

**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, 2023

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**

(State or other jurisdiction of  
incorporation or organization)

**6600 Dumbarton Circle  
Fremont, California**

(Address of principal executive offices)

**27-5411038**

(I.R.S. Employer  
Identification No.)

**94555**

(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 August 1, 2023 was 48,518,901.

PERSONALIS, INC.

Form 10-Q  
For the Quarterly Period Ended June 30, 2023

TABLE OF CONTENTS

	<u>Page</u>
<a href="#">Note Regarding Forward-Looking Statements</a>	3
<b><u>PART I—FINANCIAL INFORMATION</u></b>	
Item 1. <a href="#">Financial Statements</a>	4
<a href="#">Condensed Consolidated Balance Sheets</a>	4
<a href="#">Condensed Consolidated Statements of Operations</a>	5
<a href="#">Condensed Consolidated Statements of Comprehensive Loss</a>	6
<a href="#">Condensed Consolidated Statements of Stockholders' Equity</a>	8
<a href="#">Condensed Consolidated Statements of Cash Flows</a>	9
<a href="#">Index to Notes</a>	10
<a href="#">Notes to Unaudited Condensed Consolidated Financial Statements</a>	11
Item 2. <a href="#">Management's Discussion and Analysis of Financial Condition and Results of Operations</a>	20
Item 3. <a href="#">Quantitative and Qualitative Disclosures About Market Risk</a>	28
Item 4. <a href="#">Controls and Procedures</a>	28
<b><u>PART II—OTHER INFORMATION</u></b>	
Item 1. <a href="#">Legal Proceedings</a>	29
Item 1A. <a href="#">Risk Factors</a>	29
Item 2. <a href="#">Unregistered Sales of Equity Securities and Use of Proceeds</a>	70
Item 3. <a href="#">Defaults Upon Senior Securities</a>	70
Item 4. <a href="#">Mine Safety Disclosures</a>	70
Item 5. <a href="#">Other Information</a>	70
Item 6. <a href="#">Exhibits</a>	71
<a href="#">Signatures</a>	72

## 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,” “continue,” “could,” “estimate,” “expect,” “intend,” “may,” “might,” “objective,” “ongoing,” “plan,” “potential,” “predict,” “project,” “should,” “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 and the timing thereof, expenses, use of cash and other resources, cost savings, capital requirements, and our needs for additional financing;
- future reimbursement and reimbursement rulings;
- our ability to enter into and compete in new markets;
- the impact our collaboration agreements and key opinion leaders may have on the broader use of our platform in the future;
- the potential impacts of inflation, macroeconomic conditions, and geopolitical conflicts on our business and operations;
- the benefits of our products and services, including their ability to increase the probability of clinical trial success;
- our ability to compete effectively with existing competitors and new market entrants;
- our business strategies, including our aim to focus on certain indications and the timing thereof;
- our planned closure of our operations in China and the timing thereof;
- our ability to benefit from the scaling of our infrastructure and new facility in Fremont;
- 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;
- our success in defending and enforcing our intellectual property rights, including patents;
- potential effects of extensive government regulation;
- our ability to hire and retain key personnel;
- our ability to obtain financing when needed;
- our belief that approval of personalized cancer therapies by the U.S. Food and Drug Administration may drive benefits to our business;
- our future business with the U.S. Department of Veterans Affairs' Million Veteran Program (“VA MVP”), Natera, Inc., and other collaboration partners and customers; 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.*

## PART I—FINANCIAL INFORMATION

## Item 1. Financial Statements

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

	June 30, 2023	December 31, 2022
<b>Assets</b>		
Current assets		
Cash and cash equivalents	\$ 97,195	\$ 89,128
Short-term investments	40,012	78,530
Accounts receivable, net	10,132	16,642
Inventory and other deferred costs	8,140	8,591
Prepaid expenses and other current assets	5,476	6,808
Total current assets	160,955	199,699
Property and equipment, net	59,486	61,935
Operating lease right-of-use assets	24,660	26,480
Other long-term assets	3,937	4,586
Total assets	\$ 249,038	\$ 292,700
<b>Liabilities and Stockholders' Equity</b>		
Current liabilities		
Accounts payable	\$ 8,847	\$ 12,854
Accrued and other current liabilities	16,408	19,013
Contract liabilities	3,337	1,264
Total current liabilities	28,592	33,131
Long-term operating lease liabilities	40,326	41,041
Other long-term liabilities	4,034	389
Total liabilities	72,952	74,561
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; 48,507,101 and 46,707,084 shares issued and outstanding at June 30, 2023 and December 31, 2022, respectively	5	5
Additional paid-in capital	589,418	579,456
Accumulated other comprehensive loss	(313)	(912)
Accumulated deficit	(413,024)	(360,410)
Total stockholders' equity	176,086	218,139
Total liabilities and stockholders' equity	\$ 249,038	\$ 292,700

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,	
	2023	2022	2023	2022
Revenue	\$ 16,699	\$ 18,240	\$ 35,559	\$ 33,467
Costs and expenses				
Cost of revenue	11,907	13,959	26,037	24,908
Research and development	17,852	16,288	34,425	33,386
Selling, general and administrative	12,134	15,874	26,231	31,360
Restructuring and other charges	152	—	4,037	—
Total costs and expenses	42,045	46,121	90,730	89,654
Loss from operations	(25,346)	(27,881)	(55,171)	(56,187)
Interest income	1,465	349	2,718	493
Interest expense	(39)	(50)	(86)	(109)
Other income (expense), net	1	50	(25)	69
Loss before income taxes	(23,919)	(27,532)	(52,564)	(55,734)
Provision for income taxes	36	14	50	21
Net loss	\$ (23,955)	\$ (27,546)	\$ (52,614)	\$ (55,755)
Net loss per share, basic and diluted	\$ (0.50)	\$ (0.60)	\$ (1.11)	\$ (1.23)
Weighted-average shares outstanding, basic and diluted	47,669,513	45,637,838	47,204,891	45,316,795

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,	
	2023	2022	2023	2022
Net loss	\$ (23,955)	\$ (27,546)	\$ (52,614)	\$ (55,755)
Other comprehensive income (loss), net of tax				
Foreign currency translation adjustment	(37)	(194)	(9)	(202)
Change in unrealized gain (loss) on available-for-sale debt securities	179	(195)	608	(896)
Comprehensive loss	\$ (23,813)	\$ (27,935)	\$ (52,015)	\$ (56,853)

See notes to condensed consolidated financial statements.

**PERSONALIS, INC.**  
**CONDENSED CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY (unaudited)**  
For the Three Months Ended June 30, 2023 and 2022  
(in thousands, except share data)

	Common Stock		Additional Paid-In Capital	Accumulate d Other Comprehen sive Income (Loss)	Accumulate d Deficit	Total Stockholder s' Equity
	Shares	Amount				
Balance—March 31, 2023	46,774,490	\$ 5	\$ 583,151	\$ (455)	\$ (389,069)	\$ 193,632
Proceeds from sales of common stock under ATM facility, net of commissions	900,000	—	1,873	—	—	1,873
Proceeds from exercise of stock options	8	—	—	—	—	—
Proceeds from ESPP	468,643	—	909	—	—	909
Restricted stock units vested	363,960	—	—	—	—	—
Stock-based compensation	—	—	3,485	—	—	3,485
Foreign currency translation adjustment	—	—	—	(37)	—	(37)
Unrealized gain on available-for-sale debt securities	—	—	—	179	—	179
Net loss	—	—	—	—	(23,955)	(23,955)
Balance—June 30, 2023	48,507,101	\$ 5	\$ 589,418	\$ (313)	\$ (413,024)	\$ 176,086
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	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

See notes to condensed consolidated financial statements.

**PERSONALIS, INC.**  
**CONDENSED CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY (unaudited)**  
For the Six Months Ended June 30, 2023 and 2022  
(in thousands, except share data)

	Common Stock		Additional Paid-In Capital	Accumulate d Other Comprehen sive Income (Loss)	Accumulate d Deficit	Total Stockholder s' Equity
	Shares	Amount				
Balance—December 31, 2022	46,707,084	\$ 5	\$ 579,456	\$ (912)	\$ (360,410)	\$ 218,139
Proceeds from sales of common stock under ATM facility, net of commissions	900,000	—	1,873	—	—	1,873
Proceeds from exercise of stock options	8	—	—	—	—	—
Proceeds from ESPP	468,643	—	909	—	—	909
Restricted stock units vested	431,366	—	—	—	—	—
Stock-based compensation	—	—	7,180	—	—	7,180
Foreign currency translation adjustment	—	—	—	(9)	—	(9)
Unrealized gain on available-for-sale debt securities	—	—	—	608	—	608
Net loss	—	—	—	—	(52,614)	(52,614)
	48,507,101	\$ 5	\$ 589,418	\$ (313)	\$ (413,024)	\$ 176,086
Balance—June 30, 2023	48,507,101	\$ 5	\$ 589,418	\$ (313)	\$ (413,024)	\$ 176,086
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	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)
	45,891,458	\$ 5	\$ 568,741	\$ (1,264)	\$ (302,850)	\$ 264,632
Balance—June 30, 2022	45,891,458	\$ 5	\$ 568,741	\$ (1,264)	\$ (302,850)	\$ 264,632

See notes to condensed consolidated financial statements.



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

	Six Months Ended June 30,	
	2023	2022
<b>Cash flows from operating activities:</b>		
Net loss	\$ (52,614)	\$ (55,755)
Adjustments to reconcile net loss to net cash used in operating activities		
Stock-based compensation expense	7,180	9,231
Depreciation and amortization	5,630	3,594
Noncash operating lease cost	1,120	2,443
Amortization of premium (discount) on short-term investments	(740)	481
Noncash restructuring and other charges	476	—
Other	234	19
Changes in operating assets and liabilities		
Accounts receivable	6,510	5,591
Inventory and other deferred costs	295	(2,276)
Prepaid expenses and other assets	1,538	2,144
Accounts payable	(1,353)	80
Accrued and other current liabilities	(2,357)	(165)
Contract liabilities	5,703	(3,626)
Operating lease liabilities	2,219	(45)
Other long-term liabilities	—	(422)
Net cash used in operating activities	<u>(26,159)</u>	<u>(38,706)</u>
<b>Cash flows from investing activities:</b>		
Purchases of available-for-sale debt securities	(23,894)	(90,060)
Proceeds from maturities of available-for-sale debt securities	63,755	123,405
Purchases of property and equipment	(6,519)	(18,944)
Lease incentive cash receipts	—	5,459
Net cash provided by investing activities	<u>33,342</u>	<u>19,860</u>
<b>Cash flows from financing activities:</b>		
Proceeds from sales of common stock under ATM facility, net of commissions	1,873	—
Repayments of loans	(1,857)	(1,857)
Proceeds from issuance of common stock under employee equity plans	909	1,952
Net cash provided by financing activities	<u>925</u>	<u>95</u>
Effect of exchange rates on cash, cash equivalents and restricted cash	(41)	(103)
Net change in cash, cash equivalents and restricted cash	8,067	(18,854)
Cash, cash equivalents and restricted cash, beginning of period	90,918	107,375
Cash, cash equivalents and restricted cash, end of period	<u>\$ 98,985</u>	<u>\$ 88,521</u>
<b>Reconciliation of cash, cash equivalents and restricted cash to the condensed consolidated balance sheets:</b>		
Cash and cash equivalents	\$ 97,195	\$ 86,731
Restricted cash, included in other long-term assets	1,790	1,790
Total cash, cash equivalents and restricted cash	<u>\$ 98,985</u>	<u>\$ 88,521</u>

See notes to condensed consolidated financial statements.

**PERSONALIS, INC.**  
**INDEX FOR NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

	<b>Page</b>
Note 1. <a href="#">Company and Nature of Business</a>	11
Note 2. <a href="#">Summary of Significant Accounting Policies</a>	11
Note 3. <a href="#">Revenue</a>	12
Note 4. <a href="#">Balance Sheet Details</a>	13
Note 5. <a href="#">Fair Value Measurements</a>	14
Note 6. <a href="#">Loans</a>	14
Note 7. <a href="#">Leases</a>	15
Note 8. <a href="#">Stock-Based Compensation</a>	16
Note 9. <a href="#">Commitments and Contingencies</a>	17
Note 10. <a href="#">Basic and Diluted Net Loss Per Common Share</a>	18
Note 11. <a href="#">Restructuring and Other Charges</a>	19

**PERSONALIS, INC.**  
**NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

**Note 1. Company and Nature of Business**

Personalis, Inc. (the "Company") is a provider of advanced genomic tests for precision oncology and personalized testing. The Company also provides sequencing and data analysis services to support population sequencing initiatives. The Company's genomic tests are sold primarily to pharmaceutical companies, biopharmaceutical companies, diagnostics 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.

The Company was incorporated in Delaware in February 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. Management is in the process of closing its operations in China. Refer to Note 11 for further information. The Company operates and manages its business as one reportable operating segment, which is the sale of sequencing and data analysis services.

The Company has incurred losses to date and expects to incur additional losses for the foreseeable future. The Company continues to invest the majority of its resources in the development and growth of its business, including investments in product development and studies to prove the clinical validity and utility of the Company's tests. 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, 2022.

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, 2023.

***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, revenue recognition, 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.

***At-the-Market Equity Offerings***

In December 2021, the Company entered into an At-the-Market ("ATM") 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.

During the three and six months ended June 30, 2023, the Company issued and sold 0.9 million shares of its common stock under the Sales Agreement. The shares were sold at a weighted-average price of \$2.12 per share. The Company received \$1.9 million in proceeds, net of commissions. As of June 30, 2023, up to \$98.1 million in aggregate sales of common stock remained available for sale 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 performs regular reviews of customer activity and associated credit risks and does not require collateral. Historically, the Company has not experienced significant credit losses from accounts receivable. Multiple customers have provided more than 10% of total revenue in the periods presented, or accounted for more than 10% of accounts receivable at each respective balance sheet date, as follows:

	Revenue				Accounts Receivable	
	Three Months Ended June 30,		Six Months Ended June 30,		June 30, 2023	December 31, 2022
	2023	2022	2023	2022		
Natera, Inc.	44%	38%	47%	33%	34%	43%
VA MVP	18%	22%	17%	23%	*	*
Merck & Co., Inc.	10%	*	*	*	17%	*
Pfizer Inc.	*	*	*	*	12%	10%
GSK plc	*	*	*	*	*	12%

\* Less than 10% of revenue or accounts receivable

### Significant Accounting Policies

As of June 30, 2023, the Company's significant accounting policies are consistent with those discussed in Note 2 - "Summary of Significant Accounting Policies" in its consolidated financial statements included in the Company's Annual Report on Form 10-K for the year ended December 31, 2022.

### Recent Accounting Pronouncements

#### New Accounting Pronouncements 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 adopted the new guidance as of the beginning of the first quarter of 2023 by means of a cumulative-effect adjustment to opening retained earnings. The adoption did not have a significant impact on the condensed consolidated financial statements.

### Note 3. Revenue

The Company disaggregates revenue by the following four customer types:

- **Pharma tests and services** includes sales of testing services and data analytics for clinical trials and research to pharmaceutical companies in support of their drug development programs. Individual contracts typically contemplate a single project and involve a range of tests and analytics deliverables from the Company that are suitable for each particular project.
- **Enterprise sales** includes sales of tumor profiling and diagnostic tests directly to other businesses as an input to their products. The Company is typically contracted to deliver a limited number of tests and analytics deliverables, but in high volume over time, and may offer tiered pricing. Revenue from the Company's partnership with Natera to provide advanced tumor analysis for use in Natera's MRD test makes up substantially all of the revenue in this category.

- **Population sequencing** includes sales of genomic sequencing services and data analytics to support large-scale genetic research programs. The Company is typically contracted to deliver whole genome sequencing and provide data that can be used for analysis across a large volume of samples. All of the revenue within this category is from the Company's partnership with the VA MVP.
- **Other** includes sales of genomic tests and analytics to universities and non-profits.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
Pharma tests and services	\$ 6,083	\$ 7,257	\$ 12,416	\$ 14,819
Enterprise sales	7,386	6,891	16,844	11,007
Population sequencing	3,000	4,055	6,005	7,556
Other	230	37	294	85
<b>Total revenue</b>	<b>\$ 16,699</b>	<b>\$ 18,240</b>	<b>\$ 35,559</b>	<b>\$ 33,467</b>

Revenue from countries outside of the United States, based on the billing addresses of customers, represented approximately 6% of the Company's revenue for each of the three months ended June 30, 2023 and 2022, and approximately 10% and 11% for the six months ended June 30, 2023 and 2022, respectively.

#### Contract Assets and Liabilities

Contract assets as of June 30, 2023 and December 31, 2022 were immaterial.

Amounts collected in advance of services being provided are deferred as contract 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 \$7.0 million (of which \$3.6 million was included within "Long-term liabilities") and \$1.3 million as of June 30, 2023 and December 31, 2022, respectively. As of June 30, 2023, amounts related to unsatisfied services under contracts with an original expected duration of more than one year was \$5.5 million. The Company expects to recognize approximately \$1.9 million of this amount in the next 12 months, and the remaining \$3.6 million in the 12 months after that. Revenue recognized that was included in the contract liability balance at the beginning of each reporting period was immaterial for the three and six months ended June 30, 2023, and was \$3.0 million and \$3.6 million for the three and six months ended June 30, 2022.

#### Note 4. Balance Sheet Details

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

	June 30, 2023	December 31, 2022
Raw materials	\$ 4,771	\$ 6,384
Other deferred costs	3,369	2,207
<b>Total inventory and other deferred costs</b>	<b>\$ 8,140</b>	<b>\$ 8,591</b>

*Property and equipment.* Depreciation and amortization expense for the three months ended June 30, 2023 and 2022 was \$2.8 million and \$1.8 million, respectively, and for the six months ended June 30, 2023 and 2022 was \$5.6 million and \$3.6 million, respectively. Accumulated depreciation and amortization was \$32.4 million and \$26.9 million as of June 30, 2023 and December 31, 2022, 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, 2023 and December 31, 2022, and is included in other long-term assets.

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

	June 30, 2023	December 31, 2022
Accrued compensation	\$ 7,057	\$ 9,008
Operating lease liabilities	7,643	5,391
Loans—current portion (Note 6)	430	2,218
Accrued liabilities	789	1,700
Employee ESPP contributions	367	543
Accrued taxes	100	123
Customer deposits	22	30
<b>Total accrued and other current liabilities</b>	<b>\$ 16,408</b>	<b>\$ 19,013</b>

**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, 2023 and December 31, 2022 (in thousands):

	June 30, 2023				Fair Value Level
	Adjusted Cost	Unrealized Gains	Unrealized Losses	Fair Value	
<b>Assets</b>					
Cash and cash equivalents:					
Cash	\$ 2,112	\$ —	\$ —	\$ 2,112	
Money market funds	50,650	—	—	50,650	Level 1
Commercial paper	39,444	—	(10)	39,434	Level 2
U.S. government securities	4,997	2	—	4,999	Level 2
Total cash and cash equivalents	<u>97,203</u>	<u>2</u>	<u>(10)</u>	<u>97,195</u>	
Short-term investments:					
Commercial paper	9,969	—	(11)	9,958	Level 2
U.S. agency securities	5,369	1	(6)	5,364	Level 2
U.S. government securities	24,742	1	(53)	24,690	Level 2
Total short-term investments	<u>40,080</u>	<u>2</u>	<u>(70)</u>	<u>40,012</u>	
Total assets measured at fair value	<u>\$ 137,283</u>	<u>\$ 4</u>	<u>\$ (80)</u>	<u>\$ 137,207</u>	

  

	December 31, 2022				Fair Value Level
	Adjusted Cost	Unrealized Gains	Unrealized Losses	Fair Value	
<b>Assets</b>					
Cash and cash equivalents:					
Cash	\$ 5,615	\$ —	\$ —	\$ 5,615	
Money market funds	31,401	—	—	31,401	Level 1
Commercial paper	47,135	—	(15)	47,120	Level 2
U.S. government securities	4,991	1	—	4,992	Level 2
Total cash and cash equivalents	<u>89,142</u>	<u>1</u>	<u>(15)</u>	<u>89,128</u>	
Short-term investments:					
Commercial paper	13,097	—	(51)	13,046	Level 2
U.S. agency securities	9,445	—	(105)	9,340	Level 2
U.S. government securities	56,658	1	(515)	56,144	Level 2
Total short-term investments	<u>79,200</u>	<u>1</u>	<u>(671)</u>	<u>78,530</u>	
Total assets measured at fair value	<u>\$ 168,342</u>	<u>\$ 2</u>	<u>\$ (686)</u>	<u>\$ 167,658</u>	

The Company's marketable debt securities at June 30, 2023 have maturities due in six months or less. No security has been in a continuous unrealized loss position for more than 12 months and the Company does not consider any of its marketable debt securities to be impaired.

**Note 6. Loans**
*Equipment and Software Loans*

In April 2021, the Company entered into a secured 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.

The Company entered into two more secured payment agreements in April 2021 and July 2022, with the same financing entity, to finance the purchase of \$3.1 million of computer hardware and related hardware maintenance and \$1.3 million of internal use software licenses and related ongoing support, respectively. The Company is required to pay three equal payments of \$1.0 million in July 2021, June 2022, and June 2023 for the first agreement, and three equal payments of \$0.4 million in September 2022, September 2023, and September 2024 for the second agreement. The nature of these agreements and resulting accounting treatment are the same as the payment agreement described in the preceding paragraph, except our imputed interest rate was 9% for the July 2022 agreement.

Repayments are presented as financing cash outflows in the condensed consolidated statements of cash flows. Interest expense for all periods presented was \$0.1 million or less. Amounts outstanding under the payment agreements are as follows (in thousands):

	June 30, 2023	December 31, 2022
Principal	\$ 873	\$ 2,730
Less: unamortized discount	(48)	(134)
Total carrying amount	825	2,596
Less: current portion (included in accrued and other current liabilities)	(430)	(2,218)
Long-term portion (included in other long-term liabilities)	<u>\$ 395</u>	<u>\$ 378</u>

#### Note 7. Leases

In 2015, the Company entered into a noncancelable operating lease for approximately 31,280 square feet of office and laboratory space. In 2020, the lease term was extended through November 2027. The lease includes escalating rent payments. In 2021, the Company amended the lease to expand the leased premises by an additional 14,710 square feet of space (the "Expansion Lease"). The Expansion Lease expired at the end of December 2022 and was not extended. The Company intends to vacate this space in the future when all office and laboratory activities have been moved to the Fremont headquarters.

In 2019, the Company entered into a noncancelable three-year operating lease for a co-located data center space, which was subsequently extended through September 2025. In April 2023, the Company expanded its data center space with an additional noncancelable three-year operating lease that extends through March 2026. Both leases include an option to extend the terms for a period of three years immediately following the expiration of the terms. The Company determined the extension options are not reasonably certain to be exercised.

In 2021, the Company entered into a noncancelable operating lease for approximately 100,000 square feet in Fremont, California used for its corporate headquarters and laboratory operations. The lease term is 13.5 years and commenced in October 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 contributed \$15.1 million. Such contributions were accounted for as lease incentives and are recognized as reductions to lease expense over the lease term. The lease expires at the end of March 2036 and includes two options to extend the term for a period of five-years per option at prevailing market rates. The Company determined the extension options are not reasonably certain to be exercised. The lease also includes escalating rent payments.

The Company had an operating lease for laboratory space in Shanghai, China that was terminated early upon both parties' approval during the second quarter of 2023. The early termination did not result in any material penalties or charges in the Company's condensed consolidated statements of operations. Separately, the Company also has various other short-term leases.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
Lease cost				
Operating lease cost	\$ 1,843	\$ 2,174	\$ 3,592	\$ 4,348
Short-term lease cost	25	8	124	37
Variable lease cost	390	385	883	646
Total lease cost	<u>\$ 2,258</u>	<u>\$ 2,567</u>	<u>\$ 4,599</u>	<u>\$ 5,031</u>

As of June 30, 2023, the Company's operating leases had a weighted-average remaining lease term of 10.6 years and a weighted-average discount rate of 10.5%. 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, 2023 were as follows (in thousands):

	Amount
2023 (remaining six months)	\$ 3,850
2024	8,383
2025	8,306
2026	7,292
2027	7,189
2028 and thereafter	48,013
Total future minimum lease payments	83,033
Less: imputed interest	(35,064)
Present value of future minimum lease payments	47,969
Less: current portion of operating lease liability	(7,643)
Long-term operating lease liabilities	<u>\$ 40,326</u>

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, 2023 and 2022, was \$2.2 million and \$1.9 million, respectively. Right-of-use assets obtained in exchange for new operating lease liabilities during the six months ended June 30, 2023 and 2022 were \$1.3 million and zero, 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, 2023
Outstanding stock awards	9,478,696
Reserved for future award grants	3,227,847
Reserved for future ESPP	614,307
Total common stock reserved for stock awards	<u>13,320,850</u>

### 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, 2023 is as follows:

	Outstanding Options			
	Number of Shares	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value
(in thousands, except share and per share data)				
Balance—December 31, 2022	5,451,132	\$ 9.90	5.31	\$ 7
Options granted	2,510,500	2.66		
Options exercised	(8)	2.44		
Options forfeited or expired	(633,716)	9.53		
Balance—June 30, 2023	<u>7,327,908</u>	\$ 7.45	6.26	\$ 2
Options vested and exercisable as of June 30, 2023	<u>3,983,216</u>	\$ 9.04	3.68	\$ 2

The weighted-average grant date fair value of options granted was \$1.51 and \$3.19 per share for the three months ended June 30, 2023 and 2022, and \$1.84 and \$3.99 per share for the six months ended June 30, 2023 and 2022, respectively. As of June 30, 2023, the unrecognized stock-based compensation cost of unvested options was \$10.1 million, which is expected to be recognized over a weighted-average period of 2.4 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,	
	2023	2022	2023	2022
Expected term (in years)	5.50 - 6.02	5.50 - 6.08	5.50 - 6.02	5.50 - 6.08
Volatility	78.47 - 79.31%	69.70 - 71.56%	78.47 - 79.31%	68.37 - 71.56%
Risk-free interest rate	3.47 - 3.98%	2.82 - 3.39%	3.47 - 3.98%	1.62 - 3.39%
Dividend yield	—%	—%	—%	—%

### Performance-Based Stock Option Activity

No performance-based stock option activity occurred during the six months ended June 30, 2023. As of June 30, 2023, performance-based stock options for 421,000 shares with an exercise price of \$5.10 and a remaining contractual term of 0.50 years remained outstanding. The stock options are fully vested and exercisable and had no intrinsic value as of June 30, 2023.



### Restricted Stock Units ("RSU") 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, 2023 is as follows:

(in thousands, except share and per share data)	Unvested Restricted Stock Units		
	Number of Shares	Weighted-Average Grant Date Fair Value	Aggregate Fair Value
Balance—December 31, 2022	2,621,482	\$ 9.33	\$ 5,191
RSUs granted	23,200	2.20	
RSUs vested	(431,366)	10.60	979
RSUs forfeited	(483,528)	9.05	
Balance—June 30, 2023	1,729,788	\$ 8.99	\$ 3,252

As of June 30, 2023, the unrecognized stock-based compensation cost of unvested RSUs was \$13.7 million, which is expected to be recognized over a weighted-average period of 2.3 years.

### ESPP Activity and Valuation

During the six months ended June 30, 2023 and 2022, 468,643 and 204,775 shares of common stock were purchased under the ESPP. The fair value of stock purchase rights granted under the ESPP was estimated using the following assumptions:

	Three and Six Months Ended June 30,	
	2023	2022
Expected term (in years)	0.50	0.50
Volatility	84.88 %	82.35 %
Risk-free interest rate	5.14 %	1.49 %
Dividend yield	—%	—%
Grant-date fair value per share	\$ 0.91	\$ 2.23

### 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,	
	2023	2022	2023	2022
Stock options	\$ 1,505	\$ 2,008	\$ 2,848	\$ 4,404
RSUs	1,757	2,227	3,880	4,395
ESPP	223	180	452	432
Total stock-based compensation expense	\$ 3,485	\$ 4,415	\$ 7,180	\$ 9,231

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
Cost of revenue	\$ 436	\$ 445	\$ 926	\$ 903
Research and development	1,241	1,319	2,486	2,660
Selling, general and administrative	1,808	2,651	3,768	5,668
Total stock-based compensation expense	\$ 3,485	\$ 4,415	\$ 7,180	\$ 9,231

## 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 (the "District Court") 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. On August 17, 2022, the Company filed an amended complaint for patent infringement against Foresight. The amended complaint added our U.S. Patent No.

11,408,033 (the "'033 Patent"), entitled "Methods and Systems for Genetic Analysis." The '033 Patent was granted on August 9, 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. On October 12, 2022, Foresight filed its answer and counterclaims in the matter, alleging and seeking declaratory judgment that its solid tumor recurrence test does not infringe the Company's asserted patents and that the claims of our asserted patents are invalid and/or unenforceable. On November 2, 2022, the Company filed its answer to Foresight's counterclaims. The Company intends to vigorously defend against these counterclaims.

Between November 30, 2022 and February 10, 2023, inclusive, Foresight filed four *inter partes* review petitions with the USPTO, seeking to invalidate the four patents that we are asserting against Foresight in our patent infringement action. Also on November 30, 2022, Foresight filed a motion to stay our patent infringement action in the District Court pending the resolution of the *inter partes* review proceedings that Foresight has requested. On January 24, 2023, the District Court granted Foresight's motion to stay. On June 13, 2023, the USPTO issued decisions granting *inter partes* reviews of the '394 and '033 Patents. On August 8, 2023, the USPTO issued decisions granting *inter partes* reviews of the '611 and '783 Patents.

On June 26, 2023, the Company filed a second complaint in the District Court against Foresight for patent infringement. The complaint is based on the Company's U.S. Patent No. 11,584,968 (the "'968 Patent"), entitled "Methods For Using Mosaicism in Nucleic Acids Sampled Distal to Their Origin," our U.S. Patent No. 11,649,507 (the "'507 Patent"), entitled "Methods for Using Mosaicism in Nucleic Acids Sampled Distal to Their Origin," and our U.S. Patent No. 11,643,685 (the "'685 Patent"), entitled "Methods and Systems For Genetic Analysis." The '968 Patent was granted on February 21, 2023, and relates to methods for improving detection and monitoring of human diseases. The '507 Patent was granted on May 16, 2023, and relates to methods for detection and monitoring of human disease by providing spatial or developmental localization of mutations within the body which is used in monitoring states of health in tissues of the body. The '685 Patent was granted on May 9, 2023, 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. Foresight has yet to file its answer in the matter.

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 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. Except for the matter described in the first three paragraphs of this Note 9, as of June 30, 2023, 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, 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, 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 basic and diluted net loss per share attributable to common stockholders (in thousands, except share and per share amounts):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
Net loss	\$ (23,955)	\$ (27,546)	\$ (52,614)	\$ (55,755)
Weighted-average common shares outstanding—basic and diluted	47,669,513	45,637,838	47,204,891	45,316,795
Net loss per common share—basic and diluted	<u>(0.50)</u>	<u>\$ (0.60)</u>	<u>\$ (1.11)</u>	<u>\$ (1.23)</u>

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,	
	2023	2022	2023	2022
Options to purchase common stock	7,748,908	5,051,580	7,748,908	5,051,580
Unvested RSUs	1,729,788	1,548,567	1,729,788	1,548,567
ESPP	427,009	125,613	427,009	125,613
Total	<u>9,905,705</u>	<u>6,725,760</u>	<u>9,905,705</u>	<u>6,725,760</u>

#### Note 11. Restructuring and Other Charges

Restructuring and Other Charges in the condensed consolidated statements of operations consist of restructuring charges in connection with the Company's 2023 reduction in workforce and charges in connection with the closure of the Company's China operations.

*Restructuring.* In January 2023, the Company initiated a reduction in the Company's workforce to reduce operating costs and improve operating efficiency. The workforce reduction affected nearly 100 employees and was substantially completed during the first quarter of 2023. The Company recognized \$3.1 million in one-time employee termination benefits during the first quarter of 2023 in connection with the reduction in workforce, comprising separation pay and healthcare benefits payable in cash, all of which were paid as of June 30, 2023.

*Closure of China Operations.* In February 2023, the Company resolved to terminate operations, carry out liquidation work, and dissolve the Company's Personalis (Shanghai) Ltd entity in China with the objective of streamlining international operations and reducing operating costs. The Company anticipates completing the dissolution of the entity by the end of 2023. The disposal does not qualify for reporting as a discontinued operation because it does not represent a strategic shift that has or will have a major effect on our operations and financial results.

During the three and six months ended June 30, 2023, expenses of \$0.1 million and \$0.9 million were recognized, respectively, in connection with closure activities. \$0.3 million of such expenses related to one-time employee termination benefits for the Company's 12 employees located in China and were payable in cash. Substantially all of the terminations were completed during the first quarter of 2023, along with the related cash outlays. The remaining \$0.6 million in expenses were comprised primarily of non-cash charges, including losses on disposal of fixed assets and impairments of other assets. The Company may incur additional costs as closure activities continue throughout 2023, however, such future costs are not expected to be significant.

## 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 unaudited 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, 2022 filed with the Securities and Exchange Commission (the "SEC") on February 23, 2023 (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 "Note Regarding Forward-Looking Statements" for a discussion of forward-looking statements and in Part II, Item 1A, "Risk Factors" for a discussion of factors that could cause actual results to differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis and elsewhere in this Quarterly Report on Form 10-Q and in our Annual Report.*

### Overview

We strive to develop the most comprehensive and actionable cancer genomic tests in the world to help patients live better and longer lives. We believe we have one of the most discerning technologies to both characterize and monitor cancer – with the aim of driving a new paradigm for cancer management and guiding care from biopsy through the life of the patient. Our assays combine tumor-and-normal profiling with proprietary algorithms to deliver advanced insights even as cancer evolves over time. Our products are designed to detect recurrence at the earliest timepoints, enable selection of targeted therapies based on ultra-comprehensive genomic profiling, and enhance biomarker strategy for drug development.

Today, our platforms are routinely used by many of the largest oncology-focused pharmaceutical companies for analysis of patient samples in their clinical trials and drug development programs. Our advanced genomic sequencing and analytics also support the development of personalized cancer vaccines and other next-generation cancer immunotherapies. For example, we are providing genomic testing to Moderna, Inc. ("Moderna") in its ongoing clinical trials evaluating a personalized cancer vaccine. In addition, we partner with diagnostics companies by providing our advanced tumor profiling and analysis capabilities as an input to their products. More recently, we launched new diagnostic offerings for the clinical setting and are preparing for future expansion in the clinical diagnostics market. Finally, we have also pursued non-cancer related business opportunities, specifically within the population sequencing market, by providing whole genome sequencing ("WGS") services under contract with the U.S. Department of Veterans Affairs Million Veteran Program ("VA MVP").

As part of one of our new strategies for 2023 and beyond, we are working with a growing number of leading cancer centers and world-class academic research institutions to build and publish the clinical evidence-base to support our products and our key indications. Specifically, because of the high sensitivity of our technology, we aim to focus on three indications in the next 2-3 years: immunotherapy (IO) monitoring, breast cancer, and lung cancer. We have collaborations with Cancer Research UK, University College London, and the Francis Crick Institute (the TRACERx study); Vall d'Hebron Institute of Oncology ("VHIO"); BC Cancer; Duke University; UCSF; and Criterium and the Academic Breast Cancer Consortium that will focus on building the evidence-base for our technology and these indications. If the key opinion leaders ("KOLs") we are collaborating with have a positive experience using our platform, we are optimistic this will support broader use of our platform by other KOLS, as well as clinicians in the future.

Our work in oncology is underpinned by our experience and capacity for next-generation sequencing at scale. We have the capacity to sequence and analyze approximately 200 trillion bases of DNA per week in our facility. We believe that our capacity is already larger than most cancer genomics companies, and we continue to build automation and other infrastructure to scale further as demand increases. To date, we have sequenced more than 340,000 human samples, of which more than 170,000 were whole human genomes.

In October 2022, we relocated our corporate headquarters from Menlo Park, California to a new facility in Fremont, California. We signed a 13.5-year lease that extends to 2036 for the 100,000 square foot facility, which is approximately triple the size of our Menlo Park location. The new facility allows for expansion of our laboratory to support pharmaceutical customers and clinical diagnostic testing. 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. We intend to vacate our Menlo Park facility in the future when all office and laboratory activities have been moved to the Fremont headquarters.

### Second Quarter 2023 Highlights

Total revenue decreased 8%, or \$1.5 million, during the second quarter of 2023 compared to the same period of last year, primarily due to lower revenue from pharma tests and population sequencing. Revenue from pharma tests was \$6.1 million in the second quarter of 2023 compared to \$7.3 million in the second quarter of 2022, a decrease of 16%. Revenue from population sequencing was \$3.0 million in the second quarter of 2023 compared to \$4.0 million in the second quarter of 2022, a decrease of 26%. Partially offsetting these decreases was higher sales to Natera under our partnership to provide advanced tumor analysis for use in Natera's minimal residual disease ("MRD") testing offerings, which increased from \$6.9 million in the second quarter of 2022 to \$7.4 million in the second quarter of 2023, or 7%.

We announce new product offerings, business developments, and research collaborations at various times during the year. Significant developments during the second quarter of 2023 included the following:

- Announced a collaboration with National Cancer Center Hospital East and Ono Pharmaceutical Co. Ltd to perform exploratory biomarker analysis using highly sensitive and comprehensive genomic tests from Personalis to better predict immunotherapy response for resectable rectal cancer with mismatch repair deficiency (dMMR).
- Received notice from the VA MVP that it has exercised the first of four one-year renewal options under the September 2022 contract.
- Filed second patent infringement lawsuit against Foresight Diagnostics as part of the Company's continuing efforts to protect its investment and industry-leading intellectual property position in whole genome, tumor-informed minimal residual disease (MRD) testing.

## Components of Operating Results

### Revenue

We derive our revenue primarily from sales of advanced sequencing and analytics to the following four groups of customers:

- **Pharma tests and services** includes sales of testing services and data analytics for clinical trials and research to pharmaceutical companies in support of their drug development programs.
- **Enterprise sales** includes sales of tumor profiling and diagnostic tests directly to other businesses as an input to their products. Revenue from our partnership with Natera to provide advanced tumor analysis for use in Natera's MRD test currently makes up substantially all of the revenue in this category.
- **Population sequencing** includes sales of genomic sequencing services and data analytics to support large-scale genetic research programs. All of the revenue in this category is from our partnership with the VA MVP.
- **Other** includes sales of genomic tests and analytics to universities and non-profits. This category also includes sales of diagnostics tests ordered by healthcare providers for cancer patients, which was insignificant to date in 2023.

Our ability to increase revenue will depend on our ability to further increase sales to these groups of customers and expand our customer base within each group. To do this, we are developing a growing set of state-of-the-art services and products, advancing our operational infrastructure, building our regulatory credentials, focusing our marketing efforts on large pharmaceutical companies, and seeking additional partnerships such as ours with Natera. 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.

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 variability in our gross margins over the medium-term due to fluctuations in customer mix and volume, investments in new capabilities such as automation of laboratory workflows, processing of diagnostic tests for the clinical market while we work to secure reimbursement, and costs related to our new Fremont facility. Over the long-term, we anticipate higher gross margins as growing revenue leads to economies of scale.

#### 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. 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, product development, collaborations, and studies; 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 research and development expenses to stabilize overall in the medium term as we expand collaborations for clinical validation to secure reimbursement and develop our NeXT Personal test as an LDT for the clinical diagnostics market, offset by cost reductions from our first quarter 2023 reduction in workforce and anticipated savings from our closure of operations in China.

### *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.

Selling, general and administrative expenses have decreased significantly since the completion of our first quarter 2023 reduction in workforce. We expect slight increases from this lower level going forward due to investments in our diagnostic sales outreach efforts.

### *Restructuring and Other Charges*

Restructuring and other charges consists of restructuring charges in connection with our 2023 reduction in workforce and charges in connection with the closure of our China operations.

### *Interest Income and Interest Expense*

Interest income consists primarily of interest earned on our cash and cash equivalents and short-term investments. Interest expense 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.

## **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):

	<b>Three Months Ended June 30,</b>		<b>Six Months Ended June 30,</b>	
	<b>2023</b>	<b>2022</b>	<b>2023</b>	<b>2022</b>
Revenue	\$ 16,699	\$ 18,240	\$ 35,559	\$ 33,467
Costs and expenses				
Cost of revenue	11,907	13,959	26,037	24,908
Research and development	17,852	16,288	34,425	33,386
Selling, general and administrative	12,134	15,874	26,231	31,360
Restructuring and other charges	152	—	4,037	—
Total costs and expenses	42,045	46,121	90,730	89,654
Loss from operations	(25,346)	(27,881)	(55,171)	(56,187)
Interest income	1,465	349	2,718	493
Interest expense	(39)	(50)	(86)	(109)
Other income (expense), net	1	50	(25)	69
Loss before income taxes	(23,919)	(27,532)	(52,564)	(55,734)
Provision for income taxes	36	14	50	21
Net loss	\$ (23,955)	\$ (27,546)	\$ (52,614)	\$ (55,755)
Net loss per share, basic and diluted	\$ (0.50)	\$ (0.60)	\$ (1.11)	\$ (1.23)
Weighted-average shares outstanding, basic and diluted	47,669,513	45,637,838	47,204,891	45,316,795
			<b>June 30, 2023</b>	<b>December 31, 2022</b>
Cash and cash equivalents, and short-term investments		\$	137,207	\$ 167,658
Working capital			132,363	166,568
Total assets			249,038	292,700
Total debt			825	2,596
Long-term obligations			44,360	41,430
Total liabilities			72,952	74,561
Total stockholders' equity			176,086	218,139

## Revenue

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

	Three Months Ended June 30,		Change	Six Months Ended June 30,		Change
	2023	2022		2023	2022	
Pharma tests and services	\$ 6,083	\$ 7,257	(16%)	\$ 12,416	\$ 14,819	(16%)
Enterprise sales	7,386	6,891	7%	16,844	11,007	53%
Population sequencing	3,000	4,055	(26%)	6,005	7,556	(21%)
Other	230	37	522%	294	85	246%
Total revenue	\$ 16,699	\$ 18,240	(8%)	\$ 35,559	\$ 33,467	6%

The following table shows customers that made up at least 10% of total revenue in each period presented:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
Natera, Inc.	44%	38%	47%	33%
VA MVP	18%	22%	17%	23%
Merck & Co., Inc.	10%	*	*	*

\* Less than 10% of revenue

### Pharma tests and services

Revenue from pharma tests and services decreased 16%, or \$1.2 million, in the second quarter of 2023, and decreased 16%, or \$2.4 million, in the first six months of 2023. This was primarily the result of variability in timing and spending levels on clinical trial projects by our pharmaceutical customers in general, and non-recurring projects with certain customers. For example, we recognized \$0.5 million in revenue during the first six months of 2022 from an ImmunID NeXT project with one of our largest pharmaceutical customers whereas we recognized no revenue from that same customer in the first six months of 2023. Additionally, revenue recognized for one of our biobank customers decreased \$0.5 million during the second quarter of 2023 and \$0.9 million during the first six months of 2023 as we are strategically shifting away from lower-margin pharma customer projects.

### Enterprise sales

Revenue from enterprise sales increased 7%, or \$0.5 million, in the second quarter of 2023, and increased 53%, or \$5.8 million in the first six months of 2023. This was due to an increase in the volume of samples we tested for Natera for use in Natera's MRD testing offerings, partially offset by lower selling prices as a result of volume-based tiered pricing. The number of samples processed increased approximately 40% and 85% in the second quarter and first six months of 2023, respectively, as compared to the same periods of 2022.

We entered into a new agreement with Natera during the second quarter of 2023 that replaces the previous tiered-pricing arrangement. We agreed to new fixed prices that are lower than the prices paid by Natera under the old arrangement during the first half of 2023, in exchange for minimum volume commitments that extend through at least the first quarter of 2024.

### Population sequencing

Population sequencing revenue is made up entirely of sales to the VA MVP. The decline in revenue during 2023 was related to the timing of our fulfillment of samples received from the VA MVP under our annual task orders.

In September 2022, we entered into a new contract with the VA MVP to continue providing them WGS services. The performance period under the new contract includes a base period of one year, with four one-year renewal option periods that may be exercised upon discretion of the VA MVP. We concurrently received an initial task order with a value of up to \$10.0 million, of which we have recognized \$6.9 million to date. We expect to recognize the remaining \$3.1 million unfulfilled portion of the order during the third quarter of 2023. We have received notice from the VA MVP that it has exercised the first of the four renewal option periods. The first renewal option period extends from September 30, 2023 through September 29, 2024.

### Other

Other revenue increased 522% and 246% in the second quarter and six months of 2023, respectively, or \$0.2 million for both periods, due to higher revenue from university research projects.



## Costs and Expenses

	Three Months Ended June 30,		Change	Six Months Ended June 30,		Change
	2023	2022		2023	2022	
	(in thousands)			(in thousands)		
Cost of revenue	\$ 11,907	\$ 13,959	(15%)	\$ 26,037	\$ 24,908	5%
Research and development	17,852	16,288	10%	34,425	33,386	3%
Selling, general and administrative	12,134	15,874	(24%)	26,231	31,360	(16%)
Restructuring and other charges	152	—	100%	4,037	—	100%
Total costs and expenses	<u>\$ 42,045</u>	<u>\$ 46,121</u>	(9%)	<u>\$ 90,730</u>	<u>\$ 89,654</u>	1%

### Cost of revenue

The decrease in cost of revenue of 15%, or \$2.1 million, in the second quarter of 2023 was due to lower revenue levels and dedication of more laboratory resources to support sample processing required for clinical evidence generation, which is a non-revenue generating activity and thus reported as R&D expense. Specific components of the decrease were a \$1.9 million decrease in shared laboratory costs due to said greater usage of our laboratory capacity for R&D activities and a \$1.0 million decrease in direct material costs due to lower revenue levels, partially offset by a \$0.4 million increase in facilities costs, a \$0.3 million increase in laboratory supplies and consumables (enterprise customer orders require more supplies to process as compared to other customer categories), and a \$0.1 million increase in labor costs.

The increase in cost of revenue of 5%, or \$1.1 million, in the first six months of 2023 was primarily due to higher revenue levels as well as higher fixed laboratory costs. Specific components of the increase were a \$1.1 million increase in facilities costs and maintenance on lab equipment, a \$0.5 million increase in raw material costs to support higher revenue levels, a \$0.5 million increase in laboratory supplies and consumables (enterprise customer orders require more supplies to process as compared to other customer categories), and a \$0.3 million increase in labor costs, partially offset by a \$1.2 million decrease in shared laboratory costs due to greater usage of our laboratory capacity for R&D activities.

### Research and development

The increases in research and development expenses of 10%, or \$1.6 million, in the second quarter of 2023, and 3%, or \$1.0 million, in the first six months of 2023 were primarily due to increases in costs associated with clinical evidence generation and collaborations. Additionally, allocated facility costs have increased in 2023 as a result of the R&D function moving into our new Fremont facility.

Specific components of the increase in the second quarter of 2023 were a \$2.3 million increase in sample processing costs incurred in our laboratory for product development, collaborations, and clinical evidence generation; and a \$1.4 million increase in facilities costs; partially offset by a \$2.1 million decrease in personnel-related costs related to the 2023 reduction in workforce.

Specific components of the increase in the first six months of 2023 were a \$2.9 million increase in facilities costs and a \$1.3 million increase in sample processing costs incurred in our laboratory for product development, collaborations, and clinical evidence generation, partially offset by a \$3.2 million decrease in personnel-related costs primarily related to the 2023 reduction in workforce.

### Selling, general and administrative

The decreases in selling, general and administrative expenses of 24%, or \$3.7 million, in the second quarter of 2023, and 16%, or \$5.1 million, in the first six months of 2023 were primarily due to cost savings from our 2023 reduction in workforce.

Specific components of the decrease in the second quarter of 2023 were a \$2.8 million decrease in personnel-related costs primarily related to the 2023 reduction in workforce, a \$1.9 million decrease in facilities costs as a result of the R&D function moving into our new Fremont facility and consequently receiving a share of such facility costs that were previously allocated to SG&A, and a \$0.4 million decrease in professional services, partially offset by a \$1.4 million increase in depreciation of office-related fixtures and furniture (driven by our new Fremont headquarters).

Specific components of the decrease in the first six months of 2023 were a \$4.6 million decrease in personnel-related costs primarily related to the 2023 reduction in workforce and a \$3.6 million decrease in facilities costs as a result of the R&D function moving into our new Fremont facility and consequently receiving a share of such facility costs that were previously allocated to SG&A, partially offset by a \$2.8 million increase in depreciation of office-related fixtures and furniture (driven by our new Fremont headquarters), and a \$0.3 million increase in sales-related expenses.

### Restructuring and other charges

The \$4.0 million in restructuring and other charges recognized during the first six months of 2023 is comprised of \$3.1 million in charges related to our 2023 reduction in workforce and \$0.9 million in charges related to the closure of our China operations.



The workforce reduction affected nearly 100 employees and was substantially completed during the first quarter of 2023. We recognized \$3.1 million in expenses during the first quarter in connection with these terminations, comprised of separation pay and healthcare benefits payable in cash, all of which were paid as of June 30, 2023.

During the second quarter and first six months of 2023, expenses of \$0.1 million and \$0.9 million were recognized, respectively, in connection with China closure activities. \$0.3 million of such expenses related to one-time employee termination benefits for the Company's 12 employees located in China and were payable in cash. Substantially all of the terminations were completed during the first quarter of 2023, along with the related cash outlays. The remaining \$0.6 million in expenses were comprised primarily of non-cash charges, including losses on disposal of fixed assets and impairments of other assets. We may incur additional costs as closure activities continue throughout 2023, however, such future costs are not expected to be significant.

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

	Three Months Ended June 30,		Change	Six Months Ended June 30,		Change
	2023	2022		2023	2022	
Interest income	\$ 1,465	\$ 349	320%	\$ 2,718	\$ 493	451%
Interest expense	(39)	(50)	(22%)	(86)	(109)	(21%)
Other income (expense), net	1	50	(98%)	(25)	69	
Total	<u>\$ 1,427</u>	<u>\$ 349</u>		<u>\$ 2,607</u>	<u>\$ 453</u>	

#### *Interest income and interest expense*

The increases in interest income in the second quarter and first six months of 2023 were due to increased yields on our investments. Interest expense in both 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, 2023	December 31, 2022
Cash and cash equivalents, and short-term investments	\$ 137,207	\$ 167,658
Property and equipment, net	59,486	61,935
Contract liabilities	6,967	1,264
Working capital	132,363	166,568

From our inception through June 30, 2023, 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, \$89.6 million from issuance of redeemable convertible preferred stock, \$1.9 million in net proceeds from our ATM facility, as well as cash from operations and debt financings. As of June 30, 2023, we had cash and cash equivalents of \$97.2 million and short-term investments of \$40.0 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, 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 our ATM facility. As of June 30, 2023, \$98.1 million in common stock remained available for future issuance under the facility. 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, 2023, cash and cash equivalents held by foreign subsidiaries was \$1.1 million, the majority of which was held by our China subsidiary. We announced the closure of our China operations early in 2023 and plan to repatriate any cash balances back to our headquarters by the end of 2023. Additionally, 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.

### Cash Flows

	Six Months Ended June 30,	
	2023	2022
Net cash used in operating activities	\$ (26,159)	\$ (38,706)
Net cash provided by investing activities	33,342	19,860
Net cash provided by financing activities	925	95

The \$12.5 million decrease in cash used in operating activities during the first six months of 2023 as compared to the first six months of 2022 was primarily due to higher customer deposits received (primarily in connection with our agreement with Moderna to support its ongoing clinical trials evaluating a personalized cancer vaccine) and lower inventory purchases.

The \$13.5 million increase in cash provided by investing activities during the first six months of 2023 as compared to the first six months of 2022 was primarily due to a reduction in capital expenditures, which were significantly higher during 2022 in connection with the build-out of our Fremont facility, and higher net proceeds from short-term investments.

The \$0.8 million increase in cash provided by financing activities during the first six months of 2023 as compared to the first six months of 2022 was driven by \$1.9 million in proceeds from sales of common stock under our ATM facility, partially offset by lower proceeds from employee stock option exercises.

### Material Cash Requirements

Our material cash requirements in the short- and long-term consist primarily of variable costs of revenue, operating expenditures, capital 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 \$137.2 million as of June 30, 2023, 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.

*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. We currently expect spending in this area to increase in 2023 relative to 2022 to support expected higher levels of revenue.

*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 decrease our spend in these areas as a result of our first quarter 2023 workforce reduction. On a long-term basis, we manage future cash requirements relative to our long-term business plans.

*Capital expenditures.* Capital expenditures are expected to decrease significantly from 2022 levels as we have substantially completed the one-time build-out of our new headquarters and laboratory facility in Fremont, California as of the end of 2022. Going forward, our capital expenditures are expected to consist primarily of laboratory equipment and computer equipment. We currently expect capital expenditures to be approximately \$8 million in 2023 and between \$5 million to \$7 million in each of the years 2024 and 2025.

*Property leases.* Our noncancelable operating lease payments were \$83.0 million as of June 30, 2023. 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 Unaudited Condensed Consolidated Financial Statements in Note 7, "Leases."

*Other.* As of June 30, 2023, we had one outstanding noninterest bearing loan that was used to finance the purchase of internal use software licenses and related ongoing support. We will make payments of \$0.4 million in each of September 2023 and September 2024 to pay off this loan. Further discussion of this loan can be found in Part I, Item 1 of this Form 10-Q in the Notes to Unaudited Condensed 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, 2022 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 section titled “Summary of Significant Accounting Policies—Recent Accounting Pronouncements” 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, 2023, 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.
- 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 currently derive a substantial portion of our revenue from one of our largest customers, Natera, and in the past have derived a substantial portion of our revenue from another of our largest customers, the VA MVP.
- We rely on a limited number of suppliers, or in some cases, a sole supplier, for some laboratory instruments and materials, and we may not be able to replace or immediately transition to alternative suppliers 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.

#### 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.
- Failure or perceived failure to comply with existing or future laws, regulations, contracts, self-regulatory schemes, standards, and other obligations related to data privacy and security (including security incidents) could harm our business. Compliance or the actual or perceived failure to comply with such obligations could increase the cost of our offerings, limit their use or adoption, and otherwise negatively affect our operating results and business.
- 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, 2022 (Annual Report), which was filed with the SEC on February 23, 2023.*

### 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, 2022, 2021, and 2020 we had net losses of \$113.3 million, \$65.2 million, and \$41.3 million, respectively. For the six months ended June 30, 2023, we had a net loss of \$52.6 million. As of June 30, 2023, we had an accumulated deficit of \$413.0 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 CLIA-certified, 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 and through gaining acceptance in medical communities. 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.

***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 tests 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., BostonGene Corporation, C2i Genomics, Inc., Caris Life Sciences, Inc., Covance Inc., which was acquired by Laboratory Corporation of America Holdings ("Labcorp") 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, Guardant Health, Inc., Haystack Oncology, Inc., which was acquired by Quest Diagnostics Incorporated in June 2023, Inivata Limited, which was acquired by NeoGenomics, Inc. in June 2021, Invitae Corporation, Natera, NeoGenomics, Inc., Personal Genome Diagnostics, Inc., which was acquired by Labcorp in February 2022, Predicine, Inc., Roche Molecular Systems, Inc., Strata Oncology, 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, 2023, revenue under our agreement accounted for 47% 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. 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 currently derive a substantial portion of our revenue from one of our largest customers, Natera, and in the past have derived a substantial portion of our revenue from another of our largest customers, the VA MVP.\****

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 17% and 23% of our revenue for the six months ended June 30, 2023 and 2022, respectively. Revenue from Natera accounted for 47% and 33% of our revenue for the six months ended June 30, 2023 and 2022, respectively. Our top five customers, including the VA MVP and Natera, accounted for 82% and 77% of our revenue for the six months ended June 30, 2023 and 2022, 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. 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 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 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, in the first six months of 2023, revenue under our agreement accounted for 47% of our total revenue. In May 2023, we entered into a new agreement with Natera that replaces the previous tiered-pricing arrangement with new fixed prices that are lower than the prices paid by Natera under the old arrangement, in exchange for minimum volume commitments that extend through at least the first quarter of 2024. 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 have 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.

***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, or if our new contract with the VA MVP were to be terminated, 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. That contract did not include a renewal option. In September 2022, we entered into a new contract with the VA MVP to continue providing them WGS services. The performance period under the new contract includes a base period of one year, with four one-year renewal option periods that may be exercised upon discretion of the VA MVP. We concurrently received an initial task order with a value of up to \$10.0 million, subject to the receipt of samples from the VA MVP. We received notice that the VA MVP has elected to exercise its first of the four renewal options under the September 2022 contract. However, there is no guarantee that the VA MVP will exercise any subsequent renewal option.

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 orders received in September 2021 and 2022 had values of \$9.7 million and \$10.0 million, respectively, which represents a substantial decline. 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. The priorities of the VA, the VA MVP, or the U.S. government may change, including in response to COVID-19 or another health epidemic or 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. The timing and number of VA MVP samples may also be negatively affected by a public health crisis, such as COVID-19. 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 values of the September 2021 and 2022 VA MVP contracted orders 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. A resurgence of COVID-19 or another health epidemic or pandemic may negatively impact the value of any potential new VA MVP contract or order.

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

Our customers other than the VA MVP 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 a public health crisis), failures in their clinical trials (which failures are statistically much more likely to occur than not at some point in the clinical development process, notwithstanding any enhanced patient stratification from the use of our proprietary tests and algorithms), 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.

***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 offering, is uncertain. We are seeking reimbursement for our NeXT Dx offering 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 current or future tests. The commercial success of current or 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 current or 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 current or future in vitro diagnostic tests we develop for insurance coverage and adequate reimbursement.

***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 our 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. 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 pricing 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, COVID-19 previously disrupted Illumina's ability to fulfill our purchase orders for reagents or other materials in a timely manner and a resurgence of COVID-19 or another health epidemic or pandemic may disrupt the ability of Illumina and our other suppliers to fulfill our purchase orders in a timely manner or at all. Our suppliers, including Illumina, could cease supplying these materials and equipment at any time, could increase the price of these materials or equipment (including the promotional pricing offered to us by Illumina for our 2022 VA MVP Agreement and certain other projects) 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. We have also experienced, and may experience in the future, delays or difficulties in upgrading to newer versions or replacements of these materials and equipment, which may have better performance or be more cost-effective than the current versions. Any such interruption, delay or difficulty 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 Files that we filed with the FDA, which are focused on the technology, quality management, and validation of our platform, specifically on its use for the development of personalized immunotherapies, are predicated on our use of specified equipment and processes, including Illumina sequencers and related equipment. The detailed information in the Device Master Files is not shared with our customers, but with our permission they can reference our FDA file numbers 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 Files 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 Files, 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 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, our only clinical reference or research and development laboratory facilities are our facilities in Menlo Park, California and 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. Northern California continues to experience 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. For example, from January 2023 through April 2023, we experienced substantial disruption to our use of the Fremont facility due to a failure of an electrical bus duct serving the facility. See “—The process of opening our new laboratory facilities in Fremont, California has diverted and could continue to divert management’s attention and has disrupted and could continue to disrupt our ongoing business.” 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, and our services typically involve using biological samples provided by or on behalf of our customers or

collaborators. 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, or if these biological samples or the resulting data were otherwise lost, damaged or compromised due to equipment malfunction, human error or other causes, our ability to pursue our research and development projects or provide our services, as well as our reputation, could be jeopardized. For example, we have experienced from time to time, and may experience in the future, equipment malfunctions that have resulted in lost, damaged or compromised samples or resulting data. We carry insurance for damage to our property or to our customer's property while in our possession, and we also carry insurance for the disruption of our business, but these types of insurance may not be sufficient to cover all of our potential losses or liabilities and may not continue to be available to us on acceptable terms, if at all.

Further, if our laboratory facilities became inoperable, we would likely not be able to license or transfer our technology to other facilities with the qualifications, including state licensure and CLIA certification, that would be necessary to cover the scope of our current and our planned future services. Even if we were to find facilities with such qualifications to perform our services, they may not be available to us on commercially reasonable terms.

***Our success depends on our ability to provide reliable 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. The collective efforts of each of our executives and others working with them as a team are critical to us as we continue to develop our technologies, services, products, and research and development programs. As a result of the difficulty in locating qualified new management, the loss or incapacity of existing members of our executive management team could adversely affect our operations. If we were to lose one or more of these key employees, we could experience difficulties in finding qualified successors, competing effectively, developing our technologies, and implementing our business strategy. Effective December 31, 2022, John West retired from his role as our Chief Executive Officer. Aaron Tachibana, our Chief Financial Officer, served as our interim Chief Executive Officer from December 31, 2022 until March 2, 2023, when Christopher Hall, who served as our SVP and Head, Diagnostics Business, was appointed Chief Executive Officer, in addition to his role as our President. As

with any change in leadership, there is a risk to organizational effectiveness and employee retention as well as the potential for disruption to our business. Integrating members into new or different management roles could prove disruptive to our operations, require substantial resources and management attention and ultimately prove unsuccessful. 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 or replace them in the event we lose their services. 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.

***The process of opening our new laboratory facilities in Fremont, California has diverted and could continue to divert management's attention and has disrupted and could continue to disrupt our ongoing business.\****

We have relocated our corporate headquarters to Fremont, California. We also plan to move our laboratory operations to our Fremont facility in 2023. These efforts have involved, and will continue to involve, significant tenant improvements, construction and regulatory compliance activities to be undertaken. Such efforts have distracted and may continue to distract management from current operations, have disrupted and may continue to disrupt planned research, development or regulatory compliance activities, and have resulted in and may continue to 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. For example, delays in the completion of updates to our new corporate headquarters delayed our previously planned move-in date. Additionally, from January 2023 through April 2023, we experienced substantial disruption to our use of the Fremont facility due to a failure of an electrical bus duct serving the facility. We used backup generators to power our laboratories and emergency lights at the facility through February 2023 but were unable to use the office portions of the facility, or use the facility's heating, ventilation and air conditioning system during this time. We were able to restore full power to the facility on a temporary basis during March 2023 and April 2023 using additional generators, and regular electrical service to the facility has since been restored. However, we may experience additional disruptions in the future. We incurred costs in maintaining temporary power to the facility and in attempting to permanently remedy the problem, including obtaining additional backup generators, equipment, and back up batteries, and purchasing fuel for the generators on a daily basis. While the bus duct and related electrical main equipment are the landlord's responsibility under our lease for the facility, and we expect the landlord to reimburse our costs incurred in connection with remedying the electrical failure, there is no guarantee we will be successful in obtaining such reimbursement within a reasonable timeframe or at all. If we experience additional disruptions to our power supply, it could further delay the completion of our move to the Fremont facility, may result in a loss in productivity, including delays to research and development programs, and could render it difficult or impossible for us to sell or perform certain of our services for some period of time. Additionally, if the backup generators were to fail, it could result in damage to biological samples stored within the Fremont facility, which may include certain customer samples. See “—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 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 new facility 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 Cancer Research UK, University College London, and the Francis Crick Institute (the TRACERx study); Vall d'Hebron Institute of Oncology ("VHIO"); BC Cancer; Duke University; UCSF; and Criterium and the Academic Breast Cancer Consortium) 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 operations and employees face risks related to health crises 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 that could cause significant disruption in the operations of our customers and third-party suppliers upon whom we rely. Our laboratory facilities, 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 were previously impacted by the 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 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 cause similar effects on our operations. COVID-19 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 use certain 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 another health epidemic or pandemic or if other supply chain issues arise as a result of such a public health crisis. Several of our customers were 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 in the event of a resurgence of COVID-19 or the emergence of another health epidemic or pandemic.

Moreover, the ultimate impact of a health epidemic or pandemic on our business, operations, or the global economy as a whole is highly uncertain, but a continued and prolonged public health crisis could have a material negative impact on our business, financial condition, and operating results.

***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. 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 or authorities 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 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 and authorities 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” Act (the “VALID Act”) would clarify and enhance FDA’s authority to regulate LDTs, including pre-market review of non-exempted tests. 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. 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 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 (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 or authorities 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 laboratories in Fremont and Menlo Park, California. To renew this certificate, we are subject to survey and inspection every two years. Because we are a CAP-accredited laboratory, the CMS does not perform this survey and inspection and relies on our CAP survey and inspection. We also may be subject to additional unannounced inspections.



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, 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 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 for our clinical reference laboratory where we believe we are required to be licensed, we may become aware of other states that require out-of-state laboratories to obtain licensure in order to accept specimens from the state, and it is possible that other states currently have such requirements or will have such requirements in the future. We may also be subject to regulation in foreign jurisdictions as we seek to expand international utilization of our tests or such jurisdictions adopt new licensure requirements, which may require review of our tests in order to offer them or may have other limitations such as restrictions on the transport of human blood necessary for us to perform our tests that may limit our ability to make our tests available outside of the U.S. Complying with licensure requirements in new jurisdictions may be expensive and/or time-consuming, may subject us to significant and unanticipated delays, or may be in conflict with other applicable requirements.

Failure to comply with applicable clinical laboratory licensure requirements may result in a range of enforcement actions, including license suspension, limitation, or revocation, directed plan of action, onsite monitoring, civil monetary penalties, and criminal sanctions as well as significant adverse publicity. Any sanction imposed under CLIA, its implementing regulations or state or foreign laws or regulations governing clinical laboratory licensure, or our failure to renew our CLIA certificate, a state or foreign license or accreditation, could have a material adverse effect on our business, financial condition, and results of operations. Even if we were able to bring our laboratory back into compliance, we could incur significant expenses and potentially lose revenue in doing so.

Failure to comply with the IVDR may result in a range of enforcement actions 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 and authorities 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 information technology systems or data, or those of third parties upon which we rely, are or were compromised, we could experience adverse consequences resulting from such compromise, including but not limited to regulatory investigations or actions; litigation; fines and penalties; disruptions of our business operations; reputational harm; loss of revenue or profits; loss of customers or sales; and other adverse consequences.\****

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 (collectively, "process") proprietary, confidential, and sensitive information, including protected health information ("PHI"), personal information, credit card and other financial information, intellectual property, trade secrets, medical information, biometric information and genomic information (collectively, "sensitive information") owned or controlled by ourselves or our customers, payors, and other parties.

Cyberattacks, malicious internet-based activity, and online and offline fraud, and other similar activities threaten the confidentiality, integrity, and availability of our sensitive information and information technology systems, and those of the third parties upon which we rely. Such threats are prevalent and continue to increase, are becoming increasingly difficult to detect, and come from a variety of sources, including traditional computer "hackers," threat actors, "hacktivists," organized criminal threat actors, personnel (such as through theft or misuse), sophisticated nation states, and nation-state-supported actors. Some actors now engage and are expected to continue to engage in cyberattacks, including without limitation nation-state actors for geopolitical reasons and in conjunction with military conflicts and defense activities. 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 retaliatory cyberattacks, that could materially disrupt our systems and operations, supply chain, and ability to produce, sell, and distribute our platform, products, and services.

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 deep fakes, which may be increasingly more difficult to identify as fake, and 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), credential harvesting, 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, telecommunications failures, natural disasters, terrorism, and other similar threats. In particular, severe ransomware attacks 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. Most of our employees are working remotely at least part of the time and such remote work has increased risks to our information technology systems and data, as more of our employees utilize network connections, computers and devices outside our premises or network, including working at home, while in transit and in public locations. Future or past business transactions (such as acquisitions or integrations) could expose us to additional cybersecurity risks and vulnerabilities, as our systems could be negatively affected by vulnerabilities present in acquired or integrated entities' systems and technologies. Furthermore, we may discover security issues that were not found during due diligence of such acquired or integrated entities, and it may be difficult to integrate companies into our information technology environment and security program.

We rely on third-party service providers and technologies to operate critical business systems to process sensitive information in a variety of contexts, including, without limitation, on-site systems and cloud-based data centers, systems handling human resources, financial reporting and controls, customer relationship management, regulatory compliance, and other infrastructure operations. 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 sensitive information, including research and development information, patient data, commercial information, and business and financial information. Our ability to monitor these third parties' security practices is limited, and these third parties may not have adequate security measures in place. If any of our third-party service providers experience a security incident or other interruption, we could experience adverse consequences. While we may be entitled to damages if any of our third-party service providers fail to satisfy their privacy or security-related obligations to us, any award may be insufficient to cover our damages, or we may be unable to recover such award. In addition, 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.

Despite the 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 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 of the previously identified or similar threats could cause a security incident or other interruption that could result in unauthorized, unlawful, or accidental acquisition, modification, destruction, loss, alteration, encryption, disclosure of, or access to our sensitive information or our information technology systems, or those of the third parties upon whom we rely. 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 data privacy and security obligations may require us to implement and maintain certain measures to protect our information technology systems and sensitive information.

While we have implemented security measures designed to protect against security incidents, there can be no assurance that these measures will be effective. We take steps to detect and remediate vulnerabilities, but we may not be able to detect and remediate all vulnerabilities because the threats and techniques used to exploit the vulnerability change frequently and are often sophisticated in nature. Therefore, such vulnerabilities could be exploited but may not be detected until after a security incident has occurred. These vulnerabilities pose material risks to our business. Further, if the information technology systems of the third parties upon which we rely become subject to security incidents, 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.

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. Further, we may experience delays in developing and deploying remedial measures designed to address any such identified vulnerabilities. For example, like many companies, we use Log4j with respect to certain software or systems to log security and performance information. In early 2022, we

discovered a Log4j vulnerability in our environment although to date we have found no indication that our or our partners' data was exposed. Upon learning of this vulnerability, we applied a patch and made updates to our systems and infrastructure intended to reduce risks associated with the vulnerability.

Applicable data privacy and security obligations, including applicable federal and/or state breach notification laws and foreign equivalents, may require us to notify relevant stakeholders and other individuals of security incidents. Such disclosures are costly, and the disclosure or the failure to comply with such requirements could lead to adverse consequences. If we (or a third party upon whom we rely) experience a security incident or are perceived to have experienced a security incident, we may experience adverse consequences, such as government enforcement actions (for example, investigations, fines, penalties, audits, and inspections); additional reporting requirements and/or oversight; restrictions on processing sensitive information (including personal information); litigation (including class claims); indemnification obligations; negative publicity; reputational harm; monetary fund diversions; interruptions in our operations (including availability of data); financial loss; and other similar harms. Security incidents and attendant consequences may cause customers to stop using our platform, products, and services, deter new customers from using our platform, products, and services, and negatively impact our ability to grow and operate our business.

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 data privacy and security obligations. We cannot be sure that our insurance coverage will be adequate or sufficient to protect us from or to mitigate liabilities arising out of our data privacy and security practices. 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.

In addition to experiencing a security incident, third parties may gather, collect, or infer sensitive information about us from public sources, data brokers, or other means that reveals competitively sensitive details about our organization and could be used to undermine our competitive advantage or market position. Additionally, our sensitive information could be leaked, disclosed, or revealed as a result of or in connection with our employee's, personnel's, or vendor's use of generative artificial intelligence ("AI") technologies.

***We are subject to stringent and evolving U.S. and foreign laws, regulations, rules, contractual obligations, policies and other obligations related to data privacy and security. Our actual or perceived failure to comply with such obligations could lead to regulatory investigations or actions; litigation (including class claims) and mass arbitration demands; fines and penalties; disruptions of our business operations; reputational harm; loss of revenue or profits; loss of customers or sales; and other adverse business consequences.\****

In the ordinary course of business, we process sensitive information, including data we collect from our customers about trial participants in connection with clinical trials. Our data processing activities may subject us to numerous data privacy and security obligations, such as various laws, regulations, guidance, industry standards, external and internal privacy and security policies, contractual requirements, and other obligations relating to data privacy and security.

In the United States, federal, state, and local governments have enacted numerous data privacy, and security laws, including data breach notification laws, personal information 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. Penalties for failure to comply with HIPAA and HITECH include significant civil monetary penalties and criminal penalties in certain circumstances with fines up to \$250,000 per violation and/or imprisonment. 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 and applicable to us, we may 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. Similarly, the California Consumer Privacy Act of 2018 ("CCPA") applies to personal information of consumers, business representatives, and employees, and requires businesses to provide specific disclosures in privacy notices and honor requests of California residents to exercise certain privacy rights. The CCPA provides for administrative fines of up to \$7,500 per violation and allows private litigants affected by certain data breaches to recover significant statutory damages. 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. In addition, the California Privacy Rights Act of 2020 expands the CCPA's requirements, including by adding a new right for individuals to correct their personal information and establishing a new regulatory agency to implement and enforce the law. Other states, such as Virginia, Colorado, Connecticut and Utah have also passed comprehensive privacy laws, and similar laws are being considered in several other states, as well as at the federal and local levels. While these states, like the CCPA, also exempt some data processed in the context of clinical trials, these developments further complicate compliance efforts, and increase legal risk and compliance costs for us, the third parties upon whom we rely and our customers. Additionally, several states and localities have enacted statutes banning or restricting the collection of biometric information and regulators, such as the Federal Trade Commission, have indicated that use of biometric technologies (including facial recognition technologies) may be subject to additional scrutiny.

Outside the U.S., an increasing number of laws, regulations, and industry standards may govern data privacy and security. For example, the General Data Protection Regulation 2016/679 ("EU GDPR"), the United Kingdom's GDPR ("UK GDPR"), Brazil's General Data Protection Law (Lei Geral de Proteção de Dados Pessoais) (Law No. 13,709/2018), and China's Personal Information Protection



Law (“PIPL”) impose strict requirements for processing personal information. Under the EU GDPR and UK GDPR, companies may face temporary or definitive bans on data processing and other corrective actions; fines of up to 20 million Euros under the EU GDPR, 17.5 million pounds sterling under the UK GDPR or, in each case, 4% of annual global revenue, whichever is greater; or private litigation related to processing of personal information brought by classes of data subjects or consumer protection organizations authorized at law to represent their interests. In Canada, the Personal Information Protection and Electronic Documents Act (“PIPEDA”) and various related provincial laws, as well as Canada’s Anti-Spam Legislation (“CASL”), applies to our operations. We also receive personal information from customers in Asia and may be subject to new and emerging data privacy and security regimes in Asia, including Japan’s Act on the Protection of Personal Information.

In the ordinary course of business, we may transfer personal information from Europe and other jurisdictions to the U.S. or other countries. Europe and other jurisdictions have enacted laws requiring data to be localized or limiting the transfer of personal information to other countries. In particular, the EEA and the U.K. have significantly restricted the transfer of personal information to the U.S. and other countries whose data privacy and security laws they generally believe are inadequate. Other jurisdictions may adopt similarly stringent interpretations of their data localization and cross-border data transfer laws. Although there are currently various mechanisms that may be used to transfer personal information from the EEA and U.K. to the U.S. in compliance with law, such as the EEA and UK’s standard contractual clauses and the EU-U.S. Data Privacy Framework (which allows for transfers for relevant U.S.-based organizations who self-certify compliance and participate in such framework), these mechanisms are susceptible to legal challenges, and there is no assurance that we can satisfy or rely on these measures to lawfully transfer personal information to the U.S. If there is no lawful manner for us to transfer personal information from the EEA, the U.K. or other jurisdictions to the U.S., or if the requirements for a legally-compliant transfer are too onerous, we could face significant adverse consequences, including the interruption or degradation of our operations, the need to relocate part of or all of our business or data processing activities to other jurisdictions at significant expense, increased exposure to regulatory actions, substantial fines and penalties, the inability to transfer data and work with partners, vendors and other third parties, and injunctions against our processing or transferring of personal information necessary to operate our business. Additionally, companies that transfer personal information out of the EEA and U.K. to other jurisdictions, particularly to the U.S., are subject to increased scrutiny from regulators, individual litigants, and activist groups. Some European regulators have ordered certain companies to suspend or permanently cease certain transfers out of Europe for allegedly violating the GDPR’s cross-border data transfer limitations. EEA countries may also introduce national legislation further limiting the processing of personal 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.

In addition to data privacy and security laws, because we process some credit card payments through a third-party payment processing partner, we are contractually subject to industry standards adopted by industry groups and may become subject to such obligations in the future. For example, we may also be subject to the Payment Card Industry Data Security Standard (“PCI DSS”). The PCI DSS requires companies to adopt certain measures to ensure the security of cardholder information, including using and maintaining firewalls, adopting proper password protections for certain devices and software, and restricting data access. Noncompliance with PCI-DSS can result in penalties ranging from \$5,000 to \$100,000 per month by credit card companies, litigation, damage to our reputation, and revenue losses.

We also rely on vendors to process payment card data, who may be subject to PCI DSS, and our business may be negatively affected if our vendors are fined or suffer other consequences as a result of PCI DSS noncompliance. We are also bound by contractual obligations related to data privacy and security, and our efforts to comply with such obligations may not be successful. For example, certain privacy laws, such as the GDPR, require our customers to impose specific contractual restrictions on their service providers. We publish privacy policies, marketing materials and other statements regarding data privacy and security. If these policies, materials or statements are found to be deficient, lacking in transparency, deceptive, unfair, or misrepresentative of our practices, we may be subject to investigation, enforcement actions by regulators or other adverse consequences.

Our employees and personnel may use generative AI technologies to perform their work, and the disclosure and use of personal information in generative AI technologies is subject to various data privacy laws and other privacy obligations. Governments have passed and are likely to pass additional laws regulating generative AI. Our use of this technology could result in additional compliance costs, regulatory investigations and actions, and consumer lawsuits. If we are unable to use generative AI, it could make our business less efficient and result in competitive disadvantages.

Obligations related to data privacy and security are quickly changing, becoming increasingly stringent, and creating regulatory uncertainty. Additionally, these obligations may be subject to differing applications and interpretations, which may be inconsistent or conflict among jurisdictions. Preparing for and complying with these obligations requires us to devote significant resources, which may necessitate changes to our platform, products and/or services, information technologies, systems, and practices and to those of any third parties that process personal information on our behalf. In addition, these obligations may require us to change our business model. Our business model materially depends on our ability to process personal information, so we are particularly exposed to the risks associated with the rapidly changing legal landscape. For example, because we process PHI, personal information and sensitive information, we may be at heightened risk of regulatory scrutiny, and any changes in the regulatory framework could require us to fundamentally change our business model, including causing 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 particularly with respect to our RUO and clinical trial services, and we also typically rely on each provider ordering our LDTs or diagnostic services to obtain valid and appropriate consent from each of his or her patients whose genetic samples and data we process on such patient’s behalf. Given that we do not typically obtain direct consent from such data subjects or patients, and we do not audit our customers or the

ordering providers to ensure that they have obtained the necessary consents required by law, the failure of our customers or the order providers to obtain consents that are valid under applicable law could result in our own non-compliance with data privacy and security laws. For example, our NeXT Personal RUO test leverages WGS, and the scope of existing consents from our customers' clinical trial subjects may be insufficient to cover use of NeXT Personal on their samples, which may either limit uptake of NeXT Personal or expose our customers and ourselves to risk of exceeding the scope of prior consent for specimen testing. 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 data privacy and 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.

If we or the third parties on which we rely fail, or are perceived to have failed, to address or comply with applicable data privacy and security obligations, we could face significant consequences, including but not limited to: government enforcement actions (e.g., investigations, fines, penalties, audits, inspections, and similar); litigation (including class-action claims) and mass arbitration demands; additional reporting requirements and/or oversight; bans on processing personal information; orders to destroy or not use personal information; and imprisonment of company officials. In particular, plaintiffs have become increasingly more active in bringing data privacy-related claims against companies, including class claims and mass arbitration demands. Some of these claims allow for the recovery of statutory damages on a per violation basis, and, if viable, carry the potential for monumental statutory damages, depending on the volume of data and the number of violations. Any of these events could have a material adverse effect on our reputation, business, or financial condition, including but not limited to: loss of customers; interruptions or stoppages in our business operations (including, clinical trials); interruptions or stoppages of data collection needed to train our algorithms; inability to process personal information or to operate in certain jurisdictions; limited ability to develop or commercialize our platform, products, and services; expenditure of time and resources to defend any claim or inquiry; adverse publicity; or substantial changes to our business model or 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;
- the 14-Day Rule, also known as the Medicare Date of Service Rule, which prohibits a laboratory supplier from billing the Medicare program for tests performed on samples collected during or within 14 days of an inpatient hospital stay, unless an exception applies, and requires the laboratory supplier to bill the hospital in those cases. Penalties may apply to the laboratory supplier if Medicare determines that the Medicare program was inappropriately billed for testing that should have been billed to the hospital where the sample was collected;
- 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 the Centers for Medicare & Medicaid Services (“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 and authorities 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, disgorgement, 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.

***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. 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. Further, on August 16, 2022, President Biden signed the Inflation Reduction Act of 2022 (the "IRA 2022") into law, which among other things, extends enhanced subsidies for individuals purchasing health insurance coverage in ACA marketplaces through plan year 2025. The IRA 2022 also eliminates the "donut hole" under the Medicare Part D program beginning in 2025 by significantly lowering the beneficiary maximum out-of-pocket cost and through a newly established manufacturer discount program. 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 future 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 until 2032 unless additional Congressional action is taken. On January 2, 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, reduced Medicare payments to several providers, including hospitals, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. The Medicare Access and CHIP Reauthorization Act of 2015, enacted on April 16, 2015 ("MACRA") repealed the formula by which Medicare made annual payment adjustments to physicians and replaced the former formula with fixed annual updates, and established a quality payment incentive program, also referred to as the Quality Payment Program. This program provides clinicians with two ways to participate, including through the 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 continue to impact 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 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.



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. 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. Therefore, even if favorable coverage and reimbursement status is attained, less favorable coverage policies and reimbursement rates may be implemented in the future.

***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.

***Changes in tax laws or regulations could adversely affect our business and financial condition.***

On December 22, 2017, former President Trump signed into law comprehensive tax legislation (the "Tax Cuts and Jobs Act") that significantly revised the Internal Revenue Code of 1986, as amended (the "Code"). Future guidance from the U.S. Internal Revenue Service and other tax authorities with respect to the Tax Cuts and Jobs Act may affect us, and certain aspects of the Tax Cuts and Jobs Act could be repealed or modified in future legislation. For example, on March 27, 2020, the CARES Act was enacted, which includes changes to the tax provisions that benefit business entities and makes certain technical corrections to the Tax Cuts and Jobs Act. On December 27, 2020, the Consolidated Appropriations Act, a coronavirus relief package that extended and expanded various tax provisions, was signed into law. The IRA 2022 includes provisions that will impact the U.S. federal income taxation of corporations, including imposing a minimum tax on the book income of certain large corporations and an excise tax on certain corporate stock repurchases that would be imposed on the corporation repurchasing such stock. 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, IRA 2022, 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 the EU-U.K. Trade and Cooperation Agreement ("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). 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). However, all medical devices and IVDs must be registered with the MHRA, in order to be placed on the G.B. market.

The U.K. Government has introduced legislation permitting EU CE Marks to continue to be recognized in G.B. for medical devices. The duration of such recognition will, however, depend on the EU regulatory framework on the basis of which the medical devices were previously CE marked. The risk classification of the devices will also have an impact if they were CE marked in accordance with the IVDD. The U.K. government also intends to introduce legislation establishing reinforced post-market surveillance requirements in late 2023. These post-market surveillance requirements are anticipated to apply from mid-2024. The U.K. government is aiming to have core aspects of the future regulatory regime for medical devices applicable from July 1, 2025. 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.

It is anticipated that CE Marks will, at least in the short term, continue to be recognized in G.B. for medical devices. The UK MDR 2002 currently provides that CE marked medical devices will continue to be accepted on the G.B. market until June 30, 2023. However, the UK government has announced its intention to extend the acceptance of CE marked medical devices on the G.B. market. New legislation to permit CE marked medical devices to be placed on the G.B. market after June 30, 2023 is anticipated in the first half of 2023. The UK government also intends to introduce legislation establishing reinforced post-market surveillance requirements later in 2023. The UK government is aiming to have core aspects of the future regulatory regime for medical devices to be applicable from July 1, 2025. 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. Moreover, the SEC has recently proposed, and may continue to propose, certain mandated ESG reporting requirements, such as the SEC's proposed rules designed to enhance and standardize climate-related disclosures, which, if finally approved, would significantly increase our compliance and reporting costs and may also result in disclosures that certain investors or other stakeholders deem to negatively impact our reputation and/or that harm our stock price. We currently do not report our environmental emissions and absent a legal requirement to do so we currently do not plan to report our environmental emissions, and lack of reporting could result in certain investors 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 the infringement, misappropriation, or other violation of 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 a 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 an amended complaint (the "August 2022 Complaint") and, in June 2023, we filed an additional complaint in the U.S. District Court for the District of Colorado against Foresight for patent infringement and in October 2022 Foresight filed its answer and counterclaims to the August 2022 Complaint (see the section titled "Contingencies" in Note 9 to our unaudited condensed consolidated financial statements). Further, Foresight has filed four *inter partes* review petitions with the USPTO in an effort to invalidate the patents that we are asserting against Foresight in our patent infringement action. In June 2023, the USPTO issued decisions granting *inter partes* reviews of two of these patents, and in August 2023, the USPTO issued decisions granting *inter partes* reviews of the other two patents. 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 have caused and may continue to 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 may seek to raise additional capital through equity offerings, debt financings, collaborations, or licensing arrangements to continue executing on our long-term business plan. 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). 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;
- health epidemics or pandemics, geopolitical conflicts, inflation, global supply chain issues, regional or national economic slowdowns, recessions, depressions or other economic downturns; and
- other 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 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.

***Adverse developments affecting the financial services industry could adversely affect our current and projected business operations and our financial condition and results of operations.\****

Adverse developments that affect financial institutions, such as events involving liquidity that are rumored or actual, have in the past and may in the future lead to bank failures and market-wide liquidity problems. For example, on March 10, 2023, Silicon Valley Bank ("SVB") was closed by the California Department of Financial Protection and Innovation, which appointed the Federal Deposit Insurance Corporation ("FDIC") as receiver. Similarly, on March 12, 2023, Signature Bank and Silvergate Capital Corp. were each swept into receivership. In addition, on May 1, 2023, the FDIC seized First Republic Bank and sold its assets to JPMorgan Chase & Co. While the U.S. Department of Treasury, FDIC and Federal Reserve Board have implemented a program to provide up to \$25 billion of loans to financial institutions secured by certain of such government securities held by financial institutions to mitigate the risk of potential losses on the sale of such instruments, widespread demands for customer withdrawals or other liquidity needs of financial institutions for immediate liquidity may exceed the capacity of such program, there is no guarantee that such programs will be sufficient. Additionally, it is uncertain whether the U.S. Department of Treasury, FDIC and Federal Reserve Board will provide access to uninsured funds in the future in the event of the closure of other banks or financial institutions, or that they would do so in a timely fashion.



While we have not experienced any adverse impact to our liquidity or to our current and projected business operations, financial condition or results of operations as a result of the matters relating to SVB, Signature Bank, Silvergate Capital Corp and First Republic Bank, uncertainty remains over liquidity concerns in the broader financial services industry, and our business, our business partners or industry as a whole may be adversely impacted in ways that we cannot predict at this time.

Although we assess our banking relationships as we believe necessary or appropriate, our access to cash in amounts adequate to finance or capitalize our current and projected future business operations could be significantly impaired by factors that affect the financial institutions with which we have banking relationships. These factors could include, among others, events such as liquidity constraints or failures, the ability to perform obligations under various types of financial, credit or liquidity agreements or arrangements, disruptions or instability in the financial services industry or financial markets, or concerns or negative expectations about the prospects for companies in the financial services industry. These factors could also include factors involving financial markets or the financial services industry generally. The results of events or concerns that involve one or more of these factors could include a variety of material and adverse impacts on our current and projected business operations and our financial condition and results of operations. These could include, but may not be limited to, delayed access to deposits or other financial assets or the uninsured loss of deposits or other financial assets; or termination of cash management arrangements and/or delays in accessing or actual loss of funds subject to cash management arrangements.

In addition, widespread investor concerns regarding the U.S. or international financial systems could result in less favorable commercial financing terms, including higher interest rates or costs and tighter financial and operating covenants, or systemic limitations on access to credit and liquidity sources, thereby making it more difficult for us to acquire financing on acceptable terms or at all. Any decline in available funding or access to our cash and liquidity resources could, among other risks, adversely impact our ability to meet our operating expenses, financial obligations or fulfill our other obligations, result in breaches of our financial and/or contractual obligations or result in violations of federal or state wage and hour laws. Any of these impacts, or any other impacts resulting from the factors described above or other related or similar factors not described above, could have material adverse impacts on our liquidity and our current and/or projected business operations and financial condition and results of operations.

***We maintain our cash at financial institutions, often in balances that exceed federally insured limits.\****

We maintain the majority of our cash and cash equivalents in accounts at banking institutions in the United States that we believe are of high quality. Cash held in these accounts often exceed the FDIC insurance limits. If such banking institutions were to fail, we could lose all or a portion of amounts held in excess of such insurance limitations. As noted above, the FDIC recently took control of SVB, Signature Bank, Silvergate Capital Corp and First Republic Bank. While we did have an account at SVB, we were able to recover all of our deposits when the FDIC stepped in and allowed us to transfer funds held at SVB to another bank without incurring any losses. In the event of failure of any of the financial institutions where we maintain our cash and cash equivalents, there can be no assurance that we would be able to access uninsured funds in a timely manner or at all. Any inability to access or delay in accessing these funds could adversely affect our business and financial position.

***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, 2023, we had 48,507,101 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, 2023 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, 2022, we had federal and state net operating loss carryforwards of approximately \$249.1 million and approximately \$229.7 million, respectively. Certain of our federal and state net operating loss carryforwards will begin to expire, if not utilized, beginning in 2031. These net operating loss carryforwards could expire unused and be unavailable to offset future 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.

***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.***

We are a "smaller reporting company" as defined in the Exchange Act. We intend 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, 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.

We are 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.**

None.

**Item 6. Exhibits.**

Exhibit Number	Description	Incorporated by Reference			Filing Date
		Form	File No.	Exhibit	
3.1	<a href="#">Amended and Restated Certificate of Incorporation of the Registrant.</a>	8-K	001-38943	3.1	6/24/2019
3.2	<a href="#">Amended and Restated Bylaws of the Registrant.</a>	8-K	001-38943	3.1	10/31/2022
31.1#	<a href="#">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.</a>				
31.2#	<a href="#">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.</a>				
32.1†#	<a href="#">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.</a>				
32.2†#	<a href="#">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.</a>				
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.				

\* Indicates management contract or compensatory plan or arrangement.

# Filed herewith.

† The certifications attached as Exhibit 32.1 and Exhibit 32.2 that accompany this Quarterly Report on Form 10-Q are not deemed filed with the Securities and Exchange Commission and are not to be incorporated by reference into any filing of the registrant under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, whether made before or after the date of this Quarterly Report on Form 10-Q, irrespective of any general incorporation language contained in such filing.



**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

Date: August 8, 2023

Personalis, Inc.

By: /s/ Aaron Tachibana

Aaron Tachibana

Chief Financial Officer and Chief Operating Officer

*(Duly Authorized Officer)*



**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, Christopher Hall, 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 8, 2023

By: /s/ Christopher Hall  
Christopher Hall  
President and Chief Executive Officer  
(Principal Executive Officer)



**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 8, 2023

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

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**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 ended June 30, 2023 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 8, 2023

By: /s/ Christopher Hall

Christopher Hall

President and Chief Executive Officer

*(Principal Executive Officer)*

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**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 ended June 30, 2023 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 8, 2023

By: /s/ Aaron Tachibana

Aaron Tachibana

Chief Financial Officer and Chief Operating Officer

*(Principal Financial Officer)*

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