UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-Q

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

For the quarterly period ended June 30, 2021

OR

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

For the transition period from _____ to _____

Commission File Number: 001-38943

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 ☒

The number of shares of registrant's Common Stock outstanding as of July 30, 2021 was 44,412,483.

PERSONALIS, INC.

Form 10-Q
For the Quarterly Period Ended June 30, 2021

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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 enter into and compete in new markets;
- the impact of the COVID-19 pandemic on our business, our customers’ and suppliers’ businesses and the general economy;
- 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 ability to maintain proper and effective internal controls.

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.

Item 1. Financial Statements

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

	June 30, 2021	December 31, 2020
Assets		
Current assets		
Cash and cash equivalents	$ 70,080	$ 68,525
Short-term investments	258,827	134,765
Accounts receivable, net	9,278	6,349
Inventory and other deferred costs	7,321	5,639
Prepaid expenses and other current assets	8,803	5,441
Total current assets	354,309	220,719
Property and equipment, net	14,258	11,834
Operating lease right-of-use assets	11,126	10,271
Other long-term assets	3,647	2,018
Total assets	$ 383,340	$ 244,842
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable	$ 8,919	$ 8,301
Accrued and other current liabilities	13,708	11,301
Contract liabilities	11,460	21,034
Total current liabilities	34,087	40,636
Long-term operating lease liabilities	8,518	8,541
Other long-term liabilities	1,988	720
Total liabilities	44,593	49,897
Commitments and Contingencies (Note 9)		
Stockholders' equity		
Preferred stock, $0.0001 par value — 10,000,000 shares authorized; none issued	—	—
Common stock, $0.0001 par value — 200,000,000 shares authorized; 44,209,968 and 39,105,548 shares issued and outstanding at June 30, 2021 and December 31, 2020, respectively	4	4
Additional paid-in capital	547,951	376,788
Accumulated other comprehensive income (loss)	18	22
Accumulated deficit	(209,226)	(181,869)
Total stockholders' equity	338,747	194,945
Total liabilities and stockholders' equity	$ 383,340	$ 244,842

See 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 June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Revenue	$ 21,670	$ 19,495	$ 42,551	$ 38,656
Costs and expenses				
Cost of revenue	13,502	14,823	26,956	29,945
Research and development	11,687	6,465	21,183	12,855
Selling, general and administrative	11,428	7,705	21,849	14,979
Total costs and expenses	36,617	28,993	69,988	57,779
Loss from operations	(14,947)	(9,498)	(27,437)	(19,123)
Interest income	103	246	198	756
Interest expense	(65)	—	(65)	(2)
Other income (expense), net	(36)	1	(48)	9
Loss before income taxes	(14,945)	(9,251)	(27,352)	(18,360)
Provision for income taxes	8	4	5	34
Net loss	$ (14,953)	$ (9,255)	$ (27,357)	$ (18,394)
Net loss per share, basic and diluted	$ (0.34)	$ (0.29)	$ (0.63)	$ (0.58)
Weighted-average shares outstanding, basic and diluted	43,960,794	31,731,628	43,113,195	31,538,329

See notes to condensed consolidated financial statements.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Net loss	$ (14,953)	$ (9,255)	$ (27,357)	$ (18,394)
Other comprehensive income (loss), net of tax				
Foreign currency translation adjustment	19	(4)	21	(9)
Change in unrealized gain (loss) on available-for-sale debt securities	4	37	(25)	121
Comprehensive loss	$ (14,930)	$ (9,222)	$ (27,361)	$ (18,282)

See notes to condensed consolidated financial statements.

PERSONALIS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY (unaudited)
For the Three Months Ended June 30, 2021 and 2020
(in thousands, except share data)

	Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance—March 31, 2021	43,798,661	$ 4	$ 542,694	$ (5)	$ (194,273)	$ 348,420
Proceeds from exercise of stock options	270,912	—	466	—	—	466
Proceeds from Employee Stock Purchase Plan purchases	57,001	—	1,191	—	—	1,191
Restricted stock units vested	83,394	—	—	—	—	—
Stock-based compensation	—	—	3,600	—	—	3,600
Foreign currency translation adjustment	—	—	—	19	—	19
Unrealized gain on available-for-sale debt securities	—	—	—	4	—	4
Net loss	—	—	—	—	(14,953)	(14,953)
Balance—June 30, 2021	44,209,968	$ 4	$ 547,951	$ 18	$ (209,226)	$ 338,747
Balance—March 31, 2020	31,530,443	$ 3	$ 248,854	$ 73	$ (149,728)	$ 99,202
Proceeds from exercise of stock options	236,578	—	690	—	—	690
Proceeds from Employee Stock Purchase Plan purchases	71,480	—	631	—	—	631
Restricted stock units vested	33,621	—	—	—	—	—
Stock-based compensation	—	—	1,822	—	—	1,822
Foreign currency translation adjustment	—	—	—	(4)	—	(4)
Unrealized gain on available-for-sale debt securities	—	—	—	37	—	37
Net loss	—	—	—	—	(9,255)	(9,255)
Balance—June 30, 2020	31,872,122	$ 3	$ 251,997	$ 106	$ (158,983)	$ 93,123

See notes to condensed consolidated financial statements.

PERSONALIS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY (unaudited)
For the Six Months Ended June 30, 2021 and 2020
(in thousands, except share data)

	Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance—December 31, 2020	39,105,548	$ 4	$ 376,788	$ 22	$ (181,869)	$ 194,945
Proceeds from follow-on equity offering, net of offering costs	4,542,500	—	161,916	—	—	161,916
Proceeds from exercise of stock options	384,938	—	1,399	—	—	1,399
Proceeds from Employee Stock Purchase Plan purchases	57,001	—	1,191	—	—	1,191
Restricted stock units vested	119,981	—	—	—	—	—
Stock-based compensation	—	—	6,657	—	—	6,657
Foreign currency translation adjustment	—	—	—	21	—	21
Unrealized loss on available-for-sale debt securities	—	—	—	(25)	—	(25)
Net loss	—	—	—	—	(27,357)	(27,357)
Balance—June 30, 2021	44,209,968	$ 4	$ 547,951	$ 18	$ (209,226)	$ 338,747
Balance—December 31, 2019	31,243,029	$ 3	$ 247,282	$ (6)	$ (140,589)	$ 106,690
Proceeds from exercise of stock options	513,993	—	1,013	—	—	1,013
Proceeds from Employee Stock Purchase Plan purchases	71,480	—	631	—	—	631
Restricted stock units vested	43,620	—	—	—	—	—
Stock-based compensation	—	—	3,071	—	—	3,071
Foreign currency translation adjustment	—	—	—	(9)	—	(9)
Unrealized gain on available-for-sale debt securities	—	—	—	121	—	121
Net loss	—	—	—	—	(18,394)	(18,394)
Balance—June 30, 2020	31,872,122	$ 3	$ 251,997	$ 106	$ (158,983)	$ 93,123

See notes to condensed consolidated financial statements.

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

	Six Months Ended June 30,	
	2021	2020
Cash flows from operating activities:		
Net loss	$ (27,357)	$ (18,394)
Adjustments to reconcile net loss to net cash used in operating activities		
Stock-based compensation expense	6,657	3,071
Depreciation and amortization	2,909	2,815
Noncash operating lease cost	856	689
Amortization of premium (discount) on short-term investments	1,012	(34)
Other	71	(9)
Changes in operating assets and liabilities		
Accounts receivable	(2,928)	(2,075)
Inventory and other deferred costs	(1,682)	(1,918)
Prepaid expenses and other assets	(4,991)	396
Accounts payable	(75)	(348)
Accrued and other current liabilities	(1,390)	(797)
Contract liabilities	(9,573)	(7,025)
Operating lease liabilities	(819)	(496)
Other long-term liabilities	(364)	128
Net cash used in operating activities	(37,674)	(23,997)
Cash flows from investing activities:		
Purchases of available-for-sale debt securities	(206,672)	(67,108)
Proceeds from maturities of available-for-sale debt securities	76,508	60,313
Proceeds from sales of available-for-sale debt securities	5,059	—
Purchases of property and equipment	(4,544)	(855)
Net cash used in investing activities	(129,649)	(7,650)
Cash flows from financing activities:		
Proceeds from public offerings, net of underwriting discounts and commissions	162,258	—
Payments of costs related to public offerings	(342)	—
Proceeds from loans	5,167	—
Repayments of loans	(815)	—
Proceeds from exercise of equity awards	2,591	1,644
Net cash provided by financing activities	168,859	1,644
Effect of exchange rates on cash flows and cash equivalents	19	(1)
Net change in cash and cash equivalents	1,555	(30,004)
Cash and cash equivalents, beginning of period	68,525	55,046
Cash and cash equivalents, end of period	$ 70,080	$ 25,042

See notes to condensed consolidated financial statements.

Note 1. Company and Nature 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 and a wholly owned subsidiary, Shanghai Personalis Biotechnology Co., Ltd., which is referred to as "Personalis (Shanghai) Ltd" herein, in October 2020. 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 provides sequencing and data analysis services to support the development of cancer therapies. The Company also provides sequencing and data analysis services to support population sequencing initiatives, which accounts for the majority of revenue. Cancer genomic services are sold primarily to pharmaceutical companies, biopharmaceutical companies, universities, non-profits, and government entities, while services for population sequencing initiatives are sold primarily to government entities. The principal markets for the Company's services are the United States and Europe. In June 2020, the Company began partnering with a clinical genomics and life sciences company headquartered in China to expand business operations into China. The Company operates and manages its business as one reportable operating segment, which is the sale of sequencing and data analysis services.

The Company has incurred losses to date and expects to incur additional losses for the foreseeable future. The Company continues to invest the majority of its resources in the development and growth of its business, including investments in product development and sales and marketing efforts. The Company's activities have been financed to date primarily through the sale of equity securities and cash from operations.

Note 2. Summary of Significant Accounting Policies

Basis of Presentation

The 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 Annual Report on Form 10-K for the fiscal year ended December 31, 2020.

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

The 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, 2021.

Use of Estimates

The preparation of condensed consolidated financial statements in conformity with U.S. 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 revenue and expenses during the reporting period. The estimates include, but are not limited to, useful lives assigned to long-lived assets, the valuation of stock options, 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.

Follow-On Equity Offerings

On August 14, 2020, the Company completed a follow-on equity offering in which it issued and sold 6,578,947 shares of its common stock at a public offering price of $19.00 per share. The Company received net proceeds of $117.5 million after deducting underwriting discounts and commissions. The Company also incurred $0.4 million of offering costs, including legal, accounting, printing and other offering-related costs.

On January 29, 2021, the Company completed a follow-on equity offering in which it issued and sold 3,950,000 shares of its common stock at a public offering price of $38.00 per share. The Company received net proceeds of $141.1 million after deducting underwriting discounts and commissions. The underwriters of the offering exercised their option to purchase an additional 592,500 shares shortly thereafter, resulting in additional net proceeds of $21.2 million after deducting underwriting discounts and commissions. The Company also incurred $0.3 million of offering costs, including legal, accounting, printing and other offering-related costs.

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 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 as of June 30, 2021 and December 31, 2020. The Company had no bad debt expense for the periods presented.

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

	Revenue				Accounts Receivable	
	Three Months Ended June 30,		Six Months Ended June 30,		June 30, 2021	December 31, 2020
	2021	2020	2021	2020		
VA MVP	62%	76%	63%	76%	11%	*
Pfizer Inc.	15%	10%	14%	*	50%	*
Merck & Co., Inc.	*	*	*	*	12%	59%

* 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 Topic 606, 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 obligations.

The Company derives revenue from sequencing and data analysis services to support the development of personalized cancer vaccines and other next-generation cancer immunotherapies, as well as to support population sequencing initiatives. The Company's contracts are in the form of a combination of signed agreements, statements of work, and/or purchase orders. Under 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 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 condensed consolidated statements of operations.

Cost of Revenue

Cost of revenue consists of raw materials costs, personnel costs (salaries, bonuses, benefits, payroll taxes, and stock-based compensation), laboratory supplies and consumables, depreciation and maintenance on equipment, and allocated facilities and information technology ("IT") costs.

Research and Development Expenses

The Company charges research and development costs to expenses as incurred, including lab and automation development costs. The expenses primarily consist of personnel costs (salaries, bonuses, stock-based compensation, payroll taxes, and benefits), laboratory supplies and consumables, costs of purchasing samples for research purposes, depreciation and maintenance on equipment, and allocated facilities and IT costs.

Stock-Based Compensation

For options granted to employees, non-employees, and directors, stock-based compensation is measured at grant date based on the fair value of the award. The Company determines the grant-date fair value of options using the Black-Scholes option-pricing model, except for certain performance-based awards for which an alternative valuation method may be used. The Company determines the fair value of restricted stock unit awards using the closing market price of the Company's common stock on the date of grant. The grant-date fair value of awards is amortized over the employees' requisite service period on a straight-line basis, or the non-employees' vesting period as the goods are received or services rendered. Forfeitures are accounted for as they occur. Additionally, the Company's 2019 Employee Stock Purchase Plan (the "ESPP") is deemed to be a compensatory plan and therefore is included in stock-based compensation expense.

Inputs used in Black-Scholes option-pricing models to measure fair value of options are summarized as follows:

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 contractual expiration date is used as the expected term under this method. For awards with multiple vesting tranches, the assumed period for each tranche is computed separately and then averaged together to determine the expected term for the award.

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.*

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 and U.S. agency bonds, 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, asset-backed securities, and U.S. treasuries.

Unrealized gains and losses are included in accumulated other comprehensive income (loss) in stockholders' equity. 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 income (expense), net. When securities are sold, any associated unrealized gain or loss initially recorded as a separate component of stockholders' equity is reclassified out of stockholders' equity 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

Inventory, 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 revenue. Other deferred costs represent materials used in sequencing services, labor, and overhead allocations.

Leases

The Company categorizes leases with contractual terms longer than twelve months as either operating or finance leases. Finance leases are generally those leases that allow the Company to substantially utilize or pay for the entire asset over its estimated life. All other leases are categorized as operating leases. As of June 30, 2021, the Company had no finance leases.

Certain lease contracts include obligations to pay for other services, such as maintenance. The Company elected to account for these other services as a component of the lease (i.e., the Company elected the practical expedient not to separate lease and non-lease components).

Lease liabilities are recognized at the present value of the fixed lease payments, reduced by landlord incentives, using a discount rate based on the Company's current borrowing rate at the lease commencement date, adjusted for various factors including level of collateralization and term (the "incremental borrowing rate"), unless the rate implicit in the lease is readily determinable. The current portion of lease liabilities is included in "Accrued and other current liabilities." Lease assets are recognized based on the initial present value of the fixed lease payments, reduced by landlord incentives, plus any direct costs from executing the leases or lease prepayments reclassified from "Other long-term assets" upon lease commencement. Lease assets are presented as "Operating lease right-of-use assets" as a long-term asset. Leasehold improvements are capitalized at cost and amortized over the lesser of their expected useful life or the lease term. Costs associated with operating lease assets are recognized on a straight-line basis within operating expenses over the term of the lease.

The Company has made an accounting policy election not to recognize right-of-use assets and lease liabilities that arise from leases with a term of 12 months or less. Lease payments are recognized as an expense on a straight-line basis over the lease term.

Recent Accounting Pronouncements

New Accounting Pronouncements Not Yet Adopted

In June 2016, the FASB issued Accounting Standards Update ("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. The accounting update also made minor changes to the impairment model for available-for-sale debt securities. In November 2019, the FASB delayed the effective date for Topic 326 as applicable to smaller reporting companies to the first quarter of 2023. While the Company will no longer qualify as a smaller reporting company starting in the first quarter of 2022, the delayed effective date still applies to the Company. The Company is currently evaluating the impact of the new guidance on its consolidated financial statements and related disclosures. The Company will apply the new guidance by means of a cumulative-effect adjustment to the opening retained earnings as of the beginning of the first reporting period in which the guidance is effective.

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. Revenue

The following table presents revenue disaggregated by customer type (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
VA MVP	$ 13,507	$ 14,750	$ 26,717	$ 29,506
All other customers	8,163	4,745	15,834	9,150
Total revenue	$ 21,670	$ 19,495	$ 42,551	$ 38,656

Revenue from countries outside of the United States, based on the billing addresses of customers, represented approximately 6% and 1% of the Company's revenue for the three months ended June 30, 2021 and 2020, and approximately 7% and 5% for the six months ended June 30, 2021 and 2020, respectively.

Contract Assets and Liabilities

Contract assets as of June 30, 2021 and December 31, 2020 were immaterial.

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

The balance of contract liabilities was $11.5 million and $21.0 million as of June 30, 2021 and December 31, 2020, respectively. Revenue recognized for the three months ended June 30, 2021 and 2020 that were included in the contract liability balance at the beginning of each reporting period were $9.8 million and $10.8 million, respectively. Revenue recognized for the six months ended June 30, 2021 and 2020 that were included in the contract liability balance at the beginning of each period were $18.9 million and $21.5 million, respectively.

Revenue allocated to remaining performance obligations represent contracted revenue that has not yet been recognized ("contracted not recognized revenue"), which include VA MVP contract liabilities and amounts that will be invoiced and recognized as revenue in future periods. Contracted not recognized revenue was $16.8 million as of June 30, 2021, the substantial majority of which is expected to be recognized as revenue within the next quarter. The Company has elected the optional exemption that allows for the exclusion of contracts with an original expected duration of one year or less.

Note 4. Balance Sheet Details

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

	June 30, 2021	December 31, 2020
Raw materials	$ 4,225	$ 2,675
Other deferred costs	3,096	2,964
Total inventory and other deferred costs	$ 7,321	$ 5,639

Property and equipment. Depreciation and amortization expense for the three months ended June 30, 2021 and 2020 was $1.4 million, and for the six months ended June 30, 2021 and 2020 was $2.9 million and $2.8 million, respectively. Accumulated depreciation and amortization was $15.9 million and $14.5 million as of June 30, 2021 and December 31, 2020, respectively.

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

	June 30, 2021	December 31, 2020
Accrued compensation	$ 6,219	$ 8,041
Operating lease liabilities	3,360	2,445
Loans—current portion (Note 6)	2,786	—
Employee ESPP contributions	462	407
Accrued liabilities	435	313
Accrued taxes	446	95
Total accrued and other current liabilities	$ 13,708	$ 11,301

Note 5. Fair Value Measurements

The following tables show the Company's financial assets measured at fair value on a recurring basis and the level of inputs used in such measurements as of June 30, 2021 and December 31, 2020 (in thousands):

	June 30, 2021				
	Adjusted Cost	Unrealized Gains	Unrealized Losses	Fair Value	Fair Value Level
Assets					
Cash and cash equivalents:					
Cash	$ 6,565	$ —	$ —	$ 6,565	
Money market funds	21,523	—	—	21,523	Level 1
Commercial paper	41,993	—	(1)	41,992	Level 2
Total cash and cash equivalents	70,081	—	(1)	70,080	
Short-term investments:					
Asset-backed securities	18,277	2	(2)	18,277	Level 2
Commercial paper	135,889	3	(4)	135,888	Level 2
Corporate debt securities	24,377	1	(3)	24,375	Level 2
U.S. agency securities	24,056	9	—	24,065	Level 2
U.S. government securities	56,230	4	(12)	56,222	Level 2
Total short-term investments	258,829	19	(21)	258,827	
Total assets measured at fair value	$ 328,910	$ 19	$ (22)	$ 328,907	

	December 31, 2020				
	Adjusted Cost	Unrealized Gains	Unrealized Losses	Fair Value	Fair Value Level
Assets					
Cash and cash equivalents:					
Cash	$ 4,767	$ —	$ —	$ 4,767	
Money market funds	22,614	—	—	22,614	Level 1
Commercial paper	41,145	—	(1)	41,144	Level 2
Total cash and cash equivalents	68,526	—	(1)	68,525	
Short-term investments:					
Commercial paper	25,470	—	—	25,470	Level 2
Corporate debt securities	29,576	—	(8)	29,568	Level 2
U.S. agency securities	61,436	31	(1)	61,466	Level 2
U.S. government securities	18,260	1	—	18,261	Level 2
Total short-term investments	134,742	32	(9)	134,765	
Total assets measured at fair value	$ 203,268	$ 32	$ (10)	$ 203,290	

Realized gains or losses on marketable securities are immaterial for the periods presented. 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 June 30, 2021, the Company does not consider any of its marketable debt securities to be other-than-temporarily impaired.

The Company's marketable debt securities at June 30, 2021 have maturities due in one year or less, except for debt securities with an aggregate cost basis and fair value of $34.7 million that have maturities ranging from 13 to 21 months.

Note 6. Loans

In April 2021, the Company entered into a payment agreement with a financing entity to finance the purchase of $2.4 million of certain internal use software licenses and related software maintenance from a vendor. The financing entity and vendor are not related. The Company is obligated to repay the financed amount in three equal payments of $0.8 million in May 2021, May 2022, and May 2023. The payment agreement is noninterest bearing and the Company concluded that such interest rate (zero) did not represent fair and adequate compensation to the financing entity for the use of the related funds. Accordingly, the Company approximated the rate at which it could obtain financing of a similar nature from other sources at the date of the transaction. The resulting imputed interest rate was 7% and was used to establish the present value of the payment agreement. The discount is recognized as interest expense in the condensed consolidated statements of operations over the life of the payment agreement.

In April 2021, the Company entered into another payment agreement, with the same financing entity, to finance the purchase of $3.1 million of certain computer hardware and related hardware maintenance. The Company is required to pay three equal payments of $1.04 million in July 2021, June 2022, and June 2023. The nature of this agreement and resulting accounting treatment are the same as the payment agreement described in the preceding paragraph.

The total initial present value of the payment agreements was $5.2 million and presented as proceeds from loans in the condensed consolidated statements of cash flows. Such proceeds were used to purchase equipment, software, and related maintenance and are reflected as cash outflows in the investing and operating activities sections in the condensed consolidated statements of cash flows. Repayments are presented as financing cash outflows in the condensed consolidated statements of cash flows. Interest expense for the three and six months ended June 30, 2021 was $0.1 million. Amounts outstanding under the payment agreements are as follows (in thousands):

	June 30, 2021	December 31, 2020
Principal	$ 4,757	$ —
Less: unamortized discount	(339)	—
Total carrying amount	4,418	—
Less: current portion (included in “Accrued and other current liabilities”)	(2,786)	—
Long-term portion (included in “Other long-term liabilities”)	$ 1,632	$ —

Note 7. Leases

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 corporate headquarters. In April 2020, the Company extended the term of the lease through November 30, 2027. The lease includes an option to extend the term for a period of three years with rent payments equal to then current fair market rent for the space. The Company determined the extension option is not reasonably certain to be exercised. The lease contains a leasehold improvement incentive and escalating rent payments. In May 2021, the Company amended the lease to expand the premises subject to the lease to include an additional 14,710 square feet of space (the “Expansion Lease”). The Expansion Lease expires on December 31, 2022 and has no option to extend the term.

In August 2019, the Company entered into a noncancelable operating lease for a co-located data center space. The lease expires on August 31, 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 determined the extension option is not reasonably certain to be exercised. In April 2020, the lease was modified to increase the data center space available for the Company’s use for the remainder of the lease term.

Operating lease cost for the three months ended June 30, 2021 and 2020 was $0.7 million, and for the six months ended June 30, 2021 and 2020 was $1.4 million and $1.0 million, respectively.

As of June 30, 2021, the Company’s operating leases had a weighted-average remaining lease term of 5.4 years and a weighted-average discount rate of 10.3%. The Company’s discount rates are based on estimates of its incremental borrowing rate, as the discount rates implicit in the leases cannot be readily determined. Future lease payments under operating leases as of June 30, 2021 were as follows (in thousands):

	Amount
2021 (remaining six months)	$ 1,841
2022	3,318
2023	2,046
2024	2,113
2025	2,181
2026 and thereafter	4,378
Total future minimum lease payments	15,877
Less: imputed interest	(3,999)
Present value of future minimum lease payments	11,878
Less: current portion of operating lease liability	(3,360)
Long-term operating lease liabilities	$ 8,518

Cash paid for operating lease liabilities, included in cash flows from operating activities in the condensed consolidated statement of cash flows, for the six months ended June 30, 2021 and 2020, was $1.4 million and $0.8 million, respectively. Right-of-use assets obtained in exchange for new operating lease liabilities during the six months ended June 30, 2021 and 2020 were $1.7 million and $9.8 million, respectively.

Note 8. Stock-Based Compensation

2011 Equity Incentive Plan

In 2011, the Company's board of directors 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 ("RSUs"). 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.

2019 Equity Incentive Plan

The Company's board of directors adopted and the Company's stockholders approved the 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 Initial Public Offering ("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, RSUs, 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 the Company's common stock on the date of grant. Options under the 2019 Plan may be granted for periods of up to 10 years.

2020 Inducement Plan

The Compensation Committee of the Company's board of directors adopted the 2020 Inducement Plan (the "Inducement Plan") in May 2020, which became effective upon adoption. The Inducement Plan was adopted without stockholder approval, as permitted by the Nasdaq Stock Market listing rules (the "Nasdaq Listing Rules"). The Inducement Plan provides for the grant of equity-based awards, including NSOs, stock appreciation rights, restricted stock awards, RSUs, performance-based stock awards, and other forms of equity compensation, and its terms are substantially similar to the stockholder-approved 2019 Plan. In accordance with relevant Nasdaq Listing Rules, awards under the Inducement Plan may only be made to individuals not previously employees or non-employee directors of the Company (or following such individuals' bona fide period of non-employment with the Company), as an inducement material to the individuals entry into employment with the Company.

2019 Employee Stock Purchase Plan

The Company's board of directors adopted and the Company's stockholders approved the ESPP in May 2019 and June 2019, respectively. 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. The ESPP provides for separate six-month offering periods beginning on May 1 and November 1 of each year.

Shares of common stock available for issuance under the Company's equity incentive plans as of June 30, 2021 and December 31, 2020 were as follows:

	June 30, 2021	December 31, 2020
Reserved for issuance upon exercise of options outstanding under the 2011 Plan	3,030,494	3,389,711
Reserved for issuance upon exercise or settlement of awards outstanding under the 2019 Plan	3,416,066	2,399,513
Reserved and available for issuance under the 2019 Plan	2,783,091	1,977,069
Reserved for issuance upon exercise or settlement of awards outstanding under the Inducement Plan	185,100	199,300
Reserved and available for issuance under the Inducement Plan	801,900	800,700
Reserved and available for issuance under the ESPP	654,636	320,582
Total number of shares reserved	10,871,287	9,086,875

Stock Option Activity

A summary of the Company's stock option activity (excluding performance-based stock option activity summarized further below) under the 2011 Plan, 2019 Plan, and Inducement Plan for the six months ended June 30, 2021 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, 2020	4,948,306	$ 7.10	6.71	$ 146,044
Options granted	728,306	21.89		
Options exercised	(384,938)	3.64		
Options cancelled	(66,460)	9.99		
Balance—June 30, 2021	5,225,214	$ 9.38	6.76	$ 84,982
Options vested and exercisable as of June 30, 2021	3,118,662	$ 5.17	5.29	$ 62,790

Options granted to new hires generally vest 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 vest monthly over a three- or four-year period.

The aggregate intrinsic value of unexercised stock options is calculated as the difference between the closing price of the Company's common stock of $25.30 on June 30, 2021 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 $12.34 and $6.70 per share for the three months ended June 30, 2021 and 2020, and $13.55 and $4.81 per share for the six months ended June 30, 2021 and 2020, respectively. As of June 30, 2021, the unrecognized stock-based compensation cost of unvested options was $19.0 million, which is expected to be recognized over a weighted-average period of 2.5 years.

Valuation of Stock Options

The Company estimated the fair value of stock options (excluding performance-based stock options discussed below) 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 June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Expected term (in years)	5.50 - 6.27	5.50 - 6.08	5.50 - 6.27	5.50 - 6.08
Volatility	69.39 - 69.90%	67.58 - 68.18%	68.06 - 69.90%	61.74 - 68.18%
Risk-free interest rate	0.94 - 1.06%	0.36 - 0.44%	0.62 - 1.06%	0.36 - 1.66%
Dividend yield	–%	–%	–%	–%

Performance-Based Stock Option Activity

Pursuant to the 2019 Plan, in March 2020, the Company's board of directors granted the Company's Chief Executive Officer a performance-based stock option ("PSO") to purchase 421,000 shares of common stock. The PSO was subject to the Chief Executive Officer's continued service to the Company through the date of vesting and, if the performance condition is not met within 10 years from the date of grant, the PSO would be canceled. The shares subject to the PSO would vest in full if the Company's average market capitalization is equal to or greater than $1 billion over a 30 calendar day period. Upon a change in control, the vesting of the shares subject to the PSO would accelerate on a pro rata basis based on the price per share in such change in control transaction multiplied by the price per share at such time divided by $1 billion, with up to 100% of the shares eligible for such accelerated vesting. During the last quarter of 2020, the Company's average market capitalization was equal to or greater than $1 billion over a 30 calendar day period and the PSO vested in full.

A summary of the Company's performance-based stock option activity under the 2019 Plan for the six months ended June 30, 2021 is as follows:

	Outstanding Performance-Based 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, 2020	421,000	$ 5.10	9.21	$ 13,266
Options granted	—			
Options exercised	—			
Options cancelled	—			
Balance—June 30, 2021	421,000	$ 5.10	8.71	$ 8,504
Options vested and exercisable as of June 30, 2021	421,000	$ 5.10	8.71	$ 8,504

The aggregate intrinsic value of unexercised stock options is calculated as the difference between the closing price of the Company's common stock of $25.30 on June 30, 2021 and the exercise price of the underlying stock options. As of June 30, 2021, there is no remaining unrecognized stock-based compensation cost.

Valuation of Performance-Based Stock Options

The Company estimated the fair value of the PSO using a Monte Carlo Model and the following assumptions and estimates:

	2020
Performance period (in years)	10.00
Derived service period (in years)	4.55
Volatility	63.60%
Risk-free interest rate	1.02%
Dividend yield	–%
Estimated fair value per share	$ 3.31

Restricted Stock Units Activity and Valuation

A summary of the Company's RSU activity under the 2019 Plan and Inducement Plan for the six months ended June 30, 2021 is as follows:

	Unvested Restricted Stock Units		
(in thousands, except share and per share data)	Number of Shares	Weighted-Average Grant Date Fair Value	Aggregate Fair Value
Balance—December 31, 2020	619,218	$ 10.41	$ 22,670
RSUs granted	514,496	22.94	
RSUs vested	(119,981)	8.51	2,955
RSUs cancelled	(28,287)	15.86	
Balance—June 30, 2021	985,446	$ 17.03	$ 24,932

The Company granted RSUs to employees to receive shares of the Company's common stock. The RSUs awarded are subject to each individual's continued service to the Company through each applicable vesting date. RSUs granted to new hires generally vest annually over a four-year period. RSUs granted as merit awards generally vest semi-annually over a three- or four-year period, or in some cases quarterly over a three-year period. The Company accounted for the fair value of the RSUs using the closing market price of the Company's common stock on the date of grant.

The aggregate fair value of unvested RSUs is calculated using the closing price of the Company's common stock of $25.30 on June 30, 2021. As of June 30, 2021, the unrecognized stock-based compensation cost of unvested RSUs was $15.6 million, which is expected to be recognized over a weighted-average period of 2.9 years.

The Company's default tax withholding method for RSUs is the sell-to-cover method, in which shares with a market value equivalent to the tax withholding obligation are sold on behalf of the holder of the RSUs upon vesting and settlement to cover the tax withholding liability and the cash proceeds from such sales are remitted by the Company to taxing authorities.

ESPP Activity and Valuation

During the six months ended June 30, 2021 and 2020, 57,001 and 71,480 shares of common stock were purchased under the ESPP, respectively. The fair value of stock purchase rights granted under the ESPP was estimated using the following assumptions:

	Three and Six Months Ended June 30,	
	2021	2020
Expected term (in years)	0.49	0.50
Volatility	74.88%	102.10%
Risk-free interest rate	0.04%	0.12%
Dividend yield	–%	–%
Grant-date fair value per share	$ 8.21	$ 4.29

Stock Option Modifications

During March 2021, the Company's board of directors approved modifications to the outstanding stock options of two of the Company's non-employee directors. The modifications involved acceleration of unvested options and an extension of the exercise periods. The modifications resulted in incremental compensation cost of $1.2 million, all of which was recognized during the six months ended June 30, 2021. During the three months ended June 30, 2021, $0.6 million of such incremental compensation was recognized.

Stock-Based Compensation Expense

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Stock options	$ 2,325	$ 1,259	$ 4,503	$ 2,262
RSUs	1,011	310	1,655	423
ESPP	264	177	499	297
Performance-based stock options	—	76	—	89
Total stock-based compensation expense	$ 3,600	$ 1,822	$ 6,657	$ 3,071

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Cost of revenue	$ 332	$ 209	$ 620	$ 352
Research and development	900	394	1,628	653
Selling, general and administrative	2,368	1,219	4,409	2,066
Total stock-based compensation expense	$ 3,600	$ 1,822	$ 6,657	$ 3,071

Note 9. 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 condensed 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 June 30, 2021, 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 10. Basic and Diluted Net Loss Per Common Share

Basic net loss per common share is computed by dividing net loss by the weighted-average number of common shares outstanding during the period. Diluted net loss per common share is computed using net loss and the weighted-average number of common shares outstanding plus potentially dilutive common shares outstanding during the period. Potentially dilutive common shares include the assumed exercise of outstanding in-the-money stock options and common stock warrants, assumed release of outstanding RSUs, and assumed issuance of common stock under the ESPP using the treasury stock method.

The following table sets forth the computation of net loss per common share (in thousands, except share and per share amounts):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Net loss	$ (14,953)	$ (9,255)	$ (27,357)	$ (18,394)
Weighted-average common shares outstanding—basic and diluted	43,960,794	31,731,628	43,113,195	31,538,329
Net loss per common share—basic and diluted	$ (0.34)	$ (0.29)	$ (0.63)	$ (0.58)

The Company incurred net losses in the periods presented, and as a result, potential common shares from stock options, common stock warrants, RSUs, and the assumed release of outstanding shares under the ESPP were not included in the diluted shares used to calculate net loss per share, as their inclusion would have been anti-dilutive. The following table sets forth the potentially dilutive shares excluded from the computation of diluted net loss per common share because their effect was anti-dilutive:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Common stock warrants	—	127,598	—	127,598
Options to purchase common stock	5,646,214	5,624,766	5,646,214	5,624,766
Unvested RSUs	985,446	629,470	985,446	629,470
ESPP	69,380	95,403	69,380	95,403
Total	6,701,040	6,477,237	6,701,040	6,477,237

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 Annual Report on Form 10-K for the fiscal year ended December 31, 2020 filed with the Securities and Exchange Commission (the "SEC") on February 25, 2021 (the "Annual Report"). 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 Annual Report.

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 only 50 to 500 genes. In parallel with the development of our platform technology, we have also pursued business within the population sequencing market, and we have provided whole genome sequencing services under contract with the U.S. Department of Veterans Affairs (the "VA") Million Veteran Program (the "VA MVP"), which has enabled us to innovate, scale our operational infrastructure, and achieve greater efficiencies in our lab. We delivered the 125,000th whole human genome sequence dataset to the VA MVP in June 2021 with over 50,000 of these genomes delivered in the past 12 months alone. In September 2020, we announced receipt of a new task order from the VA MVP with an approximate value of up to $31 million. The cumulative value of task orders received from the VA MVP since inception is approximately $176 million, approximately $159.2 million of which we had recognized as revenue as of June 30, 2021.

In August 2020, we launched NeXT Liquid Biopsy, which is a liquid biopsy assay that analyzes all of the approximately 20,000 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 also announced in January 2020 a diagnostic test, NeXT Dx Test, which is based on our NeXT Platform, that we envision being used initially by both leading clinical cancer centers as well as biopharmaceutical companies. Most recently, in December 2020, we launched two new capabilities that are integrated into our NeXT Platform: our Systemic HLA Epitope Ranking Pan Algorithm ("SHERPA") machine learning-based tool for the comprehensive identification and characterization of cancer neoantigens, as well as our Neoantigen Presentation Score ("NEOPS") for predicting cancer immunotherapy response. SHERPA enables the development of new neoantigen-based diagnostic biomarkers, such as our NEOPS, and novel personalized therapies.

On January 29, 2021, we completed a follow-on equity offering in which we issued and sold 3,950,000 shares of common stock at a public offering price of $38.00 per share. We received net proceeds of $141.1 million after deducting underwriting discounts and commissions. The underwriters exercised their option to purchase an additional 592,500 shares shortly thereafter, resulting in additional net proceeds to us of $21.2 million after deducting underwriting discounts and commissions. In total, we raised net proceeds of $162.3 million after deducting underwriting discounts and commissions. We also incurred $0.3 million of offering costs, including legal, accounting, printing and other offering-related costs.

Our operations have been impacted by the ongoing COVID-19 pandemic. As of June 15, 2021, the Governor of California terminated executive orders that put into place the Stay Home Order and the Blueprint for a Safer Economy. The Governor also phased out the vast majority of executive actions put in place since March 2020 as part of the pandemic response. We had previously substantially closed our office facilities and limited access to our laboratory facilities to protect our employees and to comply with the now-terminated health orders. We are beginning to welcome back a select number of employees to our office facilities, consistent with our latest health and safety protocols and applicable government regulations and guidance. The previous shelter-in-place order and health orders have negatively impacted productivity, disrupted our business, and slowed research and development activities due to us limiting access to our laboratory space that would otherwise be used by our research and development group, and, to the extent such orders return in similar or more stringent form, they may continue to cause such effects on our operations. The health orders have disrupted, and may continue to disrupt if they return in similar or more stringent form, the ability of our suppliers to fulfill our purchase orders in a timely manner or at all. Additionally, we are aware of increased demand in the market for certain consumables used in COVID-19 test kits and vaccines. We use such consumables in our operations, and we have faced, and may face in the future, difficulties in acquiring such consumables if our suppliers prioritize orders related to COVID-19. Several of our customers, including the VA MVP, were delayed in sending us samples in the prior year due to the inability to collect or ship samples during the COVID-19 pandemic, and these and additional customers may be disrupted from collecting samples or sending purchase orders and samples to us in the future. Many of our customers, potential customers and potential partners have also put in place policies restricting visitors from other companies, and therefore our sales team and members of management have been unable to meet such parties in person, which may result in reduced acquisition of new customers, fewer orders from existing customers, and fewer potential partnering opportunities. We have yet to see a return to pre-pandemic conditions on this front. If a COVID-19 outbreak were to occur among our

laboratory employees, we may significantly curtail our laboratory operations or pause operations altogether until the imminent health risk to our employees subsided. Such disruptions in our operations, and our customers' and suppliers' operations, may continue to adversely affect revenue and operating results.

The global COVID-19 pandemic continues to rapidly evolve and to present serious health risks. While authorities in many areas have lifted or relaxed pandemic-related restrictions, in some cases they have subsequently re-imposed various restrictions after observing an increased rate of COVID-19 cases; for example, in December 2020, state and local authorities in California reinstated shelter-in-place orders in light of the increasing rate of COVID-19 cases and shortage of intensive care unit beds across the state. More recently, in July 2021, the County of San Mateo issued a formal recommendation to wear a mask indoors as precaution against COVID-19 amidst a rise in local COVID-19 cases and increased circulation of the Delta variant and, on August 2, 2021, the County issued a new health order requiring all individuals to wear face coverings when indoors in workplaces and public settings regardless of vaccination status, with certain limited exceptions. Our primary operations and headquarters are located in San Mateo County. There is no guarantee when or if all such restrictions and recommendations will be eliminated, such that we and our customers, manufacturers and suppliers will be able to safely resume operations consistent with our pre-COVID-19 operations. Vaccines against COVID-19 have been approved by the FDA and other regulatory authorities for emergency use, but there is uncertainty as to how quickly and to what extent the vaccines will impact the COVID-19 pandemic.

While the extent of the impact of the current COVID-19 pandemic on our business and financial results is uncertain, a continued and prolonged public health crisis such as the COVID-19 pandemic could have a material negative impact on our business, financial condition, and operating results.

Components of Operating Results

Revenue

We derive our revenue primarily from sequencing and data analysis services to support the development of next-generation cancer therapies and to support large-scale genetic research programs. We support our customers by providing high-accuracy, validated genomic sequencing and advanced analytics. Many of these analytics are related to state-of-the-art biomarkers, including those relevant to immuno-oncology therapeutics such as checkpoint inhibitors.

Our revenue is primarily generated through contracts with companies in the pharmaceutical industry, healthcare organizations, and government entities. Our ability to increase revenue will depend on our ability to further penetrate this market. To do this, we are developing a growing set of state-of-the-art products, advancing our operational infrastructure, expanding our international presence, building our regulatory credentials, and expanding our targeted marketing efforts. Unlike diagnostic or therapeutic companies, we have not to date sought reimbursement through traditional healthcare payors. We sell through a small direct sales force.

We derive a substantial portion of our current and expected future revenue from sales of our DNA sequencing and data analysis services to the VA MVP. Our contract with the VA MVP does not include specific testing turnaround times. Therefore, we have the ability to modulate the volume of samples processed for the VA MVP up or down to complement sample volumes from all other customers, which can vary from period to period.

We have one reportable segment from the sale of sequencing and data analysis services. Substantially all of our revenue to date has been derived from sales in the United States.

Costs and Expenses

Cost of Revenue

Cost of revenue consists of raw materials costs, personnel costs (salaries, bonuses, stock-based compensation, payroll taxes, and benefits), laboratory supplies and consumables, depreciation and maintenance on equipment, and allocated facilities and information technology ("IT") costs. We expect cost of revenue to increase as our revenue grows, and in the short term cost of revenue may outpace revenue growth as we invest in expanding our laboratory capacity, but over time the cost per sample processed is expected to decrease due to economies of scale we may gain as volume increases, automation initiatives, and other cost reductions.

Research and Development Expenses

Research and development expenses consist of costs incurred for the research and development of our products. These expenses consist primarily of personnel costs (salaries, bonuses, stock-based compensation, payroll taxes, and benefits), laboratory supplies and consumables, costs of purchasing samples for research purposes, depreciation and maintenance on equipment, and allocated facilities and IT costs. We include in research and development expenses the costs to further develop software we use to operate our laboratory, analyze the data it generates, and automate our operations. These expenses also include costs associated with our collaborations, which we expect to increase over time.

We expense our research and development expenses in the period in which they are incurred. We expect to increase our research and development expenses as we continue to develop new products.

Selling, General and Administrative Expenses

Selling expenses consist of personnel costs (salaries, commissions, bonuses, stock-based compensation, payroll taxes, and benefits), customer support expenses, direct marketing expenses, and market research. Our general and administrative expenses include costs for our executive, accounting, finance, legal, and human resources functions. These expenses consist of personnel costs (salaries, bonuses, stock-based compensation, payroll taxes, and benefits), corporate insurance, audit and legal expenses, consulting costs, and allocated facilities and IT costs. We expense all selling, general and administrative expenses as incurred.

We expect our selling expenses will continue to increase in absolute dollars, primarily driven by our efforts to expand our commercial capability and to expand our brand awareness and customer base through targeted marketing initiatives with an increased presence both within and outside the United States. We also expect general and administrative expenses to increase as we scale our operations.

Interest Income and Interest Expense

Interest income consists primarily of interest earned on our cash and cash equivalents and short-term investments. Since the first quarter of 2020, our interest income has been adversely impacted by declines in yields on debt securities. While our average balances of cash and cash equivalents and short-term investments have increased as compared to the same periods in the prior year (due primarily to our follow-on equity offerings), we expect that our interest income will not materially increase in the near future given the current low interest-rate environment. Interest expense in the second quarter and first six months of 2021 is the recognition of imputed interest on noninterest bearing loans.

Other Income (Expense), Net

Other income (expense), net consists primarily of foreign currency exchange gains and losses, and realized gains or losses associated with sales of marketable securities. We expect our foreign currency gains and losses to continue to fluctuate in the future due to changes in foreign currency exchange rates.

Results of Operations

The following sets forth, for the periods presented, our unaudited condensed consolidated statements of operations and selected financial data (in thousands, except share and per share data):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Revenue	$ 21,670	$ 19,495	$ 42,551	$ 38,656
Costs and expenses				
Cost of revenue	13,502	14,823	26,956	29,945
Research and development	11,687	6,465	21,183	12,855
Selling, general and administrative	11,428	7,705	21,849	14,979
Total costs and expenses	36,617	28,993	69,988	57,779
Loss from operations	(14,947)	(9,498)	(27,437)	(19,123)
Interest income	103	246	198	756
Interest expense	(65)	—	(65)	(2)
Other income (expense), net	(36)	1	(48)	9
Loss before income taxes	(14,945)	(9,251)	(27,352)	(18,360)
Provision for income taxes	8	4	5	34
Net loss	$ (14,953)	$ (9,255)	$ (27,357)	$ (18,394)
Net loss per share, basic and diluted	$ (0.34)	$ (0.29)	$ (0.63)	$ (0.58)
Weighted-average shares outstanding, basic and diluted	43,960,794	31,731,628	43,113,195	31,538,329

	June 30, 2021	December 31, 2020
Cash and cash equivalents, and short-term investments	$ 328,907	$ 203,290
Working capital	320,222	180,083
Total assets	383,340	244,842
Long-term obligations	10,506	9,261
Total liabilities	44,593	49,897
Total stockholders' equity	338,747	194,945

Revenue

The following table shows revenue by customer type (in thousands):

	Three Months Ended June 30,		Change	Six Months Ended June 30,		Change
	2021	2020		2021	2020	
VA MVP	$ 13,507	$ 14,750	(8%)	$ 26,717	$ 29,506	(9%)
All other customers	8,163	4,745	72%	15,834	9,150	73%
Total revenue	$ 21,670	$ 19,495	11%	$ 42,551	$ 38,656	10%

The following table shows concentration of revenue by customer:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
VA MVP	62%	76%	63%	76%
Pfizer Inc.	15%	10%	14%	*

* Less than 10% of revenue

VA MVP

The decrease of $1.2 million and $2.8 million in revenue from the VA MVP during the second quarter and first six months of 2021 was primarily due to a decrease in the volume of samples we tested in each period. We expect the substantial majority of our remaining backlog of $16.8 million with the VA MVP to be converted into revenue during the next quarter.

All other customers

The increase of $3.4 million in revenue from all other customers during the second quarter of 2021 was driven primarily by strong demand from large pharmaceutical customers for our NeXT Platform products which resulted in an increase in the volume of samples we tested during the period. Revenue derived from our NeXT Platform products exceeded $4.5 million during the second quarter of 2021 and was approximately $2.6 million in the second quarter of 2020. We also recognized $0.3 million in additional revenue from our biobank customer in the second quarter of 2021 as compared to the second quarter of 2020, as sample receipts from the customer were sharply reduced in the second quarter of 2020 due to the COVID-19 pandemic.

The increase of $6.7 million in revenue from all other customers during the first six months of 2021 was driven primarily by strong demand from large pharmaceutical customers for our NeXT Platform products, which resulted in an increase in the volume of samples we tested during the period. Revenue derived from our NeXT Platform products exceeded $9.0 million during the first six months of 2021 and was approximately $3.0 million during the same period of the prior year.

Costs and Expenses

	Three Months Ended June 30,		Change	Six Months Ended June 30,		Change
	2021	2020		2021	2020	
	(in thousands)			(in thousands)		
Cost of revenue	$ 13,502	$ 14,823	(9%)	$ 26,956	$ 29,945	(10%)
Research and development	11,687	6,465	81%	21,183	12,855	65%
Selling, general and administrative	11,428	7,705	48%	21,849	14,979	46%
Total costs and expenses	$ 36,617	$ 28,993	26%	$ 69,988	$ 57,779	21%

Cost of revenue

The decreases in cost of revenue in the second quarter and first six months of 2021, as compared to the comparable year ago periods, was primarily due to favorable customer mix and efficiencies within our laboratory operations. Raw materials costs were lower, relative to revenue, for non-VA MVP customer orders, resulting in favorable customer mix for the second quarter and first six months of 2021. We also observed more efficient sample processing overall during each period, including less labor and overhead required per sample processed, which was favorable for both VA MVP and non-VA MVP orders.

The cost components related to the $1.3 million decrease in cost of revenue during the second quarter of 2021 were a $0.7 million decrease in raw materials due to the favorable customer mix, a $0.4 million decrease in indirect costs due to a higher utilization of our laboratory for research and development activities, and a $0.2 million decrease in the cost of laboratory supplies and consumables.

The cost components related to the $3.0 million decrease in cost of revenue during the first six months of 2021 were a $2.0 million decrease in raw materials due to the favorable customer mix, a $0.8 million decrease in the cost of laboratory supplies and consumables, and a $0.4 million decrease in indirect costs due to a higher utilization of our laboratory for research and development activities, which were partially offset by a $0.2 million increase in personnel-related costs.

Research and development

The $5.2 million increase in research and development during the second quarter of 2021 was primarily due to the development of new products and lab automation efforts and consisted of an increase of $3.6 million in personnel-related costs primarily related to increased headcount, a $1.0 million increase in sample processing costs incurred in our laboratory for new product development, a $0.5 million increase in IT and facilities costs, and a $0.1 million increase in consulting fees.

The $8.3 million increase in research and development during the first six months of 2021 was primarily due to development of new products and lab automation efforts and consisted of an increase of $5.8 million in personnel-related costs primarily related to increased headcount, a $1.2 million increase in sample processing costs incurred in our laboratory for new product development, a $1.1 million increase in IT and facilities costs, and a $0.2 million increase in consulting fees.

Selling, general and administrative

The $3.7 million increase in selling, general and administrative during the second quarter of 2021 was primarily due to a $2.5 million increase in personnel-related costs primarily related to increased headcount, a $0.6 million increase in professional services (including corporate insurance, audit fees, and legal expenses), and a $0.6 million charge in connection with the modification of stock options held by a non-employee board member.

The $6.9 million increase in selling, general and administrative during the first six months of 2021 was primarily due to a $5.0 million increase in personnel-related costs primarily related to increased headcount, a $1.2 million charge in connection with the modification of stock options held by two non-employee board members, and a $0.9 million increase in professional services (including corporate insurance, audit fees, and legal expenses), which were partially offset by a $0.2 million decrease in travel-related costs due to pandemic-related travel restrictions and other costs.

Interest Income, Interest Expense, and Other Income (Expense), Net

	Three Months Ended June 30,		Change	Six Months Ended June 30,		Change
	2021	2020		2021	2020	
Interest income	$ 103	$ 246	(58%)	$ 198	$ 756	(74%)
Interest expense	(65)	—		(65)	(2)	
Other income (expense), net	(36)	1		(48)	9	
Total	$ 2	$ 247		$ 85	$ 763	

Interest income and interest expense

The decreases in interest income during the second quarter and first six months of 2021 was driven by declines in yields on debt securities, partially offset by higher average cash and investment balances subsequent to our follow-on equity offerings in August 2020 and January 2021. Interest expense in the second quarter and first six months of 2021 is the recognition of imputed interest on noninterest bearing loans.

Other income (expense), net

Other expense for the second quarter and first six months of 2021 consisted of foreign currency transaction losses and remeasurements. Other income in the second quarter and first six months of 2020 consisted of foreign currency remeasurements.

Liquidity and Capital Resources

The following tables present selected financial information and statistics as of and for the six months ended June 30, 2021 and 2020 (in thousands):

	As of June 30,	
	2021	2020
Cash and cash equivalents, and short-term investments	$ 328,907	$ 105,233
Property and equipment, net	14,258	12,650
Contract liabilities	11,460	28,952
Working capital	320,222	77,084

	Six Months Ended June 30,	
	2021	2020
Net cash used in operating activities	$ (37,674)	$ (23,997)
Net cash used in investing activities	(129,649)	(7,650)
Net cash provided by financing activities	168,859	1,644

From our inception through June 30, 2021, we have funded our operations primarily from $279.0 million in net proceeds from our follow-on equity offerings in January 2021 and August 2020, $144.0 million in net proceeds from our IPO in June 2019, and $89.6 million from issuance of redeemable convertible preferred stock, as well as cash from operations and debt financing. As of June 30, 2021, we held cash and cash equivalents in the amount of $70.1 million and short-term investments in the amount of $258.8 million.

We have incurred net losses since our inception. We anticipate that our current cash and cash equivalents and short-term investments, 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.

We have based these future funding requirements on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we expect. If our available cash balances, net proceeds from the offerings and anticipated cash flow from operations are insufficient to satisfy our liquidity requirements, including because of lower demand for our services or other risks described in this Quarterly Report on Form 10-Q, such as the COVID-19 pandemic, we may seek to sell additional common or preferred equity or convertible debt securities, enter into an additional credit facility or another form of third-party funding or seek other debt financing. The sale of equity and convertible debt securities may result in dilution to our stockholders and, in the case of preferred equity securities or convertible debt, those securities could provide for rights, preferences or privileges senior to those of our common stock. The terms of debt securities issued or borrowings pursuant to a credit agreement could impose significant restrictions on our operations. Additional capital may not be available on reasonable terms, or at all.

Our short-term investments portfolio is primarily invested in highly rated securities, with the primary objective of minimizing the potential risk of principal loss. Our investment policy generally requires securities to be investment grade and limits the amount of credit exposure to any one issuer.

During the six months ended June 30, 2021, cash used in operating activities of $37.7 million was a result of $27.4 million of net loss and the net negative change in operating assets and liabilities of $21.8 million ($9.6 million of which was related to reductions in outstanding customer prepayments as we fulfilled the related revenue contracts, $5.0 million due to prepayments of insurance and other service contracts, and $2.9 million due to an increase in customer accounts receivables), partially offset by non-cash adjustments to net income of $11.5 million (the most significant non-cash expenses for us in the six months ended June 30, 2021 were $6.7 million of stock-based compensation and $2.9 million of depreciation and amortization).

During the six months ended June 30, 2020, cash used in operating activities of $24.0 million was a result of $18.4 million of net loss and the net negative change in operating assets and liabilities of $12.1 million ($7.0 million of which was related to reductions in outstanding customer prepayments as we fulfilled the related revenue contracts), partially offset by non-cash adjustments to net income of $6.5 million (the most significant non-cash expenses for us in the six months ended June 30, 2020 were $3.1 million of stock-based compensation and $2.8 million of depreciation and amortization).

During the six months ended June 30, 2021, cash used in investing activities of $129.6 million was due to a $125.1 million net investment of cash into short-term investments and $4.5 million acquisitions of property and equipment. Cash provided by financing activities of $168.9 million during the same period consisted of $162.3 million net proceeds from our January 2021 follow-on equity offering, $5.1 million proceeds from loans, and $2.6 million proceeds from stock option exercises and purchases under our ESPP, partially offset by $0.8 million repayments of loans and $0.3 million of offering costs.

During the six months ended June 30, 2020, cash used in investing activities of $7.7 million was due to a $6.8 million net investment of cash into short-term investments and $0.9 million acquisitions of property and equipment. Cash provided by financing activities of $1.6 million during the same period was the proceeds from stock option exercises and purchases under our ESPP.

Material Cash Requirements

From time to time in the ordinary course of business, we enter into agreements with vendors for the purchase of raw materials, laboratory supplies and consumables to be used in the sequencing of customer samples. However, we generally do not have binding and enforceable purchase orders beyond the short term, and the timing and magnitude of purchase orders beyond such period is difficult to accurately project.

We currently expect our capital expenditures to support our growth initiatives globally to increase in 2021, as compared to capital expenditures in 2020. Such expenditures are expected to consist primarily of laboratory equipment and computer equipment. We anticipate fulfilling such expenditures with our existing cash and cash equivalents and short-term investments, which amounted to $328.9 million as of June 30, 2021.

Our noncancelable operating lease payments were $15.9 million as of June 30, 2021. The timing of these future payments, by year, can be found in Part I, Item 1 of this Form 10-Q in the Notes to Condensed Consolidated Financial Statements in Note 7, “Leases.”

During the second quarter of 2021, we entered into two noninterest bearing loans to finance the purchase of $5.5 million of computer hardware, internal use software licenses, and related ongoing support. We made a payment of $0.8 million during the second quarter of 2021 and have a remaining payment of $1.04 million due in 2021. We are required to make payments of $1.84 million in each of 2022 and 2023. Further discussion of this transaction can be found in Part I, Item 1 of this Form 10-Q in the Notes to Condensed Consolidated Financial Statements in Note 6, “Loans.”

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 June 30, 2021, we had approximately $11.5 million in customer deposits, including $10.5 million from one customer. 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. When a customer that has prepaid us for future services cancels its contract with us, reduces the level of services that it expects to receive, or we determine that a prepayment is no longer necessary, we will repay that customer's deposit. We do not expect such repayments to require material amounts of cash.

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, revenue, 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 and stock-based compensation 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 Annual Report on Form 10-K for the fiscal year ended December 31, 2020 under the caption "Critical Accounting Policies and Estimates" in Management's Discussion and Analysis of Financial Condition and Results of Operations, set forth in Part II, Item 7.

JOBS Act Accounting Election

We are 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. We have irrevocably elected not to avail ourselves of this exemption from new or revised accounting standards, and therefore, we will be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies.

Recent Accounting Pronouncements

See the sections titled "Summary of Significant Accounting Policies—Recent Accounting Pronouncements" and "—Recent Accounting Pronouncements Not Yet Adopted" in Note 2 to our unaudited condensed consolidated financial statements for additional information.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

As a "smaller reporting company," we are not required to provide the information under this item.

Item 4. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our chief executive officer, or CEO, and chief financial officer, or CFO, has evaluated 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, or Exchange Act), as of the end of the period covered by this Quarterly Report on Form 10-Q. Based on that evaluation, our CEO and CFO have concluded that as of June 30, 2021, our disclosure controls and procedures were effective in providing reasonable assurance that information required to be disclosed by us in reports that we file or submit under the Exchange Act, is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission's rules and forms, and that such information is accumulated and communicated to our management, including our CEO and CFO, as appropriate to allow timely decisions regarding required disclosures.

Changes in Internal Control

None.

Limitations on Controls

Our disclosure controls and procedures and internal control over financial reporting are designed to provide reasonable assurance of achieving their objectives as specified above. Management does not expect, however, that our disclosure controls and procedures or our internal control over financial reporting will prevent or detect all error and fraud. Any control system, no matter how well designed and operated, is based upon certain assumptions and can provide only reasonable, not absolute, assurance that its objectives will be met. Further, no evaluation of controls can provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud, if any, within the Company have been detected.

PART II—OTHER INFORMATION

Item 1. Legal Proceedings.

None.

Item 1A. Risk Factors.

Summary of Risk Factors

The following is a summary of the principal risks and uncertainties that could materially adversely affect our business, financial condition, or results of operations. You should read this summary together with the more detailed description of risk factors below under the heading "Risk Factors".

Operational, Strategic and Business Risks

- We have a history of losses and we expect to incur significant losses for the foreseeable future and may not be able to generate sufficient revenue to achieve or sustain profitability.
- If we are unable to increase sales of our current services or products or successfully develop and commercialize other services or products, or are unable to successfully compete with our competitors, we may fail to generate sufficient revenue to achieve profitability and sustain our business.
- Our operations and employees face risks related to health crises, such as the ongoing COVID-19 pandemic, that could adversely affect our operations, our financial condition, and our operations results, and the business or operations of our customers or other third parties with whom we conduct business.
- A limited number of customers account for a substantial portion of our revenue and accounts receivable; in particular, we derive a substantial portion of our revenue from our largest customer, the VA MVP.
- We rely on a limited number of suppliers, or in some cases, a sole supplier, for some laboratory instruments and materials, and we may not be able to replace or immediately transition to alternative suppliers if necessary.
- We will need to invest in our infrastructure in advance of increased demand for our services; our failure to accurately forecast demand would negatively impact our business and ability to achieve or sustain profitability.
- If our facilities become damaged or inoperable, or we are required to vacate the facilities, our ability to sell and provide our services and pursue our research and development efforts may be jeopardized.
- If we cannot continue timely developing and improving our services and products to keep pace with rapid advances in technology, medicine, and science our operating results and competitive position could be harmed.
- Personalized cancer therapies represent new therapeutic approaches that could result in heightened regulatory scrutiny, delays in clinical development, or delays in our inability to achieve regulatory approval, commercialization, or payor coverage, any of which could adversely affect our business.
- The loss of key members of our executive management team or the inability to hire, retain, or motivate highly skilled personnel could adversely affect our business.
- We may not be able to manage our growth effectively, which could prevent execution of our business strategy.
- We may acquire businesses or assets, form joint ventures, or make investments in other companies or technologies that could harm our operating results, dilute stockholders' ownership, or cause us to incur debt or significant expense.
- Expansion into China and other international markets will subject us to increased regulatory oversight and regulatory, economic, social, health and political uncertainties.

Regulatory, Legal and Cybersecurity Risks

- Complying with numerous statutes and regulations pertaining to our business is an expensive and time-consuming process, and we may be subject to regulatory action if we or our service or product offerings do not comply with applicable requirements.
- 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 adversely affect our business.
- The actual or perceived failure by us, our customers, or vendors to comply with increasingly stringent laws, regulations and contractual obligations relating to privacy, data protection, and data security could harm our reputation, and subject us to significant fines and liability.

- Our employees may engage in misconduct or other improper activities, such as noncompliance with regulatory standards and requirements, including the Foreign Corrupt Practices Act of 1977 and other anti-bribery laws, which could cause significant liability for us and harm our reputation.

- Changes in health care policy could increase our costs, decrease our revenue, and impact sales of and reimbursement for our tests. If we decide to grow our business by developing in vitro diagnostic tests, we may be subject to reimbursement challenges.

- The exit of the United Kingdom from the EU could lead to regulatory divergence and require us to incur additional expenses in order to develop, manufacture, and commercialize our products and services.

Intellectual Property Risks

- Litigation or other proceedings or claims of intellectual property infringement, misappropriation, breach of license terms or other violations may require us to spend significant time and money, including damages, and could prevent us from selling our tests.

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

- If we are not able to obtain, maintain and enforce patent protection for our products, services or technologies, our competitors and other third parties could develop and commercialize products, services and technologies similar or identical to ours, and our ability to successfully commercialize our products, services, and technologies may be adversely affected.

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

- 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.

- 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.

Financial and Market Risks and Risks Related to Owning Our Common Stock

- Certain of our customers prepay us for a portion of the future services that they expect to order and we may be required to refund some or all of those prepayments in the event of a cancellation or a reduction of services.

- Our inability to raise additional capital on acceptable terms may adversely affect operations or expansion.

- 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.

- Our quarterly results may fluctuate significantly, which could adversely impact our common stock’s value.

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

- Sales of shares by existing stockholders, the perception that such sales could occur, or future sales and issuances by us of our common stock or rights to purchase common stock could cause the stock price of our common stock to decline.

- Achieving a return on your investment will depend on appreciation of the value 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.

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

- 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 has an exclusive forum provision, which could limit our stockholders’ ability to obtain a favorable judicial forum for disputes with us or our directors, officers, or employees.

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

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.

Operational, Strategic and Business Risks

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 revenue to achieve or sustain profitability.

We have incurred net losses since our inception. For the years ended December 31, 2020, 2019, and 2018 we had net losses of $41.3 million, $25.1 million, and $19.9 million, respectively. For the six months ended June 30, 2021, we had a net loss of $27.4 million. As of June 30, 2021, we had an accumulated deficit of $209.2 million. To date, we have not generated sufficient revenue 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 revenue 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, or if we are unable to execute our sales and marketing strategy for our services or unable to gain sufficient acceptance in the market, we may fail to generate sufficient revenue to achieve profitability and sustain our business.

We currently derive substantially all of our revenue 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 revenue to become profitable.

In addition, as a growing genomics company, we have engaged in targeted sales and marketing activities for our services. Although we have had revenue from sales of our services since 2013, our services may never gain significant acceptance in the marketplace and therefore may never generate substantial revenue 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 commercial team, including sales and business development personnel;
- the recruitment, hiring, and retention of our commercial team personnel;
- 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.

Our operations and employees face risks related to health crises, such as the ongoing COVID-19 pandemic, that could adversely affect our financial condition and operating results. The COVID-19 pandemic could materially affect our operations, including at our headquarters in the San Francisco Bay Area, which is currently subject to restrictive orders, and the business or operations of our customers or other third parties with whom we conduct business.

Our business could be adversely impacted by the effects of a health crisis, such as the ongoing COVID-19 pandemic, that could cause significant disruption in the operations of our customers and third-party suppliers upon whom we rely. Our laboratory facilities (other than the facilities being developed for our use in Shanghai, China), executive team, and most of our employees are located in the San Francisco Bay Area. In the event of a health crisis that becomes widespread in or around the San Francisco Bay Area, we may proactively, or be ordered by government officials to, take precautionary measures such as suspending our lab operations, implementing alternative work arrangements for our employees, and limiting our employees' travel activities.

Our operations have been impacted by the ongoing COVID-19 pandemic. As of June 15, 2021, the Governor of California terminated executive orders that put into place the Stay Home Order and the Blueprint for a Safer Economy. The Governor also phased out the vast majority of executive actions put in place since March 2020 as part of the pandemic response. We had previously substantially closed our office facilities and limited access to our laboratory facilities to protect our employees and to comply with the now-terminated health orders. We are beginning to welcome back a select number of employees to our office facilities, consistent with our latest health and safety protocols and applicable government regulations and guidance. The previous shelter-in-place order and health orders have negatively impacted productivity, disrupted our business, and slowed research and development activities due to us limiting access to our laboratory space that would otherwise be used by our research and development group, and, to the extent such orders return in similar or more stringent form, they may continue to cause such effects on our operations. The health orders have disrupted, and may continue to disrupt if they return in similar or more stringent form, the ability of our suppliers to fulfill our purchase orders in a timely manner or at all. Additionally, we are aware of increased demand in the market for certain consumables used in COVID-19 test kits and vaccines. We use such consumables in our operations, and we have faced, and may face in the future, difficulties in acquiring such consumables if our suppliers prioritize orders related to COVID-19. Several of our customers, including the VA MVP, were delayed in sending us samples in the prior year due to the inability to collect or ship samples during the COVID-19 pandemic, and these and additional customers may be disrupted from collecting samples or sending purchase orders and samples to us in the future. Many of our customers, potential customers and potential partners have also put in place policies restricting visitors from other companies, and therefore our sales team and members of management have been unable to meet such parties in person, which may result in reduced acquisition of new customers, fewer orders from existing customers, and fewer potential partnering opportunities. We have yet to see a return to pre-pandemic conditions on this front. If a COVID-19 outbreak were to occur among our laboratory employees, we may significantly curtail our laboratory operations or pause operations altogether until the imminent health risk to our employees subsided. Such disruptions in our operations, and our customers' and suppliers' operations, may continue to adversely affect revenue and operating results.

The global COVID-19 pandemic continues to rapidly evolve and to present serious health risks. While authorities in many areas have lifted or relaxed pandemic-related restrictions, in some cases they have subsequently re-imposed various restrictions after observing an increased rate of COVID-19 cases; for example, in December 2020, state and local authorities in California reinstated shelter-in-place orders in light of the increasing rate of COVID-19 cases and shortage of intensive care unit beds across the state. More recently, in July 2021, the County of San Mateo issued a formal recommendation to wear a mask indoors as precaution against COVID-19 amidst a rise in local COVID-19 cases and increased circulation of the Delta variant and, on August 2, 2021, the County issued a new health order requiring all individuals to wear face coverings when indoors in workplaces and public settings regardless of vaccination status, with certain limited exceptions. Our primary operations and headquarters are located in San Mateo County. There is no guarantee when or if all such restrictions and recommendations will be eliminated, such that we and our customers, manufacturers and suppliers will be able to safely resume operations consistent with our pre-COVID-19 operations.

While vaccines for COVID-19 have been developed and administered, and the spread of COVID-19 may eventually be contained or mitigated, we cannot predict the timing of the vaccine roll-out globally or the efficacy of such vaccines, and we do not yet know how businesses, advertisers, or our partners will operate in a post COVID-19 environment. In addition, there is no guarantee that a future outbreak of this or any other widespread epidemics will not occur, or that the global economy will recover, either of which could seriously harm our business fully recover. The ultimate impact of the COVID-19 pandemic or a similar health epidemic on our business, operations, or the global economy as a whole remains highly uncertain.

A continued and prolonged public health crisis such as the COVID-19 pandemic could have a material negative impact on our business, financial condition, and operating results.

If we cannot compete successfully with our competitors, we may be unable to increase or sustain our revenue 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 or potential competitors, including Adaptive Biotechnologies Corporation, C2i Genomics, Inc., Caris Life Sciences, Inc., Covance Inc., which was acquired by Laboratory Corporation of America Holdings in February 2015, Foundation Medicine, Inc., which was acquired by Roche Holdings, Inc. in July 2018, Freenome, Inc., Genosity, Inc., which is in the process of being acquired by Invitae Corporation, Guardant Health, Inc., Inivata Limited, Invitae Corporation, Mount Sinai Genomics, Inc. which does business under the name Sema4, Natera, Inc., NanoString Technologies, Inc., NeoGenomics, Inc., Personal Genome Diagnostics, Inc., Roche Molecular Systems, Inc., and Tempus, Inc., may have more widespread brand recognition or substantially greater financial or technical resources, development or production capacities, or 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 more significant levels of market share. In addition, our present or potential competitors may be acquired by, receive investments from, or enter into other commercial relationships with larger, more well-established and well-financed companies. For example, in September 2020, Illumina, Inc. ("Illumina") announced it had entered into an agreement to acquire GRAIL, Inc. ("GRAIL"), a company focused on early cancer detection and potentially other forms of cancer analysis using next-generation sequencing technology, which we view as a potential competitor. 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 revenue 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. Our customers and potential customers may request, or in some cases have requested, that we consider developing and seeking FDA approval for companion diagnostic tests to accompany those customers' therapeutic product candidates, and it may be necessary for us to do so in order to successfully compete for the business of these customers. If we do not successfully develop FDA-approved companion diagnostics, we may be at a competitive disadvantage and may be unable to increase market acceptance and sales of our other product offerings, which would prevent us from increasing or sustaining our revenue or achieving or sustaining profitability. If we were to develop one or more FDA-approved companion diagnostics, we would incur increased research and development expenses, and such activities may also divert our resources or the attention of our management and may create competing internal priorities for us.

Additionally, projects related to cancer diagnostics and particularly genomics have received increased government funding, both in the United States of America (the "U.S.") and internationally. As more information regarding cancer genomics becomes available to the public, we anticipate that more products and services aimed at identifying treatment options will be developed and that these products and services 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.

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

Like other genomic profiling companies that sell to the pharmaceutical industry, we have substantial customer concentration. We currently derive a significant portion of our revenue from the U.S. Department of Veterans Affairs (the "VA") Million Veteran Program (the "VA MVP"), which accounted for 62% and 63% of our revenue for the three and six months ended June 30, 2021, respectively, and 76% for each of the three and six months ended June 30, 2020. Our top five customers, including the VA MVP, accounted for 87% of our revenue for each of the three and six months ended June 30, 2021, and 94% and 91% of our revenue for the three and six months ended June 30, 2020, respectively. There are inherent risks whenever a large percentage of revenue is concentrated with a limited number of customers. Our predictions regarding the future level of demand for our services that will be

generated by these customers may be wrong. In addition, revenue 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 factors, 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. Some of our customers have in the past suspended or terminated clinical trials or projects, received less funding than expected, experienced declining or delayed sales, or otherwise decided to reduce or eliminate their use of our services, and these and other customers may also do so in the future. As a result, 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 revenue 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 revenue, cash position, and results of operations. Similarly, if the VA MVP was eliminated, awarded its contract to one of our competitors, further reduced the size of our contract or failed to renew our contract in the future, then our revenue, cash position, and results of operations would be materially adversely impacted. Further, if any of our other significant 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 revenue 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 or if the VA MVP conducts a competitive bid process for the next contract and we do not win, our business, financial condition, operating results, and cash flows would be materially harmed.

We derive a substantial portion of our current and expected future revenue 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 contracted orders from the VA MVP in September 2017, 2018, 2019, and 2020. This contract expires in August 2021 and does not include a renewal option. Our current task order under this contract extends through August 2021. In order for us to provide additional services to the VA MVP after August 2021, we would need to receive an additional task order before the current contract expires or enter into a new services agreement with the VA MVP, neither of which had yet occurred as of the date of filing this report.

The VA MVP may initiate a competitive bidding process for its next DNA sequencing and data analysis services contract. We may not win any potential new contract in such bidding process, the value of such contract or the VA MVP contracted orders thereunder may be lower than our current contract and historical contracted orders from the VA MVP, and/or the scope or nature of the services required under such new contract may change such that we are unable to serve the VA MVP in the future.

The VA MVP's contracted orders for DNA sequencing and data analysis services have fluctuated in value over time and 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 among other factors. For example, the VA MVP contracted order received in September 2020 has a value of up to approximately $31 million, whereas the VA MVP contracted order received in September 2019 had a value of up to approximately $38.1 million. We have no certainty that funding will be made available for our services, or that the VA MVP will award any future contracts, contract renewals or contracted orders to us. If the priorities of the VA, the VA MVP, or the U.S. government change, including in response to the COVID-19 pandemic for example, 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. Similarly, if we do not win future VA MVP contracts and renewals (whether due to being outbid by a competitor or the VA MVP's decision to terminate for convenience or failure to renew for whatever reason), 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. Furthermore, we only recognize revenue under our VA MVP contract upon the receipt and processing of samples, and the timing and number of VA MVP samples we receive has been and could in the future be negatively affected by factors beyond our control, which has resulted, and may result in the future, in delaying our ability to process and recognize revenue for such samples. For example, the revenue we recognized during the contract year that began in September 2019 significantly exceeded the value of the VA MVP contracted order we received in September 2019 because we continued to receive after such date, and subsequently processed, samples under VA MVP contracted orders that remained unfulfilled as of September 2019 due to the time required for the VA to select optimal samples from its collection for research and then provide us those samples. Therefore, period-to-period comparisons of our operating results relating to VA MVP contracted orders may not be meaningful and, even if we win a potential new VA MVP contract and order with a value comparable to that of the September 2019 contracted order, the revenue we recognize under such potential new contract and order may be less than the revenue we recognized during the 2019-2020 contract year, and may also be less than the revenue we expect to recognize during the 2020-2021 contract year because we expect during the current contract year to finish processing most or all of the samples under VA MVP contracted orders that remained unfulfilled as of September 2020, in addition to samples received under the September 2020 contracted order. The timing and number of VA MVP samples may also have been or be negatively affected by the current COVID-19 pandemic. For example, in March 2020, the VA MVP announced that it was suspending sample collection due to the COVID-19 pandemic. In addition, we believe the COVID-19 pandemic may have been a contributing factor to the reduction in value of the September 2020 VA MVP contracted order compared to the September 2019 contracted order, as the VA MVP delayed new enrollment and also may have needed to divert resources to respond to the pandemic, and the COVID-19 pandemic may also negatively impact the value of any potential new VA MVP contract or order.

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 trials are expensive, can take many years to complete, and have inherently uncertain outcomes.

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 (including as a result of the COVID-19 pandemic), 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 revenue 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 revenue.

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 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. In September 2020, Illumina announced it had entered into an agreement to acquire GRAIL, a company focused on early cancer detection and potentially other forms of cancer analysis using next-generation sequencing technology. Any disruption in Illumina's operations, or our inability to negotiate an extension to our agreements with Illumina on acceptable terms, or at all, or any competitive pressure resulting from Illumina's anticipated acquisition of GRAIL, could negatively 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, would likely 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, if we were forced to replace Illumina or another supplier on which we rely, we would 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.

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 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 facilities 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 revenue does not meet our expectations we may not be able to promptly adjust or reduce our spending to levels commensurate with our revenue. 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 or products, 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.

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

We currently derive our revenue from our genomic analysis conducted in our laboratories. Currently, we do not have any clinical reference or research and development laboratory facilities other than our facilities in Menlo Park, California and the facilities being developed for our use in Shanghai, China. 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. Additionally, as a result of the ongoing COVID-19 pandemic, we have limited access to our office and laboratory facilities in Menlo Park to protect the health and safety of our employees and to comply with applicable state and local orders. 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 sequencing and analysis services, disruptions in our operations, or the backlog of samples that could develop if our facilities are 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. The limited access to our laboratory facilities as a result of the COVID-19 pandemic has resulted, and may in the future result, in a loss in productivity, including delays to research and development programs. 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 facilities 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 facilities became inoperable, we would likely not be able to license or transfer our technology to other facilities with the qualifications, including state licensure and CLIA certification, that would be necessary to cover the scope of our current and our planned future services. Even if we were to find facilities with such qualifications to perform our services, they may not be available to us on commercially reasonable terms.

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 have also been and could in the future be flaws in the databases, third-party tools or algorithms we use, or 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 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 candidates. 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.

In the EEA (and Northern Ireland) the new European Union (“EU”) In Vitro Diagnostic Device Regulation (the “IVDR”) entered into force on May 25, 2017, replacing the In-Vitro Diagnostic Directive (the “IVDD”) (and national legislation that implemented the IVDD in member states) as the primary legislation governing in-vitro diagnostic devices (“IVD”). Most requirements under the IVDR will not apply until the end of a transition period which is expected to occur on May 26, 2022. The IVDR broadens the scope of the regulation of IVDs and, among other things, tightens the requirements for clinical evidence and conformity assessment, increases transparency requirements, and introduces a requirement for a unique device identifier for every IVD. Under the IVDR there are four classes of IVDs, referred to as classes A, B, C, and D. IVDs are placed into a class based on their perceived risk to the patient and wider public. The main requirements of the IVDR apply regardless of the class which the relevant device falls into, and class A devices (including instruments and specimen receptacles) are the only devices that can be self-certified as meeting the requirements of the IVDR. The IVDR explicitly includes software used for diagnostic purposes in its scope. The IVDR requires pre-registration and post-market data collection to ensure that the device meets the relevant requirements. It is also notable that diagnostic and therapeutic services offered to customers in the EEA (and Northern Ireland) (whether directly or via intermediaries) by providers that are based outside the EEA will be covered by the IVDR. The IVDR will not apply to Great Britain (England, Wales and Scotland). These additional regulatory requirements are likely to increase the cost and time required in order to obtain regulatory approval for products in the EEA where such

approval was already necessary, and in certain cases will introduce a new requirement to obtain regulatory approval where one did not exist under the IVDD arrangements. Further, the IVDR may result in devices being classified in a higher risk category than would have been the case under the existing IVDD arrangements.

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, 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, or if one or more of these key employees were to become unable to perform his or her duties due to contracting COVID-19, 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 or extended illness 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 facilities, 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 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, and their consideration may be distracting to our management or prevent us from pursuing other opportunities. 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 such transactions by us also could result in significant write-offs, the incurrence of debt and contingent liabilities, exposure to additional liability, exposure to additional revenue concentration, additional regulatory obligations and exposure to additional potential liability, any of which could harm our operating results and future prospects. 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 we could raise additional funds carry potential risks. See "Financial and Market Risks and Risks Related to Owning Our Common Stock—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 common stock 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.

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.

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

Any current or future collaborations, including any strategic alliances or any collaborations to develop companion diagnostic tests, that we have entered (for example, our collaboration with MapKure, LLC, which is jointly-owned by BeiGene, Ltd. and SpringWorks Therapeutics, Inc.) or may 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 include that:

- we may incur increased research and development expenses, and such activities may also divert management attention and resources and/or create competing internal priorities for us, which could prevent us from successfully conducting other parts of our business or collaborating with others;
- 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 services or 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 services or products, availability of funding, or other external factors, such as a business combination that diverts resources or creates competing priorities for our collaborator;
- collaborators could independently develop, or develop with third parties, services or products that compete directly or indirectly with our services or products;
- collaborators with marketing, manufacturing, and distribution rights to one or more services or 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;
- a large percentage of our revenue may be concentrated with the collaborators if the collaborations are successful and we may experience further losses if they are or later become unsuccessful;

- 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 services or 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 services or products;

- collaborators may own or co-own intellectual property covering our services or 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;

- collaborators' activities or use of our services or deliverables may create additional regulatory obligations and could lead to side effects or adverse events in patients, exposing us to potential liability or regulatory review; 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.

Our planned expansion into China entails substantial risks.

In June 2020, we announced a partnership with a clinical genomics and life sciences company headquartered in China as a means to expand business operations into China in the near term. Our first wholly owned subsidiary was formed in Shanghai in October 2020. Our expansion and investment plans are subject to substantial risks which may include, but are not limited to: the inability to protect our intellectual property rights under Chinese law, which may not offer as high a level of protection as U.S. law; unexpectedly long negotiation periods with Chinese suppliers and customers; quality issues related to supplies sourced from local vendors; unexpectedly high labor costs due to a tight labor supply; foreign investment restrictions; and difficulty in repatriating funds and selling or transferring assets. Our investments in China also expose us to additional foreign currency exchange risk. In addition, as tensions have escalated between the U.S. and China, we believe there is an enhanced risk that our planned investments in China may be subject to unforeseen risks or restrictions, which may include expropriation of the investments by the Chinese government. These and other risks may result in our not realizing a return on, or losing some, or all, of our planned investments in China, which could have a material adverse effect on our financial condition and financial performance.

Personal privacy, cyber security, and data protection are becoming increasingly significant issues in China. For example, the State Council of the People's Republic of China adopted the Regulations of the People's Republic of China on Administration of Human Genetic Resources, which went into effect on July 1, 2019. The regulations establish a framework for the collection, preservation, utilization, and supply abroad of human genetic resources of China. The regulations also establish a framework for the use of data and other information generated from use of human genetic resources of China. The regulations also provide that foreign organizations, individuals and entities established or controlled by them are prohibited to collect or preserve China's human genetic resources or transport them abroad. Due to the lack of detailed interpretations and implementations, it is not clear whether the agency in China responsible for enforcing the regulations will grant the necessary approvals for use by us and our partners of our NeXT Platform or our other current or future products in research or clinical projects involving China's human genetic resources or information generated therefrom. For example, we understand that the initial application by one of our pharmaceutical customers for such a project approval was recently rejected by such agency in China for reasons relating to data retention by our customer and sharing of rights to research results with our customer's collaborator in China. Although it is our understanding that the agency's decision was not based on the use of our NeXT Platform in the project, we are supporting and expect in the future to support the preparation of multiple such applications, and there is no guarantee that any such applications will be approved by such agency. The Chinese government separately has various regulations relating to the collection, use, storage, disclosure, and security of data, among other things. We cannot assure you that we will be able to comply with all of these regulatory requirements. Any failure to comply with relevant regulations and policies could result in significant cost and liability to us and could adversely affect our business and results of operations. Any additional new regulations or the amendment or modification of previously implemented regulations, or the failure to receive any necessary approvals for use of our products in connection with such projects, could require us and our partners to change our business plans and incur additional costs, and could limit our ability to generate revenue in China.

Expansion into international markets would subject us to increased regulatory oversight and regulatory, economic, social, health 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. For example, in June 2020, we announced our intention to expand into China. As 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 instability, local or regional health crises, 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 United Kingdom (the "U.K.") 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 U.K. 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.

Regulatory, Legal and Cybersecurity Risks

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 U.S. 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.

The IVDR includes limited exemptions for LDTs, but such exemptions only apply to laboratories that are part of health institutions established in the EEA, and so any services undertaken outside of the EEA (for example at our facilities in the U.S.) will not be covered by such exemptions. In any event, such exemptions are limited in their scope, and only apply if a number of conditions are met, including that the health institution justifies that the "target patient group's specific needs cannot be met, or cannot be met at the appropriate level of performance by an equivalent device available on the market" and do not cover devices that are manufactured on an "industrial scale". Even where an exemption is applicable, such IVDs will still be subject to certain requirements under the IVDR. It is therefore unlikely that our tests will benefit from any exemption on the basis of being LDTs and will have to comply with the IVDR in full if we offer such tests to customers in the EEA (and Northern Ireland) (whether directly or via intermediaries).

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 12 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. 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 for a sponsor's subsequent GHR tests once the assessment system has been reviewed and cleared by FDA, 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 revenue 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 U.S. 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 revenue in doing so.

Failure to comply with the IVDR may result in a range of enforcement actions. Penalties under the IVDR are devolved to national governments, but the IVDR requires that such measures are "effective, proportionate, and dissuasive." Initial indications suggest that penalties for breaches of the IVDR are likely to include fines and, potentially, prison sentences.

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 revenue, 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.

If our security measures are compromised, or our information technology systems or those of our vendors, and other relevant third parties fail or suffer security breaches, loss or leakage of data, and other disruptions, this could result in a material disruption of our services, compromise sensitive information related to our business, harm our reputation, trigger breach notification obligations, prevent us from accessing critical information, and expose us to liability or other adverse effects to our business.

In the ordinary course of our business, we collect, process, and store proprietary, confidential, and sensitive information, including protected health information ("PHI"), personally identifiable information ("PII"), credit card and other financial information, intellectual property, trade secrets, and proprietary business information owned or controlled by ourselves or our customers, payors, and other parties. It is critical that we do so in a secure manner to maintain the confidentiality, integrity, and availability of such information. We depend on information technology and telecommunications systems for significant elements of our operations and 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. 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, as we have outsourced elements of our operations to third parties and as a result a number of third-party vendors and other contractors and consultants have access to our proprietary, confidential, and sensitive information.

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. 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.

Notwithstanding 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 proprietary, confidential, and sensitive information that they maintain, such information technology systems are potentially vulnerable to breakdown, 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 personnel, 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 accidental actions or omissions by trusted insiders, cyber-attacks or cyber intrusions, including by computer hackers, viruses, 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; in particular, during the COVID-19 pandemic we have observed an increase in attempted attacks against our data systems. Additionally, in connection with the ongoing COVID-19 pandemic, most of our personnel are working remotely, which may increase the risk of security breaches, loss of data, and other disruptions as a consequence of more personnel accessing sensitive and critical information from remote locations. 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, hostile foreign governments or agencies, or cybersecurity researchers. 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.

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.

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 personnel 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 domestic or foreign privacy, data protection, and data security laws 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 penalties. Notice of certain security 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. 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. Similarly, the California Consumer Privacy Act (“CCPA”) allows consumers a private right of action when certain personal information is subject to unauthorized access and exfiltration, theft or disclosure due to a business’ failure to implement and maintain reasonable security procedures. 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 revenue and/or subject us to additional liabilities.

The actual or perceived failure by us, our customers, or vendors to comply with increasingly stringent laws, regulations and contractual obligations relating to privacy, data protection, and data security could harm our reputation, and subject us to significant fines and liability.

We are subject to numerous domestic and foreign laws and regulations regarding privacy, data protection, and data security, the scope of which is changing, subject to differing applications and interpretations and may be inconsistent among countries, or conflict with other rules. We are also subject to the terms of our contractual obligations to customers and third parties related to privacy, data protection, and data security. The actual or perceived failure by us, our customers, our vendors, or other relevant third parties to address or comply with these laws, regulations, and obligations could increase our compliance and operational costs, expose us to regulatory scrutiny, actions, fines and penalties, result in reputational harm, lead to a loss of customers, reduce the use of our services, result in litigation and liability, and otherwise cause a material adverse effect on our business, financial condition, and results of operations.

For example, the EU adopted the General Data Protection Regulation (EU) 2016/679 (“GDPR”), which imposes onerous and comprehensive privacy, data protection, and data security obligations onto data controllers and processors, including, as applicable, contractual privacy, data protection, and data security commitments, expanded disclosures to data subjects about how their personal information is used, honoring individuals’ data protection rights, limitations on retention of personal information, additional requirements pertaining to sensitive information (such as health data) and pseudonymized (i.e., key-coded) data, data breach notification requirements, and higher standards for obtaining consent from data subjects. Penalties for non-compliance with the GDPR can be significant and include fines in the amount of the greater of €20 million or 4% of global turnover and restrictions or prohibitions on data processing, which could limit our ability to do business in the EU, reduce demand for our services, and adversely impact our business and results of operations. The GDPR also 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, require us to change our practices, adversely impact our business, and harm our financial condition. Assisting our customers, partners, and vendors in complying with the GDPR, or complying with the GDPR ourselves, may cause us to incur substantial operational costs or require us to change our business practices.

European privacy, data protection, and data security laws, including the GDPR, generally restrict the transfer of personal information from the U.K., EEA and Switzerland to the U.S. and most other countries unless the parties to the transfer have implemented specific safeguards to protect the transferred personal information. There is uncertainty on how to implement such safeguards and how to conduct such transfers in compliance with the GDPR, and certain safeguards may not be available or applicable with respect to some or all of the personal information processing activities necessary to research, develop and market our products and services. One of the primary safeguards allowing U.S. companies to import personal information from Europe has been certification to the EU-U.S. Privacy Shield and Swiss-U.S. Privacy Shield frameworks. However, the EU-U.S. Privacy Shield framework was invalidated in July 2020 in a decision by the Court of Justice of the EU and the Swiss-U.S. Privacy Shield Framework was declared as inadequate by the Swiss Federal Data Protection and Information Commissioner. The decision by the Court of Justice and the announcement by the Swiss Commissioner both raised questions about whether one of the primary alternatives to the Privacy Shield frameworks, the European Commission’s Standard Contractual Clauses, can lawfully be used for personal information transfers from Europe to the U.S. or most other countries. Authorities in the U.K. may similarly invalidate use of the EU-U.S. Privacy Shield and raise questions on the viability of the Standard Contractual Clauses. In November 2020, EU regulators proposed a new set of Standard Contractual Clauses, which impose additional obligations and requirements with respect to the transfer of EU personal data to other jurisdictions, which may increase the legal risks and liabilities under the GDPR and local EU laws associated with cross-border data transfers, and result in material increased compliance and operational costs. If we are unable to implement a valid solution for personal information transfers to the U.S. and other countries, we will face increased exposure to regulatory actions, substantial fines, and injunctions against processing or transferring personal information from Europe, and we may be required to increase our data processing capabilities in Europe at significant expense. Inability to import personal information from Europe to the U.S. or other countries may decrease demand for our products and services as our customers that are subject to the GDPR may seek alternatives that do not involve personal information transfers out of Europe. At present, there are few, if any, viable alternatives to the Privacy Shield and the Standard Contractual Clauses.

In addition, it is unclear whether the transfer of personal information from the EU to the U.K. will continue to remain lawful under the GDPR in light of Brexit. Pursuant to a post-Brexit trade deal between the U.K. and the EU, transfers of personal information from the EEA to the U.K. are not considered restricted transfers under the GDPR for a period of up to six months from January 1, 2021. However, unless the EU Commission makes an adequacy finding with respect to the U.K. before the end of that period, the U.K. will be considered a “third country” under the GDPR and transfers of European personal information to the U.K. will require an adequacy mechanism to render such transfers lawful under the GDPR. Additionally, although U.K. privacy, data protection and data security law is designed to be consistent with the GDPR, uncertainty remains regarding how data transfers to and from the U.K. will be regulated notwithstanding Brexit.

Regulation of privacy, data protection, and data security has also become more stringent in the U.S. New laws are also being considered at both the state and federal levels, and legislatures of states such as California have already passed and enacted privacy legislation. For example, the CCPA, which took effect on January 1, 2020, gives California residents expanded rights to access and delete their personal information, opt out of certain personal information sharing, and receive detailed information about how their personal information is used. The CCPA provides for civil penalties for violations, as well as a private right of action for data breaches that is expected to increase data breach litigation. The CCPA may increase our compliance costs and potential liability. Some observers have noted that the CCPA could mark the beginning of a trend toward more stringent state privacy, data protection and data security legislation in the U.S., which could increase our potential liability and adversely affect our business. The CCPA will be expanded substantially on January 1, 2023, when the California Privacy Rights Act of 2020 ("CPRA") becomes fully operative. The CPRA imposes additional obligations relating to consumer data on companies doing business in California beginning January 1, 2022, with implementing regulations expected on or before July 1, 2022, and enforcement beginning July 1, 2023. The CPRA significantly modifies the CCPA and will, among other things, give California residents the ability to limit use of certain sensitive personal information, further restrict the use of cross-contextual advertising, establish restrictions on the retention of personal information, expand the types of data breaches subject to the CCPA's private right of action, provide for increased penalties for CPRA violations concerning California residents under the age of 16, and establish a new California Privacy Protection Agency to implement and enforce the new law.

Compliance with U.S. and foreign privacy, data protection, and data security 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 typically 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 typically 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 valid under applicable law could result in our own non-compliance with privacy laws. Such failure to comply with U.S. and foreign privacy, data protection, and data security 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 privacy, data protection, and data security 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 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.

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 laws, among other things, prohibit 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;

- he 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"), with certain exceptions, to report annually to CMS information related to (i) payments and other transfers of value to physicians (defined to include doctors, dentists, optometrists, podiatrists, and chiropractors) and teaching hospitals, and (ii) ownership and investment interests held by physicians and their immediate family members, which will be expanded beginning in 2022, to require applicable manufacturers to report information regarding payments and other transfers of value provided to physician assistants, nurse practitioners, clinical nurse specialists, certified registered nurse anesthetists, anesthesiologist assistants, and certified nurse midwives during the previous year;

- 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 U.S. 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.

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 U.K.'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.

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, including our NeXT Dx test, is uncertain. If we decide to seek reimbursement for our NeXT Dx test or other in vitro diagnostic tests we may develop, and if such tests are inadequately covered by insurance or 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.

Changes in health care policy could increase our costs, decrease our revenue, 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:

- 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 and Medicaid Innovation at CMS to test innovative payment and service delivery models to lower Medicare and Medicaid spending.

There remain judicial and Congressional challenges to certain aspects of the ACA, as well as efforts by the former Trump administration to repeal or replace certain aspects of the ACA. Since January 2017, former President Trump signed several Executive Orders and other directives to delay the implementation of certain requirements of the ACA. Concurrently, Congress 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 eliminating the implementation of certain ACA-mandated fees. 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. Additionally, on December 18, 2019, the U.S. Court of Appeals for the 5th Circuit upheld the District Court ruling that the individual mandate was unconstitutional and remanded the case back to the District Court to determine whether the remaining provisions of the ACA are invalid as well. The U.S. Supreme Court is currently reviewing the case, although it is uncertain when or how the Supreme Court will rule. 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 ACA 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 2030, with the exception of a temporary suspension from May 1, 2020 through March 31, 2021, 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 established a quality payment incentive program, also referred to as the Quality Payment Program. This program provides clinicians with two ways to participate, including through the Advanced Alternative Payment Models, or APMs, and the Merit-based Incentive Payment System, or MIPS. In November 2019, CMS issued a final rule finalizing the changes to the Quality Payment Program. At this time, it is unclear how the introduction of the Quality Payment Program will impact overall physician reimbursement under the Medicare program. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors.

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. In January 2020, CMS announced that data reporting for clinical diagnostic laboratory tests is delayed by one year. Moreover, the Coronavirus Aid, Relief, and Economic Security ("CARES") Act, enacted in March 2020, further delays the reporting period by an additional year. Therefore, data that was originally supposed to be reported between January 1, 2020 and March 31, 2020 must now be reported between January 1, 2022 and March 31, 2022. Covered laboratories must report data from the original data collection period of January 1, 2019 through June 30, 2019. Data reporting for these tests will then resume on a three year cycle beginning in 2025. The payment rate applies to laboratory tests furnished by a hospital laboratory if the test is separately paid under the hospital outpatient prospective payment system. It is still too early to predict the full impact on reimbursement for our products in development. In addition, CMS updated the statutory phase-in provisions such that, for 2020, the rates for clinical diagnostic laboratory tests may not be reduced by more than 10% of the rates for 2019. Pursuant to the CARES Act, the statutory phase-in of payment reductions has been extended through 2024 with a 0% reduction cap for 2021 and a 15% reduction cap for each of 2022, 2023, and 2024. 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.

Further, it is possible that additional governmental action is taken to address the COVID-19 pandemic. We also 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.

The 2017 tax reform law, as modified by 2020 tax legislation, and possible future changes in tax laws or regulations could adversely affect our business and financial condition.

On December 22, 2017, former 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"). Future guidance from the U.S. Internal Revenue Service and other tax authorities with respect to the Tax Cuts and Jobs Act may affect us, and certain aspects of the Tax Cuts and Jobs Act could be repealed or modified in future legislation. For example, on March 27, 2020, the CARES Act was enacted, which includes changes to the tax provisions that benefit business entities and makes certain technical corrections to the Tax Cuts and Jobs Act. On June 29, 2020, California Assembly Bill 85 (AB 85) was signed into law, which suspends the use of California net operating losses and limits the use of California research tax credits for tax years beginning in 2020 and before 2023. On December 27, 2020, the Consolidated Appropriations Act, a coronavirus relief package that extended and expanded various tax provisions, was signed into law. Changes in corporate tax rates, the realization of net deferred tax assets relating to our U.S. operations, the taxation of foreign earnings, and the deductibility of expenses under the Tax Cuts and Jobs Act, the CARES Act, or future tax reform legislation could have a material impact on the value of our deferred tax assets, could result in significant one-time charges in the current or future taxable years, and could increase our future U.S. tax expense. The foregoing items, as well as any other future changes in tax laws, could have a material adverse effect on our business, cash flow, financial condition, or results of operations. In addition, it is uncertain if and to what extent various states will conform to the Tax Cuts and Jobs Act, the CARES Act, or any newly enacted federal tax legislation.

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 well as various non-U.S. jurisdictions. As a result, our effective tax rate is derived from a combination of applicable tax rates in the various jurisdictions that we operate. In preparing our financial statements, we estimate the amount of tax that will become payable in each jurisdiction. 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 and the CARES 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.

The exit of the U.K. from the EU, commonly referred to as "Brexit" could lead to regulatory divergence and require us to incur additional expenses in order to develop, manufacture, and commercialize our products and services.

Following the result of a referendum in 2016, the U.K. left the EU on January 31, 2020, commonly referred to as "Brexit." Pursuant to the formal withdrawal arrangements agreed between the U.K. and the EU, the U.K. was subject to a transition period until December 31, 2020 (the "Transition Period"), during which EU rules continued to apply. A deal that outlines the future trading relationship between the U.K. and the EU was agreed in December 2020 and has been approved by each EU member state and the U.K.

While the deal provides for, in most cases, tariff-free trade of goods between the U.K. and the EU, there are additional non-tariff costs to such trade which did not exist prior to the end of the Transition Period. For example, a UKCA mark will be required to sell medical devices to customers in Great Britain, rather than a CE mark.

Should the U.K. or Great Britain further diverge from the EU from a regulatory perspective (for example, by not mirroring the provisions of the IVDR), tariffs could be put into place in the future. We could therefore, both now and in the future, face significant additional expenses (when compared to the position prior to the end of the Transition Period) to operate our business, which could significantly and materially harm or delay our ability to generate revenue or achieve profitability of our business. Any further changes in international trade, tariff and import/export regulations as a result of Brexit or otherwise may impose unexpected duty costs or other non-tariff barriers on us. These developments, or the perception that any of them could occur, may significantly reduce global trade and, in particular, trade between the impacted nations and the U.K. It is also possible that Brexit may negatively affect our ability to attract and retain employees, particularly those from the EU.

Intellectual Property Risks

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. In order to avoid infringing these third-

party patents, we may find it necessary 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 U.S. 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 U.S. 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 U.S. 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 a 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") 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 U.S., the first to invent the claimed invention was entitled to the patent, while outside the U.S., the first to file a patent application was entitled to the patent. On or after March 16, 2013, under the AIA, the U.S. 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 U.S. 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 are 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 U.S. 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 U.S. 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 U.S., 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 U.S., 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 2038, 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 2041. In addition, although upon issuance in the U.S., 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 U.S. 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 U.S. 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 U.S. 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 U.S. allow for various post-grant opposition proceedings, such as *inter partes* review proceedings, providing additional methods for others to challenge our patents. 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 U.S., 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 U.S. 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 or the products of our competitors. 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 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 enforce our 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 U.S. can be less extensive than those in the U.S. 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 U.S. 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 U.S., and many companies have encountered significant challenges in establishing and enforcing their proprietary rights outside of the U.S. 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 U.S. 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 EU 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 U.S. 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 U.S. 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 products. 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.

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.

Financial and Market Risks and Risks Related to Owning Our Common Stock

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 June 30, 2021, we had approximately $11.5 million in customer deposits, including $10.5 million from one customer. However, as of that date, we had $328.9 million of cash and cash equivalents, and short-term investments. 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. When a customer that has prepaid us for future services cancels its contract with us, reduces the level of services that it expects to receive, or we determine that a prepayment is no longer necessary, we will repay that customer's deposit. 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.

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. Our ability to raise additional capital may be adversely impacted by potential worsening global economic conditions and the recent disruption to and volatility in the credit and financial markets in the U.S. and worldwide resulting from the ongoing COVID-19 pandemic. 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, and short-term investments 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 revenue from commercial sales to adequately fund our operating needs or achieve or sustain profitability.

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, as our largest customer;
- 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;
- the long-term macroeconomic effects of the COVID-19 pandemic, including potential global, regional or national economic slowdowns, recessions, depressions or other economic downturns; 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, including very recently in connection with the ongoing COVID-19 pandemic, which has resulted in depressed stock prices for many companies notwithstanding the lack of a fundamental change in their underlying business models or prospects. 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 revenue 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 revenue 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 MVP and other large customers are not obliged to deliver tissue samples or other specimens to us at any particular time or at all. The rate at which we receive tissue samples or other specimens can vary dramatically from quarter to quarter, and is difficult or impossible for us to accurately forecast. Our receipt and processing of tissue samples and other specimens 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 revenue from quarter to quarter. For example, we often see fluctuations in receipt and processing of samples and revenue in the fourth quarter due, in part, to the concentration of holidays in late November and in December, and some of our biopharmaceutical customers have fiscal years ending in December, which we believe may impact the timing of samples or payments provided by such customers. 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.

Acting together, our directors, executive officers and their affiliates, and holders of greater than five percent of our outstanding common stock are able to exercise significant influence over our management and affairs and matters requiring stockholder approval, including the election of directors and approval of significant corporate transactions, such as mergers, consolidations or the sale of substantially all of our 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.

Sales of a substantial number of shares of our common stock into the public market, including sales by members of our management or board of directors or entities affiliated with such members, could occur at any time. These sales, or the perception in the market that the holders of a large number of shares intend to sell shares, could reduce the market price of our common stock and could impair our ability to raise capital through the sale of additional equity or equity-related securities. We are unable to predict the effect that such sales may have on the prevailing market price of our common stock. As of June 30, 2021, we had 44,209,968 shares of common stock outstanding, all of which shares were eligible as of such date for sale in the public market, subject in some cases to the volume limitations and manner of sale and other requirements under Rule 144. In addition, upon issuance, shares of common stock subject to outstanding options under our stock option plans as of June 30, 2021 will become eligible for sale in the public market in the future, subject to certain legal and contractual limitations. Moreover, certain holders of shares of our common stock 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.

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, rights to purchase 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, rights to purchase 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. In addition, 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.

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

As of December 31, 2020, we had federal and state net operating loss carryforwards of approximately $159.2 million and approximately $112.7 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, as modified by the CARES Act, federal net operating losses incurred in tax years beginning in 2018 and in future years may be carried forward indefinitely, but the deductibility of such federal net operating losses for tax years beginning after 2020 is limited. It is uncertain if and to what extent various states will conform to the Tax Cuts and Jobs Act, as modified by the CARES 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 have experienced ownership changes in the past, and 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 could harm our future operating results by effectively increasing our future tax obligations. In addition, for California income tax purposes, California net operating losses and California research tax credits will be suspended and limited, respectively, for tax years beginning after 2019 but before 2023.

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 U.S. 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 that is 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. Furthermore, Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all such Securities Act actions. Accordingly, both state and federal courts have jurisdiction to entertain such claims. To prevent having to litigate claims in multiple jurisdictions and the threat of inconsistent or contrary rulings by different courts, among other considerations, our amended and restated certificate of incorporation further provides that the federal district courts of the U.S. will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act. While the Delaware courts have determined that such choice of forum provisions are facially valid, a stockholder may nonetheless seek to bring a claim in a venue other than those designated in the exclusive forum provisions. In such instance, we would expect to vigorously assert the validity and enforceability of the exclusive forum provisions of our amended and restated certificate of incorporation. This may require significant additional costs associated with resolving such action in other jurisdictions, and there can be no assurance that the provisions will be enforced by a court in those other jurisdictions.

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 further significant additional costs associated with resolving the dispute in other jurisdictions, all of which could seriously harm our business.

The requirements of being a public company consume substantial resources, may result in litigation and may 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 may be required 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.

As a public company, it may be increasingly 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 have reduced strategic flexibility as compared to our competitors that are privately-held companies, and are 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.

Our status as an emerging growth company will end on December 31, 2021, because we will qualify as a "large accelerated filer" as of such date since we had at least $700 million of equity securities held by non-affiliates on June 30, 2021.

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 an emerging growth 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 the 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 U.S. 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 implemented additional procedures to remediate this material weakness, however, we cannot assure you that these or other measures will prevent future material weaknesses from occurring. Remediation of the material weakness involved hiring a Chief Financial Officer in March 2019 and four additional accounting resources in the second, third, and fourth 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.

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

None.

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

Not applicable.

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	Inline XBRL Document Set for the condensed consolidated financial statements and accompanying notes in Part I, Item 1, “Financial Statements” of this Quarterly Report on Form 10-Q.				
104	Inline XBRL for the cover page of this Quarterly Report on Form 10-Q, included in the Exhibit 101 Inline XBRL Document Set.				

† 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: August 4, 2021

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)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

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

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

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

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

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

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

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

Date: August 4, 2021

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)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

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

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

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

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

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

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

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

Date: August 4, 2021

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 June 30, 2021 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: August 4, 2021

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 June 30, 2021 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: August 4, 2021

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