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, 2022

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 28, 2022 was 45,918,389.

PERSONALIS, INC.

Form 10-Q
For the Quarterly Period Ended June 30, 2022

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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 and products;
- 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 ongoing 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 services and products to new customers;
- our ability to establish and maintain intellectual property protection for our services and 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;
- expectations regarding our relationship with the U.S. Department of Veterans Affairs’ Million Veteran Program; 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, 2022	December 31, 2021
Assets		
Current assets		
Cash and cash equivalents	$ 86,731	$ 105,585
Short-term investments	146,759	181,479
Accounts receivable, net	12,877	18,468
Inventory and other deferred costs	7,885	5,610
Prepaid expenses and other current assets	5,788	7,089
Total current assets	260,040	318,231
Property and equipment, net	47,585	19,650
Operating lease right-of-use assets	45,915	53,822
Other long-term assets	4,439	4,825
Total assets	$ 357,979	$ 396,528
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable	$ 21,395	$ 9,221
Accrued and other current liabilities	19,755	18,110
Contract liabilities	356	3,982
Total current liabilities	41,506	31,313
Long-term operating lease liabilities	51,836	52,797
Other long-term liabilities	5	2,117
Total liabilities	93,347	86,227
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; 45,891,458 and 44,904,512 shares issued and outstanding at June 30, 2022 and December 31, 2021, respectively	5	4
Additional paid-in capital	568,741	557,558
Accumulated other comprehensive loss	(1,264)	(166)
Accumulated deficit	(302,850)	(247,095)
Total stockholders' equity	264,632	310,301
Total liabilities and stockholders' equity	$ 357,979	$ 396,528

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,	
	2022	2021	2022	2021
Revenue	$ 18,240	$ 21,670	$ 33,467	$ 42,551
Costs and expenses				
Cost of revenue	13,959	13,502	24,908	26,956
Research and development	16,288	11,687	33,386	21,183
Selling, general and administrative	15,874	11,428	31,360	21,849
Total costs and expenses	46,121	36,617	89,654	69,988
Loss from operations	(27,881)	(14,947)	(56,187)	(27,437)
Interest income	349	103	493	198
Interest expense	(50)	(65)	(109)	(65)
Other income (expense), net	50	(36)	69	(48)
Loss before income taxes	(27,532)	(14,945)	(55,734)	(27,352)
Provision for income taxes	14	8	21	5
Net loss	$ (27,546)	$ (14,953)	$ (55,755)	$ (27,357)
Net loss per share, basic and diluted	$ (0.60)	$ (0.34)	$ (1.23)	$ (0.63)
Weighted-average shares outstanding, basic and diluted	45,637,838	43,960,794	45,316,795	43,113,195

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,	
	2022	2021	2022	2021
Net loss	$ (27,546)	$ (14,953)	$ (55,755)	$ (27,357)
Other comprehensive income (loss), net of tax				
Foreign currency translation adjustment	(194)	19	(202)	21
Change in unrealized gain (loss) on available-for-sale debt securities	(195)	4	(896)	(25)
Comprehensive loss	$ (27,935)	$ (14,930)	$ (56,853)	$ (27,361)

See notes to condensed consolidated financial statements.

PERSONALIS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY (unaudited)
For the Three Months Ended June 30, 2022 and 2021
(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, 2022	45,250,087	$ 5	$ 562,889	$ (875)	$ (275,304)	$ 286,715
Proceeds from exercise of stock options	195,839	—	463	—	—	463
Proceeds from ESPP purchases	204,775	—	974	—	—	974
Restricted stock units vested	240,757	—	—	—	—	—
Stock-based compensation	—	—	4,415	—	—	4,415
Foreign currency translation adjustment	—	—	—	(194)	—	(194)
Unrealized loss on available-for-sale debt securities	—	—	—	(195)	—	(195)
Net loss	—	—	—	—	(27,546)	(27,546)
Balance—June 30, 2022	45,891,458	$ 5	$ 568,741	$ (1,264)	$ (302,850)	$ 264,632
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 ESPP 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

See notes to condensed consolidated financial statements.

PERSONALIS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY (unaudited)
For the Six Months Ended June 30, 2022 and 2021
(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, 2021	44,904,512	$ 4	$ 557,558	$ (166)	$ (247,095)	$ 310,301
Proceeds from exercise of stock options	475,044	1	978	—	—	979
Proceeds from ESPP purchases	204,775	—	974	—	—	974
Restricted stock units vested	307,127	—	—	—	—	—
Stock-based compensation	—	—	9,231	—	—	9,231
Foreign currency translation adjustment	—	—	—	(202)	—	(202)
Unrealized loss on available-for-sale debt securities	—	—	—	(896)	—	(896)
Net loss	—	—	—	—	(55,755)	(55,755)
Balance—June 30, 2022	45,891,458	$ 5	$ 568,741	$ (1,264)	$ (302,850)	$ 264,632
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 ESPP 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

See notes to condensed consolidated financial statements.

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

	Six Months Ended June 30,	
	2022	**2021**
Cash flows from operating activities:		
Net loss	$ (55,755)	$ (27,357)
Adjustments to reconcile net loss to net cash used in operating activities		
Stock-based compensation expense	9,231	6,657
Depreciation and amortization	3,594	2,909
Noncash operating lease cost	2,443	856
Amortization of premium on short-term investments	481	1,012
Other	19	71
Changes in operating assets and liabilities		
Accounts receivable	5,591	(2,928)
Inventory and other deferred costs	(2,276)	(1,682)
Prepaid expenses and other assets	2,144	(4,991)
Accounts payable	80	(75)
Accrued and other current liabilities	(165)	(1,390)
Contract liabilities	(3,626)	(9,573)
Operating lease liabilities	(45)	(819)
Other long-term liabilities	(422)	(364)
Net cash used in operating activities	(38,706)	(37,674)
Cash flows from investing activities:		
Purchases of available-for-sale debt securities	(90,060)	(206,672)
Proceeds from maturities of available-for-sale debt securities	123,405	76,508
Proceeds from sales of available-for-sale debt securities	—	5,059
Purchases of property and equipment	(18,944)	(4,544)
Lease incentive cash receipts	5,459	—
Net cash provided by (used in) investing activities	19,860	(129,649)
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	(1,857)	(815)
Proceeds from exercise of equity awards	1,952	2,591
Net cash provided by financing activities	95	168,859
Effect of exchange rates on cash, cash equivalents and restricted cash	(103)	19
Net change in cash, cash equivalents and restricted cash	(18,854)	1,555
Cash, cash equivalents, and restricted cash, beginning of period	107,375	68,525
Cash, cash equivalents and restricted cash, end of period	$ 88,521	$ 70,080
Reconciliation of cash, cash equivalents and restricted cash to the condensed consolidated balance sheets:		
Cash and cash equivalents	$ 86,731	$ 70,080
Restricted cash, included in other long-term assets	1,790	—
Total cash, cash equivalents and restricted cash	$ 88,521	$ 70,080

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 provider of advanced genetic tests for cancer. The Company also provides sequencing and data analysis services to support population sequencing initiatives. The Company's genetic tests for cancer 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 in 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 service and product development and sales and marketing efforts. The Company's activities have been financed to date primarily through the sale of its 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 (the "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, 2021.

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, 2022.

Use of Estimates

The preparation of 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 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, discount rates for lease accounting, 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 consolidated financial position and results of operations.

Follow-On and At-the-Market Equity Offerings

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.

On December 30, 2021, the Company entered into an At-the-Market Sales Agreement (the "Sales Agreement") with BTIG, LLC ("BTIG") under which it may offer and sell its common stock having aggregate sales proceeds of up to $100.0 million from time to time through BTIG as its sales agent. BTIG will use commercially reasonable efforts to sell the Company's common stock from time to time, based upon instructions from the Company (including any price, time or size limits or other customary parameters or conditions the Company may impose). The Company will pay BTIG a commission of up to 3% of the gross sales proceeds of any common stock sold through BTIG under the Sales Agreement. The Company is not obligated to make any sales of common stock under the Sales Agreement. No shares of the Company's common stock have been offered or sold under the Sales Agreement.

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, 2022 and December 31, 2021. 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, 2022	December 31, 2021
	2022	2021	2022	2021		
Natera, Inc.	38%	*	33%	*	28%	39%
U.S. Department of Veterans Affairs Million Veteran Program (the "VA MVP")	22%	62%	23%	63%	*	*
Pfizer Inc.	*	15%	*	14%	20%	*
AbbVie Inc.	*	*	*	*	*	18%
Merck & Co., Inc.	*	*	*	*	21%	15%

* 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 next-generation cancer therapies and to support large-scale genetic research programs. 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 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 processing 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. Treasury bills, 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, U.S. Treasury bills, and non-U.S. Government notes.

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 liability (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 12 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, 2022, 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 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 plus any direct costs from executing the leases and any lease prepayments. 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. Fixed lease payments are recognized as an expense on a straight-line basis over the lease term. Variable lease costs are amounts owed by us to a lessor that are not fixed, such as reimbursement for common area maintenance, operating expenses, utilities, or other costs that are subject to fluctuation from period to period. The Company has also elected to include expenses related to leases with a term of one month or less in the short-term lease cost disclosure.

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. The Company is currently evaluating the impact of the new guidance on its consolidated financial statements and related disclosures. The Company will adopt the new guidance in the first quarter of 2023 by means of a cumulative-effect adjustment to opening retained earnings.

Note 3. Revenue

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
VA MVP	$ 4,055	$ 13,507	$ 7,556	$ 26,717
All other customers	14,185	8,163	25,911	15,834
Total revenue	$ 18,240	$ 21,670	$ 33,467	$ 42,551

Revenue from countries outside of the United States, based on the billing addresses of customers, represented approximately 6% of the Company's revenue for the three months ended June 30, 2022 and 2021, and approximately 11% and 7% for the six months ended June 30, 2022 and 2021, respectively.

Contract Assets and Liabilities

Contract assets as of June 30, 2022 and December 31, 2021 were immaterial.

Amounts collected in advance of services being provided are deferred as current liabilities in the condensed consolidated balance sheets. The associated revenue is recognized and the contract liability is reduced as the contracted services are subsequently performed. The balance of contract liabilities was $0.4 million and $4.0 million as of June 30, 2022 and December 31, 2021, respectively. Revenue recognized for the three months ended June 30, 2022 and 2021 that were included in the contract liability balance at the beginning of each reporting period were $3.0 million and $9.8 million, respectively. Revenue recognized for the six months ended June 30, 2022 and 2021 that were included in the contract liability balance at the beginning of each period were $3.6 million and $18.9 million, respectively.

Note 4. Balance Sheet Details

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

	June 30, 2022	December 31, 2021
Raw materials	$ 6,507	$ 4,081
Other deferred costs	1,378	1,529
Total inventory and other deferred costs	$ 7,885	$ 5,610

Property and equipment. Depreciation and amortization expense for the three months ended June 30, 2022 and 2021 was $1.8 million and $1.4 million, respectively, and for the six months ended June 30, 2022 and 2021 was $3.6 million and $2.9 million, respectively. Accumulated depreciation and amortization was $22.6 million and $19.0 million as of June 30, 2022 and December 31, 2021, respectively.

Restricted cash. The Company's restricted cash is pledged as collateral for a standby letter of credit related to a property lease. The balance of restricted cash was $1.8 million as of June 30, 2022 and December 31, 2021, and is included in other long-term assets.

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

	June 30, 2022	December 31, 2021
Accrued compensation	$ 7,882	$ 10,673
Operating lease liabilities	4,640	3,728
Accrued liabilities	4,720	883
Loans—current portion (Note 6)	1,745	1,806
Employee ESPP contributions	232	517
Accrued taxes	506	121
Customer deposits	30	382
Total accrued and other current liabilities	$ 19,755	$ 18,110

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, 2022 and December 31, 2021 (in thousands):

	June 30, 2022				
	Adjusted Cost	Unrealized Gains	Unrealized Losses	Fair Value	Fair Value Level
Assets					
Cash and cash equivalents:					
Cash	$ 10,172	$ —	$ —	$ 10,172	
Money market funds	32,069	—	—	32,069	Level 1
Commercial paper	40,504	—	(5)	40,499	Level 2
U.S. government securities	3,991	—	—	3,991	Level 2
Total cash and cash equivalents	86,736	—	(5)	86,731	
Short-term investments:					
Commercial paper	25,405	—	(41)	25,364	Level 2
Non-U.S. government securities	3,007	—	(6)	3,001	Level 2
U.S. agency securities	17,516	—	(173)	17,343	Level 2
U.S. government securities	101,937	—	(886)	101,051	Level 2
Total short-term investments	147,865	—	(1,106)	146,759	
Total assets measured at fair value	$ 234,601	$ —	$ (1,111)	$ 233,490	

	December 31, 2021				
	Adjusted Cost	Unrealized Gains	Unrealized Losses	Fair Value	Fair Value Level
Assets					
Cash and cash equivalents:					
Cash	$ 6,094	$ —	$ —	$ 6,094	
Money market funds	49,488	—	—	49,488	Level 1
Commercial paper	50,005	—	(2)	50,003	Level 2
Total cash and cash equivalents	105,587	—	(2)	105,585	
Short-term investments:					
Asset-backed securities	75,787	—	(154)	75,633	Level 2
Commercial paper	18,068	—	(2)	18,066	Level 2
Corporate debt securities	18,059	—	(7)	18,052	Level 2
U.S. agency securities	19,738	—	(35)	19,703	Level 2
U.S. government securities	50,040	—	(15)	50,025	Level 2
Total short-term investments	181,692	—	(213)	181,479	
Total assets measured at fair value	$ 287,279	$ —	$ (215)	$ 287,064	

Realized gains or losses on marketable debt securities are immaterial for the periods presented. No security has been in an unrealized loss position for 12 months or greater, except for a limited number of securities with insignificant combined unrealized losses. The Company has 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, 2022, 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, 2022 have maturities due in one year or less, except for debt securities with an aggregate cost basis of $6.0 million and fair value of $5.8 million that have maturities ranging from 13 to 15 months.

Note 6. Loans

Equipment and Software Loans

In April 2021, the Company entered into a payment agreement with a financing entity to finance the purchase of $2.4 million of 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 $1.0 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, 2022 was $0.1 million. Amounts outstanding under the payment agreements are as follows (in thousands):

	June 30, 2022	December 31, 2021
Principal	$ 1,857	$ 3,714
Less: unamortized discount	(112)	(220)
Total carrying amount	1,745	3,494
Less: current portion (included in accrued and other current liabilities)	(1,745)	(1,806)
Long-term portion (included in other long-term liabilities)	$ —	$ 1,688

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 fair market rent. 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.

In August 2021, the Company entered into a noncancelable operating lease for approximately 100,000 square feet of space in Fremont, California to be used as the Company's future corporate headquarters and expanded laboratory facility. The lease term is 13.5 years and commenced in June 2022. The Company gained early access to the premises upon entering the lease for the purpose of constructing and installing tenant improvements, for which the landlord has agreed to contribute up to approximately $15.5 million, $5.5 million of which has been received through June 30, 2022. Such contributions become payable only upon approval by the landlord of applications for payment and are accounted for as lease incentives once the Company has incurred costs and the amounts qualify for reimbursement by the landlord. The lease incentives are then recognized as reductions to lease expense over the remainder of the lease term. The lease expires on November 30, 2035 and includes two options to extend the term for a period of five-years per option with rent payments equal to fair market rent. The Company determined the extension options are not reasonably certain to be exercised. The lease also contains escalating rent payments.

The Company also has a noncancelable operating lease for approximately 5,100 square feet of space in Shanghai, China used for its China operations, which expires on June 30, 2024, as well as various other short-term leases.

Components of lease cost were as follows (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
Lease cost				
Operating lease cost	$ 2,174	$ 769	$ 4,348	$ 1,421
Short-term lease cost	8	192	37	262
Variable lease cost	385	165	646	394
Total lease cost	$ 2,567	$ 1,126	$ 5,031	$ 2,077

As of June 30, 2022, the Company's operating leases had a weighted-average remaining lease term of 12.0 years and a weighted-average discount rate of 6.6%. 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, 2022 were as follows (in thousands):

	Amount
2022 (remaining six months)	$ 1,980
2023	6,194
2024	6,802
2025	7,001
2026	7,217
2027 and thereafter	53,527
Total future minimum lease payments	82,721
Less: imputed interest	(26,245)
Present value of future minimum lease payments	56,476
Less: current portion of operating lease liability	(4,640)
Long-term operating lease liabilities	$ 51,836

Cash paid for operating lease liabilities, included in cash flows from operating activities in the condensed consolidated statements of cash flows, for the six months ended June 30, 2022 and 2021, was $1.9 million and $1.4 million, respectively. Right-of-use assets obtained in exchange for new operating lease liabilities during the six months ended June 30, 2022 and 2021 were zero and $1.7 million, respectively.

Note 8. Stock-Based Compensation

Shares of common stock reserved for issuance under the Company's equity incentive plans were as follows:

	June 30, 2022
Outstanding stock awards	6,600,147
Reserved for future award grants	4,456,303
Reserved for future ESPP	827,618
Total common stock reserved for stock awards	11,884,068

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, 2022 was 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, 2021	5,002,419	$ 10.66	6.89	$ 28,308
Options granted	221,601	6.31		
Options exercised	(475,044)	2.06		
Options forfeited or expired	(118,396)	13.92		
Balance—June 30, 2022	4,630,580	$ 11.25	6.72	$ 550
Options vested and exercisable as of June 30, 2022	2,967,710	$ 8.33	5.81	$ 549

The weighted-average grant date fair value of options granted was $3.19 and $12.34 per share for the three months ended June 30, 2022 and 2021, and $3.99 and $13.55 per share for the six months ended June 30, 2022 and 2021, respectively. As of June 30, 2022, the unrecognized stock-based compensation cost of unvested options was $14.3 million, which is expected to be recognized over a weighted-average period of 2.1 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,	
	2022	2021	2022	2021
Expected term (in years)	5.50 - 6.08	5.50 - 6.27	5.50 - 6.08	5.50 - 6.27
Volatility	69.70 - 71.56%	69.39 - 69.90%	68.37 - 71.56%	68.06 - 69.90%
Risk-free interest rate	2.82 - 3.39%	0.94 - 1.06%	1.62 - 3.39%	0.62 - 1.06%
Dividend yield	–%	–%	–%	–%

Performance-Based Stock Option Activity

No performance-based stock option activity occurred during the six months ended June 30, 2022. As of June 30, 2022, stock options for 421,000 shares with an exercise price of $5.10 and a remaining contractual term of 7.71 years remained outstanding. The stock options are fully vested and exercisable and had no intrinsic value as of June 30, 2022.

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, 2022 was 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, 2021	1,679,696	$ 16.35	$ 23,969
RSUs granted	232,015	6.65	
RSUs vested	(307,127)	14.93	1,621
RSUs forfeited	(56,017)	17.35	
Balance—June 30, 2022	1,548,567	$ 15.14	$ 5,343

As of June 30, 2022, the unrecognized stock-based compensation cost of unvested RSUs was $21.3 million, which is expected to be recognized over a weighted-average period of 2.5 years.

ESPP Activity and Valuation

During the six months ended June 30, 2022 and 2021, 204,775 and 57,001 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,	
	2022	2021
Expected term (in years)	0.50	0.49
Volatility	82.35%	74.88%
Risk-free interest rate	1.49%	0.04%
Dividend yield	–%	–%
Grant-date fair value per share	$ 2.23	$ 8.21

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,	
	2022	2021	2022	2021
Stock options	$ 2,008	$ 2,325	$ 4,404	$ 4,503
RSUs	2,227	1,011	4,395	1,655
ESPP	180	264	432	499
Total stock-based compensation expense	$ 4,415	$ 3,600	$ 9,231	$ 6,657

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
Cost of revenue	$ 445	$ 332	$ 903	$ 620
Research and development	1,319	900	2,660	1,628
Selling, general and administrative	2,651	2,368	5,668	4,409
Total stock-based compensation expense	$ 4,415	$ 3,600	$ 9,231	$ 6,657

Note 9. Commitments and Contingencies

Contingencies

On August 2, 2022, the Company filed a complaint in the U.S. District Court for the District of Colorado against Foresight Diagnostics Inc. ("Foresight") for patent infringement. The complaint is based on the Company's U.S. Patent No. 10,450,611 (the "'611 Patent"), entitled "Personalized Genetic Testing," our U.S. Patent No. 11,299,783 (the "'783 Patent"), entitled "Methods and Systems For Genetic Analysis," and our U.S. Patent No. 11,384,394 (the "'394 Patent"), entitled "Methods and Systems for Genetic Analysis." The '611 Patent was granted on October 22, 2019 and relates to methods for personalized genetic testing by performance of sequencing assays on biological samples. The '783 Patent was granted on April 12, 2022 and relates to methods for sample processing and data analysis by performance of sequencing assays on biological samples that can aid in the diagnosis, monitoring, treatment, and prevention of one or more diseases. The '394 Patent was granted on July 12, 2022 and relates to methods for sample

processing and analysis to aid in the diagnosis, monitoring, treatment, and prevention of disease. The Company is seeking remedies including injunctive relief, damages and costs.

Litigation is inherently unpredictable, and, except for events that have already occurred, it is too early in the foregoing proceedings to predict the outcome of these proceedings, or any impact they may have on us. As such, the estimated financial effect associated with this complaint cannot be made as of the date of filing of this Quarterly Report on Form 10-Q. Litigation is a significant ongoing expense with an uncertain outcome and may in the future be a material expense for us. Management believes this investment is important to protect our intellectual property position, even recognizing the uncertainty of the outcome.

The Company is also subject to claims and assessments from time to time in the ordinary course of business. Accruals for litigation and loss 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, 2022, the Company was not involved in any material adverse 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 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 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,	
	2022	2021	2022	2021
Net loss	$ (27,546)	$ (14,953)	$ (55,755)	$ (27,357)
Weighted-average common shares outstanding—basic and diluted	45,637,838	43,960,794	45,316,795	43,113,195
Net loss per common share—basic and diluted	$ (0.60)	$ (0.34)	$ (1.23)	$ (0.63)

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,	
	2022	2021	2022	2021
Options to purchase common stock	5,051,580	5,646,214	5,051,580	5,646,214
Unvested RSUs	1,548,567	985,446	1,548,567	985,446
ESPP	125,613	69,380	125,613	69,380
Total	6,725,760	6,701,040	6,725,760	6,701,040

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, 2021 filed with the Securities and Exchange Commission (the "SEC") on February 24, 2022 (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

Personalis' strategy is to develop some of the world's most advanced genetic tests for cancer. Today our tests are routinely used by many of the largest oncology-focused pharmaceutical companies for analysis of patient samples from their clinical trials. More recently, we have also begun to work with a growing number of leading cancer centers for clinical diagnostic use of our tests. We believe that adoption and publication by these key opinion leaders will advance standard of care for cancer patients and drive eventual broad use clinically. We believe that our tests can meaningfully improve outcomes for cancer patients, and estimate that an annual market opportunity of approximately $30 billion could materialize in the U.S. in the future.

Recent updates specific to our planned entrance into the clinical diagnostic market follows in the next four paragraphs.

In December 2021, we launched NeXT Personal, a next-generation, liquid biopsy test designed to detect and quantify minimal residual disease ("MRD") and recurrence in patients previously diagnosed with cancer. NeXT Personal is designed to deliver industry-leading MRD sensitivity down to the 1 part-per-million range, an approximately 10- to 100-fold improvement over other available technologies. NeXT Personal leverages whole genome sequencing of a patient's tumor to identify up to 1,800 specially-selected somatic variants that are subsequently used to create a personalized liquid biopsy panel for each patient. We believe this enables earlier detection across a broader variety of cancers and stages, including typically challenging early stage, low mutational burden, and low-shedding cancers. NeXT Personal is also designed to simultaneously detect and quantify clinically relevant mutations in ctDNA that may be used in the future to help guide therapy, when cancer is detected. These include known targetable cancer mutations, drug resistance mutations, and new variants which can emerge and change over time, especially under therapeutic pressure. We consider this approach not just "tumor-informed", but "comprehensively tumor-informed". Our ultimate goal is not just to detect cancer, but to provide key information that is actionable by oncologists over the entire course of the patient's disease. We believe this can be better for patients, more informative for pharmaceutical customers, and a larger business opportunity for us. NeXT Personal is currently available as a research use only ("RUO") test and has not yet been validated as a laboratory developed test ("LDT"). In other words, NeXT Personal is not yet offered directly to cancer patients. Certain pharmaceutical customers have ordered NeXT Personal as an RUO test and we have generated revenue upon delivery of these tests.

Early in 2020, we launched NeXT Dx Test, a comprehensive genomic solid tumor test that enables physicians to identify potential therapies, evidence of drug resistance, and clinical trial options for cancer patients. Our NeXT Dx Test is one of the first cancer diagnostic platforms to profile approximately 20,000 genes in both the tumor exome and transcriptome, providing a comprehensive genomic testing solution that goes beyond many existing cancer diagnostic panels that focus on a few hundred genes. The NeXT Dx Test includes advanced analytics to provide a diagnostic report on genetic alterations in medically important cancer genes, as well as emerging immunotherapy composite biomarkers of medical importance. Immunotherapy-related biomarkers such as microsatellite instability ("MSI") status and tumor mutational burden ("TMB") are included in the clinical report. We are currently in the process of completing a validation study on an updated version of NeXT Dx as a clinical test and anticipate revenue from this test in the second half of 2022. We plan to submit data to the Palmetto MolDx technology assessment process and anticipate a favorable reimbursement ruling from MolDx in early 2023.

An important component of our commercial strategy is to work with world-class medical institutions. To that end, in the fourth quarter of 2021, we announced a collaboration with the Mayo Clinic and in the first quarter of 2022, we announced one with the Moores Cancer Center at UC San Diego Health. We entered these collaborations to provide clinical diagnostic testing and analysis services using our tissue-based NeXT Dx Test and may also use our liquid biopsy NeXT Personal test in the future. We have begun to test clinical patient samples from the Moores Cancer Center at UC San Diego Health, and are excited about the opportunity to work with these renowned cancer centers. Given the advanced nature of our NeXT Dx Test, we believe it is a good fit for high-end cancer centers, which have a dual mandate for both clinical care and research. If these key opinion leaders have a positive experience using our tests, we are optimistic that this will also support broader use of our platform by other clinicians in the future.

Additionally, we have initiated the hiring of a national clinical sales force that plans to actively engage with oncologists and surgeons at academic medical centers and community oncology practices. We also have begun building out critical support functions for our clinical testing business, such as customer service and billing.

We have the capacity to sequence and analyze approximately 200 trillion bases of DNA per week in our facility. We believe that capacity is already larger than most cancer genomics companies, and we continue to build automation and other infrastructure to

scale further as demand increases and in support of our NeXT Liquid Biopsy, NeXT Dx Test and NeXT Personal offerings. To date, we have sequenced more than 260,000 human samples, of which more than 150,000 were whole human genomes.

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 Million Veteran Program (the "VA MVP"), which has enabled us to innovate, scale our operational infrastructure, and achieve greater efficiencies in our lab. The VA MVP is the largest population sequencing effort in the United States and we have delivered over 150,000 whole human genome sequence datasets to the VA MVP to date. The cumulative value of orders received from the VA MVP since inception is $185.7 million, all of which we had recognized as revenue as of June 30, 2022. In September 2021, we received a task order from the VA MVP with a value of $9.7 million, which was significantly less than in prior years. At that time, we expected the reduced order amount to be followed by a formal request for proposal ("RFP") process and a potential new contract to be awarded sometime late in the third quarter of 2022. We are aware that the VA MVP recently initiated a request for information process seeking potential sources to provide high-throughput whole genome sequencing services, and that the VA MVP more recently issued a pre-solicitation notice announcing its intent to award a firm-fixed price, requirements contract for such services. However, we are not certain whether there will be a RFP process in 2022, and the pre-solicitation notice does not obligate the VA MVP to issue a solicitation for proposals this year.

In August 2021, we announced that we will relocate our corporate headquarters from Menlo Park to a new facility in Fremont, California. We plan to begin moving into the new facility in the third quarter of this year. We signed a 13.5-year lease for the 100,000 square foot facility, which is approximately double the amount of space in our current Menlo Park location. The new facility is intended to allow for expansion of our laboratory for clinical testing to support biopharma customers, clinical diagnostic testing and pursuit of U.S. Food and Drug Administration (the "FDA") approval for our tests. In addition, the new space is intended to support the expansion of research and development efforts to bring leading edge products and services to the marketplace. The new facility will also provide more office space for our selling, general and administrative workforce.

Our operations have been impacted, and may be impacted in the future, by the ongoing COVID-19 pandemic. For example, the previous shelter-in-place order and health orders negatively impacted productivity, disrupted our business, and slowed research and development activities due to limited 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 COVID-19 pandemic has also disrupted, and may disrupt in the future, 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 have been delayed in sending us samples 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.

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 as the global COVID-19 pandemic continues to evolve and to present serious health risks. 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. The full extent of the impact of the COVID-19 pandemic on our business, operations and plans remains uncertain and will depend on future developments that cannot be predicted at this time. Such developments include the continued spread of the Omicron variant and subvariants in the U.S. and other countries and the potential emergence of other SARS-CoV-2 variants or subvariants that may prove especially contagious or virulent, the ultimate duration of the pandemic and the resulting impact on our business and other third parties with whom we do business, and the effectiveness of actions taken globally to contain and treat the disease.

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 tests with 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 services and products, advancing our operational infrastructure, expanding our international presence, building our regulatory credentials, and expanding our targeted marketing efforts. We sell through a small direct sales force. We also anticipate increasing our revenue in the future through entrance into the clinical diagnostics market and have begun building our regulatory, clinical, and reimbursement capabilities, including hiring a national clinical sales force.

Since 2018, we have derived a substantial portion of our revenue from sales of our DNA sequencing and data analysis services to the VA MVP. However, we currently do not anticipate deriving such substantial portions of our revenue from the VA MVP going forward.

We have one reportable segment from the sale of sequencing and data analysis services. Most 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, including additional costs associated with our future laboratory in Fremont, California. 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 services and products and costs related to conducting studies and collaborations with partners to validate the clinical utility of our offerings. These expenses consist primarily of personnel costs (salaries, bonuses, stock-based compensation, payroll taxes, and benefits), laboratory supplies and consumables, costs of processing 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.

We expense our research and development costs in the period in which they are incurred. We expect to increase our research and development expenses as we continue to develop new services and products and expand collaborations for clinical validation to secure reimbursement opportunities.

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 costs 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 expect general and administrative expenses to increase as we scale our operations and incur additional costs associated with ramping up our new headquarters facility in Fremont, California.

Interest Income and Interest Expense

Interest income consists primarily of interest earned on our cash and cash equivalents and short-term investments. Interest expense in 2022 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 exchange 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,	
	2022	2021	2022	2021
Revenue	$ 18,240	$ 21,670	$ 33,467	$ 42,551
Costs and expenses				
Cost of revenue	13,959	13,502	24,908	26,956
Research and development	16,288	11,687	33,386	21,183
Selling, general and administrative	15,874	11,428	31,360	21,849
Total costs and expenses	46,121	36,617	89,654	69,988
Loss from operations	(27,881)	(14,947)	(56,187)	(27,437)
Interest income	349	103	493	198
Interest expense	(50)	(65)	(109)	(65)
Other income (expense), net	50	(36)	69	(48)
Loss before income taxes	(27,532)	(14,945)	(55,734)	(27,352)
Provision for income taxes	14	8	21	5
Net loss	$ (27,546)	$ (14,953)	$ (55,755)	$ (27,357)
Net loss per share, basic and diluted	$ (0.60)	$ (0.34)	$ (1.23)	$ (0.63)
Weighted-average shares outstanding, basic and diluted	45,637,838	43,960,794	45,316,795	43,113,195

	June 30, 2022	December 31, 2021
Cash and cash equivalents, and short-term investments	$ 233,490	$ 287,064
Working capital	218,534	286,918
Total assets	357,979	396,528
Total debt	1,745	3,494
Long-term obligations	51,841	54,914
Total liabilities	93,347	86,227
Total stockholders' equity	264,632	310,301

Revenue

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

	Three Months Ended June 30,		Change	Six Months Ended June 30,		Change
	2022	2021		2022	2021	
VA MVP	$ 4,055	$ 13,507	(70%)	$ 7,556	$ 26,717	(72%)
All other customers	14,185	8,163	74%	25,911	15,834	64%
Total revenue	$ 18,240	$ 21,670	(16%)	$ 33,467	$ 42,551	(21%)

The following table shows concentration of revenue by customer:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
Natera, Inc.	38%	*	33%	*
VA MVP	22%	62%	23%	63%
Pfizer Inc.	*	15%	*	14%

* Less than 10% of revenue

VA MVP

The decreases of $9.5 million and $19.2 million in revenue from the VA MVP in the second quarter and first six months of 2022, respectively, compared to the same periods in 2021 were primarily due to a decrease in the volume of samples we tested in these periods. As of June 30, 2022, we have fulfilled all orders received from the VA MVP under the existing contract.

The recognition of significant revenue from the VA MVP in future periods is contingent on receipt of a new contract with the VA MVP and it may not award us a new contract. Further, the value of any such potential new contract may be lower than our historical contracted orders and/or the scope or nature of the services required under any new contract may change such that we are unable to serve the VA MVP in the future. The most recent order received from the VA MVP in September 2021 had a value of $9.7 million, which represented a substantial decline compared to orders received prior to that point. At that time, we expected the reduced order amount

to be followed by a formal RFP process and a potential new contract to be awarded sometime late in the third quarter of 2022. We are aware that the VA MVP recently initiated a request for information process seeking potential sources to provide high-throughput whole genome sequencing services, and that the VA MVP more recently issued a pre-solicitation notice announcing its intent to award a firm-fixed price, requirements contract for such services. However, we are not certain whether there will be a RFP process in 2022, and the pre-solicitation notice does not obligate the VA MVP to issue a solicitation for proposals.

All other customers

The increase of $6.0 million in revenue from all other customers in the second quarter of 2022 compared to the second quarter of 2021 was driven primarily by an increase of $6.5 million in revenue from Natera, Inc. ("Natera") due to increased sample receipts under our agreement to provide advanced tumor analysis for use in Natera's MRD testing offerings. This increase was partially offset by a $0.5 million decline in revenue from our pharmaceutical customers due to lower sample receipts during the quarter. Revenue derived from our NeXT Platform services and products, which includes revenue from Natera, was $10.9 million in the second quarter of 2022, compared to $5.0 million in the second quarter of 2021, an increase of $5.9 million.

The increase of $10.1 million in revenue from all other customers during the first six months of 2022 compared to the same period in 2021 was driven primarily by an increase of $10.4 million in revenue from Natera due to increased sample receipts during the period, partially offset by a $0.3 million decline in revenue from our pharmaceutical customers due to lower sample receipts during the period. Revenue derived from our NeXT Platform products, which includes revenue from Natera, was $18.7 million in the first six months of 2022, compared to $9.3 million in the first six months of 2021, an increase of $9.4 million.

Costs and Expenses

	Three Months Ended June 30,		Change	Six Months Ended June 30,		Change
	2022	2021		2022	2021	
	(in thousands)			(in thousands)		
Cost of revenue	$ 13,959	$ 13,502	3%	$ 24,908	$ 26,956	(8%)
Research and development	16,288	11,687	39%	33,386	21,183	58%
Selling, general and administrative	15,874	11,428	39%	31,360	21,849	44%
Total costs and expenses	$ 46,121	$ 36,617	26%	$ 89,654	$ 69,988	28%

Cost of revenue

The $0.5 million increase in cost of revenue in the second quarter of 2022 compared to the second quarter of 2021, despite lower revenue, was primarily due to higher fixed laboratory costs, including labor, equipment, and facilities costs. Higher indirect supplies costs also contributed to the increase as Natera and pharmaceutical customer orders require more supplies to process as compared to VA MVP orders. Specific components of the increase were a $1.2 million increase in laboratory supplies and consumables, a $0.8 million increase in labor costs due to higher headcount, a $0.7 million increase in depreciation and maintenance on lab equipment, and a $0.2 million increase in other costs, partially offset by a $2.4 million decrease in direct material costs due to a more favorable mix of customer orders during the period.

The $2.0 million decrease in cost of revenue in the first six months of 2022 compared to the same period in 2021 was primarily due to lower levels of revenue, partially offset by higher fixed laboratory costs, including labor, equipment, and facilities costs. Higher indirect supplies costs also contributed to the increase as Natera and pharmaceutical customer orders require more supplies to process as compared to VA MVP orders. Specific components of the decrease were a $6.0 million decrease in direct material costs due to lower revenue levels and a more favorable mix of customer orders during the period, a $1.0 million decrease in costs due to greater usage of our laboratory capacity for research and development activities, partially offset by a $2.0 million increase in labor costs due to higher headcount, a $1.8 million increase in laboratory supplies and consumables, and a $1.2 million increase in depreciation and maintenance on lab equipment.

Research and development

The increases of $4.6 million and $12.2 million in research and development expenses in the second quarter and first six months of 2022, respectively, compared to the same periods in 2021 were primarily due to new service and product development, increased hiring to build our clinical and medical infrastructure, and the cost of testing samples for clinical validation work.

Specific components of the $4.6 million increase in the second quarter of 2022 compared to the second quarter of 2021 were a $2.5 million increase in personnel-related costs primarily related to increased headcount, a $0.8 million increase in sample processing costs incurred in our laboratory for new service and product development, a $0.8 million increase in IT and fixed facilities costs, and a $0.5 million increase in depreciation and maintenance on research and development equipment.

Specific components of the $12.2 million increase in the first six months of 2022 compared to the same period in 2021 were a $6.4 million increase in personnel-related costs primarily related to increased headcount, a $3.4 million increase in sample processing

costs incurred in our laboratory for new service and product development, a $1.6 million increase in IT and fixed facilities costs, a $0.6 million increase in depreciation and maintenance on research and development equipment, and a $0.2 million increase in other costs.

Selling, general and administrative

The increases of $4.4 million and $9.5 million in selling, general and administrative expenses in the second quarter and first six months of 2022, respectively, compared to the same periods in 2021 were primarily due to expansion of our commercial and clinical diagnostics teams.

Specific components of the $4.4 million increase in the second quarter of 2022 compared to the second quarter of 2021 were a $2.1 million increase in personnel-related costs related to increased headcount, a $1.3 million increase in facilities costs driven by our new Fremont facility, a $0.7 million increase in professional services (including corporate insurance, audit fees, and legal expenses), and a $0.3 million increase in other sales-related activities such as travel.

Specific components of the $9.5 million increase in the first six months of 2022 compared to the same period in 2021 were a $4.9 million increase in personnel-related costs related to increased headcount, a $2.7 million increase in facilities costs driven by our new Fremont facility, and a $1.9 million increase in professional services (including corporate insurance, audit fees, and legal expenses).

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

	Three Months Ended June 30,		Change	Six Months Ended June 30,		Change
	2022	2021		2022	2021	
Interest income	$ 349	$ 103	239%	$ 493	$ 198	149%
Interest expense	(50)	(65)	(23%)	(109)	(65)	68%
Other income (expense), net	50	(36)		69	(48)	
Total	$ 349	$ 2		$ 453	$ 85	

Interest income and interest expense

The increases in interest income in the second quarter and first six months of 2022 compared to the same periods in 2021 were due to increased yields on our investments. Interest expense in all periods presented was the recognition of imputed interest on noninterest bearing loans.

Other income (expense), net

Other income (expense), net during the periods presented consisted mainly of foreign currency remeasurements.

Liquidity and Capital Resources

The following tables present selected financial information and cash flow information (in thousands):

	June 30, 2022	December 31, 2021
Cash and cash equivalents, and short-term investments	$ 233,490	$ 287,064
Property and equipment, net	47,585	19,650
Contract liabilities	356	3,982
Working capital	218,534	286,918

	Six Months Ended June 30,	
	2022	2021
Net cash used in operating activities	$ (38,706)	$ (37,674)
Net cash provided by (used in) investing activities	19,860	(129,649)
Net cash provided by financing activities	95	168,859

From our inception through June 30, 2022, we have funded our operations primarily from $279.0 million in net proceeds from our follow-on equity offerings in August 2020 and January 2021, $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 financings. As of June 30, 2022, we had cash and cash equivalents of $86.7 million and short-term investments of $146.8 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 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 ongoing 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. We filed a prospectus supplement in January 2022 pursuant to which we could offer and sell additional shares of our common stock up to an aggregate amount of $100.0 million through an at-the-market offering program. 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.

As of June 30, 2022, cash and cash equivalents held by foreign subsidiaries was $1.8 million. Our intent is to indefinitely reinvest funds held outside the United States and our current plans do not demonstrate a need to repatriate them to fund our domestic operations. However, if in the future, we encounter a significant need for liquidity domestically or at a particular location that we cannot fulfill through borrowings, equity offerings, or other internal or external sources, or the cost to bring back the money is not significant from a tax perspective, we may determine that cash repatriations are necessary or desirable. Repatriation could result in additional material taxes. These factors may cause us to have an overall tax rate higher than other companies or higher than our tax rates have been in the past.

During the six months ended June 30, 2022, cash used in operating activities of $38.7 million was a result of $55.8 million of net loss, partially reduced by non-cash expenses of $15.8 million (the most significant non-cash expenses were $9.2 million of stock-based compensation and $3.6 million depreciation and amortization) and a net positive change in working capital of $1.3 million (of which $5.6 million was due to collections of accounts receivable).

During the six months ended June 30, 2022, cash provided by investing activities was $19.9 million due to $33.3 million of net proceeds from short-term investments and $5.5 million cash receipts in connection with our Fremont facility lease incentives, partially offset by $18.9 million in property and equipment purchases. Cash provided by financing activities of $0.1 million during the same period consisted of $1.0 million proceeds from stock option exercises and $1.0 million proceeds from employee purchases under our ESPP, partially offset by $1.9 million repayments of noninterest bearing loans.

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, partially reduced by non-cash expenses of $11.5 million (the most significant non-cash expenses were $6.7 million of stock-based compensation and $2.9 million depreciation and amortization) and a net negative change in working capital of $21.8 million (of which $9.6 million was related to reductions in outstanding customer prepayments as we fulfilled the related revenue contracts and $5.0 million related to reductions in prepaid expenses).

During the six months ended June 30, 2021, cash used in investing activities was $129.6 million due to a $125.1 million net investment of cash into short-term investments and $4.5 million in property and equipment purchases. 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 noninterest bearing loans, $1.4 million proceeds from stock option exercises, and $1.2 million proceeds from employee ESPP purchases, partially offset by $0.8 million repayments of noninterest bearing loans and $0.3 million of equity offering costs.

Material Cash Requirements

Our material cash requirements in the short- and long-term consist primarily of capital expenditures, variable costs of revenue, operating expenditures, property leases, and other. We plan to fund our material cash requirements with our existing cash and cash equivalents and short-term investments, which amounted to $233.5 million as of June 30, 2022, as well as anticipated cash receipts from customers. To fund our material cash requirements in the short- and long-term, we may also 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.

Capital expenditures. We expect to increase capital expenditures in future periods to support our global growth initiatives. Such expenditures are expected to consist primarily of facility renovations and improvements, laboratory equipment, and computer equipment. We currently expect capital expenditures to be between $45 and $50 million in 2022 and between $7 and $10 million in each of the next two fiscal years. In connection with our new headquarters and laboratory facility in Fremont, California, we expect to spend between $30 and $35 million (net of expected landlord reimbursements) in combined leasehold improvements, renovations, administrative, and other costs through the end of 2022. This is the reason for greater expected capital expenditures in 2022 as compared to the following two years.

Variable costs of revenue. 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. Another primary use of cash within variable costs of revenue relates to paying our workforce. We currently expect spend to decrease in 2022 due to temporarily lower revenue levels but increase in years thereafter to support revenue growth.

Operating expenditures. Our primary use of cash relates to paying employees, spend on professional services, spend related to research and development projects, and other costs related to our research and development, selling, general and administrative functions. We currently expect to increase our spend in these areas to support our business growth in 2022. On a long-term basis, we manage future cash requirements relative to our long-term business plans.

Property leases. Our noncancelable operating lease payments were $82.7 million as of June 30, 2022. 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 Consolidated Financial Statements in Note 7, “Leases.”

Other. During the second quarter of 2021, we entered into two noninterest bearing loans to finance the purchase of $5.6 million of computer hardware, internal use software licenses, and related ongoing support. In connection with these loans, we made a payment of $1.86 million in 2022 and have remaining payments of $1.86 million due in 2023, with no further payments due in 2022. Further discussion of this transaction can be found in Part I, Item 1 of this Form 10-Q in the Notes to Consolidated Financial Statements in Note 6, “Loans.”

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, stock-based compensation, and leases 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, 2021 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.

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, 2022, 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 SEC’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

Our management is responsible for establishing and maintaining adequate internal control over financial reporting as such term is defined in Rule 13a-15(f) of the Exchange Act. An evaluation was also performed under the supervision and with the participation of our management, including our CEO and our CFO, of any change in our internal control over financial reporting that occurred during our last fiscal quarter and that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting. That evaluation did not identify any change in our internal control over financial reporting that occurred during our latest fiscal quarter that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

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.

See the section titled “Contingencies” in Note 9 to our unaudited condensed consolidated financial statements.

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 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.
- 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 the business or operations of our customers or other third parties with whom we conduct business.
- We have substantial customer concentration, with a limited number of customers accounting for a substantial portion of our revenue and accounts receivable; in particular, we have derived a substantial portion of our revenue from one of our largest customers, the VA MVP, and we currently derive a substantial portion of our revenue from another of our largest customers, Natera.
- 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 should we need to do so.
- We will need to invest in our infrastructure in advance of increased demand for our services; our failure to accurately forecast demand would have a negative impact on our business and our 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 develop 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 future growth effectively, which could make it difficult to execute 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. When we 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 further 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 services and 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

- 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.

- 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.

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

- 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.

- 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.

- 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. The risk factors set forth below that are marked with an asterisk (*) contain changes to the similarly titled risk factors included in, or did not appear as separate risk factors in, Item 1A of our Annual Report on Form 10-K for the year ended December 31, 2021 (Annual Report), which was filed with the SEC on February 24, 2022.

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.*

We have incurred net losses since our inception. For the years ended December 31, 2021, 2020, and 2019 we had net losses of $65.2 million, $41.3 million, and $25.1 million, respectively. For the six months ended June 30, 2022, we had a net loss of $55.8 million. As of June 30, 2022, we had an accumulated deficit of $302.9 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 and potential customers;
- the success of our commercial team, including sales and business development personnel;
- the recruitment, hiring, and retention of our commercial team personnel;
- whether our customers and potential customers accept that our services are sufficiently sensitive and specific;
- our ability to convince our customers and potential customers 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 operations, our financial condition, 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. For example, 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 COVID-19 pandemic has disrupted, and may disrupt in the future, 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 or if other supply chain issues arise as a result of the COVID-19 pandemic. Several of our customers have been delayed in sending us samples 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 or samples to us in the future.

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 as the global COVID-19 pandemic continues to evolve and to present serious health risks. 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. The full extent of the impact of the COVID-19 pandemic on our business, operations and plans remains uncertain and will depend on future developments that cannot be predicted at this time. Such developments include the continued spread of the Omicron variant and subvariants in the U.S. and other countries and the potential emergence of other SARS-CoV-2 variants or subvariants that may prove especially contagious or virulent, the ultimate duration of the pandemic and the resulting impact on our business and other third parties with whom we do business, and the effectiveness of actions taken globally to contain and treat the disease.

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. 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, but a continued and prolonged public health crisis 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 and potential 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. In addition, our suppliers or competitors may announce the development of new products, services or features that results in our customers' or potential customers' decision to reduce, postpone or cancel orders from us while they wait to determine which products, services or features are or will be perceived as technologically superior, more commercially successful or adopted as standards in the industry; such decisions by our customers or potential customers may be influenced by their concerns regarding the potential obsolescence of data generated using our services and features if our services or features are or will not be perceived as technologically superior, commercially successful or adopted as standards in the industry.

Some of our present or potential competitors, including Adaptive Biotechnologies Corporation, Adela, Inc., ArcherDx, Inc., which was acquired by Invitae Corporation in October 2020, BillionToOne, Inc., C2i Genomics, Inc., Caris Life Sciences, Inc., Covance Inc., which was acquired by Laboratory Corporation of America Holdings in February 2015, Foresight Diagnostics Inc. ("Foresight"), Foundation Medicine, Inc., which was acquired by Roche Holdings, Inc. in July 2018, Freenome, Inc., Geneseeq Technology Inc., Genosity, Inc., which was acquired by Invitae Corporation in April 2021, GRAIL, which Illumina announced that it had acquired in August 2021, Guardant Health, Inc., Inivata Limited, which was acquired by NeoGenomics, Inc. in June 2021, Invitae Corporation, Mount Sinai Genomics, Inc. which does business under the name Sema4, Natera, NanoString Technologies, Inc., NeoGenomics, Inc., Personal Genome Diagnostics, Inc., Predicine, 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. Also, we have

had, and may have in the future, customer or supply relationships with our present or potential competitors. For example, we have an agreement with Natera to provide advanced tumor analysis for use in Natera's MRD testing offerings. During the six months ended June 30, 2022, revenue under our agreement accounted for 33% of our total revenue. See "—We currently derive a substantial portion of our revenue from DNA sequencing and data analysis services that we provide to Natera. If Natera's demand for our DNA sequencing and data analysis services were to be substantially reduced, our business, financial condition, revenue and other operating results, and cash flows may be materially harmed." 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 August 2021, Illumina announced it completed its acquisition of 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. Illumina is also one of our significant suppliers. See "—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." 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, or if we cannot maintain successful customer or supply relationships with Natera, Illumina or other present or potential 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 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 service or 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. In addition, we have limited experience developing diagnostics, have never developed an FDA-approved companion diagnostic, and may be unable to successfully compete against companies with more experience developing and commercializing companion diagnostics.

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 and products 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; in particular, we have derived a substantial portion of our revenue from one of our largest customers, the VA MVP, and we currently derive a substantial portion of our revenue from another of our largest customers, Natera.*

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 VA MVP, which accounted for 23% and 63% of our revenue for the six months ended June 30, 2022 and 2021, respectively. Revenue from Natera accounted for 33% of our revenue for the six months ended June 30, 2022. Our top five customers, including the VA MVP and Natera, accounted for 77% and 87% of our revenue for the six months ended June 30, 2022 and 2021, respectively. There are inherent risks whenever a large percentage of revenue is concentrated with a limited number of customers. While we have attempted to grow our customer base and diversify our revenue concentration beyond the VA MVP and Natera, we may not be able to successfully do so in the future. 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, including Natera, 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 we do not win future VA MVP contracts and renewals with a value comparable to that of our historical contracted orders, it may 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. Likewise, if Natera or any of our other significant customers were to reduce or cease their use of our services, then our revenue, cash position, and results of operations may be materially adversely impacted. Further, if any of our significant customers were to 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 have derived a substantial portion of our current revenue from DNA sequencing and data analysis services that we provided 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 continues to be substantially reduced, if the VA MVP conducts a competitive bid process for the next contract and we do not win, or if the VA MVP does not award any such contract on a timely basis or at all, our business, financial condition, revenue and other operating results, and cash flows will be materially harmed.*

We have derived a substantial portion of our 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 optional 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, 2020, and 2021. The current contract does not include a renewal option. For us to provide additional services to the VA MVP, we would need to receive an additional task order and/or enter into a new services agreement with the VA MVP, neither of which had occurred as of the date of filing this quarterly report.

The VA MVP may initiate a competitive bidding process for its next DNA sequencing and data analysis services contract, if any. However, there may not be any such potential bidding process or new contract awarded on a timely basis or at all, we may not win any such potential new contract in any such potential bidding process, the value of any such potential new contract or the VA MVP contracted orders thereunder may be lower than our 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 significantly 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, if any, for our services among other factors. For example, the VA MVP contracted order received in September 2020 had a value of $30.9 million, whereas the VA MVP contracted order received in September 2021 had a value of $9.7 million, which represents a substantial decline. We are aware that the VA MVP recently initiated a request for information process seeking potential sources to provide high-throughput whole genome sequencing services, and that the VA MVP more recently issued a pre-solicitation notice announcing its intent to award a firm-fixed price, requirements contract for such services. However, we are not certain there will be a RFP process in 2022, and the pre-solicitation notice does not obligate the VA MVP to issue a solicitation for proposals.

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 have changed or change in the future, including in response to the ongoing 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 will 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 not to award a future contract on a timely basis or at all, or to terminate for convenience or failure to renew any contract, for whatever reason) with a value comparable to that of our historical contracted orders, our business, financial condition, revenue and other operating results and cash flows may be materially harmed. We have only recognized revenue under our VA MVP contract upon the receipt and processing of samples, and the timing and number of VA MVP samples we have received 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 2020 significantly exceeded the value of the VA MVP contracted order we received in September 2020 because we continued to receive after such date, and subsequently processed, samples under VA MVP contracted orders that remained unfulfilled as of September 2020 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. For example, even if the VA MVP initiates a new RFP process in 2022 and we win a contract and order with a value comparable to that of the September 2020 contracted order, the revenue we recognize under such potential new contract and order may be less than the revenue we recognized during the 2020-2021 contract year. The timing and number of VA MVP samples may also continue to be negatively affected by the 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 2021 VA MVP contracted order compared to the September 2020 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.

We currently derive a substantial portion of our revenue from DNA sequencing and data analysis services that we provide to Natera. If Natera's demand for our DNA sequencing and data analysis services were to be substantially reduced, our business, financial condition, revenue and other operating results, and cash flows may be materially harmed.*

In February 2021, we entered into a partnership in the field of personalized oncology with Natera, pairing our NeXT tumor profiling and diagnostic services and products with Natera's personalized ctDNA platform Signatera™ for treatment monitoring and MRD assessment. Under this non-exclusive agreement, Natera is responsible for validating the design of, and commercialization of, Signatera personalized ctDNA assays using matched tumor and normal exome sequence data from us. The agreement covers MRD testing for both clinical use and research use. Since that time, Natera's sample volumes have increased such that we currently derive a significant portion of our revenue from sales of our DNA sequencing and data analysis services to Natera under our agreement. For example, during the first six months of 2022, revenue under our agreement accounted for 33% of our total revenue. While our agreement with Natera is a long-term contractual arrangement, Natera is not required to purchase a minimum number of analyses from us under the agreement, and we have only limited visibility to Natera's forecasted sample volumes for future periods. We are aware that Natera has at least one third party supplier of DNA sequencing and analysis services, such that Natera has elected, and may continue to elect in the future, to send a portion (or all) of its samples to its other supplier(s) instead of us, which it is not contractually prohibited from doing, given the non-exclusive nature of our agreement. Natera may also bring a portion (or all) of such services in-house in the future, which may result in them purchasing fewer (or no) such services from us, or none from us at all. Our agreement with Natera requires us to achieve certain quality and turnaround time metrics for Natera samples. Recently, the volumes of samples sent to us by Natera have fluctuated significantly and may continue to do so in the future, which could cause us to experience difficulty in achieving such metrics from time to time, or to meet our other obligations under our agreement. If we consistently fail to achieve such metrics, or any of our other obligations under our agreement with Natera, Natera may elect to send a portion (or all) of its samples to its other supplier(s) and/or bring such services in-house.

Additionally, Natera may allege that such failures to achieve the required metrics are a breach of our agreement and seek to terminate our agreement and/or pursue any remedies available to it under the agreement, at law or in equity. Relatedly, we have incurred expenses in connection with our scale-up activities under our agreement with Natera, and we may incur additional expenses to increase our laboratory's capacity to process increased sample volumes from Natera, in addition to those from our other customers, in the future. Our activities under our agreement with Natera have had, and may continue to have, an impact on our business, including diversion of our resources and the attention of our management, including with respect to our internal research and development objectives and projects for our other customers, collaborators and/or partners. If we are unable to successfully increase our laboratory's capacity and manage any such competing objectives and/or projects for other customers, we may be unable to meet the quality and timing requirements of our agreement with Natera or our other customers, collaborators and/or partners. We may also be unable to successfully research, develop, launch and/or commercialize our services or service capabilities. Furthermore, we recently announced the launch of NeXT Personal, a next-generation, tumor-informed liquid biopsy assay designed to detect and quantify MRD and recurrence in patients previously diagnosed with cancer. If NeXT Personal or any of our other services is seen as competing with Signatera or any of Natera's other services, we will still be required to fulfill our obligations to Natera under our agreement, although Natera may elect to send a portion (or all) of its samples to its other supplier(s) and/or bring such services in-house. If the volume of samples received under our agreement with Natera were to be significantly reduced or eliminated, or if our agreement with Natera were to be terminated, for these or other reasons, or if we are unable to successfully research, develop, launch and/or commercialize our services or service capabilities, including NeXT Personal, our business, financial condition, revenue and other operating results, and cash flows may be materially harmed.

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 and Natera 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 other materials used in our routine laboratory operations, and as the sole provider of maintenance and repair services for these sequencers. Our various pricing agreements with Illumina are set to expire on various dates up to December 2022. In August 2021, Illumina completed its acquisition of 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 acquisition of GRAIL, could negatively impact our supply chain and laboratory operations and our ability to conduct our business and generate revenue. Additionally, the ongoing COVID-19 pandemic has disrupted, and may continue to disrupt, Illumina's ability to fulfill our purchase orders for reagents or other materials in a timely manner and the pandemic has also disrupted, and may continue to disrupt, the ability of our other suppliers to fulfill our purchase orders in a timely manner or at all. Our suppliers could cease supplying these materials and equipment at any time, or fail to provide us with sufficient quantities of materials or equipment that meet our specifications. Our laboratory operations have been and in the future could be interrupted if we encounter delays or difficulties in securing sequencers or other equipment or materials, 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. Likewise, we believe that there are a limited number of manufacturers and suppliers for other reagents and materials necessary for our laboratory operations, such as the sample preparation reagents required for our ACE technology, which enables our NeXT Platform to provide more comprehensive sequencing coverage, as well as those required to create personalized liquid biopsy panels for each patient as part of our NeXT Personal assay. Although we have evaluated and may continue in the future to evaluate equipment and materials from other suppliers, 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. Additionally, an existing supplier of ours may allege that such activities constitute a breach of its agreement with us and may cease supplying us with sufficient quantities of materials or equipment that meet our specifications, in a timely manner or at all. Moreover, an existing supplier or third party may allege that such activities, replacement equipment or materials infringe, misappropriate or otherwise violate its intellectual property, and may bring infringement or other intellectual property-related claims against us. See "—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." 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 other 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 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; 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 and planned future facilities in Fremont, California. Our facilities and equipment could be harmed or rendered inoperable by natural or man-made disasters, including fires, earthquakes, flooding, and power outages, which may render it difficult or impossible for us to sell or perform our services for some period of time. 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 planned opening of our new headquarters and laboratory facilities in Fremont, California could divert management's attention and disrupt our ongoing business.

We plan to relocate our corporate headquarters to an existing building located in Fremont, California that was leased in August 2021. We also plan to build and operate new laboratory facilities in the building. These efforts will involve significant tenant improvements, construction and regulatory compliance activities to be undertaken, including state licensure and CLIA certification for such laboratory facilities. Such efforts may distract management from current operations, disrupt planned research, development or regulatory compliance activities, and result in greater than expected liabilities and expenses, any of which could result in a material adverse effect on our business prospects, financial condition, or results of operations.

Our success depends on our ability to provide reliable and timely, 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. In addition, our customers require timely turnaround of high-quality genomic data and analyses, and if we were not able to meet our customers' specific requirements, it could also have a significant adverse effect 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, lack of efficacy, side effects or adverse events in patients who use our tests, or who rely on our tests to determine therapies to develop, select or monitor, including treatment-related death, and could lead to termination of our services or result in 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 European Economic Area (and Northern Ireland) (“EEA”), in order to place an in vitro diagnostic medical device ("IVD"), or an accessory to an IVD, on the market, or put it into service in the EEA, the device must be designed, developed, manufactured and marketed in compliance with the relevant legal framework. On May 26, 2022, the Regulation on In-Vitro Diagnostic Devices (Regulation (EU) 2017/746) (“IVDR”) entered into application, repealing and replacing the Directive on In-Vitro Diagnostic Devices (98/79/EC) (the “IVDD”). The IVDR and its associated guidance documents and harmonized standards governing, among other things, device design and development, preclinical and clinical or performance testing, premarket conformity assessment, registration and listing, manufacturing, labeling, storage, claims, sales and distribution, export and import and post-market surveillance, vigilance, and market surveillance. IVDs must comply with the General Safety and Performance Requirements (“GSPRs”) set out in Annex I of the IVDR.

Compliance with these requirements is a prerequisite to be able to affix the CE Mark to IVDs, without which they cannot be marketed or sold in the EEA.

In accordance with the IVDR, devices that are not placed on the market but are used within the context of a commercial activity, whether in return for payment or free of charge, for the provision of a diagnostic or therapeutic service offered by means of information society services, as defined in point (b) of Article 1(1) of Directive (EU) 2015/1535, or by other means of communication, directly or through intermediaries, to a natural or legal person established in the EEA (and Northern Ireland) will be subject to the IVDR. As a result, 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.

Fulfillment of the obligations imposed by the IVDR are likely to increase the cost and time required in order to obtain regulatory approval for products and services in the EEA. If we offer tests or services to customers within the EEA (and Northern Ireland) (whether directly or via intermediaries) that fall within the scope of the IVDR, we may be unable to fulfill these obligations, or a Notified Body, where applicable, may consider that we have not adequately demonstrated compliance with our related obligations to merit a CE Certificate of Conformity on the basis of the IVDR. Our ability, and the ability of our customers, to commercialize diagnostic tests based on our technology will depend in part on the extent to which coverage and reimbursement for these tests will be available from third-party payors. Coverage and reimbursement of new products and services is uncertain, and whether the companies that use our instruments to develop their own products or services will attain coverage and adequate reimbursement is unknown. In the U.S. and the EU, there is no uniform policy for determining coverage and reimbursement. Coverage can differ from payor to payor, and the process for determining whether a payor will provide coverage may be separate from the process for setting the reimbursement rate. In addition, the U.S. government, state legislatures and foreign governments have shown significant interest in implementing cost containment programs to limit the growth of government-paid healthcare costs, including price controls and restrictions on reimbursement.

Physicians, hospitals, and third-party payors often are slow to adopt new products, services, 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 Medical 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 (“CLS”), 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. For example, California has a shortage of qualified CLS, who must be licensed by the California Department of Public Health to perform clinical testing in laboratories located in California such as our CLIA-certified and CAP-accredited laboratory. We face intense competition for, and we have experienced and may in the future experience difficulty attracting and retaining, sufficient numbers of licensed and qualified CLS to support the needs of our business and our laboratory capacity expansion efforts. 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, including licensed and qualified CLS, 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 (such as our planned future facilities in Fremont, California), 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 collaborations with the Mayo Clinic, MapKure, LLC ("MapKure"), which is jointly-owned by BeiGene, Ltd. and SpringWorks Therapeutics, Inc., and Moores Cancer Center at UC San Diego Health) 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 entered into 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, including those that restrict foreign investment in the development and application of gene diagnosis and treatment technologies (which we believe prevent us from directly offering our NeXT Dx Test, or other diagnostic tests based on our NeXT Platform, to patients in China); 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 or new restrictions imposed by the U.S. government on the export of necessary goods or technologies to our Shanghai subsidiary. 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 services and 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 previously 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, and that the agency subsequently approved applications by our customer for this project

and another project also involving the use of our NeXT Platform, we are supporting and expect in the future to support the preparation of multiple such applications, and there is no guarantee that any such additional applications will be approved by such agency in the future. The Chinese government separately has various regulations relating to the collection, use, storage, disclosure, and security of data, among other things, including the new Personal Information Protection Law ("PIPL") passed by the Standing Committee of China's National People's Congress on August 20, 2021, which took effect on November 1, 2021 and contains provisions similar to those of the General Data Protection Regulation (EU) 2016/679 ("GDPR") adopted by the EU, including extraterritorial reach, restrictions on data transfer, compliance obligations and sanctions for non-compliance. We cannot assure you that we will be able to comply with all 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. For example, the consequences for failing to comply with the PIPL could potentially include monetary penalties, business suspension and revocation of business licenses. 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 services or 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 and entered into 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. 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 Foreign Corrupt Practices Act of 1977, as amended (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 FDA, or equivalent foreign regulatory authorities and/or CLIA requirements for quality laboratory testing or equivalent foreign requirements.*

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 devices 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. We and/or our collaborators may also voluntarily submit one or more of our tests for premarket notification, review, clearance or approval by the FDA as medical devices. For example, under our collaboration with MapKure, we expect to develop new, advanced biomarkers selected by MapKure for regulatory submission and approval as a companion diagnostic, in which case we would also be subject to potentially burdensome additional regulatory controls and submissions for one or more of our tests. 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. For example, the proposed "Verifying Accurate, Leading-edge IVCT Development" (VALID) Act (the "VALID Act"), most recently introduced in June 2021, would clarify and enhance FDA's authority to regulate LDTs, including pre-market review of non-exempted tests. As currently proposed, the VALID Act would grandfather existing CLIA-compliant LDTs but would allow the FDA to subject otherwise grandfathered tests to pre-market review under certain conditions. We cannot predict whether the VALID Act will become legislation and 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. For example, if the VALID Act as currently proposed becomes legislation, we may be required to seek FDA pre-market review of the LDT version of our NeXT Personal assay that we plan to launch in the future, particularly if the LDT version of our NeXT Personal assay is ineligible for the grandfathered test exemption, which could increase the cost of, or delay, limit or prohibit, our development, introduction or continued offering of the LDT version of our NeXT Personal assay. In addition, 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.

In the EEA, IVDs are generally governed by the IVDR and must comply with the requirements of the IVDR in order to be placed on the market or put into service in the EEA. The IVDR does not specifically address the regulation of products falling within the description "laboratory-developed tests". Moreover, while the Regulation includes only limited exemptions for devices that are manufactured and used only within health institutions established in the EEA, diagnostic and therapeutic services undertaken outside of the EEA (for example at our facilities in the U.S.) would not fall within the scope of such exemptions. We do not currently offer tests or services to customers established in the EEA which would fall within the scope of the IVDR. If, in the future, we offer tests or services to customers within the EEA (and Northern Ireland) (whether directly or via intermediaries) that fall within the scope of the IVDR, it is unlikely that we will benefit from IVDR exemptions foreseen for health institutions established in the EEA. This means that we will have to comply with the IVDR in full.

If the FDA determines that our services are subject to enforcement as medical devices, or if foreign regulatory authorities regulate our products as IVDs, we could incur substantial costs and time delays associated with satisfying statutory and regulatory requirements such as pre-market clearance, approval or certification, 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, or if we voluntarily submit one or more of our tests for premarket notification, review, clearance or approval by the FDA as medical devices, 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, or if we voluntarily submit one or more of our tests for premarket notification, review, clearance or approval by the FDA as medical devices, 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 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 device 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, or if we voluntarily submit one or more of our tests for premarket notification, review, clearance or approval by the FDA as medical devices, one classification regulation that could be relevant to one or more of our tests is a classification for genetic health risk ("GHR") assessment tests, codified at 21 C.F.R. § 866.5950. If our tests are considered medical devices that are not subject to enforcement discretion, or if we voluntarily submit one or more of our tests for premarket notification, review, clearance or approval by the FDA as medical devices, 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 service and product development costs, delay commercialization of any future services or products, and interrupt sales of our current services and 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 devices 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. Similar actions and obligations may be imposed by the competent authorities of an EU Member State, or a foreign regulatory authority.

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

In addition, any clearance or approval we obtain for our services or 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 services or 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 service or product marketing;
- warning letters;
- withdrawal or recall of services or 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 device'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.

In addition, many of the products we use to perform our tests, including sequencers and various associated reagents supplied to us by Illumina, are labeled as research use only ("RUO") in the U.S. RUO products are exempt from FDA medical device requirements provided their manufacturers comply with specified labeling and restrictions on distribution. The products must bear the statement: "For Research Use Only. Not for Use in Diagnostic Procedures." Manufacturers of RUO products cannot make any claims related to safety, effectiveness or diagnostic utility, and RUO products cannot be intended by the manufacturer for clinical diagnostic use. A product promoted for diagnostic use may be viewed by the FDA as adulterated and misbranded under the FDC Act and is subject to FDA enforcement activities, including requiring the manufacturer to seek marketing authorization for the products. We currently use Illumina and other RUO products for our clinical diagnostic tests. If the FDA were to require clearance, approval or authorization for the sale of Illumina's RUO products and if Illumina does not obtain such clearance, approval or authorization, we would have to find an alternative sequencing platform for some or all of our clinical diagnostic tests. We currently have not validated an alternative sequencing platform on which our tests could be run in a commercially viable manner. If we were not successful in selecting, acquiring on commercially reasonable terms and implementing an alternative platform on a timely basis, our business, financial condition and results of operations would be adversely affected. Similarly, a finding that any of our other suppliers failed to comply with applicable requirements could result in interruptions in our ability to supply our services to the market and adversely affect our operations.

In addition, if we offer tests or services to customers within the EEA (and Northern Ireland) (whether directly or via intermediaries) that fall within the scope of the IVDR, we would be required to comply with strict requirements in order to affix the CE mark to our products, including requirements for clinical evidence, pre-market assessment of safety and performance, quality management system, traceability of products, promotion and advertising, and conduct costly post-market testing and surveillance to monitor the safety or effectiveness of our products in the EEA and detailed reporting obligations.

Failure to comply with federal, state, and foreign laboratory licensing requirements and the applicable requirements of the FDA or any other regulatory authority, or equivalent foreign 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 will need a need a new CLIA certificate to operate our laboratory in the new Fremont facility. Any delay in inspection for or approval of our new CLIA certificate for the Fremont facility could result in a material disruption to our operations.

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 test-specific basis by New York as an out-of-state laboratory, and our LDTs must be approved by the New York State Department of Health (the "NYDOH") on a test-by-test 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 will need new state license from California and New York to continue our current laboratory operation in the new Fremont facility. Any delay in inspection for or approval of these state laboratory licenses for the Fremont facility could result in a material disruption to our operations. 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 by the regulatory authorities of EU Member States as well as repercussions for any CE Certificates of Conformity issued by Notified Bodies, including fines, suspension variation or withdrawal of CE Certificates of Conformity, product seizures, injunctions or the imposition of civil or criminal penalties which would adversely affect our business, operating results and prospects.

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, if any of our services or products otherwise fail to comply with FDA regulatory requirements as enforced, or if we voluntarily submit one or more of our tests for premarket notification, review, clearance or approval by the FDA as medical devices, 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 services or 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 services and 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, receive, generate, use, transfer, disclose, make accessible, protect, secure, dispose of, transmit, share 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. Our ability to monitor these third parties' security practices is limited, and these third parties may not have adequate security measures in place.

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 cyberattacks by malicious third parties, which may compromise our system infrastructure, or that of our third-party partners, or lead to data leakage. During times of war and other major conflicts, including the war in Ukraine, we and the third parties upon which we rely may be vulnerable to a heightened risk of these attacks, including cyberattacks, that could materially disrupt our systems and operations and supply chain. Cyberattacks, malicious internet-based activity, and online and offline fraud are prevalent and continue to increase. These threats are becoming increasingly difficult to detect. We and the third parties upon which we rely may be subject to a variety of evolving threats, including but not limited to social-engineering attacks (including through phishing attacks), malicious code (such as viruses and worms), malware (including as a result of advanced persistent threat intrusions), denial-of-service attacks (such as credential stuffing), personnel misconduct or error, ransomware attacks, supply-chain attacks, software bugs, server malfunctions, software or hardware failures, loss of data or other information technology assets, adware, and other similar threats. Ransomware attacks, including by organized criminal threat actors, nation-states, and nation-state-supported actors, are becoming increasingly prevalent and severe and can lead to significant interruptions in our operations, loss of data and income, reputational harm, and diversion of funds. Extortion payments may alleviate the negative impact of a ransomware attack, but we may be unwilling or unable to make such payments due to, for example, applicable laws or regulations prohibiting such payments. Similarly, supply-chain attacks have increased in frequency and severity, and we cannot guarantee that third parties and infrastructure in our supply chain or our third-party partners' supply chains have not been compromised or that they do not contain exploitable defects or bugs that could result in a breach of or disruption to our information technology systems or the third-party information technology systems that support us and our services.

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, threat actors, viruses, sophisticated nation states, and nation-state-supported actors, 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 and technologies 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. Additionally, we cannot be sure that such coverage will continue to be available on commercially reasonable terms or at all, or that such coverage will pay future claims. 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. Our contracts may not contain limitations of liability, and even where they do, there can be no assurance that limitations of liability in our contracts are sufficient to protect us from liabilities, damages, or claims related to our privacy, data protection, and data security obligations.

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 of the previously identified or similar threats could cause a security incident or other interruption, which could result in unauthorized, unlawful, or accidental acquisition, modification, destruction, loss, alteration, encryption, disclosure of, or access to our proprietary, confidential, or sensitive information. A security incident or other interruption could disrupt our ability (and that of third parties upon whom we rely) to provide our platform, products, and services. We may expend significant resources or modify our business activities (including our clinical trial activities) to try to protect against security incidents. Additionally, certain privacy, data protection, or data security obligations may require us to implement and maintain certain measures to protect our information technology systems and sensitive information.

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. We may be unable in the future to detect vulnerabilities in our information technology systems because such threats and techniques change frequently, are often sophisticated in nature, and may not be detected until after a security incident has occurred. 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.

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”) as amended by the Health Information Technology for Economic and Clinical Health (“HITECH”), and penalties. Applicable privacy, data protection, or data security obligations may require us to notify relevant stakeholders of security incidents. Such disclosures are costly, and the disclosure or the failure to comply with such requirements could lead to adverse consequences. 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 CCPA also allows for statutory fines for noncompliance of up to $7,500 per violation. 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 policies, industry standards, and 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.

The collection and use of personal health data in the EEA is governed by the General Data Protection Regulation 2016/679, or GDPR, which entered into application on May 25, 2018. The GDPR applies to the processing of personal data by any company established in the EEA and to companies established outside the EEA to the extent they process personal data in connection with the offering of goods or services to data subjects in the EEA or the monitoring of the behavior of data subjects in the EEA. The GDPR enhances data protection obligations for data controllers of personal data, including stringent requirements relating to the consent of data subjects, expanded disclosures about how personal data is used, requirements to conduct privacy impact assessments for "high risk" processing, limitations on retention of personal data, mandatory data breach notification and "privacy by design" requirements, and creates direct obligations on service providers acting as processors. The GDPR also imposes strict rules on the transfer of personal data outside of the EEA to countries that do not ensure an adequate level of protection, like the United States. Failure to comply with the requirements of the GDPR and the related national data protection laws of the EU Member States and Norway, Iceland and Liechtenstein may result in fines up to €20 million or 4% of a company's global annual revenues for the preceding financial year, whichever is higher. Moreover, the GDPR grants data subjects the right to claim material and non-material damages resulting from infringement of the GDPR. EEA countries may also introduce national legislation further limiting the processing of genetic, biometric, or health data, which could limit our ability to collect, use and share data originating from the EEA, or could cause our compliance costs to increase, require us to change our practices, adversely impact our business, and harm our financial condition. Given the breadth and depth of changes in data protection obligations, assisting our customers, partners, and vendors in complying with the GDPR, or maintaining compliance with the GDPR ourselves will require significant time, resources and expense, and we may be required to put in place additional controls and processes ensuring compliance with the new data protection rules that may cause us to incur substantial operational costs or require us to change our business practices. This may be onerous and adversely affect our business, financial condition and results of operations.

In addition, further to the U.K.'s exit from the EU on January 31, 2020, the GDPR ceased to apply in the U.K. at the end of the transition period on December 31, 2020. However, as of January 1, 2021, the U.K.'s European Union (Withdrawal) Act 2018 incorporated the GDPR (as it existed on December 31, 2020 but subject to certain U.K. specific amendments) into U.K. law (the "U.K. GDPR"). The U.K. GDPR and the U.K. Data Protection Act 2018 set out the U.K.'s data protection regime, which is independent from but aligned to the EU's data protection regime. Non-compliance with the U.K. GDPR may result in monetary penalties of up to £17.5 million or 4% of worldwide revenue, whichever is higher. On June 28, 2021, the European Commission adopted an adequacy decision permitting flows of personal data between the EU and the U.K. to continue without additional requirements. However, the U.K. adequacy decision will automatically expire in June 2025 unless the European Commission re-assesses and renews/extends that decision and remains under review by the European Commission during this period. The relationship between the U.K. and the EU in relation to certain aspects of data protection law remains unclear, and it is unclear how U.K. data protection laws and regulations will develop in the medium to longer term, and how data transfers to and from the U.K. will be regulated in the long term. These changes may lead to additional costs and increase our overall risk exposure.

If we or our third-party partners fail to comply or are alleged to have failed to comply with data protection and privacy laws and regulations, or if we were to experience a data breach involving personal data, we could be subject to government enforcement actions or private lawsuits. Any associated claims, inquiries, or investigations or other government actions could lead to unfavorable outcomes that have a material impact on our business including through significant penalties or fines, monetary judgments or settlements including criminal and civil liability for us and our officers and directors, increased compliance costs, delays or impediments in the development of new products, negative publicity, increased operating costs, diversion of management time and attention, or other remedies that harm our business, including orders that we modify or cease existing business practices.

Recent legal developments in Europe have created complexity and compliance uncertainty regarding certain transfers of personal data from Europe. For example, on July 16, 2020, the Court of Justice of the EU (the "CJEU") invalidated the E.U.-U.S. Privacy Shield Framework (the "Privacy Shield") under which personal data could be transferred from the EEA to United States entities who had self-certified under the Privacy Shield scheme. While the CJEU upheld the adequacy of the standard contractual clauses ("SCCs") (a standard form of contract approved by the European Commission as an adequate personal data transfer mechanism, and potential alternative to the Privacy Shield), it made clear that reliance on them alone may not necessarily be sufficient in all circumstances. Use of SCCs must now be assessed on a case-by-case basis taking into account the legal regime applicable in the destination country, in particular applicable surveillance laws and rights of individuals. On June 4, 2021, the European Commission published a decision adopting an updated set of SCCs designed to address issues identified by the CJEU. The revised SCCs must be used for relevant new data transfers from September 27, 2021; and existing SCCs arrangements must be migrated to the revised clauses by December 27, 2022. The new SCCs apply only to the transfer of personal data outside of the EEA and not the U.K. The U.K. is not subject to the European Commission's new SSCs but has published its own transfer mechanism, the International Data Transfer Agreement ("IDTA"), which enables transfers from the U.K. We will be required to implement these new safeguards when conducting restricted data transfers under the GDPR and the U.K. GDPR and doing so will require significant effort and cost. In addition, additional measures may be required even when relying on SSCs or the IDTA, where the laws of the importer's country do not offer an adequate level of protection, such as the United States.

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 the EEA, and we may be required to increase our data processing capabilities in the EEA at significant expense. Inability to import personal information from the EEA to the U.S. or other countries may decrease demand for our products and services as our customers that are subject to the GDPR or the U.K. GDPR may seek alternatives that do not involve personal information transfers out of the EEA. At present, there are few, if any, viable alternatives to the SSCs and the IDTA.

Similar laws have been proposed in other foreign jurisdictions in which we do, or expect to do, business. For example, the PIPL was adopted in China on August 20, 2021, and it went into effect on November 1, 2021. The PIPL shares certain similarities with the GDPR, including extraterritorial application, requirements for data minimization, data localization, and purpose limitation, and obligations to provide certain notices to and honor data subject rights from individuals located in the PRC. The PIPL allows for fines of up to 50 million yuan or 5% of a covered company's revenue in the prior year. The PIPL, and other new and evolving laws and regulations relating to privacy, data protection, and data security in China and other relevant foreign jurisdictions, increase our risk exposure, and may require us to modify our operations, may limit our ability to collect, retain, store, use, share, disclose, transfer, disseminate, and otherwise process personal information, may require additional investment of resources in compliance programs, and could result in increased compliance costs or changes in our ongoing or planned business practices, policies or strategies.

In the United States, federal, state, and local governments have enacted numerous privacy, data protection, and data security laws, including data breach notification laws, personal data privacy laws, and consumer protection laws. For example, HIPAA, as amended by HITECH, imposes specific requirements relating to the privacy, security, and transmission of individually identifiable health information. 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. It allows for statutory fines for noncompliance (up to $7,500 per violation). Although the CCPA exempts some data processed in the context of clinical trials, the CCPA may increase our compliance costs and potential liability with respect to other personal information we maintain about California residents. 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 as of January 1, 2022, with 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.

The enactment of the CCPA has led a wave of similar legislative developments in other states in the U.S., which creates the potential for a patchwork of overlapping but different state laws and could mark the beginning of a trend toward more stringent privacy legislation in the U.S., which could increase our potential liability and adversely affect our business, financial condition and results of operations. For example, in March 2021, Virginia enacted the Virginia Consumer Data Protection Act, a comprehensive privacy, data protection, and data security statute that becomes effective on January 1, 2023 (at the same time as the CPRA) and shares similarities with the CCPA, the CPRA, and legislation proposed in other states. In June 2021, Colorado enacted a similar law, the Colorado Privacy

Act, which becomes effective on July 1, 2023. Utah and Connecticut recently enacted similar laws. Many other states are considering proposed comprehensive data privacy legislation and all 50 states have passed some form of legislation relating to privacy or cybersecurity (for example, all 50 states have enacted laws requiring disclosure of certain personal information breaches). Additionally, several states and localities have enacted statutes banning or restricting the collection of biometric information. At the federal level, the United States Congress is considering various proposals for comprehensive federal privacy, data protection, and data security legislation and, while no such law currently exists, we are subject to applicable existing federal laws and regulations, such as the rules and regulations promulgated under the authority of the Federal Trade Commission, which regulates unfair or deceptive acts or practices, including with respect to privacy, data protection, and data security. These state statutes, and other similar state or federal laws, may require us to modify our data processing practices and policies and incur substantial compliance-related costs and expenses. Additionally, many laws and regulations relating to privacy and the collection, storing, sharing, use, disclosure, and other processing or protection of certain types of data are subject to varying degrees of enforcement and new and changing interpretations by courts. These laws and other changes in laws or regulations relating to privacy, data protection, and data security, particularly any new or modified laws or regulations, or changes to the interpretation or enforcement of such laws or regulations, that require enhanced protection of certain types of data or new obligations with regard to data retention, transfer, or disclosure, could greatly increase our operating costs, or require changes to our operations.

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. If we fail, or are perceived to have failed, to address or 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 are or 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, which, 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;
- state client billing laws, which specify whether a person that did not perform the service is permitted to submit the claim for payment and if so, whether the non-performing person is permitted to mark up the cost of the services in excess of the price the purchasing provider paid for such services. For example, California has an anti-markup statute which prohibits providers from charging for any laboratory test that it did not perform unless the provider (a) notifies the patient, client or customer of the name, address, and charges of the laboratory performing the test, and (b) charges no more than what the provider was charged by the clinical laboratory which performed the test except for any other service actually rendered to the patient by the provider (for example, specimen collection, processing and handling) (California Business and Professions Code Section 655.5). This provision applies, with certain limited exceptions, to licensed persons such as physicians and clinical laboratories regulated under the Business and Professions Code. In addition, many states also have "direct-bill" laws, which means that the services actually performed by an individual or entity must be billed by such individual or entity, thus preventing ordering physicians from purchasing services from a laboratory and rebilling for the services they order. For example, California has a direct bill rule specific to anatomic pathology services that prohibits any provider from billing for anatomic pathology services if those services were not actually rendered by that person or under his or her direct supervision with some exemptions (California Business and Professions Code Section 655.7);
- 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 services and assistance with obtaining reimbursement to persons who bill payors. Private individuals can bring False Claims Act "qui tam" actions, on behalf of the government and such individuals, commonly known as "whistleblowers," may share in amounts paid by the entity to the government in fines or settlement;
- the federal Civil Monetary Penalties Law, which prohibits, among other things, the offering or transfer of remuneration to a Medicare or state healthcare program beneficiary if the person knows or should know it is likely to influence the beneficiary's selection of a particular provider, practitioner, or supplier of services reimbursable by Medicare or a state healthcare program, unless an exception applies;
- the federal Physician Payments Sunshine Act, which requires certain manufacturers of drugs, biologicals, and medical devices or supplies that require premarket approval by or notification to the FDA, and for which payment is available under Medicare, Medicaid, or the Children's Health Insurance Program, 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), other healthcare professionals (such as physicians assistants and nurse practitioners) and teaching hospitals, and (ii) ownership and investment interests held by physicians and their immediate family members;
- the HIPAA fraud and abuse provisions, which created federal civil and criminal statutes that prohibit, among other things, defrauding healthcare programs, willfully obstructing a criminal investigation of a healthcare offense, and falsifying or concealing a material fact or making any materially false statements in connection with the payment for healthcare benefits, items or services. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- HIPAA, as amended by HITECH, and their respective implementing regulations, which impose obligations on certain healthcare providers, health plans, and healthcare clearinghouses, known as covered entities, as well as individuals and entities that create, receive, maintain or transmit individually identifiable health information for or on behalf of a covered entity, known as business associates, as well as their covered subcontractors, with respect to safeguarding the privacy, security and transmission of individually identifiable health information. HITECH also created new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in U.S. federal courts to enforce the federal HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions;
- the Eliminating Kickbacks in Recovery Act of 2018 ("EKRA"), which prohibits payments for referrals to recovery homes, clinical treatment facilities, and laboratories and is similar to the federal Anti-Kickback Statute in that it creates criminal penalties for knowing or willful payment or offer, or solicitation or receipt, of any remuneration, whether directly or indirectly, overtly or covertly, in cash or in kind, in exchange for the referral or inducement of laboratory testing unless a specific exception applies. Unlike the federal Anti-Kickback Statute, EKRA's reach extends beyond federal health care programs to include private insurance (i.e., it is an "all payer" statute). Additionally, most of the safe harbors available under the federal Anti-Kickback Statute are not reiterated under EKRA, and certain EKRA safe harbors conflict with the safe harbors available under the federal Anti-Kickback Statute. Therefore, compliance with a federal Anti-Kickback safe harbor does not guarantee protection under EKRA. Because EKRA is a new law, there is very little additional guidance to indicate how and to what extent it will be interpreted, applied and enforced by the government. Currently, there is no proposed regulation interpreting or implementing EKRA, nor any public guidance released by a federal agency concerning EKRA;

- 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 as discussed above; 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, including services we provide under our agreement with Natera, 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 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.

When we 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. We intend to seek reimbursement for our NeXT Dx Test and 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 derive revenue from any such future tests. The commercial success of future services and 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, or equivalent foreign 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 services or products are less safe, less effective, or less cost-effective than existing or later-introduced services or 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 have been executive, 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 June 17, 2021 the U.S. Supreme Court dismissed a challenge on procedural grounds that argued the ACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress. Thus, the ACA will remain in effect in its current form. Further, prior to the U.S. Supreme Court ruling, on January 28, 2021, President Biden issued an executive order that initiated a special enrollment period for purposes of obtaining health insurance coverage through the ACA marketplace The executive order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the ACA. It is possible that the ACA will be subject to judicial or Congressional challenges in the future. Efforts to repeal, substantially modify or invalidate some or all of the provisions of the ACA create considerable uncertainties for all businesses involved in healthcare, including our own. It is unclear how such 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 2031, with the exception of a temporary suspension from May 1, 2020 through March 31, 2022, unless additional Congressional action is taken. Under current legislation, the actual reduction in Medicate payments will vary from 1% in 2022 to up to 3% in the final fiscal year of this sequester. 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. 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 revenue 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. Reporting of payment data under PAMA for clinical diagnostic laboratory tests has been delayed on numerous occasions. Based on current law, between January 1, 2023 and March 31, 2023, applicable laboratories will be required to report on data collected during January 1, 2019 and June 30, 2019. This data will be utilized to determine 2024 to 2026 Clinical Laboratory Fee Schedule rates. 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 current tests or those in development. In addition, CMS updated the statutory phase-in provisions such that the rates for clinical diagnostic laboratory tests in 2020 could not be reduced by more than 10% of the rates for 2019.

Pursuant to the CARES Act, the statutory phase-in of the payment reductions has been extended through 2024 with a 0% reduction cap for 2021-2022 and a 15% reduction cap for 2023 through 2025. 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. President Biden is considering further repeals and/or replacement of the Tax Cuts and Jobs Act which may affect us. On June 29, 2020, California Assembly Bill 85 (AB 85) was signed into law, which suspended the use of California net operating losses and limited the use of California research tax credits for tax years beginning in 2020 and before 2023, although California legislation enacted in early February 2022 ends the suspension and limitation for tax year 2022. 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. The foregoing items could increase our future tax expense, change our future intentions regarding reinvestment of foreign earnings, and could have a material adverse effect on our business, financial condition and results of operations. 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 could lead to further 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. The U.K. and the EU have signed a EU-U.K. Trade and Cooperation Agreement, or TCA, which became provisionally applicable on January 1, 2021 and entered into force on May 1, 2021. This agreement provides details on how some aspects of the U.K. and EU's relationship will operate in the future. However, there are still many uncertainties. On May 26, 2022, the IVDR entered into application in the EU. However, the IVDR is not applicable in the U.K. In the U.K., IVDs are governed by the Medical Devices Regulations 2002 (SI 2002 No 618, as amended) (UK MDR 2002)

which retains a regulatory framework similar to the framework set out by the IVDD. As a result, there will be some regulatory divergence in the U.K. from the EU in light of the fact that the CE marking process is set out in EU law, which no longer applies in the U.K. The U.K. has devised a new route to market culminating in a U.K. Conformity Assessed ("UKCA") mark to replace the CE Mark for placing IVDs on the market in Great Britain (“G.B.”). Northern Ireland will, however, continue to be covered by the regulations governing CE Marks (a CE Mark or a CE Mark and UKNI Mark will be required to place products on the Northern Ireland market). CE Marks will continue to be recognized in G.B. for medical devices until June 30, 2023, however, all medical devices and IVDs must be registered with the MHRA, in order to be placed on the G.B. market. The EU legal framework, including the IVDR, remains applicable in Northern Ireland (any products placed on the market in the NI must be compliant with EU law). From July 1, 2023, a UKCA mark will be required in order to place a device on the G.B. market, however, manufacturers can use the UKCA mark on a voluntary basis prior to July 1, 2023 if they wish to do so. The nature of any new regulation in the U.K. is uncertain, and as such, we may experience delays in obtaining future access to the U.K. and other European markets. The U.K.’s departure from the EU has also impacted customs regulations and impacted timing and ease of shipments into the EU from the U.K.

Should the U.K. or G.B. further diverge from the EU from a regulatory perspective, tariffs could be put into place in the future. We could therefore, both now and in the future, face significant additional expenses 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 EU and the U.K. It is also possible that Brexit may negatively affect our ability to attract and retain employees in the U.K., particularly those from the EU.

Our business could be negatively impacted by environmental, social and corporate governance (ESG) matters or our reporting of such matters.*

There is an increasing focus from certain investors, employees, partners, and other stakeholders concerning ESG matters. We may be, or be perceived to be, not acting responsibly in connection with these matters, which could negatively impact us. For instance, the SEC has recently proposed climate change and ESG reporting requirements, which, if approved, would significantly increase our costs. We currently do not report our environmental emissions, and lack of reporting or future reporting could result in certain investors from declining to invest in our common stock.

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, including with regard to liquid biopsy assays such as those designed to detect or quantify MRD or recurrence in patients previously diagnosed with cancer. 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 liability related to an allegation of infringement of 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.

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 or potential 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, services 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 services or 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 services and 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.

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 or services. 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 2042. 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 services or 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, services 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, services, 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, services, 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, services, 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 or services 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, services, 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 are involved in legal proceedings to enforce our intellectual property rights and may in the future become involved in other lawsuits to protect or enforce our patents or other intellectual property, which could be expensive, time consuming, and unsuccessful.*

Our intellectual property rights involve complex factual, scientific and legal questions. We operate in an industry characterized by significant intellectual property litigation. Even though we may believe that we have a valid patent on a particular technology, others may infringe our patents or the patents of our licensing partners. For example, in August 2022, we filed a complaint in the U.S. District Court for the District of Colorado against Foresight for patent infringement (see the section titled "Contingencies" in Note 9 to our unaudited condensed consolidated financial statements). 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 services or 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 services or product or the services or 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 services 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 services and products may compete with our services and 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, services 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, services or technologies 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 technologies 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 or provision of our services. 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 and services 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

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, when we grow our business by developing in vitro diagnostic tests, our capital expenditures and operating expenses will 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 macroeconomic conditions, actual or perceived changes in interest rates and inflation, geopolitical conflicts (including the Russia-initiated military action against Ukraine), as well as 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, cash equivalents and short-term investments will be sufficient to meet our anticipated cash requirements for at least the next 12 months, rising costs and interest rates due to inflation or other economic conditions may cause our capital expenditures and operating expenses to increase more than expected, and we cannot assure you that we will generate sufficient revenue from commercial sales to adequately fund our operating needs or achieve or sustain profitability. If we are unable to raise additional funding on acceptable terms, or at all, or if we consume our existing capital more quickly than expected, it could negatively impact our ability to retain and attract employees and our competitive position, business, financial condition, results of operations, and prospects will be adversely affected.

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 relating to significant acquisitions, strategic partnerships, joint ventures, collaborations, capital commitments, or by or pertaining to our customers, particularly the VA MVP and Natera, as our largest customers;
- 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 ongoing 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 in connection with the ongoing COVID-19 pandemic, global supply chain challenges, inflation and fears of economic recession, which have 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, Natera 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.

Unstable market, economic and geo-political conditions may have serious adverse consequences on our business, financial condition and stock price.*

The global credit and financial markets have experienced extreme volatility and disruptions in the past. These disruptions can result in severely diminished liquidity and credit availability, increases in inflation, declines in consumer confidence, declines in economic growth, increases in unemployment rates and uncertainty about economic stability. There can be no assurance that further deterioration in credit and financial markets and confidence in economic conditions will not occur, including actual or perceived changes

in interest rates and inflation. Our general business strategy may be adversely affected by any such economic downturn, volatile business environment, higher inflation, or continued unpredictable and unstable market conditions. If the current equity and credit markets deteriorate, it may make any necessary debt or equity financing more difficult, more costly and more dilutive. Our portfolio of corporate and government bonds could also be adversely impacted. Failure to secure any necessary financing in a timely manner and on favorable terms could have a material adverse effect on our operations, growth strategy, financial performance and stock price and could require us to delay or abandon development or commercial initiatives. In addition, there is a risk that one or more of our current service providers, manufacturers and other partners may not survive an economic downturn or rising inflation, which could directly affect our ability to attain our operating goals on schedule and on budget.

Other international and geo-political events could also have a serious adverse impact on our business. For instance, in February 2022, Russia initiated military action against Ukraine. In response, the United States and certain other countries imposed significant sanctions and trade actions against Russia and could impose further sanctions, trade restrictions, and other retaliatory actions. While we cannot predict the broader consequences, the conflict and retaliatory and counter-retaliatory actions could continue to affect, and potentially materially adversely affect, global trade, currency exchange rates, inflation, regional economies, and the global economy, which in turn may increase our costs, disrupt our supply chain, impair our ability to raise or access additional capital when needed on acceptable terms, if at all, or otherwise adversely affect our business, financial condition, and results of operations.

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, 2022, we had 45,891,458 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, 2022 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, 2021, we had federal and state net operating loss carryforwards of approximately $222.5 million and approximately $166.3 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 taxable income. 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 thereafter 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 Sections 382 and 383 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 were suspended and limited, respectively, for tax years beginning after 2019 but before 2023, although California legislation enacted in early February 2022 ends the suspension and limitation for tax year 2022.

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 in the event we no longer qualify as a "smaller reporting company" as defined in the Exchange 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 document 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 a smaller reporting company, and any decision on our part to avail ourselves of certain reduced reporting and disclosure requirements applicable to smaller reporting companies could make our common stock less attractive to investors.*

On June 30, 2022, the market value of our common equity held by non-affiliates, or public float, was less than $560 million and we therefore qualify as a "smaller reporting company," as defined in the Exchange Act. We may choose to take advantage of exemptions from various reporting requirements applicable to other public companies that are not smaller reporting companies, including scaled disclosure on executive compensation.

We cannot predict if investors will find our common stock less attractive if we choose to rely on any of the exemptions afforded smaller reporting 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.

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.

If we fail to maintain effective internal control over financial reporting in the future, the accuracy and timing of our financial reporting may be adversely affected.*

Effective internal control over financial reporting is necessary for us to provide reliable financial reports and, together with adequate disclosure controls and procedures, are designed to prevent fraud. Any failure to implement required new or improved controls, or difficulties encountered in their implementation could cause us to fail to meet our reporting obligations. In addition, any testing by us conducted in connection with Section 404(a) of the Sarbanes-Oxley Act, or any testing by our independent registered public accounting firm conducted in connection with Section 404(b) of the Sarbanes-Oxley Act, may reveal deficiencies in our internal control over financial reporting that are deemed to be material weaknesses or that may require prospective or retroactive changes to our financial statements or identify other areas for further attention or improvement. Inferior internal control over financial reporting could also cause investors to lose confidence in our reported financial information, which could have a negative effect on the trading price of our common stock.

As a result of our public float on June 30, 2022, commencing on December 31, 2022 we will become a non-accelerated filer. For so long as we remain a non-accelerated filer, our independent registered public accounting firm will not be required to attest to the effectiveness of our internal control over financial reporting pursuant to Section 404(b) of the Sarbanes-Oxley Act. An independent assessment of the effectiveness of our internal control over financial reporting could detect problems that our management's assessment might not. Undetected material weaknesses in our internal control over financial reporting could lead to financial statement restatements and require us to incur the expense of remediation.

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.

Appointment of Director

On August 2, 2022, upon recommendation of the nominating and corporate governance committee of our board of directors, our board of directors appointed Lonnie Shoff, to our board of directors as a Class II director. Ms. Shoff's term will expire, along with the terms of the other Class II directors, at our annual meeting of stockholders in 2024. Our board of directors also appointed Ms. Shoff to serve as a member of the compensation committee of our board of directors.

There are no arrangements or understandings between Ms. Shoff and any other persons pursuant to which she was selected as a director. Our board of directors has determined that Ms. Shoff qualifies as an independent director under the independence requirements set forth under Rule 5605(a)(2) of the Nasdaq Stock Market LLC Rules and listing standards. Additionally, there are no transactions involving the company and Ms. Shoff that we would be required to report pursuant to Item 404(a) of Regulation S-K.

In connection with her appointment to our board of directors and the compensation committee, and pursuant to our amended and restated non-employee director compensation policy (the "Non-Employee Director Compensation Policy"), Ms. Shoff will receive annual cash retainers for her service on the board of directors and any committee of the board of directors, an initial equity grant and annual equity grants, each in the amounts set forth in the Non-Employee Director Compensation Policy.

We have also entered into our standard form of indemnification agreement with Ms. Shoff.

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	6/24/2019
3.2	Amended and Restated Bylaws of the Registrant.	8-K	001-38943	3.2	6/24/2019
10.1	Amendment No. 2 to Lease, by and between Ardenwood Ventures I, LLC and the Registrant, dated June 9, 2022.				
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 3, 2022

Personalis, Inc.

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

Exhibit 10.1

AMENDMENT NO. 2 TO LEASE

This **AMENDMENT NO. 2 TO LEASE** ("Amendment") is dated as of June 9, 2022 (the "**Amendment Date**") by and between **ARDENWOOD VENTURES I, LLC**, a Delaware limited liability company ("**Landlord**"), and **PERSONALIS, INC.**, a Delaware corporation ("**Tenant**").

RECITALS

A. Landlord and Tenant entered into that certain Lease Agreement dated as of August 24, 2021, as amended by that certain Amendment No. 1 to Lease dated as of December 8, 2021 (collectively, the "**Lease**") for premises located at 6600 Dumbarton Circle in Fremont, California, comprised of approximately 100,808 rentable square feet of floor area as more particularly described in the Lease.

B. The Initial TI Budget is defined in the Lease as "the September 27, 2021 budget delivered to Landlord by Tenant, which includes reasonable detail on the estimated construction cost of all Tenant Improvement work and materials for the entire Leased Premises, and the estimated cost of all professional services, fees and permits in connection therewith" and totaled $33,409,720.

C. Tenant has concluded that the Initial TI Budget understated the actual anticipated cost of the Tenant Improvements, which is $37,709,000 (the "**Revised TI Budget**").

D. Landlord and Tenant now desire to amend the Lease on the terms and conditions set forth herein in order to bring their respective funding obligations into balance.

AGREEMENT

NOW THEREFORE, for good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, Landlord and Tenant hereby agree as follows:

1. Recitals. The foregoing Recitals are hereby incorporated into this Amendment and agreed to by Landlord and Tenant.

2. Definitions. All capitalized terms used in this Amendment but not otherwise defined shall have the meanings assigned to them in the Lease.

3. Funding Percentages. The parties hereby agree that the Revised TI Budget shall retroactively replace the Initial TI Budget for purposes of determining each party's proportionate funding obligations pursuant to Paragraph 3(b)(iii) of the Work Letter, and further agree as follows:

(a) Based on the Revised TI Budget, the proportionate funding percentages are 40.10% (Landlord) and 59.90% (Tenant).

(b) Because the Initial TI Budget totaled $33,409,720, prior to the Amendment Date the proportionate funding percentages of each draw pursuant to Paragraph 3(b)(iii) of the Work Letter were 45.26% (Landlord) and 54.74% (Tenant), which has resulted in a cumulative overfunding by Landlord of
$475,790 for the first seven (7) draws.

(c) With regard to the next payment to be made by Landlord from the Tenant Improvement Allowance pursuant to Paragraph 3(b)(iii) of the Work Letter, such payment shall equal (a)(i) the total payment request properly set forth in the application for payment, multiplied by (ii) 40.10%, minus (b)
$475,790.

(d) With regard to all future payments to be made by Landlord from the Tenant Improvement Allowance, such payments shall be made pursuant to and in accordance with Paragraph 3(b)(iii) of the Work Letter, which is hereby amended in its entirety to read as follows from and after the Amendment Date:

> "Prior to the TI Allowance Deadline, on or before the 30th day following submission of the application for payment, so long as Tenant is not in monetary default, or material non- monetary default beyond the expiration of any notice and cure periods expressly set forth in the Lease or this Work Letter, under the terms of this Work Letter or the Lease, Landlord shall pay a share of such payment pari passu with Tenant, determined by multiplying the amount of such payment by 40.10%, and Tenant shall pay the balance of such payment, provided that (i) to the extent the anticipated cost of the Tenant Improvements at any time is anticipated to exceed $37,709,000, whether due to change orders or otherwise, such excess amount shall be paid entirely by Tenant and Tenant shall exclude such excess amount from its application(s) for payment, and (ii) at such time as Landlord has paid the entire Tenant Improvement Allowance on account of such Tenant Improvement work, all billings shall be paid entirely by Tenant. If upon completion of the Tenant Improvement work and payment in full to the Tenant Improvement Contractor, the architect and engineer, and payment in full of all fees and permits, the portion of the cost of the Tenant Improvement work, architects' and engineers' fees, permits and fees theretofore paid by Landlord is less than the Tenant Improvement Allowance, Landlord shall reimburse Tenant for costs expended by Tenant for Tenant Improvement work up to the amount by which the Tenant Improvement Allowance exceeds the portion of such cost theretofore paid by Landlord, it being the intent of the parties that Tenant shall in such case be entitled to the benefit of the entire Tenant Improvement Allowance. Landlord shall have no obligation to advance the Tenant Improvement Allowance to the extent it exceeds the total cost of the Tenant Improvement work. In no event shall Landlord have any responsibility for the cost of the Tenant Improvement work in excess of the Tenant Improvement Allowance. Landlord shall have no obligation to make any payments to Tenant Improvement Contractor's material suppliers or subcontractors or to determine whether amounts due them from Tenant Improvement Contractor in connection with the Tenant Improvement work have, in fact, been paid."

4. Ratification. The Lease, as amended by this Amendment, is hereby ratified by Landlord and Tenant and Landlord and Tenant hereby agree that the Lease, as so amended, shall continue in full force and effect.

5. Miscellaneous.

5.1 Voluntary Agreement. The parties have read this Amendment and the mutual releases contained in it, and on the advice of counsel they have freely and voluntarily entered into this Amendment.

5.2 Attorney's Fees. If either party commences an action against the other party arising out of or in connection with this Amendment, the prevailing party shall be entitled to recover from the non- prevailing party, reasonable attorney's fees and costs of suit.

5.3 Successors. This Amendment shall be binding on and inure to the benefit of the parties and their successors.

5.4 Counterparts. This Amendment may be signed in two or more counterparts. When at least one such counterpart has been signed by each party, this Amendment shall be deemed to have been

fully executed, each counterpart shall be deemed to be an original, and all counterparts shall be deemed to be one and the same agreement.

5.5 Capitalized Terms. Capitalized terms used in this Amendment and not otherwise defined herein shall have the same meaning ascribed to such terms in the Lease.

In Witness Whereof, Landlord and Tenant have executed this Amendment as of the date first written above.

LANDLORD:		**TENANT:**	
ARDENWOOD VENTURES I, LLC,		**PERSONALIS, INC.**,	
a Delaware limited liability company		a Delaware corporation	
By:	/s/ Mark Pearson	By:	/s/ Carol Tillis
Printed Name:	Mark Pearson	Printed Name:	Carol Tillis
Title:	Authorized Signatory	Title:	VP, Finance and Administration

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 3, 2022

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 3, 2022

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, 2022 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 3, 2022

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, 2022 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 3, 2022

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