, or litigate against third-party claims, which would be expensive, and, if we lose, we may lose some of our intellectual property rights. Furthermore, these lawsuits may divert the attention of our management and technical personnel. Any of the foregoing could have a material adverse effect on our competitive position, business, financial condition, results of operations, and prospects.

Once granted, patents may remain open to opposition, interference, re-examination, post-grant review, *inter partes* review, nullification or derivation action in court or before patent offices or similar proceedings for a given period after allowance or grant, during which time third parties can raise objections against such initial grant. In the course of such proceedings, which may continue for a protracted period of time, the patent owner may be compelled to limit the scope of the granted claims thus attacked, or may lose the granted claims altogether. An adverse determination in any such proceeding or litigation could reduce the scope of, or invalidate, our patent rights, allow third parties to commercialize our technology or products and compete directly with us, without payment to us, or result in our inability to commercialize our products, services and technologies without infringing third-party patent rights. Such proceedings also may result in substantial cost and require significant time from our scientists and management, even if the eventual outcome is favorable to us. If the breadth or strength of protection provided by our patents and patent applications is threatened, regardless of the outcome, it could dissuade companies from collaborating with us to license, develop or commercialize current or future products or technologies. In addition, there can be no assurance that:

- others will not or may not be able to make, use, offer to sell, or sell tests that are the same as or similar to our products or services but that are not covered by the claims of the patents that we own or license;
- we or our future licensors or collaborators are the first to make the inventions covered by each of our issued patents and pending patent applications that we own or license;
- we or our future licensors or collaborators are the first to file patent applications covering certain aspects of our inventions;
- others will not independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights;
- a third party may not challenge our patents and, if challenged, a court would hold that our patents are valid, enforceable, and infringed;
- any issued patents that we own or may license will provide us with any competitive advantages, or will not be challenged by third parties;
- we may develop or in-license additional proprietary technologies that are patentable;
- pending patent applications that we own or may license will lead to issued patents;
- the patents of others will not have a material or adverse effect on our business, financial condition, results of operations, and prospects; and
- our competitors do not conduct research and development activities in countries where we do not have enforceable patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets.

The issuance of a patent is not conclusive as to its inventorship, scope, validity, or enforceability. Some of our patents or patent applications may be challenged at a future point in time in opposition, derivation, reexamination, *inter partes* review, post-grant review, or interference proceedings. Any successful opposition to these patents or any other patents owned by or, if applicable in the future, licensed to us could deprive us of rights necessary for the practice of our technologies or the successful commercialization of any products or technologies that we may develop, which could lead to increased competition to our business and harm our business. Since patent applications in the United States and most other countries are confidential for a period of time after filing, we cannot be certain that we or our licensors were the first to file any patent application related to our technologies, products, or services. Furthermore, an interference proceeding can be provoked by a third party or instituted by the USPTO to determine who was the first to invent any of the subject matter covered by the patent claims of our applications for any application with an effective filing date before March 16, 2013.

Where we obtain licenses from or collaborate with third parties, in some circumstances, we may not have the right to control the preparation, filing, and prosecution of patent applications, or to maintain the patents, covering technology that we license from third parties. We may also require the cooperation of our licensors and collaborators to enforce any licensed patent rights, and such cooperation may not be provided. Therefore, these patents and applications may not be prosecuted and enforced in a manner consistent with the best interests of our business. Moreover, if we do obtain necessary licenses, we will likely have obligations under those licenses, and any failure to satisfy those obligations could give our licensor the right to terminate the license. Termination of a necessary license could have a material adverse impact on our business.

It is also possible that we fail to file patent applications covering inventions made in the course of development and commercialization activities before a competitor or another third party files a patent application covering, or publishes information disclosing, a similar, independently-developed invention. Such competitor's patent application may pose obstacles to our ability to obtain or limit the scope of patent protection we may obtain. Although we enter into non-disclosure and confidentiality agreements with parties who have access to confidential or patentable aspects of our research and development output, such as our employees, collaborators, contract manufacturers, consultants, advisors, and other third parties, any of these parties may breach the agreements and disclose such output before a patent application is filed, thereby jeopardizing our ability to seek patent protection. In addition, publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, we cannot be certain that we or our licensors were the first to make the inventions claimed in our owned or licensed patents or pending patent applications, or were the first to file for patent protection of such inventions. To determine the priority of these inventions, we may have to participate in interference proceedings, derivation proceedings, *inter partes* review proceedings, or other post-grant proceedings declared by the USPTO that could result in substantial cost to us. The outcome of such proceedings is uncertain. No assurance can be given that other patent applications will not have priority over our patent applications. In addition, changes to the patent laws of the United States allow for various post-grant opposition proceedings, such as *inter partes* review proceedings, that have not been extensively tested, and their outcome is therefore uncertain. An unfavorable outcome could require us to cease using the related technology or to attempt to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms or at all, or if a non-exclusive license is offered and our competitors gain access to the same technology. Furthermore, if third parties bring these proceedings against our patents, we could experience significant costs and management distraction.

We may become involved in lawsuits to protect or enforce our patents or other intellectual property, which could be expensive, time consuming, and unsuccessful.

Competitors may also infringe our patents or the patents of our licensing partners. In addition, our patents or the patents of our licensors may become involved in inventorship, priority, or validity disputes. To counter or defend against such claims can be expensive and time consuming. In an infringement proceeding, a court may refuse to stop the other party from using the technology at issue on the grounds that our owned and in-licensed patents do not cover the technology in question. Further in such proceedings, the defendant could counterclaim that our asserted patent covering our product is invalid or unenforceable, and the court may agree that our asserted patent is invalid or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness or non-enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with the prosecution of the patent withheld relevant information from the USPTO, or made a misleading statement, during prosecution. Third parties may also raise similar claims before administrative bodies in the United States or abroad, even outside the context of litigation. Such mechanisms include re-examination, post grant review, *inter partes* review, and equivalent proceedings in foreign jurisdictions (e.g., opposition proceedings). Such proceedings could result in revocation or amendment to our patents in such a way that they no longer cover our product. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art, of which we and the patent examiner were unaware during prosecution. An adverse result in any litigation or other proceeding could put one or more of our owned or in-licensed patents at risk of being invalidated or interpreted narrowly. Such a loss of patent protection could have a material adverse impact on our business. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation.

Even if resolved in our favor, litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses and could distract our personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions, or other interim proceedings or developments, and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing, or distribution activities. We may not have sufficient financial or other resources to conduct such litigation or proceedings adequately. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources and more mature and developed intellectual property portfolios. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace.

If we are unable to protect the confidentiality of our trade secrets and know-how, our business and competitive position would be harmed.

We seek protection for certain aspects of our technologies, products, and services through the filing of patents, registration of copyrights, and use of non-disclosure agreements. In addition, we also expect to rely on trade secrets 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, know-how, and confidential information by entering into confidentiality agreements with parties who have access to them, such as our employees, collaborators, contract manufacturers, consultants, advisors, and other third parties. We cannot guarantee that we have entered into such agreements with each party that may have or have had access to our trade secrets or proprietary technology and processes. Moreover, there can be no assurance that any confidentiality agreements that we have with our employees, consultants, or other third parties will provide meaningful protection for our trade secrets, know-how, and confidential information or will provide adequate remedies in the event of unauthorized use or disclosure of such information. Despite these efforts, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Monitoring unauthorized uses and disclosures is difficult, and we do not know whether the steps we have taken to protect our proprietary technologies will be effective. Accordingly, there also can be no assurance that our trade secrets or know-how will not otherwise become known or be independently developed by competitors.

Enforcing a claim that a party illegally disclosed or misappropriated a trade secret can be difficult, expensive, and time-consuming, and the outcome is unpredictable. In addition, trade secrets may be independently developed by others in a manner that could prevent legal recourse by us. If any of our confidential or proprietary information, such as our trade secrets, were to be disclosed or misappropriated, or if any such information was independently developed by a competitor, our competitive position would be materially and adversely harmed.

Trade secrets and know-how can be difficult to protect as trade secrets and know-how will over time be disseminated within the industry through independent development, the publication of journal articles, and the movement of personnel skilled in the art from company to company or academic to industry scientific positions. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor or other third party, we would have no right to prevent such competitor from using that technology or information to compete with us, which could harm our competitive position. Because from time to time we expect to rely on third parties in the development, manufacture and distribution of our products and provision of our services, we must, at times, share trade secrets with them. We seek to protect our proprietary technology in part by entering into confidentiality agreements and, if applicable, material transfer agreements, license agreements, collaboration agreements, supply agreements, consulting agreements, or other similar agreements with our advisors, employees, collaborators, licensors, suppliers, third-party contractors, and consultants prior to beginning research or disclosing proprietary information. These agreements typically limit the rights of the third parties to use or disclose our confidential information, including our trade secrets and know-how. Despite the contractual provisions employed when working with third parties, the need to share trade secrets, know-how, and other confidential information increases the risk that such trade secrets and know-how become known by our competitors, are inadvertently incorporated into the technology of others, or are disclosed or used in violation of these agreements. Given that our proprietary position is based, in part, on our know-how and trade secrets, a competitor's discovery of our trade secrets or know-how, or other unauthorized use or disclosure would impair our competitive position and may have an adverse effect on our business and results of operations.

In addition, these agreements typically restrict the ability of our advisors, employees, collaborators, licensors, suppliers, third-party contractors, and consultants to publish data potentially relating to our trade secrets or know-how, although our agreements may contain certain limited publication rights. Despite our efforts to protect our trade secrets and know-how, our competitors may discover our trade secrets or know-how, either through breach of our agreements with third parties, independent development, or publication of information by any of our third-party collaborators. A competitor's discovery of our trade secrets or know-how would impair our competitive position and have a material adverse impact on our business.

We may not be able to enforceour intellectual property rights throughout the world.

Filing, prosecuting, maintaining, defending, and enforcing patents on our products, services, and technologies in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States can be less extensive than those in the United States. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we have patent protection or licenses but enforcement is not as strong as that in the United States. These products may compete with our products, and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing. In addition, 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 of the United States. These challenges can be caused by the absence or inconsistency of the application of rules and methods for the establishment and enforcement of intellectual property rights outside of the United States. In addition, the legal systems of some countries, particularly developing countries, do not favor the enforcement of patents and other intellectual property protection, especially those relating to healthcare. This could make it difficult for us to stop the infringement of our patents, if obtained, or the misappropriation of our other intellectual property rights. For example, many foreign countries, including European Union countries, India, Japan, and China, have compulsory licensing laws under which a patent owner may be compelled under specified circumstances to grant licenses to third parties. In addition, many countries limit the enforceability of patents against third parties, including government agencies or government contractors. In these countries, patents may provide limited or no benefit given that we may have limited remedies available if patents are infringed or if we are compelled to grant a license to a third party, which could materially diminish the value of those patents and limit our potential revenue opportunities. Furthermore, patent protection must ultimately be sought on a country-by-country basis, which is an expensive and time-consuming process with uncertain outcomes. Accordingly, we may choose not to seek patent protection in certain countries, and we will not have the benefit of patent protection in such countries.

Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business. Accordingly, our efforts to protect our intellectual property rights in such countries may be inadequate. In addition, changes in the law and legal decisions by courts in the United States and foreign countries may affect our ability to obtain adequate protection for our products, services and other technologies and the enforcement of intellectual property. Any of the foregoing could have a material adverse effect on our competitive position, business, financial condition, results of operations, and prospects.

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

The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other provisions during the patent application and prosecution process. Periodic maintenance fees, renewal fees, annuity fees, and various other governmental fees on patents and/or applications will be due to be paid to the USPTO and various other governmental patent agencies outside of the United States in several stages over the lifetime of the patents and/or applications. We employ reputable professionals and rely on such third parties to help us comply with these requirements and effect payment of these fees with respect to the patents and patent applications that we own. Noncompliance events that could result in abandonment or lapse of a patent or patent application include failure to respond to official communications within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. In many cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. However, there are situations in which noncompliance can result in abandonment or lapse of a patent or patent application, resulting in loss of patent rights in the relevant jurisdiction. In such an event, competitors might be able to enter the market earlier than would otherwise have been the case, which could have a material adverse effect on our competitive position, business, financial condition, results of operations, and prospects.

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 or otherwise engaged with universities or genetic testing, diagnostic or other healthcare companies, including our competitors or potential competitors.

Although we have policies 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 parties. Further, we may be subject to ownership disputes in the future arising, for example, from conflicting obligations of consultants or others who are involved in developing our intellectual property. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees. Such claims could have a material adverse effect on our business, financial condition, results of operations, and prospects.

In addition, while it is our policy to require our employees and contractors who may be involved in the conception or development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who, in fact, conceives or develops intellectual property that we regard as our own. The assignment of intellectual property rights may not be self-executing, or the assignment agreements may be breached, and we may be forced to bring claims against third parties, or defend claims that they may bring against us, to determine the ownership of what we regard as our intellectual property. Such claims could have a material adverse effect on our business, financial condition, results of operations, and prospects.

Our use of "open source" software could subject our proprietary software to general release, adversely affect our ability to sell our products and services, and subject us to possible litigation.

A portion of the products or technologies licensed, developed, and/or distributed by us incorporate so-called "open source" software and we may incorporate open source software into other products in the future. Such open source software is generally licensed by its authors or other third parties under open source licenses. Some open source licenses contain requirements that we disclose source code for modifications we make to the open source software and that we license such modifications to third parties at no cost. In some circumstances, distribution of our software in connection with open source software could require that we disclose and license some or all of our proprietary code in that software, as well as distribute our products or provide our services that use particular open source software at no cost to the user. We monitor our use of open source software in an effort to avoid uses in a manner that would require us to disclose or grant licenses under our proprietary source code; however, there can be no assurance that such efforts will be successful. Open source license terms are often ambiguous and such use could inadvertently occur. There is little legal precedent governing the interpretation of many of the terms of these licenses, and the potential impact of these terms on our business may result in unanticipated obligations regarding our products and technologies. Companies that incorporate open source software into their products have, in the past, faced claims seeking enforcement of open source license provisions and claims asserting ownership of open source software incorporated into their product. If an author or other third party that distributes such open source software were to allege that we had not complied with the conditions of an open source license, we could incur significant legal costs defending ourselves against such allegations. In the event such claims were successful, we could be subject to significant damages or be enjoined from the distribution of our products. In addition, if we combine our proprietary software with open source software in certain ways, under some open source licenses, we could be required to release the source code of our proprietary software, which could substantially help our competitors develop products that are similar to or better than ours and otherwise adversely affect our business. These risks could be difficult to eliminate or manage, and, if not addressed, could have a material adverse effect on our business, financial condition, and results of operations.

If we fail to comply with our obligations under license or technology agreements with third parties, we may be required to pay damages and we could lose license rights that are critical to our business.

We license certain intellectual property that is important to our business, and in the future we may enter into additional agreements that provide us with licenses to valuable intellectual property or technology. For example, our agreements with third parties, such as Illumina, include certain non-exclusive license rights that are essential to the operation of our business as it is currently conducted. If we fail to comply with any of the obligations under our license agreements, we may be required to pay damages and the licensor may have the right to terminate the license. Termination by the licensor would cause us to lose valuable rights, and could prevent us from selling our products and services, or inhibit our ability to commercialize future products and services. Our business would suffer if any current or future licenses terminate, if the licensors fail to abide by the terms of the license, if the licensors fail to enforce licensed patents against infringing third parties, if the licensed patents or other rights are found to be invalid or unenforceable, or if we are unable to enter into necessary licenses on acceptable terms. In addition, our rights to certain technologies, including those of Illumina, are licensed to us on a non-exclusive basis. The owners of these non-exclusively licensed technologies are therefore free to license them to third parties, including our competitors, on terms that may be superior to those offered to us, which could place us at a competitive disadvantage. Moreover, our licensors may own or control intellectual property that has not been licensed to us and, as a result, we may be subject to claims, regardless of their merit, that we are infringing or otherwise violating the licensor's rights.

Any collaboration arrangements that we may enter into in the future may not be successful, which could adversely affect our ability to develop and commercialize our products.

Any future collaborations that we enter into may not be successful. The success of our collaboration arrangements will depend heavily on the efforts and activities of our collaborators. Collaborations are subject to numerous risks, which may include that:

- collaborators have significant discretion in determining the efforts and resources that they will apply to collaborations;
- collaborators may not pursue development and commercialization of our products or may elect not to continue or renew development or commercialization programs based on trial or test results, changes in their strategic focus due to the acquisition of competitive products, availability of funding, or other external factors, such as a business combination that diverts resources or creates competing priorities;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our products;
- collaborators with marketing, manufacturing, and distribution rights to one or more products may not commit sufficient resources to or otherwise not perform satisfactorily in carrying out these activities;
- we could grant exclusive rights to our collaborators that would prevent us from collaborating with others;
- collaborators may not properly maintain or defend our intellectual property rights or may use our intellectual property or proprietary information in a way that gives rise to actual or threatened litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential liability;
- disputes may arise between us and a collaborator that causes the delay or termination of the research, development, or commercialization of our current or future products or that results in costly litigation or arbitration that diverts management attention and resources;
- collaborations may be terminated, and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable current or future products;
- collaborators may own or co-own intellectual property covering our products that results from our collaborating with them, and in such cases, we would not have the exclusive right to develop or commercialize such intellectual property; and
- collaborators' sales and marketing activities or other operations may not be in compliance with applicable laws resulting in civil or criminal proceedings.

If we are unable to successfully obtain rights to required third-party intellectual property rights or maintain the existing intellectual property rights we have, we may have to abandon development of that program and our business and financial condition could suffer.

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

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

If our trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our markets of interest and our business may be adversely affected.

Our trademarks or trade names may be challenged, infringed, circumvented, or declared generic or determined to be infringing on other marks. We may not be able to protect our rights to these trademarks and trade names or may be forced to stop using these names, which we need for name recognition by potential partners or customers in our markets of interest. During trademark registration proceedings, we may receive rejections. Although we would be given an opportunity to respond to those rejections, we may be unable to overcome such rejections. In addition, in the USPTO and in comparable agencies in many foreign jurisdictions, third parties are given an opportunity to oppose pending trademark applications and to seek to cancel registered trademarks. Opposition or cancellation proceedings may be filed against our trademarks, and our trademarks may not survive such proceedings. If we are unable to establish brand name recognition based on our trademarks and trade names, we may not be able to compete effectively and our business may be adversely affected.

Risks Related to Being a Public Company

The requirements of being a public company may strain our resources, result in litigation and divert management's attention.

As a public company, we are subject to the reporting requirements of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), the Sarbanes-Oxley Act of 2002, as amended (the "Sarbanes-Oxley Act"), the Dodd-Frank Wall Street Reform and Consumer Protection Act, the listing requirements of The Nasdaq Global Market and other applicable securities rules and regulations. Complying with these rules and regulations has increased and will increase our legal and financial compliance costs, make some activities more difficult, time-consuming, or costly and increase demand on our systems and resources, particularly after we are no longer an "emerging growth company" as defined in the Jumpstart our Business Startups Act of 2012 (the "JOBS Act"). The Exchange Act requires, among other things, that we file annual, quarterly, and current reports with respect to our business and operating results. The Sarbanes-Oxley Act requires, among other things, that we maintain effective disclosure controls and procedures and internal control over financial reporting. We are required to disclose changes made in our internal control and procedures on a quarterly basis. In order to maintain and, if required, improve our disclosure controls and procedures and internal control over financial reporting to meet this standard, significant resources and management oversight may be required. As a result, management's attention may be diverted from other business concerns, which could adversely affect our business and operating results. We will need to hire additional employees or engage outside consultants to comply with these requirements, which will increase our costs and expenses.

In addition, changing laws, regulations, and standards relating to corporate governance and public disclosure are creating uncertainty for public companies, increasing legal and financial compliance costs and making some activities more time-consuming. These laws, regulations, and standards are subject to varying interpretations, in many cases due to their lack of specificity, and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices. We intend to invest resources to comply with evolving laws, regulations, and standards, and this investment will result in increased general and administrative expenses and a diversion of management's time and attention from revenue-generating activities to compliance activities. If our efforts to comply with new laws, regulations and standards differ from the activities intended by regulatory or governing bodies due to ambiguities related to their application and practice, regulatory authorities may initiate legal proceedings against us and our business may be adversely affected. By disclosing information in this prospectus and in filings required of a public company, our business and financial condition will become more visible, which we believe may result in threatened or actual litigation, including by competitors and other third parties. If those claims are successful, our business could be seriously harmed. Even if the claims do not result in litigation or are resolved in our favor, the time and resources needed to resolve them could divert our management's resources and seriously harm our business.

We also expect that being a public company and these new rules and regulations will make it more expensive for us to obtain director and officer liability insurance and, in the future, we may be required to accept reduced coverage or incur substantially higher costs to obtain coverage. These factors could also make it more difficult for us to attract and retain qualified members of our board of directors, particularly to serve on our audit committee and compensation committee, and qualified executive officers.

In addition, as a result of our disclosure obligations as a public company, we will have reduced strategic flexibility and will be under pressure to focus on short-term results, which may materially and adversely affect our ability to achieve long-term profitability.

We are an emerging growth company, and any decision on our part to comply only with certain reduced reporting and disclosure requirements applicable to emerging growth companies could make our common stock less attractive to investors.

We are an "emerging growth company," as defined in the JOBS Act, and, for as long as we continue to be an emerging growth company, we may choose to take advantage of exemptions from various reporting requirements applicable to other public companies but not to emerging growth companies, including:

- not being required to have our independent registered public accounting firm audit our internal control over financial reporting under Section 404 of the Sarbanes-Oxley Act;
- reduced disclosure obligations regarding executive compensation in our periodic reports and annual report on Form 10-K; and
- exemptions from the requirements of holding non-binding advisory votes on executive compensation and stockholder approval of any golden parachute payments not previously approved.

We could be an emerging growth company for up to five years following the closing of our IPO. Our status as an emerging growth company will end as soon as any of the following takes place:

- the last day of the fiscal year in which we have more than $1.07 billion in annual revenue;
- the date we qualify as a "large accelerated filer," with at least $700 million of equity securities held by non-affiliates;
- the date on which we have issued, in any three-year period, more than $1.0 billion in non-convertible debt securities; or
- the last day of the fiscal year ending after the fifth anniversary of the closing of our IPO.

We cannot predict if investors will find our common stock less attractive if we choose to rely on any of the exemptions afforded emerging growth companies. If some investors find our common stock less attractive because we rely on any of these exemptions, there may be a less active trading market for our common stock and the market price of our common stock may be more volatile.

Under the JOBS 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 accommodation and, therefore, we will be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies.

Material weaknesses in our internal control over financial reporting may cause us to fail to timely and accurately report our financial results or result in a material misstatement of our financial statements.

Management evaluates our internal control systems, processes, and procedures for compliance with the requirements of a smaller reporting company under Section 404 of the Sarbanes-Oxley Act of 2002 ("Section 404"). This evaluation includes disclosure of any material weaknesses identified by our management in our internal control over financial reporting. A "material weakness" is a deficiency, or a combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected on a timely basis.

In connection with preparation of our financial statements for the years ended December 31, 2017 and 2018, management identified a material weakness in our internal controls due to a lack of sufficient full-time accounting staff with requisite experience and deep technical accounting knowledge to (i) identify and resolve complex accounting issues under generally accepted accounting principles in the United States ("GAAP") and (ii) allow for appropriate segregation of duties. The identified material weakness could result in misstatements to our consolidated financial statements that would be material and would not be prevented or detected on a timely basis.

We are evaluating and implementing additional procedures to remediate this material weakness, however, we cannot assure you that these or other measures will fully remediate the material weakness in a timely manner or prevent future material weaknesses from occurring. As part of our remediation plan to address the material weakness identified above, we hired a new Chief Financial Officer in March 2019 and five additional accounting resources in the second and third quarters of 2019, including two Certified Public Accountants with the specific technical accounting and financial reporting experience necessary for a public company. We will continue to assess the adequacy of our accounting personnel and resources, and will add additional personnel, as well as adjust our resources, as necessary, commensurate with any increase in the size and complexity of our business.

If we identify future material weaknesses in our internal controls over financial reporting or fail to meet the demands that are placed upon us as a public company, including the requirements of the Sarbanes-Oxley Act, we may be unable to accurately report our financial results or report them within the timeframes required by law or stock exchange regulations. Failure to comply with Section 404 could also potentially subject us to sanctions or investigations by the U.S. Securities and Exchange Commission (the "SEC") or other regulatory authorities. If additional material weaknesses exist or are discovered in the future, and we are unable to remediate any such material weakness, our reputation, financial condition, and operating results could suffer.

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

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. We believe that 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.

Risks Related to Our Common Stock

An active trading market for our common stock may never develop or be sustained.

Our common stock is currently listed on The Nasdaq Global Market under the symbol "PSNL." However, we cannot assure you that an active trading market for our common stock will develop on that exchange or elsewhere or, if developed, that any market will be sustained. Accordingly, we cannot assure you of the likelihood that an active trading market for our common stock will develop or be maintained, the liquidity of any trading market, your ability to sell your shares of our common stock when desired, or the prices that you may obtain for your shares. Further, an inactive market may also impair our ability to raise capital by selling our common stock and may impair our ability to enter into strategic partnerships or acquire businesses, products, or technologies using our common stock as consideration.

The market price of our common stock may be volatile or may decline steeply or suddenly regardless of our operating performance, we may not be able to meet investor or analyst expectations, and you may lose all or part of your investment.

The market price of our common stock may fluctuate or decline significantly in response to numerous factors, many of which are beyond our control, including:

- actual or anticipated fluctuations in our operating results;
- 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 reports by securities analysts or changed recommendations for our stock;
- competition from existing tests or new tests that may emerge;
- announcements by us or our competitors of significant acquisitions, strategic partnerships, joint ventures, collaborations, capital commitments, or by or pertaining to our customers, particularly the VA MVP;
- the timing and amount of our investments in the growth of our business;
- actual or anticipated changes in regulatory oversight of our business or issues we may face with regulators;
- additions or departures of key management or other personnel;
- inability to obtain additional funding;
- sales of our common stock by us or our stockholders in the future;
- disputes or other developments related to our intellectual property or other matters, including litigation; and
- general economic, industry, and market conditions, including factors unrelated to our operating performance or the operating performance of our competitors.

In addition, the stock market in general, and the market for life sciences companies in particular, has experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of those companies. Broad market and industry factors may seriously 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 these companies. This litigation, if instituted against us, could result in substantial costs and a diversion of our management's attention and resources.

Moreover, because of these fluctuations, comparing our operating results on a period-to-period basis may not be meaningful. You should not rely on our past results as an indication of our future performance. This variability and unpredictability could also result in our failing to meet the expectations of industry or financial analysts or investors for any period. If our revenues or operating results fall below the expectations of analysts or investors or below any forecasts we may provide to the market, or if the forecasts we provide to the market are below the expectations of analysts or investors, the price of our common stock could decline substantially. Such a stock price decline could occur even when we have met any previously publicly stated revenues or earnings forecasts that we may provide.

Our quarterly results may fluctuate significantly, which could adversely impact the value of our common stock.

Our quarterly results of operations, including our revenue, gross margin, profitability, and cash flows, may vary significantly in the future, and period-to-period comparisons of our operating results may not be meaningful. Accordingly, our quarterly results should not be relied upon as an indication of future performance. Our quarterly financial results may fluctuate as a result of a variety of factors, many of which are outside of our control. For example, the VA and other large customers are not obliged to deliver tissue samples to us at any particular time or at all. The rate at which we receive tissue samples can vary dramatically from quarter to quarter, and is difficult or impossible for us to accurately forecast. Our receipt and processing of tissue samples from our customers leads to our recognition of revenue, and as such the variable rates of delivery of customer samples will lead to variations in our revenues from quarter to quarter. Fluctuations in quarterly results may adversely impact the value of our common stock. Factors that may cause fluctuations in our quarterly financial results include, without limitation, those listed elsewhere in this "Risk Factors" section. We also may face competitive pricing pressures, and we may not be able to maintain our pricing in the future, which would adversely affect our operating results.

Insiders may exercise significant control over our company and will be able to influence corporate matters.

Our directors, executive officers, and 5% or greater stockholders and their affiliates beneficially owned, in the aggregate, approximately 47.6% of our outstanding capital stock as of September 30, 2019. As a result, these stockholders will be able to exercise significant influence over all matters submitted to our stockholders for approval, including the election of directors and approval of significant corporate transactions, such as a merger or sale of our company or its assets. This concentration of ownership may have the effect of delaying or preventing a third party from acquiring control of our company and could adversely affect the market price of our common stock, and may not be in the best interests of our other stockholders.

Future sales of shares by existing stockholders, or the perception that such sales could occur, could cause our stock price to decline.

As of September 30, 2019, we had outstanding 31,142,643 shares of common stock. Our executive officers, directors, and the holders of substantially all of our capital stock and securities convertible into or exchangeable for our capital stock have entered into market standoff agreements with us or lock-up agreements with the underwriters in connection with our IPO under which they have agreed, subject to specific exceptions, not to sell any of our capital stock until December 17, 2019.

However, after the market standoff agreements and lock-up agreements referred to above expire, substantially all of such shares will be eligible for sale in the public market. In addition, upon issuance, shares of common stock subject to outstanding options under our stock option plans as of September 30, 2019 will become eligible for sale in the public market in the future, subject to certain legal and contractual limitations. Moreover, 180 days after the closing of the IPO, holders of up to an aggregate of 18,790,983 shares of our common stock will have the right to require us to register these shares under the Securities Act pursuant to an investors' rights agreement. If our existing stockholders sell substantial amounts of our common stock in the public market, or if the public perceives that such sales could occur, this could have an adverse effect on the market price of our common stock.

We do not currently intend to pay dividends on our common stock and, consequently, your ability to achieve a return on your investment will depend on appreciation of the value of our common stock.

We have never declared or paid cash dividends on our capital stock. We currently intend to retain any future earnings to finance the operation and expansion of our business, and we do not expect to pay any cash dividends on our common stock in the foreseeable future. In addition, our ability to pay cash dividends on our capital stock is limited by our credit agreement and may be prohibited or limited by the terms of any future debt financing arrangement. As a result, any investment returns on our common stock will depend upon increases in the value for our common stock, which are not certain.

Our ability to use net operating losses to offset future taxable income may be subject to limitations.

As of December 31, 2018, we had federal and state net operating loss carryforwards of approximately $87 million and approximately $48.6 million, respectively. Certain of our federal and state net operating loss carryforwards will begin to expire, if not utilized, beginning in 2031. These net operating loss carryforwards could expire unused and be unavailable to offset future income tax liabilities. Under the Tax Cuts and Jobs Act, federal net operating losses incurred in 2018 and in future years may be carried forward indefinitely, but the deductibility of such federal net operating losses is limited. It is uncertain if and to what extent various states will conform to the Tax Cuts and Jobs Act. In addition, under Section 382 of the Code, and corresponding provisions of state law, if a corporation undergoes an "ownership change," which is generally defined as a greater than 50% change, by value, in its equity ownership over a three-year period, the corporation's ability to use its pre-change net operating loss carryforwards and other pre-change tax attributes (including certain tax credits) to offset its post-change income or taxes may be limited. We may experience ownership changes in the future as a result of subsequent shifts in our stock ownership, some of which may be outside of our control. If an ownership change occurs and our ability to use our net operating loss carryforwards is materially limited, it would harm our future operating results by effectively increasing our future tax obligations.

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

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. We also expect to issue common stock to employees, directors, and consultants pursuant to our equity incentive plans. If we sell common stock, convertible securities, or other equity securities in subsequent transactions, or common stock is issued pursuant to equity incentive plans, investors may be materially diluted. New investors in such subsequent transactions could gain rights, preferences, and privileges senior to those of holders of our common stock.

If securities or industry analysts do not publish research or reports about our business, or publish inaccurate or unfavorable research about our business, our stock price and trading volume could decline.

The trading market for our common stock will depend in part on the research and reports that equity research analysts publish about us and our business. We do not control these analysts or the content and opinions included in their reports. Securities analysts may elect not to provide research coverage of our company, and such lack of research coverage may adversely affect the market price of our common stock. The price of our common stock could also decline if one or more equity research analysts downgrade our common stock or issue other unfavorable commentary or cease publishing reports about us or our business. If one or more equity research analysts cease coverage of our company, we could lose visibility in the market, which in turn could cause our stock price to decline.

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

Pursuant to our amended and restated certificate of incorporation, our board of directors is authorized to issue up to 10,000,000 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.

Delaware law and provisions in our amended and restated certificate of incorporation and amended and restated bylaws could make a merger, tender offer, or proxy contest difficult, thereby depressing the trading price of our common stock.

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

- establish a classified board of directors so that not all members of our board of directors are elected at one time;
- authorize the issuance of "blank check" preferred stock that our board of directors could use to implement a stockholder rights plan;
- permit the board of directors to establish the number of directors and fill any vacancies and newly-created directorships;
- provide that directors may only be removed for cause;

- require super-majority voting to amend some provisions in our certificate of incorporation and bylaws;
- eliminate the ability of our stockholders to call special meetings of stockholders;
- prohibit stockholder action by written consent, which requires all stockholder actions to be taken at a meeting of our stockholders;
- provide that the board of directors is expressly authorized to make, alter, or repeal our bylaws;
- restrict the forum for certain litigation against us to Delaware; and
- establish advance notice requirements for nominations for election to our board of directors or for proposing matters that can be acted upon by stockholders at annual stockholder meetings.

Any provision of our amended and restated certificate of incorporation or amended and restated bylaws, or Delaware law that has the effect of delaying or deterring a change in control could limit the opportunity for our stockholders to receive a premium for their shares of our common stock, and could also affect the price that some investors are willing to pay for our common stock.

Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware and the federal district courts of the United States will be the exclusive forums for substantially all disputes between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers, or employees.

Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware is the exclusive forum for the following types of actions or proceedings under Delaware statutory or common law:

- any derivative action or proceeding brought on our behalf;
- any action asserting a breach of fiduciary duty;
- any action asserting a claim against us arising under the Delaware General Corporation Law, our amended and restated certificate of incorporation, or our amended and restated bylaws; and
- any action asserting a claim against us governed by the internal affairs doctrine.

This provision would not apply to suits brought to enforce a duty or liability created by the Exchange Act or any other claim for which the U.S. federal courts have exclusive jurisdiction.

Our amended and restated certificate of incorporation further provides that the federal district courts of the United States will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act, subject to and contingent upon a final adjudication in the State of Delaware of the enforceability of such exclusive forum provision.

These exclusive-forum provisions 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 lawsuits against us and our directors, officers, and other employees. If a court were to find either exclusive-forum provision in our amended and restated certificate of incorporation to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving the dispute in other jurisdictions, which could seriously harm our business. For example, the Court of Chancery of the State of Delaware recently determined that a provision stating that U.S. federal district courts are the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act is not enforceable. However, this decision may be reviewed and ultimately overturned by the Delaware Supreme Court.

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

(b) Use of proceeds

On June 19, 2019, the registration statement on Form S-1 (Registration No. 333-231703) for our IPO of our common stock was declared effective by the SEC. On June 24, 2019, we closed our IPO and sold an aggregate of 9,109,725 shares of our common stock, inclusive of the exercise in full by the underwriters of their option to purchase up to an additional 1,188,225 shares of common stock, for an aggregate price of approximately $155 million. Upon completion of the sales of the shares of our common stock, our IPO terminated.

The underwriters of our IPO were Morgan Stanley & Co. LLC, BofA Securities, Inc., Cowen and Company, LLC, and Oppenheimer & Co. Inc. We paid the underwriters of our IPO an underwriting discount and commission totaling $10.8 million and incurred $4.2 million in offering costs. Thus, the net offering proceeds, after deducting underwriting discounts and offering expenses, were approximately $139.8 million. No payments were made to our directors or officers or their associates, holders of 10% or more of any class of our equity securities, or any affiliates.

There has been no material change in the planned use of proceeds from our IPO as described in our final prospectus filed with the SEC on June 20, 2019 pursuant to Rule 424(b)(4).

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

None.

Item 5. Other Information.

None.

Item 6. Exhibits.

Exhibit Number	Description	Incorporated by Reference			
		Form	File No.	Exhibit	Filing Date
3.1	Amended and restated Certificate of Incorporation of the Registrant.	8-K	001-38943	3.1	June 24, 2019
3.2	Amended and Restated Bylaws of the Registrant.	8-K	001-38943	3.2	June 24, 2019
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 Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.				
32.2†	Certification of 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.

† The certifications attached as Exhibit 32.1 and Exhibit 32.2 that accompany this Quarterly Report on Form 10-Q are not deemed filed with the Securities and Exchange Commission and are not to be incorporated by reference into any filing of the Registrant 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 this Quarterly Report on Form 10-Q, irrespective of any general incorporation language contained in such filing.

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.

Date: November 13, 2019

Personalis, Inc.

By: /s/ Aaron Tachibana
Aaron Tachibana
Chief Financial Officer (Duly Authorized Officer)

Exhibit 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

I, John West, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Personalis, 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 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)) for the registrant and have:

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

   (b) 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 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 13, 2019

By: /s/ John West

John West
Chief Executive Officer
(Principal Executive Officer)

Exhibit 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

I, Aaron Tachibana, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Personalis, 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 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)) for the registrant and have:

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

   (b) 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 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 13, 2019

By: /s/ Aaron Tachibana

Aaron Tachibana
Chief Financial Officer
(Principal Financial Officer)

Exhibit 32.1

CERTIFICATION OF CHIEF EXECUTIVE OFFICER 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 of Personalis, Inc. (the "Company") on Form 10-Q for the period ending September 30, 2019 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

(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 results of operations of the Company.

Date: November 13, 2019

By: /s/ John West
John West
Chief Executive Officer
(Principal Executive Officer)

Exhibit 32.2

CERTIFICATION OF CHIEF FINANCIAL OFFICER 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 of Personalis, Inc. (the "Company") on Form 10-Q for the period ending September 30, 2019 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

(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 results of operations of the Company.

Date: November 13, 2019

By: /s/ Aaron Tachibana
Aaron Tachibana
Chief Financial Officer
(Principal Financial Officer)