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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 10-Q

(Mark One)

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

FOR THE QUARTERLY PERIOD ENDED SEPTEMBER 30, 2021

☐ **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: 001-38613

Bionano Genomics, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**26-1756290**
(State or Other Jurisdiction of Incorporation or Organization)	(I.R.S. Employer Identification No.)
9540 Towne Centre Drive, Suite 100, San Diego, CA	**92121**
(Address of Principal Executive Offices)	(Zip Code)

(858) 888-7600
(Registrant's Telephone Number, Including Area Code)

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, $0.0001 par value per share	BNGO	The Nasdaq Stock Market, LLC
Warrants to purchase Common Stock	BNGOW	The Nasdaq Stock Market, LLC

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 x 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 x No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a 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 registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No x

As of October 31, 2021, the registrant had 289,184,109 shares of Common Stock ($0.0001 par value) outstanding.

BIONANO GENOMICS, INC.
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PART I. FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

BIONANO GENOMICS, INC.
Condensed Consolidated Balance Sheets

	(Unaudited) September 30, 2021	December 31, 2020
Assets		
Current assets:		
Cash and cash equivalents	$ 140,736,000	$ 38,449,000
Investments	185,333,000	—
Accounts receivable, net of allowance for doubtful accounts of, 2,015,000 and 2,119,000 as of September 30, 2021 and December 31, 2020, respectively	2,996,000	2,775,000
Inventory, net	9,020,000	3,316,000
Prepaid expenses and other current assets	3,962,000	2,250,000
Total current assets	342,047,000	46,790,000
Property and equipment, net	8,554,000	4,910,000
Intangible assets, net	1,238,000	1,475,000
Goodwill	7,173,000	7,173,000
Other long-term assets	645,000	103,000
Total assets	$ 359,657,000	$ 60,451,000
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 7,875,000	$ 2,930,000
Accrued expenses	9,416,000	5,599,000
Contract liabilities	411,000	416,000
Total current liabilities	17,702,000	8,945,000
Long-term debt	—	16,326,000
Long-term contract liabilities	158,000	98,000
Other non-current liabilities	232,000	—
Total liabilities	18,092,000	25,369,000
Commitments and contingencies (Note 7)		
Stockholders' equity:		
Preferred stock, $0.0001 par value; 10,000,000 shares authorized and no shares issued or outstanding as of September 30, 2021 and December 31, 2020	—	—
Common stock, $0.0001 par value, 400,000,000 shares authorized at September 30, 2021 and December 31, 2020; 281,441,000 and 189,953,000 shares issued and outstanding at September 30, 2021 and December 31, 2020, respectively	28,000	19,000
Additional paid-in capital	534,823,000	178,747,000
Accumulated deficit	(193,170,000)	(143,684,000)
Accumulated other comprehensive loss	(116,000)	—
Total stockholders' equity	341,565,000	35,082,000
Total liabilities and stockholders' equity	$ 359,657,000	$ 60,451,000

See accompanying notes to the unaudited condensed consolidated financial statements

BIONANO GENOMICS, INC.
Condensed Consolidated Statements of Operations
(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Revenue:				
Product revenue	$ 3,300,000	$ 1,580,000	$ 7,845,000	$ 3,503,000
Service and other revenue	1,355,000	616,000	3,834,000	1,010,000
Total revenue	4,655,000	2,196,000	11,679,000	4,513,000
Cost of revenue:				
Cost of product revenue	2,340,000	1,136,000	5,723,000	2,426,000
Cost of service and other revenue	1,161,000	324,000	2,321,000	493,000
Total cost of revenue	3,501,000	1,460,000	8,044,000	2,919,000
Operating expenses:				
Research and development	6,505,000	2,304,000	13,270,000	7,379,000
Selling, general and administrative	15,327,000	8,659,000	38,683,000	21,640,000
Total operating expenses	21,832,000	10,963,000	51,953,000	29,019,000
Loss from operations	(20,678,000)	(10,227,000)	(48,318,000)	(27,425,000)
Other income (expense):				
Interest income (expense)	27,000	(589,000)	(721,000)	(1,911,000)
Gain on forgiveness of Paycheck Protection Program loan	—	—	1,775,000	—
Loss on debt extinguishment	—	—	(2,076,000)	—
Other income (expense)	(67,000)	54,000	(96,000)	—
Total other income (expense)	(40,000)	(535,000)	(1,118,000)	(1,911,000)
Loss before income taxes	(20,718,000)	(10,762,000)	(49,436,000)	(29,336,000)
Provision for income taxes	(35,000)	(30,000)	(50,000)	(40,000)
Net loss	$ (20,753,000)	$ (10,792,000)	$ (49,486,000)	$ (29,376,000)
Net loss per share, basic and diluted	$ (0.07)	$ (0.08)	$ (0.18)	$ (0.34)
Weighted-average common shares outstanding basic and diluted	280,173,000	132,942,000	274,392,000	86,632,000

See accompanying notes to the unaudited condensed consolidated financial statements.

BIONANO GENOMICS, INC.
Condensed Consolidated Statements of Comprehensive Loss
(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Net Loss:	$ (20,753,000)	$ (10,792,000)	$ (49,486,000)	$ (29,376,000)
Unrealized (loss) on investment securities	(116,000)	—	(116,000)	—
Comprehensive Loss	$ (20,869,000)	$ (10,792,000)	$ (49,602,000)	$ (29,376,000)

See accompanying notes to the unaudited condensed consolidated financial statements.

BIONANO GENOMICS, INC.
Condensed Consolidated Statements of Stockholders' Equity (Deficit) (Unaudited)

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Loss	Total Stockholders' Equity (Deficit)
	Shares	Amount				
Balance at January 1, 2020	34,274,000	$ 3,000	$ 106,188,000	$ (102,577,000)	$ —	$ 3,614,000
Stock-based compensation expense	—	—	328,000	—	—	328,000
Issue stock for warrant exercises	3,478,000	—	2,355,000	—	—	2,355,000
Net loss	—	—	—	(10,510,000)	—	(10,510,000)
Balance at March 31, 2020	37,752,000	$ 3,000	$ 108,871,000	$ (113,087,000)	$ —	$ (4,213,000)
Stock-based compensation expense	—	—	328,000	—	—	328,000
Issue common stock, net of issuance costs	16,896,000	2,000	16,364,000	—	—	16,366,000
Issue stock for employee stock purchase plan	44,000	—	21,000	—	—	21,000
Issue stock for covenant waiver	873,000	—	300,000	—	—	300,000
Issue stock for warrant exercises	36,410,000	4,000	1,105,000	—	—	1,109,000
Net loss	—	—	—	(8,074,000)	—	(8,074,000)
Balance at June 30, 2020	91,975,000	$ 9,000	$ 126,989,000	$ (121,161,000)	$ —	$ 5,837,000
Stock-based compensation expense	—	—	447,000	—	—	447,000
Issue stock for warrant exercises	50,205,000	5,000	15,078,000	—	—	15,083,000
Issue stock for acquisition	6,168,000	1,000	4,100,000	—	—	4,101,000
Net loss	—	—	—	(10,792,000)	—	(10,792,000)
Balance at September 30, 2020	148,348,000	$ 15,000	$ 146,614,000	$ (131,953,000)	$ —	$ 14,676,000
Balance at January 1, 2021	189,953,000	19,000	178,747,000	(143,684,000)	$ —	$ 35,082,000
Stock option exercises	102,000	—	333,000	—	—	333,000
Stock-based compensation expense	—	—	371,000	—	—	371,000
Issue common stock, net of issuance costs	78,000,000	8,000	327,478,000	—	—	327,486,000
Issue stock for warrant exercises	10,739,000	1,000	9,392,000	—	—	9,393,000
Net loss	—	—	—	(9,947,000)	—	(9,947,000)
Balance at March 31, 2021	278,794,000	$ 28,000	$ 516,321,000	$ (153,631,000)	$ —	$ 362,718,000
Stock option exercises	60,000	—	89,000	—	—	89,000
Stock-based compensation expense	—	—	1,758,000	—	—	1,758,000
Issue stock for warrant exercises	50,000	—	22,000	—	—	22,000
Issue stock for employee stock purchase plan	150,000	—	65,000	—	—	65,000
Net loss	—	—	—	(18,786,000)	—	(18,786,000)
Balance at June 30, 2021	279,054,000	$ 28,000	$ 518,255,000	$ (172,417,000)	$ —	$ 345,866,000
Stock option exercises	209,000	—	242,000	—	—	242,000
Stock-based compensation expense	—	—	2,788,000	—	—	2,788,000
Issue common stock, net of issuance costs	2,178,000	—	13,537,000	—	—	13,537,000
Issue stock for warrant exercises	—	—	1,000	—	—	1,000
Net loss	—	—	—	(20,753,000)	—	(20,753,000)
Comprehensive Loss	—				(116,000)	(116,000)
Balance at September 30, 2021	281,441,000	$ 28,000	$ 534,823,000	$ (193,170,000)	$ (116,000)	$ 341,565,000

See accompanying notes to the unaudited condensed consolidated financial statements

BIONANO GENOMICS, INC.
Condensed Consolidated Statements of Cash Flows
(Unaudited)

	Nine Months Ended September 30,	
	2021	2020
Operating activities:		
Net loss	$ (49,486,000)	$ (29,376,000)
Adjustments to reconcile net loss to net cash used by operating activities:		
Depreciation and amortization expense	1,490,000	909,000
Non-cash interest	178,000	952,000
Stock-based compensation	4,917,000	1,103,000
Provision for bad debt expense	—	1,334,000
Gain on forgiveness of PPP Loan	(1,775,000)	—
Loss on debt extinguishment	2,076,000	—
Changes in operating assets and liabilities:		
Accounts receivable	(336,000)	1,709,000
Inventory	(10,346,000)	(3,612,000)
Prepaid expenses and other current assets	(2,072,000)	(566,000)
Accounts payable	4,945,000	925,000
Accrued expenses and contract liabilities	4,104,000	412,000
Net cash used in operating activities	(46,305,000)	(26,210,000)
Investing Activities:		
Lineagen acquisition, net of cash acquired	—	(2,450,000)
Purchases of property and equipment	(344,000)	—
Purchase of available for sale securities	(205,334,000)	—
Sale of available for sale securities	20,000,000	—
Sale of property and equipment	126,000	—
Net cash used in investing activities	(185,552,000)	(2,450,000)
Financing activities:		
Repayment of term-loan debt	(17,010,000)	(5,000,000)
Proceeds from PPP Loan	—	1,775,000
Proceeds from borrowing from line of credit	—	761,000
Repayments of borrowing from line of credit	—	(2,258,000)
Proceeds from sale of common stock	342,712,000	17,963,000
Offering expenses on sale of common stock	(1,704,000)	(1,597,000)
Proceeds from sale of common stock under employee stock purchase plan	65,000	21,000
Proceeds from warrant and option exercises	10,081,000	18,551,000
Net cash provided by financing activities	334,144,000	30,216,000
Net increase in cash and cash equivalents	102,287,000	1,556,000
Cash and cash equivalents at beginning of period	38,449,000	17,311,000
Cash and cash equivalents at end of period	$ 140,736,000	$ 18,867,000
Supplemental cash flow disclosures:		
Cash paid for interest	$ 490,000	$ 991,000
Supplemental disclosure of non-cash investing and financing activities:		
Fair value of common stock issued related to Lineagen acquisition	$ —	$ 4,100,000
Transfer of instruments and servers from property and equipment into inventory	$ 544,000	$ 134,000
Transfer of instruments and servers from inventory to property and equipment	$ 5,074,000	$ 2,618,000
Forgiveness of PPP Loan	$ 1,775,000	$ —
Stock issued for services	$ 15,000	$ —
Issue stock for covenant waiver	$ 116,000	$ 300,000
Warrant exercise pursuant to cashless exercise	$ 129,000	$ —

See accompanying notes to the unaudited condensed consolidated financial statements

BIONANO GENOMICS, INC.
NOTES TO CONDENSED FINANCIAL STATEMENTS
(Unaudited)

1. Organization and Basis of Presentation

Description of Business

Bionano Genomics, Inc. (collectively, with its consolidated subsidiaries, the "Company") is a provider of genome analysis solutions that can enable researchers and clinicians to reveal answers to challenging questions in biology and medicine. The Company's mission is to transform the way the world sees the genome through optical genome mapping ("OGM") solutions, diagnostic services and software. The Company offers OGM solutions for applications across basic, translational and clinical research. Through its Lineagen, Inc. ("Lineagen") business, the Company also provides diagnostic testing for patients with clinical presentations consistent with autism spectrum disorder and other neurodevelopmental disabilities. Through its BioDiscovery, Inc. ("BioDiscovery") business, the Company also offers an industry-leading, platform-agnostic software solution, which integrates next-generation sequencing and microarray data designed to provide analysis, visualization, interpretation and reporting of copy number variants, single-nucleotide variants and absence of heterozygosity across the genome in one consolidated view.

Basis of Presentation

The accompanying financial information has been prepared by the Company pursuant to the rules and regulations of the Securities and Exchange Commission (the "SEC") for interim reporting purposes. The condensed consolidated financial statements are unaudited. The unaudited condensed consolidated financial statements reflect, in the opinion of the Company's management, all adjustments, consisting of only normal recurring adjustments, necessary for a fair presentation of financial position, results of operations, changes in equity, and comprehensive loss and cash flows for each period presented in accordance with United States generally accepted accounting principles ("U.S. GAAP"). All intercompany transactions and balances have been eliminated. These interim condensed consolidated financial statements should be read in conjunction with the audited consolidated financial statements and related notes thereto included in the Company's Annual Report on Form 10-K for the year ended December 31, 2020.

Liquidity

As of September 30, 2021, the Company had approximately $140.7 million in cash and cash equivalents, $185.3 million in available-for-sale investment securities, and working capital of $324.3 million as a result of common stock offerings executed in the quarters ended December 31, 2020, March 31, 2021, and September 30, 2021. In February 2021, we applied for forgiveness of our Paycheck Protection Program Loan of approximately $1.8 million ("the PPP Loan") , and in March 2021, the PPP Loan, including all accrued interest, was forgiven in full. During the previous quarter ended June 30, 2021, the outstanding term loan with Innovatus (as defined below) was paid in full, including all accrued interest, an end of term fee, and a prepayment fee for a total of $17.0 million.

The Company believes its available cash balance will be sufficient to fund operations, obligations as they become due and capital investments for at least the next twelve months. However, the Company expects to continue to incur net losses for the foreseeable future. The Company plans to continue to fund its losses from operations and capital funding needs through a combination of equity offerings, debt financings or other sources, including potential collaborations, licenses and other similar arrangements. If the Company is not able to secure adequate additional funding, the Company may be forced to make reductions in spending, potentially harming the Company's business.

COVID-19

The Company is subject to additional risks and uncertainties as a result of the continued spread of COVID-19 and uncertain market conditions, which could continue to have a material impact on the Company's business and financial results. The Company closely monitors and complies with various applicable guidelines and legal requirements in the jurisdictions in which it operates, which may continue to result in reduced business operations in response to new or existing stay-at-home orders, travel restrictions and other social distancing measures. The Company's manufacturing partners, suppliers, and customers, have implemented similar operational restrictions. Despite reporting an increase in revenue for the three and nine months ended September 30, 2021 when compared to the same period in 2020, the Company believes travel restrictions and overall reduced activity had a continued negative impact on the Company's third quarter 2021 financial results. Given the continued evolution of the COVID-19 pandemic and the related complexities and uncertainties associated with the additional variants, the future effects of COVID-19 are unknown and the Company's financial results may continue to be negatively affected in the future.

There may be long-term negative effects of the COVID-19 pandemic, even after it has subsided. Specifically, product demand may be reduced due to an economic recession, a decrease in corporate capital expenditures, prolonged unemployment, reduction in consumer confidence, or any similar negative economic condition. These negative effects could have a material impact on the Company's operations, business, earnings, and liquidity.

Significant Accounting Policies

During the three and nine months ended September 30, 2021, there were no changes to the Company's significant accounting policies as described in the Company's Annual Report on Form 10-K for the year ended December 31, 2020, other than the accounting policy indicated below.

Fair Value Measurements

The Company measures certain financial assets and liabilities at fair value on a recurring basis. Fair value is the price the Company would receive to sell an asset or pay to transfer a liability in an orderly transaction with a market participant at the measurement date.

ASC 820, "Fair Value Measurements and Disclosures", defines and establishes a framework for measuring fair value and expands disclosures about fair value measurements. In accordance with ASC 820, the Company has categorized its financial assets and liabilities, based on the priority of the inputs to the valuation technique, into a three-level fair value hierarchy as set forth below.

Level 1 – Assets and liabilities whose values are based on unadjusted quoted prices for identical assets or liabilities in an active market that the company has the ability to access at the measurement date.

Level 2 – Assets and liabilities whose values are based on quoted prices for similar attributes in active markets; quoted prices in markets where trading occurs infrequently; and inputs other than quoted prices that are observable, either directly or indirectly, for substantially the full term of the asset or liability.

Level 3 – Assets and liabilities whose values are based on prices or valuation techniques that require inputs that are both unobservable and significant to the overall fair value measurement.

If the inputs used to measure the financial instruments fall within different levels of the hierarchy, the categorization is based on the lowest level input that is significant to the fair value measurement of the instrument.

Investment Securities

All investments have been classified as "available-for-sale" and are carried at fair value as determined based upon quoted market prices or pricing models for similar securities at period end. Investments with contractual maturities less than 12 months at the balance sheet date are considered short-term investments. Investments with contractual maturities beyond one year are also classified as short-term due to the Company's ability to liquidate the investment for use in operations within the next 12 months. Realized gains and losses on investment securities are included in earnings and are derived using the specific identification method for determining the cost of securities sold. The Company has not realized any significant gains or losses on sales of available-for-sale investment securities during any of the periods presented. As all the Company's investment holdings are in the form of debt securities, unrealized gains and losses that are determined to be temporary in nature are reported as a component of accumulated other comprehensive income (loss). A decline in the fair value of any security below cost that is deemed other than temporary results in a charge to earnings and the establishment of a new cost basis for the security. Interest income is recognized when earned, as are the amortization of purchase premiums and accretion of purchase discounts on investment securities.

Recently Issued But Not Yet Adopted Accounting Pronouncements

In February 2015, the FASB issued Accounting Standards Update ("ASU") 2016-2, *Leases (Topic 842)*, which amends the accounting guidance for leases and increases transparency and comparability among organizations by recognizing lease assets and lease liabilities on the balance sheet and requires disclosures of key information about leasing arrangements. ASU 2016-2 initially mandated a modified retrospective transition method, however, in July 2018, the FASB issued ASU 2018-11, *Leases (Topic 842): Targeted Improvements*, which amends ASU 2016-2, permitting entities the option to adopt this standard prospectively with a cumulative-effect adjustment to opening equity in the year of adoption and include required disclosures for prior periods but will not restate prior periods. The Company anticipates implementing the accounting guidance for leases using the alternative method beginning with the annual reporting period ending December 31, 2021 and interim reporting periods in 2022. The Company is in the process of evaluating the impact of adoption of the lease accounting guidance on the consolidated financial statements.

In June 2016, the FASB issued ASU No. 2016-13, *Financial Instruments - Credit Losses: Measurement of credit Losses on Financial Instruments (ASU 2016-13)*, which amends the impairment model by requiring entities to use a forward looking approach based on expected losses to estimate credit losses on certain types of financial instruments, including trade receivables and available-for-sale debt securities. The standard is effective for the company beginning in the first quarter of 2023, with early adoption permitted. The Company is currently evaluating the expected impact of *ASU 2016-13* on its financial statements.

In May 2021, the FASB issued ASU No. 2021-04, *Issuer's Accounting for Certain Modifications or Exchanges for Freestanding Equity-Classified Written Call Options* to clarify the accounting for modifications or exchanges of equity-

classified warrants.The standard is effective for fiscal years beginning after December 15, 2021. Early adoption is permitted. The Company is in the process of evaluating the expected impact of *ASU 2021-04* on its financial statements.

2. Net Loss Per Share

Basic net loss per share is calculated by dividing the net loss by the weighted-average number of common shares outstanding for the period. Diluted net loss per share is computed by dividing the net loss by the weighted average number of common shares and common share equivalents outstanding for the period. Common stock equivalents are only included when their effect is dilutive. The Company's potentially dilutive securities which include warrants, outstanding stock options, and Restricted Stock Units ("RSUs") under the Company's equity incentive plan have been excluded from the computation of diluted net loss per share as they would be anti-dilutive to the net loss per share. For all periods presented, there is no difference in the number of shares used to calculate basic and diluted shares outstanding.

Potentially dilutive securities not included in the calculation of diluted net loss per share attributable to common stockholders because to do so would be anti-dilutive are as follows (in common stock equivalent shares):

	September 30, 2021	September 30, 2020
Stock options	10,661,000	5,331,000
Warrants	4,361,000	29,709,000
RSUs	820,000	—
Total	15,842,000	35,040,000

3. Revenue Recognition

Revenue by Source

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Instruments	$ 1,468,000	$ 724,000	$ 3,507,000	$ 1,487,000
Consumables	1,832,000	856,000	4,338,000	2,016,000
Total product revenue	3,300,000	1,580,000	7,845,000	3,503,000
Service and other	1,355,000	616,000	3,834,000	1,010,000
Total revenue	$ 4,655,000	$ 2,196,000	$ 11,679,000	$ 4,513,000

Revenue by Geographic Location

	Three Months Ended September 30,				Nine Months Ended September 30,			
	2021		2020		2021		2020	
	$	%	$	%	$	%	$	%
North America	$ 2,557,000	55 %	$ 874,000	40 %	$ 6,419,000	55 %	$ 2,388,000	53 %
EMEIA	1,234,000	27 %	1,204,000	55 %	3,762,000	32 %	1,908,000	42 %
Asia Pacific	864,000	18 %	118,000	5 %	1,498,000	13 %	217,000	5 %
Total	$ 4,655,000	100 %	$ 2,196,000	100 %	$ 11,679,000	100 %	$ 4,513,000	100 %

The table above provides revenue from contracts with customers by source and geographic region (based on the customer's billing address) on a disaggregated basis. North America consists of the United States and Canada. EMEIA consists of Europe, the Middle East, India and Africa. Asia Pacific includes China, Japan, South Korea, Singapore and Australia. For the three months ended September 30, 2021 and 2020, the United States represented 44.2% and 40.0% of total revenue, respectively. Additionally, for the three months ended September 30, 2021, China and Canada represented 17.9% and 10.8% of total revenue, respectively. For the three months ended September 30, 2020, no countries other than the United States represented greater than 10% of revenue. For the nine months ended September 30, 2021 and 2020, the United States represented 50.0% and 51.0% of total revenue, respectively. No other countries represented greater than 10% of revenue during the nine months ended September 30, 2021 and 2020.

Remaining Performance Obligations

As of September 30, 2021, the estimated revenue expected to be recognized in the future related to performance obligations that are unsatisfied was $569,000. These remaining performance obligations primarily relate to extended warranty and support and maintenance obligations. The Company expects to recognize approximately 30.7% of this amount as revenue during the remainder of 2021, 49.9% in 2022, and 19.5% in 2023 and thereafter. Warranty revenue is included in Service and other revenue.

The Company recognized revenue of $79,000 and $66,000 during the three months ended September 30, 2021 and 2020, respectively, and revenue of $326,000 and $299,000 during the nine months ended September 30, 2021 and 2020, respectively, which was included in the contract liability balance at the end of the previous year.

4. Balance Sheet Account Details

Accounts Receivable

	September 30, 2021	December 31, 2020
Accounts receivable, net:		
Accounts receivable, trade	$ 5,011,000	$ 4,894,000
Less allowance for doubtful accounts	(2,015,000)	(2,119,000)
	$ 2,996,000	$ 2,775,000

The Company extends credit to its customers in the normal course of business. For diagnostic testing services, receivables are based on either contractual rates with third-party payors, plus the amounts expected to be collected for any patient-responsibility portion, or for non-contracted arrangements, using the amounts expected to be collected from third-party payors and/or the patient-customer based on historical collection experience. The Company does not perform credit evaluations and therefore subsequent adjustments to the amount expected to be collected are recorded to revenue. The balance of our Lineagen accounts receivable balance as of September 30, 2021 was $680,000.

For optical genome mapping (“OGM”) products and services, credit is extended based upon an evaluation of each customer’s credit history, financial condition, and other factors. Estimates of allowances for doubtful accounts are determined by evaluating individual customer circumstances, historical payment patterns, length of time past due, and economic and other factors. Bad debt expense is recorded as necessary to maintain an appropriate level of allowance for doubtful accounts in selling, general and administrative expense. During the three and nine months ended September 30, 2021, the Company recorded a recovery of bad debt expense of $(10,000) and $(50,000), respectively, which is included in selling, general and administrative expenses. Amounts are charged to the allowance for doubtful accounts when collection efforts have been exhausted and are deemed uncollectible.

Concentrations

Accounts receivable is subject to concentration risk whenever a customer has a balance that meets or exceeds 10.0% of the Company’s total accounts receivable balance. As of September 30, 2021, no customers met or exceeded 10% of the Company’s total accounts receivable balance. As of December 31, 2020, two customer balances represented 27.4% of the Company’s total accounts receivable balance.

Inventory

Inventory is stated at the lower of cost or net realizable value, on a first-in, first-out basis. Inventory includes raw materials and finished goods that may be used in the research and development process and such items are expensed as consumed or expired.

Provisions for slow-moving, excess, and obsolete inventories are estimated based on product life cycles, historical experience, and usage forecasts.

The components of inventories are as follows:

	September 30, 2021	December 31, 2020
Inventory:		
Raw materials	$ 1,024,000	$ 2,283,000
Finished goods	7,996,000	1,033,000
	$ 9,020,000	$ 3,316,000

5. Debt

Paycheck Protection Program

On April 17, 2020, the Company received the PPP Loan proceeds of approximately $1.8 million pursuant to the Paycheck Protection Program under the Coronavirus Aid, Relief, and Economic Security Act (the "CARES Act") administered by the U.S. Small Business Administration (the "SBA").

The PPP Loan accrued interest at a rate of 1.00% per annum, and is subject to the standard terms and conditions applicable to loans administered by the SBA under the CARES Act. In February 2021, the Company applied for forgiveness of the PPP Loan, and in March 2021, the PPP Loan, including all accrued interest, was forgiven in full. A gain on forgiveness of Paycheck Protection Program loan of $1.8 million was recognized during the nine months ended September 30, 2021.

Innovatus LSA

In March 2019, the Company entered into a Loan and Security Agreement (the "LSA") by and among Innovatus Life Sciences Lending Fund I, LP, a Delaware limited partnership ("Innovatus"), as collateral agent and the lenders listed on Schedule 1.1 thereto, including East West Bank. The LSA provided a first term loan of $17.5 million, a second term loan of $2.5 million and a third term loan of $5.0 million (collectively, the "Term Loans") if the Company satisfied certain funding conditions. Interest on the Term Loans is due on the first of each month at a rate of 10.25% per annum in cash or a discounted rate of 7.25% in cash with 3.0% of the 10.25% per annum rate added to the principal of the loan and subject to accruing interest through the end of the interest only payment period, which ends March 1, 2022. At inception, the Company elected to pay interest in cash at a rate of 7.25% per annum and have 3.0% per annum of the interest added back to the outstanding principal. As of May 14, 2021 (the effective date of the loan payoff), the effective interest rate, including debt issuance costs, for the Term Loans was 16.7%.

The LSA provided for prepayment fees of 3.0% of the outstanding balance of the loan if the loan is repaid on or prior to March 14, 2020, 2.0% of the amount prepaid if the prepayment occurs after March 14, 2020 but prior to March 14, 2021, 1.0% of the amount prepaid after March 14, 2021 but prior to March 14, 2022 and 0% of the amount prepaid if the prepayment occurs thereafter. In addition, upon the final repayment of the total amounts borrowed, the Company is required to pay an end of term fee of $0.8 million. This end of term fee was being recognized as interest expense over the term of the LSA. As of September 30, 2021, the outstanding term loan with Innovatus was paid in full, including all accrued interest, the end of term fee, and a prepayment fee for a total of $17.0 million.

The LSA also provides for a revolving line of credit in an amount not to exceed $5.0 million (the "Revolver"), which was terminated effectively upon payment in full of the above term loan.

Summary of Debt Obligations

The Company had no debt as of September 30, 2021.The carrying value of the Company's debt as of December 31, 2020 was as follows:

	December 31, 2020
Term Loans	$ 15,981,000
PPP Loan	1,775,000
Total principal	17,756,000
Less unamortized debt issuance costs	(1,430,000)
Total carrying value of debt	$ 16,326,000

6. Stockholders' Equity and Stock-Based Compensation

Follow-on Public Offerings

On January 12, 2021, the Company completed an underwritten public offering of 33,368,851 shares of common stock, including 4,352,458 shares of common stock sold pursuant to the underwriters' exercise in full of their option to purchase additional shares. The price to the public in the offering was $3.05 per share and the underwriters purchased the shares from the Company pursuant to the underwriting agreement at a price of $2.867 per share. The gross proceeds were approximately $101.8 million before deducting underwriting discounts and commissions and other offering expenses of $293,000.

On January 25, 2021, the Company completed an underwritten public offering of 38,333,352 shares of common stock, including 5,000,002 shares of common stock sold pursuant to the underwriters' exercise in full of their option to purchase additional shares. The price to the public in the offering was $6.00 per share and the underwriters purchased the shares from the

Company pursuant to the underwriting agreement at a price of $5.64 per share. The gross proceeds were approximately $230.0 million before deducting underwriting discounts and commissions and other offering expenses of $435,000.

Shelf Registration Statements; Ladenburg and Cowen At-the-Market Facilities

In August 2020, the Company filed a shelf registration statement on Form S-3 with the SEC covering the offering, issuance and sale of up to $125.0 million of the Company's securities, including up to $40.0 million of common stock pursuant to an At Market Issuance Sales Agreement, with Ladenburg Thalmann & Co. Inc. acting as sales agent (the "Ladenburg ATM"). During October through December 2020, the Company sold 27,025,384 shares of common stock under the Ladenburg ATM at an average share price of $0.82, and received gross proceeds of approximately $22.1 million before deducting offering costs of $573,000. In January 2021, the Company sold an additional 6,298,152 shares of common stock under the ATM at an average share price of $2.68, and received gross proceeds of approximately $16.9 million before deducting offering costs of $422,000. The Company terminated the Ladenburg ATM in March 2021.

On January 19, 2021, the Company filed an automatically effective shelf registration statement on Form S-3 with the SEC as a "well-known seasoned issuer," allowing for the Company to issue an indeterminate number or amount of its securities from time to time in one or more offerings. On March 23, 2021, the Company entered into a Sales Agreement with Cowen and Company, LLC ("Cowen") which provides for the sale, in the Company's sole discretion, of shares of common stock having an aggregate offering price of up to $350.0 million through or to Cowen, acting as sales agent or principal (the "Cowen ATM"). The Company agreed to pay Cowen a commission of up to 3.0% of the aggregate gross proceeds from each sale of shares, reimburse legal fees and disbursements and provide Cowen with customary indemnification and contribution rights. In August and September 2021, the Company sold 2,256,000 shares of common stock under the Cowen ATM at an average share price of $6.15 per share, and received gross proceeds of approximately $13.9 million before deducting offering costs of $0.6 million.

Stock Warrants

A summary of the Company's warrant activity during the nine months ended September 30, 2021 was as follows:

	Shares of Stock under Warrants	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term	Aggregate Intrinsic Value
Outstanding at January 1, 2021	15,174,000	$ 2.34	3.76	$ 26,841,000
Granted	—			
Exercised	(10,789,000)	0.89		58,175,000
Canceled	(24,000)	3.29		
Outstanding at September 30, 2021	4,361,000	$ 5.95	2.02	$ 1,651,000

Stock Options

A summary of the Company's stock option activity during the nine months ended September 30, 2021 was as follows:

	Shares of Stock under Stock Options	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term	Aggregate Intrinsic Value
Outstanding at January 1, 2021	5,290,000	$ 1.91	8.7	$ 10,178,000
Granted	6,544,000	7.11		
Exercised	(371,000)	1.49		$ 2,187,000
Canceled	(802,000)	4.35		
Outstanding at September 30, 2021	10,661,000	$ 4.94	9.01	$ 17,822,000
Vested and exercisable at September 30, 2021	3,035,000	$ 3.31	8.11	$ 9,326,000

For the three months ended September 30, 2021 and 2020, the weighted-average grant date fair value of stock options granted was $3.64 and $0.35 per share, respectively. For the nine months ended September 30, 2021 and 2020, the weighted-average grant date fair value of stock options granted was $4.78 and $0.43 per share, respectively.

Stock-Based Compensation

The Company recognized stock-based compensation expense for the periods presented as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Research and development	$ 745,000	$ 122,000	$ 1,209,000	$ 255,000
General and administrative	2,043,000	325,000	3,708,000	848,000
Total stock-based compensation expense	$ 2,788,000	$ 447,000	$ 4,917,000	$ 1,103,000

The weighted-average assumptions used in the Black-Scholes option pricing model to determine the fair value of the employee stock option grants during the periods presented were as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Risk-free interest rate	0.9 %	0.4 %	1.1 %	0.8 %
Expected volatility	71.4 %	77.9 %	78.3 %	74.8 %
Expected term (in years)	6.0	5.5	6.0	5.9
Expected dividend yield	0.0 %	0.0 %	0.0 %	0.0 %

Restricted Stock Units

On May 12, 2021, the compensation committee of the Company's board of directors granted 580,000 RSUs to R. Erik Holmlin, Ph.D., the Company's President and Chief Executive Officer (the "Holmlin Grant"), and 240,000 RSUs to Mark Oldakowski, the Company's Chief Operating Officer (the "Oldakowski Grant"), in each case with an effective grant date and vesting commencement date of May 12, 2021.

290,000 RSUs under the Holmlin Grant are subject to time-based vesting, with 50% of the shares vesting on each of the first and second anniversaries of the vesting commencement date, subject to continued service through the vesting date, and 18 months vesting acceleration upon a termination without cause or resignation with good reason.

290,000 RSUs under the Holmlin Grant are subject to vesting upon the satisfaction of certain specified revenue targets within four years following the vesting commencement date. If Dr. Holmlin's employment with the Company is terminated without cause or he resigns with good reason, then the shares will continue to be eligible for vesting upon satisfaction of the revenue targets within a period that is the shorter of 18 months following termination or four years following the vesting commencement date.

The RSUs comprising the Oldakowski Grant are subject to time-based vesting, with 50% of the shares vesting on each of the first and second anniversaries of the vesting commencement date, subject to continued service through the vesting date.

7. Commitments and Contingencies

Litigation

From time to time, the Company may be subject to potential liabilities under various claims and legal actions that are pending or may be asserted. These matters arise in the ordinary course and conduct of the business. The Company regularly assesses contingencies to determine the degree of probability and range of possible loss for potential accrual in the financial statements. An estimated loss contingency is accrued in the financial statements if it is probable that a liability has been incurred and the amount of the loss can be reasonably estimated. Based on the Company's assessment, it currently does not have any material loss exposure as it is not a defendant in any claims or legal actions.

8. Income Taxes

The Company is subject to taxation in the United States, United Kingdom and various state jurisdictions. The Company computes its quarterly income tax provision by using a forecasted annual effective tax rate and adjusts for any discrete items arising during the quarter. The primary difference between the effective tax rate and the federal statutory tax rate relates to the full valuation allowance on the Company's U.S. net operating losses.

9. Acquisitions

Acquisition of Lineagen

On August 21, 2020, the Company, Alta Merger Sub, Inc., a wholly owned subsidiary of the Company ("Merger Sub"), Lineagen, a Delaware corporation, and Michael S. Paul, Ph.D., solely in his capacity as exclusive agent and attorney-in-fact of the security-holders of Lineagen, entered into an Agreement and Plan of Merger (the "Merger Agreement"). Pursuant to the terms and conditions of the Merger Agreement, Merger Sub merged with and into Lineagen whereupon the separate corporate existence of Merger Sub ceased, with Lineagen continuing as the surviving corporation of the Merger as a wholly owned subsidiary of the Company. Lineagen's expertise in development, commercialization and reimbursement of laboratory-developed tests provides a platform for accelerating sales growth for the Company's Saphyr system.

The unaudited pro forma financial information in the table below summarizes the combined results of operations for the Company and Lineagen as if the companies had been combined as of January 1, 2019. The unaudited pro forma financial information is for informational purposes only and is not necessarily indicative of the results of operations that would have been achieved as if the acquisition had taken place as of January 1, 2019.

	Three Months Ended September 30, (Unaudited)	Nine Months Ended September 30, (Unaudited)
	2020	2020
Revenue	$ 3,018,000	$ 7,948,000
Net loss	(10,087,000)	(30,375,000)
Basic and diluted net loss per share	$ (0.07)	$ (0.33)

Acquisition of BioDiscovery

On October 8, 2021, the Company entered into an Agreement and Plan of Merger (the "Merger Agreement"), pursuant to which the Company agreed to acquire BioDiscovery, Inc ("Biodiscovery"). Under the terms of the Merger Agreement,, Bionano purchased 100% of the outstanding shares of BioDiscovery on October 18, 2021.

Pursuant to the Merger Agreement, the Company paid upfront consideration consisting of a combination of approximately $50 million in cash and $40 million in shares of Company common stock. The upfront consideration is subject to adjustment for, among other things, cash, unpaid indebtedness, unpaid transaction expenses and working capital relative to a target. Approximately $27 million worth of shares of Company common stock issued as upfront consideration pursuant to the Merger Agreement are subject to vesting based on continued service, subject to the terms and conditions of a stock restriction agreement. Under the Merger Agreement, the Company has also agreed to pay a milestone payment of $10 million in cash based on the achievement of certain commercial milestones. The Merger Agreement has a customary post-closing purchase price adjustment mechanism.

10. Fair Value Measurements

The Company holds investment securities that consist of highly liquid, investment grade debt securities. The Company determines the fair value of its investment securities based upon one or more valuations reported by its investment accounting and reporting service provider. The investment service provider values the securities using a hierarchical security pricing model that relies primarily on valuations provided by an industry-recognized valuation service. Such valuations may be based on trade prices in active markets for identical assets or liabilities (Level 1 inputs) or valuation models using inputs that are observable either directly or indirectly (Level 2 inputs), such as quoted prices for similar assets or liabilities, yield curves, volatility factors, credit spreads, default rates, loss severity, current market and contractual prices for the underlying instruments or debt, and broker and dealer quotes, as well as other relevant economic measures.

The following table presents the Company's financial assets and liabilities measured at fair value on a recurring basis in the Unaudited Consolidated Balance Sheets:

	September 30, 2021			
	Total Fair Value and Carrying Value on Balance Sheet	Fair Value Measurement Category		
		Level 1	Level 2	Level 3
Assets:				
Commercial Paper	$ 97,939,000	$ —	$ 97,939,000	$ —
Corporate Notes/Bonds	$ 87,394,000	$ —	$ 87,394,000	$ —
Total Investments:	$ 185,333,000	$ —	$ 185,333,000	$ —
Money Market Funds	$ 114,331,000	$ 114,331,000	$ —	$ —

Money Market Funds are classified as cash equivalents on the balance sheet. The Company did not hold any investments as of December 31, 2020. As of September 30, 2021, the Company held 44 securities in an unrealized loss position. None of the Company's available-for-sale investment securities were in a material unrealized loss position at September 30, 2021. As such, the Company has not recognized any impairment in its financial statements related to its available-for-sale investment securities.

As of September 30, 2021, the following table summarizes the amortized cost and the unrealized gains (losses) of the available for sale securities:

	Commercial Paper		Corporate Notes/Bonds	
	Amortized Cost	Unrealized gains (losses)	Amortized Cost	Unrealized gains (losses)
Less than 1 year	$ 97,957,000	$ (18,000)	$ 12,234,000	$ (7,000)
Due after one year through five years	—	—	75,258,000	(91,000)
Total	$ 97,957,000	$ (18,000)	$ 87,492,000	$ (98,000)

Included in interest income for the three-month period ended September 30, 2021 was interest income related to the Company's available for sale securities of $13,000. All interest income related to the available for sale securities in 2021 related to three-month period ended September 30, 2021. All available-for-sale securities are classified as current assets, even if the maturity when acquired by the Company is greater than one year due to the ability to liquidate within the next 12 months.

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 consolidated financial statements and related notes included in this Quarterly Report on Form 10-Q and the audited consolidated financial statements and notes thereto as of and for the year ended December 31, 2020 and the related Management's Discussion and Analysis of Financial Condition and Results of Operations, both of which are contained in our Annual Report on Form 10-K, or our Annual Report, filed with the Securities and Exchange Commission, or the SEC, on March 23, 2021. Unless the context requires otherwise, references in this Quarterly Report on Form 10-Q to "we," "us," and "our" refer to Bionano Genomics, Inc. and its subsidiaries or, as the context may require, Bionano Genomics, Inc. only.

Forward-Looking Statements

The information in this Quarterly Report on Form 10-Q contains forward-looking statements and information within the meaning of Section 27A of the Securities Act of 1933, as amended, or the Securities Act, and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act, which are subject to the "safe harbor" created by those sections. These forward-looking statements include, but are not limited to any statements concerning the potential effects of the COVID-19 pandemic on our business, statements concerning our strategy, future operations, future financial position, future revenues, projected costs, prospects and plans and objectives of management. The words "anticipates," "believes," "estimates," "expects," "intends," "may," "plans," "projects," "will," "would" and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. 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. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements that we make. These forward-looking statements involve risks and uncertainties that could cause our actual results to differ materially from those in the forward-looking statements, including, without limitation, the risks set forth in our filings with the SEC. The forward-looking statements are applicable only as of the date on which they are made, and we do not assume any obligation to update any forward-looking statements.

Overview

We are a provider of genome analysis solutions that can enable researchers and clinicians to reveal answers to challenging questions in biology and medicine. Our mission is to transform the way the world sees the genome through optical genome mapping, or OGM, solutions, diagnostic services and software. We offer OGM solutions for applications across basic, translational and clinical research. Through our Lineagen, Inc., or Lineagen, business, we also provides diagnostic testing for patients with clinical presentations consistent with autism spectrum disorder and other neurodevelopmental disabilities. Through our BioDiscovery, Inc., or BioDiscovery, business, we also offer an industry-leading, platform-agnostic software solution, which integrates next-generation sequencing and microarray data designed to provide analysis, visualization, interpretation and reporting of copy number variants, single-nucleotide variants and absence of heterozygosity across the genome in one consolidated view.

We have incurred losses in each year since our inception. Our net loss was $20.8 million and $49.5 million for the three and nine months ended September 30, 2021, respectively. As of September 30, 2021, we had an accumulated deficit of $193.2 million.

We expect to continue to incur significant expenses and operating losses as we:

- expand our sales and marketing efforts to further commercialize our products;
- continue research and development efforts to improve our existing products;
- hire additional personnel;
- enter into collaboration arrangements, if any;
- add operational, financial and management information systems; and
- incur increased costs as a result of operating as a public company.

Recent Highlights

We shipped 24 Saphyr systems during the quarter ended September 30, 2021, compared to 11 systems shipped in the same quarter in 2020. The installed base of Saphyr systems was 141 as of September 30, 2021, compared to 93 as of September 30, 2020.

We sold 3,969 nanochannel array flow cells during the quarter ended September 30, 2021, compared to 1,785 in the same quarter in 2020, an increase of 122%.

We analyzed 309 samples in our Saphyr service lab during the quarter ended September 30, 2021, compared to 84 samples analyzed in the same quarter in 2020.

COVID-19 Overview

The COVID-19 pandemic, and the measures imposed to contain this pandemic in areas where we operate our business and elsewhere have disrupted and are expected to continue to impact our business. For example, to comply with applicable regulations and to safeguard the health and safety of our employees and customers, we temporarily reduced our on-site business operations, implemented work-from-home practices, and modified other business practices, including those related to employee travel and physical participation in meetings, events, and conferences. Limited access to our facilities or customer sites has adversely affected, and is expected to continue to adversely affect, our operations.

Disruptions resulting from the COVID-19 pandemic may continue to impact our operations and overall business. The impact of COVID-19 is evolving rapidly and its future effects remain uncertain. As a result of such uncertainties, the duration of the disruption and the related impact on our business, operating results and financial condition cannot be reasonably estimated at this time. We are continuing to closely monitor the impact of the COVID-19 pandemic on our business and are taking proactive efforts designed to protect the health and safety of our workforce, continue our business operations and advance our corporate objectives.

Financial Overview

Revenue

We generate product revenue from sales of our instruments and consumables. We currently sell our products for research use only applications and our customers are primarily clinical research laboratories, laboratories associated with academic and governmental research institutions, as well as pharmaceutical, biotechnology and contract research companies. Consumable revenue consists of sales of complete assays which are developed internally by us, plus sales of kits which contain all the elements necessary to run tests. We also generate service revenue from the sale of diagnostic testing services for those with autism spectrum disorder and other neurodevelopmental disabilities through our wholly owned subsidiary Lineagen. Other revenue consists of warranty and other service-based revenue.

The following table presents our revenue for the periods indicated:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Product revenue	$ 3,300,000	$ 1,580,000	$ 7,845,000	$ 3,503,000
Service and other revenue[1]	1,355,000	616,000	3,834,000	1,010,000
Total	$ 4,655,000	$ 2,196,000	$ 11,679,000	$ 4,513,000

[1] Includes $1,050,000 and $3,016,000 of revenue generated from Lineagen during the three and nine months ended September 30, 2021, respectively.

The following table reflects total revenue by geography and as a percentage of total revenue, based on the billing address of our customers. North America consists of the United States and Canada. EMEIA consists of Europe, Middle East, India and Africa. Asia Pacific includes China, Japan, South Korea, Singapore and Australia.

	Three Months Ended September 30,				Nine Months Ended September 30,			
	2021		2020		2021		2020	
	$	%	$	%	$	%	$	%
North America[2]	$ 2,557,000	55 %	$ 874,000	40 %	$ 6,419,000	55 %	$ 2,388,000	53 %
EMEIA	1,234,000	27 %	1,204,000	55 %	3,762,000	32 %	1,908,000	42 %
Asia Pacific	864,000	18 %	118,000	5 %	1,498,000	13 %	217,000	5 %
Total	$ 4,655,000	100 %	$ 2,196,000	100 %	$ 11,679,000	100 %	$ 4,513,000	100 %

[2] Includes $1,050,000 and $3,016,000 of revenue generated from Lineagen during the three and nine months ended September 30, 2021, respectively.

Cost of Revenue

Cost of product revenue for our instruments and consumables includes costs from the manufacturer, raw material parts costs and associated freight, shipping and handling costs, contract manufacturer costs, salaries and other personnel costs, overhead and other direct costs related to those sales recognized as product revenue in the period. Cost of service revenue consists of third-party laboratory costs to process the diagnostic samples, salaries of our clinical technicians who interpret and deliver the results to patients, warranty services, and other costs of servicing equipment at customer sites.

Research and Development Expenses

Research and development expenses consist of salaries and other personnel costs, stock-based compensation, research supplies, third-party development costs for new products, materials for prototypes, and allocated overhead costs that include facility and other overhead costs. We have made substantial investments in research and development since our inception, and plan to continue to make investments in the future. Our research and development efforts have focused primarily on the tasks required to support development and commercialization of new and existing products. We believe that our continued investment in research and development is essential to our long-term competitive position.

Selling, General and Administrative Expenses

Selling, general and administrative expenses consist primarily of salaries and other personnel costs, and stock-based compensation for our sales and marketing, finance, legal, human resources and general management, as well as professional services, such as legal and accounting services.

Results of Operations

Comparison of the Three Months Ended September 30, 2021 and 2020

The following table sets forth our results of operations for the three months ended September 30, 2021 and 2020:

	Three Months Ended September 30,		Period-to-Period Change	
	2021	2020	$	%
Revenues:				
Product revenue	$ 3,300,000	$ 1,580,000	$ 1,720,000	108.9 %
Service and other revenue	$ 1,355,000	$ 616,000	739,000	120.0 %
Total revenue	4,655,000	2,196,000	2,459,000	112.0 %
Cost of revenue:				
Cost of product revenue	$ 2,340,000	$ 1,136,000	1,204,000	106.0 %
Cost of other revenue	$ 1,161,000	$ 324,000	837,000	258.3 %
Total cost of revenue	3,501,000	1,460,000	2,041,000	139.8 %
Operating expenses:				
Research and development	$ 6,505,000	$ 2,304,000	4,201,000	182.3 %
Selling, general and administrative	$ 15,327,000	$ 8,659,000	6,668,000	77.0 %
Total operating expenses	21,832,000	10,963,000	10,869,000	99.1 %
Loss from operations	(20,678,000)	(10,227,000)	(10,451,000)	102.2 %
Other income (expenses):				
Interest income (expense)	$ 27,000	$ (589,000)	616,000	(104.6)%
Other income (expenses)	$ (67,000)	$ 54,000	(121,000)	(224.1)%
Total other income (expenses)	(40,000)	(535,000)	495,000	(92.5)%
Loss before income taxes	(20,718,000)	(10,762,000)	(9,956,000)	92.5 %
Provision for income taxes	$ (35,000)	$ (30,000)	(5,000)	16.7 %
Net loss	$ (20,753,000)	$ (10,792,000)	$ (9,961,000)	92.3 %

Revenue

Total revenue increased by $2.5 million, or 112.0%, to $4.7 million for the three months ended September 30, 2021 compared to $2.2 million for the same period in 2020. The increase in product sales was driven by increased demand for our Saphyr OGM solutions, including increased instrument sales and greater demand for our reagent rental program and consumables. We believe increased demand for our OGM systems was primarily driven by increased market awareness and additional published data demonstrating the utility of OGM. The increase in service and other revenue was primarily driven by sales generated by our Lineagen subsidiary. Below is a summary of changes for the three months ended September 30, 2021 as compared to the same period in 2020:

- North America revenue increased by $1.7 million, or 192.6%;
- EMEIA revenue increased by $0.03 million, or 2.5%; and
- Asia Pacific revenue increased by $0.7 million, or 632.2%.

Revenue for the three months ended September 30, 2021, includes service revenue of $1.1 million generated from our Lineagen subsidiary.

Cost of Revenue

Total cost of revenue increased by $2.0 million, or 139.8%, to $3.5 million for the three months ended September 30, 2021 compared to $1.5 million for the same period in 2020. The increase was due to an increase in sales volume. In addition, our gross margins for the three months ended September 30, 2021 were affected by higher cost of warranty repairs on OGM products and higher lab costs on our service revenues.

Research and Development Expenses

Research and development expenses increased by $4.2 million, or 182.3%, to $6.5 million for the three months ended September 30, 2021 compared to $2.3 million for the same period in 2020. The increase is primarily due to a $1.6 million increase in compensation expenses, an increase of $1.8 million in product development costs, and an increase of $0.3 million in professional services. The increase in compensation expense is primarily driven by a 73.7% increase in headcount. In addition, compensation expense included a $0.6 million increase in stock-based compensation expense as a result of increased grant date fair values of options issued this year and the increase in headcount.

Selling, General and Administrative Expenses

Selling, general and administrative expenses increased by $6.7 million, or 77.0%, to $15.3 million for the three months ended September 30, 2021 compared to $8.7 million for the same period in 2020. The increase is primarily due to a $4.7 million increase in compensation expenses, and a $0.7 million increase in other headcount-related expenses. The increase in compensation expense is driven primarily by a 67.2% increase in headcount. In addition, compensation expense included a $1.7 million increase in stock-based compensation expense as a result of increased grant date fair values of options issued and the increase in headcount. Other headcount-related expenses included the cost of recruiting, temporary employment, and facilities expenses incurred in order to support increased product demand.

Interest Expense

Interest expense decreased by $0.6 million, or 104.6%, to $0.03 million for the three months ended September 30, 2021 compared to $0.6 million for the same period in 2020, driven by payment in full of the outstanding term loan under that certain Loan and Security Agreement with Innovatus Life Sciences Lending Fund I, LP, or the LSA Innovatus Term Loan during the three months ended June 30, 2021.

Comparison of the Nine Months Ended September 30, 2021 and 2020

The following table sets forth our results of operations for the nine months ended September 30, 2021 and 2020:

	Nine Months Ended September 30,		Period-to-Period Change	
	2021	2020	$	%
Revenues:				
Product revenue	$ 7,845,000	$ 3,503,000	$ 4,342,000	124.0 %
Service and other revenue	3,834,000	1,010,000	2,824,000	279.6 %
Total revenue	11,679,000	4,513,000	7,166,000	158.8 %
Cost of revenue:				
Cost of product revenue	5,723,000	2,426,000	3,297,000	135.9 %
Cost of other revenue	2,321,000	493,000	1,828,000	370.8 %
Total cost of revenue	8,044,000	2,919,000	5,125,000	175.6 %
Operating expenses:				
Research and development	13,270,000	7,379,000	5,891,000	79.8 %
Selling, general and administrative	38,683,000	21,640,000	17,043,000	78.8 %
Total operating expenses	51,953,000	29,019,000	22,934,000	79.0 %
Loss from operations	(48,318,000)	(27,425,000)	(20,893,000)	76.2 %
Other income (expenses):				
Interest income (expense)	(721,000)	(1,911,000)	1,190,000	(62.3)%
Gain on forgiveness of Paycheck Protection Program loan	1,775,000	—	1,775,000	100.0 %
Loss on debt extinguishment	(2,076,000)	—	(2,076,000)	100.0 %
Other income (expenses)	(96,000)	—	(96,000)	100.0 %
Total other income (expenses)	(1,118,000)	(1,911,000)	793,000	(41.5)%
Loss before income taxes	(49,436,000)	(29,336,000)	(20,100,000)	68.5 %
Provision for income taxes	(50,000)	(40,000)	(10,000)	25.0 %
Net loss	$ (49,486,000)	$ (29,376,000)	$ (20,110,000)	68.5 %

Revenue

Total revenue increased by $7.2 million, or 158.8%, to $11.7 million for the nine months ended September 30, 2021 compared to $4.5 million for the same period in 2020. The increase in product sales was driven by increased demand for our Saphyr OGM solutions, including increased instrument sales and greater demand for our reagent rental program and consumables. Demand for our OGM systems is driven by increased market awareness and additional published data demonstrating the utility of OGM. The increase in service and other revenue was primarily driven by sales generated by our Lineagen subsidiary. Below is a summary of changes for the nine months ended September 30, 2021 as compared to the same period in 2020:

- North America revenue increased by $4.0 million, or 168.8%;
- EMEIA revenue increased by $1.9 million, or 97.2%; and
- Asia Pacific revenue increased by $1.3 million, or 590.3%.

Revenue for the nine months ended September 30, 2021, includes service revenue of $3.0 million generated from our Lineagen subsidiary.

Cost of Revenue

Total cost of revenue increased by $5.1 million, or 175.6%, to $8.0 million for the nine months ended September 30, 2021 compared to $2.9 million for the same period in 2020. The increase was primarily due to an increase in sales volume. Gross margins reduced due to higher cost of warranty repairs on OGM products and higher lab costs on our service revenue.

Research and Development Expenses

Research and development expenses increased by $5.9 million, or 79.8%, to $13.3 million for the nine months ended September 30, 2021 compared to $7.4 million for the same period in 2020. The increase is primarily due to a $2.7 million increase in compensation expenses, an increase of $1.7 million in product development costs, and an increase of $0.5 million in

professional services. Compensation expense included a $1.0 million increase in stock-based compensation expense as a result of increased grant date fair values of options issued this year and an increase in headcount.

Selling, General and Administrative Expenses

Selling, general and administrative expenses increased by $17.0 million, or 78.8%, to $38.7 million for the nine months ended September 30, 2021 compared to $21.6 million for the same period in 2020. The increase is primarily due to a $11.4 million increase in compensation expenses, $1.9 million in other headcount-related expenses, and $2.2 million in professional services. The increase in compensation expense is driven mainly by a 67.2% increase in headcount. In addition, compensation expense included a $2.9 million increase in stock-based compensation expense as a result of increased grant date fair values of options issued and the increase in headcount. Other headcount-related expenses include the cost of recruiting, temporary employment, and facilities expenses incurred in order to support increased product demand. Professional services include expenses incurred to expand our global marketing outreach as well consulting, audit, legal, and other fees necessary to satisfy our obligations as a public company.

Interest Expense

Interest expense decreased by $1.2 million, or 62.3%, to $0.7 million for the nine months ended September 30, 2021 compared to $1.9 million for the same period in 2020, driven by payment in full of the LSA Innovatus Term Loan during the three months ended June 30, 2021.

Gain on forgiveness of Paycheck Protection Program loan

A gain on forgiveness of Paycheck Protection Program loan of $1.8 million was recognized during the nine months ended September 30, 2021 in connection with the forgiveness of our PPP Loan, including all accrued interest in full.

Loss on debt extinguishment

A loss on debt extinguishment of $2.1 million was recognized during the nine months ended September 30, 2021 in connection with our payment in full of the LSA Innovatus Term Loan, including all accrued interest, an end of term fee, a prepayment fee, and write-off of unamortized debt issuance costs.

Liquidity and Capital Resources

Sources of Liquidity

Since our inception, we have incurred net losses and negative cash flows from operations. We have primarily generated cash flows from sales of equity securities and debt financing. We anticipate that future sources of liquidity will principally come from sales of common stock and other equity instruments, borrowings from credit facilities and revenue from our commercial operations. See Note 6 to our condensed consolidated financial statements for a discussion of our recent equity activity and Note 5 to our condensed consolidated financial statements for a discussion of terms and provisions of our previous debt facilities included elsewhere in this Quarterly Report on Form 10-Q for more information. We incurred net losses of $49.5 million and $29.4 million for the nine months ended September 30, 2021 and 2020, respectively. As of September 30, 2021, we had an accumulated deficit of $193.2 million, cash and cash equivalents of $140.7 million, and available-for-sales investment securities of $185.3 million.

Cash Flows

The following table sets forth the cash flow from operating, investing and financing activities for the periods presented:

	Nine Months Ended September 30,	
	2021	2020
Net cash provided by (used in):		
Operating activities	$ (46,305,000)	$ (26,210,000)
Investing activities	(185,552,000)	(2,450,000)
Financing activities	334,144,000	30,216,000

Operating Activities

We derive cash flows from operations primarily from the sale of our products and services. Our cash flows from operating activities are also significantly influenced by our use of cash for operating expenses to support the growth of our business. We have historically experienced negative cash flows from operating activities as we have developed our technology, expanded our business and built our infrastructure and this may continue in the future.

Net cash used in operating activities was $46.3 million during the nine months ended September 30, 2021 as compared to $26.2 million during the same period in 2020. The increase in cash used in operating activities of $20.1 million was primarily attributed to an incremental headcount growth of 69.5%.

Investing Activities

Historically, our primary investing activities have consisted of capital expenditures for the purchase of capital equipment to support our expanding infrastructure. We expect to continue to incur additional costs for capital expenditures related to these efforts in future periods. During the nine months ended September 30, 2021, cash used in investing activities was primarily attributed to the purchase of $205.3 million in available for sale investment securities..

Financing Activities

Net cash provided by financing activities was $334.1 million during the nine months ended September 30, 2021 as compared to the same period in 2020 where we had net cash provided by financing activities of $30.2 million, an increase of $303.9 million. During the nine months ended September 30, 2021, we raised approximately $342.7 million in gross proceeds from executing two follow-on offerings and sales under our at-the-market facilities with Landenburg and Cowen. In addition, we raised approximately $10.1 million from warrant and option exercises.

Paycheck Protection Program

In April 2020, we received loan proceeds of approximately $1.8 million, or the PPP Loan pursuant to the Paycheck Protection Program under the Coronavirus Aid, Relief, and Economic Security Act, or the CARES Act, administered by the U.S. Small Business Administration, or the SBA.

The PPP Loan accrued interest at a rate of 1.00% per annum, and is subject to the standard terms and conditions applicable to loans administered by the SBA under the CARES Act. In February 2021, we applied for forgiveness of the PPP Loan, and in March 2021, the PPP Loan, including all accrued interest, was forgiven in full.

The PPP Loan is also described in Note 5 to our condensed consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q.

Capital Resources

As of September 30, 2021, we had approximately $140.7 million in cash and cash equivalents, available-for-sales investment securities of $185.3 million, and working capital of $324.3 million. Approximately $50 million in cash was used to fund the acquisition of BioDiscovery subsequent to September 30, 2021 as described in Note 9 to our condensed consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q.

In August 2020, we filed a shelf registration statement on Form S-3 with the SEC covering the offering, issuance and sale of up to $125.0 million of our securities, including up to $40.0 million of common stock pursuant to an at-the-market facility, or the Ladenburg ATM with Ladenburg Thalmann & Co. Inc. acting as sales agent. During October through December 2020, we sold 27,025,384 shares of common stock under the Ladenburg ATM at an average share price of $0.82, and received gross proceeds of approximately $22.1 million before deducting offering costs of $573,263. In January 2021, we sold an additional 6,298,152 shares of common stock under the Ladenburg ATM at an average share price of $2.68, and received gross proceeds of approximately $16.9 million before deducting offering costs of $422,034. The Ladenburg ATM was terminated effective March 22, 2021.

On January 12, 2021, we completed an underwritten public offering of 33,368,851 shares of common stock, including 4,352,458 shares of common stock sold pursuant to the underwriters' exercise in full of their option to purchase additional shares. The price to the public in the offering was $3.05 per share and the underwriters purchased the shares from us pursuant to the underwriting agreement at a price of $2.867 per share. The gross proceeds were approximately $101.8 million before deducting underwriting discounts and commissions and other offering expenses.

On January 19, 2021, we filed an automatically effective shelf registration statement on Form S-3 (File No. 333-252216) with the SEC as a "well-known seasoned issuer." The registration statement allows us to issue an indeterminate number or amount of common stock, preferred stock, debt securities and warrants from time to time in one or more offerings. However, there can be no assurance that we will complete any such offerings of securities. Any future offerings under this registration statement will be dependent upon, among other factors, market conditions, available pricing, our financial condition, investor perception of our prospects, our capital needs and our ability to maintain status as a well-known seasoned issuer.

On January 25, 2021, we completed an underwritten public offering of 38,333,352 shares of common stock, including 5,000,002 shares of common stock sold pursuant to the underwriters' exercise in full of their option to purchase additional shares. The price to the public in the offering was $6.00 per share and the underwriters purchased the shares from us pursuant to the underwriting agreement at a price of $5.64 per share. The gross proceeds were approximately $230.0 million before deducting underwriting discounts and commissions and other offering expenses.

On March 23, 2021, we entered into a Sales Agreement with Cowen and Company, LLC, or Cowen, pursuant to which we may offer and sell, from time to time at our sole discretion, shares of our common stock having an aggregate offering price of up to $350.0 million, through or to Cowen, acting as sales agent or principal, or the Cowen ATM. In August and September 2021, the Company sold 2,256,000 shares of common stock under the Cowen ATM at an average share price of $6.15 per share, and received gross proceeds of approximately $13.9 million before deducting offering costs of $0.6 million.

Management believes the available cash balance will be sufficient to fund operations, obligations as they become due and capital investments for at least the next twelve months. See Note 1 to our condensed consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q for more information.

Off-Balance Sheet Arrangements

We did not have during the periods presented, and we do not currently have, any off-balance sheet arrangements, as defined under SEC rules, and similarly did not and do not have any holdings in variable interest entities.

Critical Accounting Policies and Estimates

Our management's discussion and analysis of our financial condition and results of operations is based on our consolidated financial statements, which have been prepared in accordance with generally accepted accounting principles in the United States. The preparation of our consolidated financial statements requires us to make estimates and assumptions that materially affect the reported amounts of assets, liabilities, revenues and expenses and the disclosure of contingent assets and liabilities in our consolidated financial statements and accompanying notes. We evaluate these estimates and judgments on an ongoing basis. We base our estimates on 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 materially differ from these estimates under different assumptions or conditions.

There were no material changes in our critical accounting policies and estimates during the nine months ended September 30, 2021 unless indicated in Note 1 in this Quarterly Report on Form 10-Q. See Note 2 to the condensed consolidated financial statements in our Annual Report.

Recent Accounting Pronouncements

See Note 1 to our condensed consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q for information concerning recent accounting pronouncements.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

As a smaller reporting company, we are not required to provide information typically disclosed under this Item.

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

We maintain "disclosure controls and procedures," as defined in Rule 13a-15(e) and Rule 15d-15(e) under the Securities Exchange Act of 1934, as amended or the Exchange Act. Disclosure controls and procedures are controls and other procedures designed to ensure that the information required to be disclosed by us in the 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. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is accumulated and communicated to our management, including our principal executive officer and our principal financial officer, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure.

As of September 30, 2021, our management, with the participation of our principal executive officer and principal financial officer, evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities and Exchange Act of 1934). Our management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives, and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

Based on the evaluation of our disclosure controls and procedures as of September 30, 2021, our principal executive and financial officer concluded that, as of such date, our disclosure controls and procedures were not effective at a reasonable assurance level as a result of the material weakness that existed in our internal control over financial reporting, as described below and previously reported in our Annual Report.

Material Weaknesses in Internal Control over Financial Reporting

During the preparation of our consolidated financial statements for the year ended December 31, 2020, our management assessed the effectiveness of our internal control over financial reporting using the criteria set forth by the Committee of

Sponsoring Organizations of the Treadway Commission in Internal Control-Integrated Framework (2013 Framework). Based on this assessment, our management determined that, as of December 31, 2020 and September 30, 2021, there was a material weakness in our internal control environment over financial reporting because we did not have a sufficient number of resources to support the growth and complexity of our financial reporting requirements.

A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that a reasonable possibility exists that a material misstatement of our annual or interim financial statements would not be prevented or detected on a timely basis. The foregoing material weakness contributed to a material weakness in our control activities based on the criteria set forth in the 2013 Framework. Specifically, the design of certain controls did not adequately provide appropriate segregation of duties and allow timely completion of financial reporting and accounting activities. The failure to maintain appropriate segregation of duties had a pervasive impact and as such, this deficiency resulted in a risk that could have impacted all financial statement account balances and disclosures. The material weaknesses did not result in any identified material misstatements to our financial statements, and there were no changes to previously released financial results.

Remediation of Material Weaknesses

Management has developed and is actively engaged in implementing a remediation plan to address the material weaknesses described above. The remediation efforts that we have implemented during 2021 include the following:

- Management has engaged external consultants to assist with our internal accounting functions and further enhance our internal controls, which has increased the number of external personnel involved in financial reporting.
- We hired a Senior Manager SEC Reporting & Technical Accounting, a Senior Manager of Accounting, and a Senior Accountant, which has increased the number of qualified full-time employees involved in our financial reporting and the control environment.

We anticipate that these efforts will enable us to broaden the scope and quality of our internal review of underlying information related to financial reporting and to formalize and enhance our internal control procedures. While the implementation of improved controls and procedures is ongoing, we have determined that as of September 30, 2021 that the material weaknesses described above have not been fully remediated.

Changes in Internal Control over Financial Reporting

Other than the remediation efforts underway, as described above, there were no material changes in our internal control over financial reporting during the quarter ended September 30, 2021 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

None.

ITEM 1A. RISK FACTORS

RISK FACTOR SUMMARY

Below is a summary of the principal factors that make an investment in our securities speculative or risky. This summary does not address *all of the risks that we face. Additional discussion of the risks and uncertainties summarized in this risk factor summary, and other risks and uncertainties that we face, are set forth below under the heading "Risk Factors" and should be carefully considered, together with other information in this Quarterly Report on Form 10-Q and our other filings with the SEC before making investment decisions regarding our securities.*

- We have incurred recurring net losses since we were formed and expect to incur losses in the future. We cannot be certain that we will achieve or sustain profitability;
- Our quarterly and annual operating results and cash flows have fluctuated in the past and might continue to fluctuate, which could cause the market price of our securities to decline substantially;
- We are an early-commercial-stage company and have a limited operating history, which may make it difficult to evaluate our current business and predict our future performance;
- Our business, and that of our customers, has been adversely affected by the effects of public health crises, including the COVID-19 pandemic; in particular, the COVID-19 pandemic has materially affected our operations globally, including at our headquarters in San Diego, California, as well as the business or operations of our research partners, customers and other third parties with whom we conduct business;

- Our future capital needs are uncertain and we will require additional funding in the future to advance the commercialization of Saphyr and our other products and services, as well as continue our research and development efforts; if we fail to obtain additional funding, we will be forced to delay, reduce or eliminate our commercialization and development efforts;
- If our products fail to achieve and sustain sufficient market acceptance, our revenue will be adversely affected;
- Acquisitions or joint ventures could disrupt or otherwise harm our business and may cause dilution to our stockholders;
- Our future success is dependent upon our ability to further penetrate our existing customer base and attract new customers;
- We are currently limited to "research use only" with respect to many of the materials and components used in our consumable products including our assays;
- In the near term, sales of our Saphyr system, consumables and genome analysis services will depend on levels of research and development spending by clinical research laboratories, academic and governmental research institutions and biopharmaceutical companies, a reduction in which could limit demand for our products and adversely affect our business and operating results;
- If we do not successfully manage the development and launch of new products, our financial results could be adversely affected;
- If the FDA determines that our RUO products are medical devices or if we seek to market our RUO products for clinical diagnostic or health screening use, we will be required to obtain regulatory clearance(s) or approval(s), and may be required to cease or limit sales of our then marketed products, which could materially and adversely affect our business, financial condition and results of operations. Any such regulatory process would be expensive, time-consuming and uncertain both in timing and in outcome;
- If we are unable to protect our intellectual property, it may reduce our ability to maintain any technological or competitive advantage over our competitors and potential competitors, and our business may be harmed; and
- The price of our securities may be volatile, and you could lose all or part of your investment.

RISK FACTORS

Investing in our common stock involves a high degree of risk. You should carefully consider the following risk factors, together with other information in this Quarterly Report on Form 10-Q and our other filings with the SEC, before making investment decisions regarding our securities. The occurrence of any of the following risks could harm our business, financial condition, results of operations and/or growth prospects or cause our actual results to differ materially from those contained in forward-looking statements we have made in this report and those we may make from time to time. The risks described below are not the only risks facing our company. Additional risks and uncertainties not currently known to us or that we currently deem to be immaterial also may materially adversely affect our business, financial condition or future results. We have marked with an asterisk (*) those risk factors that reflect changes from the risk factors previously disclosed in Item 1A of our Annual Report.

Risks related to our financial condition and need for additional capital

We have incurred recurring net losses since we were formed and expect to incur losses in the future. We cannot be certain that we will achieve or sustain profitability.*

We incurred net losses of $49.5 million and $29.4 million, and used cash in operations of $46.3 million and $26.2 million for the nine months ended September 30, 2021 and 2020, respectively. As of September 30, 2021, we had an accumulated deficit of $193.2 million. We cannot predict if we will achieve sustained profitability in the near future or at all. We expect that our losses will continue for the foreseeable future as we plan to invest significant additional funds toward expansion of our commercial organization and the development of our technology. In addition, as a public company, we will incur significant legal, accounting, and other expenses that we did not incur as a private company. These increased expenses will make it harder for us to achieve and sustain future profitability. We may incur significant losses in the future for a number of reasons, many of which are beyond our control, including the other risks described in this Quarterly Report on Form 10-Q, the market acceptance of our products, future product development and our market penetration and margins.

Our quarterly and annual operating results and cash flows have fluctuated in the past and might continue to fluctuate, which could cause the market price of our securities to decline substantially.*

Numerous factors, many of which are outside our control, may cause or contribute to significant fluctuations in our quarterly and annual operating results. These fluctuations may make financial planning and forecasting uncertain. In addition, these fluctuations may result in unanticipated decreases in our available cash, which could negatively affect our business and

prospects. In addition, one or more of such factors may cause our revenue or operating expenses in one period to be disproportionately higher or lower relative to the others. As a result, comparing our operating results on a period-to-period basis might not be meaningful. You should not rely on our past results as indicative of our future performance. Moreover, our stock price might be based on expectations of future performance that are unrealistic or that we might not meet and, if our revenue or operating results fall below the expectations of investors or securities analysts, the price of our securities could decline substantially.

Our operating results have varied in the past. In addition to other risk factors listed in this section, some of the important factors that may cause fluctuations in our quarterly and annual operating results include:

- adoption of our systems and related products;
- the timing of customer orders to purchase our systems;
- the rate of utilization of consumables by our customers;
- receipt and timing of revenue for services provided by our data solutions service;
- the timing of the introduction of new systems, products, system and product enhancements and services;
- our ability to successfully execute our sales and marketing strategy for our Lineagen products and diagnostic assays;
- the successful execution of our development and integration plans for our BioDiscovery software products and services; and
- the receipt and timing of revenue from our distribution and marketing arrangements.

In addition, a significant portion of our operating expense is relatively fixed in nature, and planned expenditures are based in part on expectations regarding future revenue. Accordingly, unexpected revenue shortfalls could decrease our gross margins and cause significant changes in our operating results from quarter to quarter. If this occurs, the trading price of our securities could fall substantially.

We are an early commercial-stage company and have a limited operating history, which may make it difficult to evaluate our current business and predict our future performance.

We are an early commercial-stage company and have a limited commercial history. Our limited commercial history may make it difficult to evaluate our current business and makes predictions about our future success or viability subject to significant uncertainty. We will continue to encounter risks and difficulties frequently experienced by early, commercial-stage companies, including scaling up our infrastructure and headcount. If we do not address these risks successfully, our business will suffer.

If we are unable to maintain adequate revenue growth or do not successfully manage such growth, our business and growth prospects will be harmed.

We may not achieve substantial growth rates in future periods. Investors should not rely on our operating results for any prior periods as an indication of our future operating performance. To effectively manage our anticipated future growth, we must continue to maintain and enhance our financial, accounting, manufacturing, customer support and sales administration systems, processes and controls. Failure to effectively manage our anticipated growth could lead us to over-invest or under-invest in development, operational and administrative infrastructure; result in weaknesses in our infrastructure, systems, or controls; give rise to operational mistakes, losses, loss of customers, productivity or business opportunities; and result in loss of employees and reduced productivity of remaining employees.

Our continued growth could require significant capital expenditures and might divert financial resources from other projects such as the development of new products and services. As additional products are commercialized, we may need to incorporate new equipment, implement new technology systems, or hire new personnel with different qualifications. Failure to manage this growth or transition could result in turnaround time delays, higher product costs, declining 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 products, and could damage our reputation and the prospects for our business.

If our management is unable to effectively manage our anticipated growth, our expenses may increase more than expected, our revenue could decline or grow more slowly than expected and we may be unable to implement our business strategy. The quality of our products and services may suffer, which could negatively affect our reputation and harm our ability to retain and attract customers.

Our future capital needs are uncertain and we will require additional funding in the future to advance the commercialization of Saphyr and our other products and services, as well as continue our research and development efforts. If we fail to obtain additional funding, we will be forced to delay, reduce or eliminate our commercialization and development efforts.*

Our operations have consumed substantial amounts of cash since our inception. We expect to continue to spend substantial amounts in order to continue the commercialization of our products as well as our research and development programs. During October 2020 through September 2021, as described further under the heading Liquidity and Capital Resources included in Item 2 of this Quarterly Report on Form 10-Q, we raised an aggregate of $384.7 million in gross proceeds from our at-the-market facilities and other public offerings, before deducting underwriting discounts and commissions and other offering costs and expenses. However, in the future, we may need to raise additional funding. For example, we may need to raise additional capital to:

- expand our sales and marketing efforts to further commercialize our products and services;
- expand our research and development efforts to improve our existing products and services and develop and launch new products and services, particularly if any of our products and services are deemed by the U.S. Food and Drug Administration, or FDA, to be medical devices or otherwise subject to additional regulation by the FDA;
- seek FDA approval to market our existing RUO products or new products utilized for diagnostic purposes;
- lease a larger facility or build out our existing facility as we continue to grow our employee headcount;
- hire additional personnel;
- enter into collaboration arrangements, if any, or in-license other products and technologies;
- add operational, financial and management information systems; and
- cover increased costs incurred as a result of continued operation as a public company.
- Our future funding requirements will be influenced by many factors, including:
- market acceptance of our products and services;
- the cost and timing of establishing additional sales, marketing and distribution capabilities;
- the cost of our research and development activities;
- the success of our existing distribution and marketing arrangements and our ability to enter into additional arrangements in the future; and
- the effect of competing technological and market developments.

We cannot assure you that we will be able to obtain additional funds on acceptable terms, or at all. If we raise additional funds by issuing equity or equity-linked securities, our stockholders may experience dilution. Future debt financing, if available, may involve covenants restricting our operations or our ability to incur additional debt. Any debt or equity financing may contain terms that are not favorable to us or our stockholders. If we raise additional funds through collaboration and licensing arrangements with third parties, it may be necessary to relinquish some rights to our technologies or our products, or grant licenses on terms that are not favorable to us.

If we do not have, or are not able to obtain, sufficient funds, we may have to delay development or commercialization of our products. We also may have to reduce marketing, customer support or other resources devoted to our products or cease operations. Any of these factors could have a material adverse effect on our financial condition, operating results and business. Any of the foregoing could significantly harm our business, prospects, financial condition and results of operation and could cause the price of our common stock to decline.

Our business, and that of our customers, has been adversely affected by the effects of public health crises, including the COVID-19 pandemic. In particular, the COVID-19 pandemic has materially affected our operations globally, including at our headquarters in San Diego, California, as well as the business or operations of our research partners, customers and other third parties with whom we conduct business.*

Our business could be adversely affected by health crises in regions where we have operations, concentrations of sales and marketing teams, distributors or other business operations. Such health crises could also affect the business or operations of our research partners, customers and other third parties with whom we conduct business. In particular, the COVID-19 pandemic and the measures imposed to contain this pandemic have disrupted and are expected to continue to impact our business.

In response to public health directives and orders implemented in response to the COVID-19 pandemic, we have implemented work-from-home policies for certain employees and temporarily scaled back our operations. We have also modified certain business practices, including those related to employee travel and cancellation of physical participation in meetings, events and conferences, and implemented new protocols to promote social distancing and enhance sanitary measures in our offices and facilities. The quarantine of our personnel and the inability to access our facilities or customer sites has adversely affected, and is expected to continue adversely affecting, our operations. For example, certain members of our workforce are now performing their duties remotely and these employees have not been able to maintain the same level of productivity and efficiency due a lack of resources that would otherwise be available to them in our offices and additional demands on their time, such as increased responsibilities resulting from school closures or the illness of family members. Furthermore, our remote workforce poses increased risks to our information technology systems and data as more of our personnel leverage resources not necessarily within our control.

The effects of these public health directives and orders and our related adjustments in our business have negatively impacted productivity, disrupted our business and delayed our timelines, the magnitude of which will depend, in part, on the length and severity of the restrictions and other limitations on our ability to conduct our business in the ordinary course. The spread of COVID-19 has resulted in a widespread health crisis that is also adversely affecting the economies and financial markets of many countries, including in the United States, Europe and Asia, which has resulted in an economic downturn that may negatively affect demand for our products and services and materially affect us financially. For example, customers who have committed to order minimum quantities of consumables or to purchase our Saphyr instrument could delay or default on these commitments. Further, restrictions on our ability to travel, stay-at-home orders and other similar restrictions on our business have limited our ability to support our global and domestic operations, including providing installation and training and customer service, resulting in disruptions in our sales and marketing efforts and negative impacts on our commercial strategy. In addition, disruption of global financial markets as a result of COVID-19 may limit our ability to access capital, which could negatively affect our liquidity. A recession or market correction resulting from the spread of COVID-19 could also materially affect our business and the value of our common stock even after the outbreak of COVID-19 has subsided, due to unforeseen adverse impacts on us or our third-party manufacturers, vendors and customers.

Also, in connection with our Lineagen diagnostic services, COVID-19 poses the risk that we or our employees, contractors, suppliers, courier delivery services and other partners may be prevented from conducting business activities for an indefinite period of time, including due to spread of the disease within these groups or due to shutdowns that may be requested or mandated by governmental authorities. The continued spread of COVID-19 and the measures taken by the governments of countries affected could disrupt the supply chain of materials needed for our diagnostic tests, interrupt our ability to receive specimens, impair our ability to perform or deliver the results from our tests, impede patient movement or interrupt healthcare services causing a decrease in test volumes, delay coverage decisions from Medicare and third-party payors, delay ongoing and planned clinical trials involving our tests and have a material adverse effect on our business, financial condition and results of operations.

These and similar, and perhaps more severe, disruptions in our operations could negatively impact our business, operating results and financial condition. In addition, quarantines, stay-at-home, executive and similar government orders, or the perception that such orders, shutdowns or other restrictions on the conduct of business operations could occur, could disrupt our supply chain and affect customer decision-making. For example, any actual or perceived disruption in our product distribution channel could alter customer buying decisions, prompting customers to delay or cancel their orders, which would negatively impact our sales revenue and could harm our reputation. In addition, we anticipate that ongoing disruptions in our supply chain will cause shortages in the materials required to operate our instruments, therefore limiting our ability to process customer samples and the ability of users of our system to operate our system.

In addition, we are subject to various affirmative and negative covenants in our loan agreement with our lender. If the effects of COVID-19 cause us to fall out of compliance with one or more of such covenants and we are unable to secure a waiver or negotiate an amendment to our loan agreement on reasonable terms, or at all, an event of default could occur, which would allow our lender to accelerate our repayment obligations or enforce its other rights under our loan agreement. Any such default may also require us to seek additional or alternative financing, which may not be available on commercially reasonable terms or

at all. If we are unable to access funds to repay our lender, our lender could take control of our pledged assets. Any of the foregoing events would negatively impact our financial condition and liquidity.

The ultimate impact of the COVID-19 outbreak or a similar health epidemic is highly uncertain and subject to change. We do not yet know the full extent of potential delays or impacts on our business or the global economy as a whole, and such impacts may not be fully recoverable. In addition, the current and potential adverse impacts of the COVID-19 pandemic on our business, financial condition, results of operations and growth prospects, may also have the effect of heightening many of the other risks and uncertainties described in this Quarterly Report on Form 10-Q.

Changes in tax laws or regulations that are applied adversely to us or our customers may have a material adverse effect on our business, cash flow, financial condition or results of operations.

New income, sales, use or other tax laws, statutes, rules, regulations or ordinances could be enacted at any time, which could adversely affect our business operations and financial performance. Further, existing tax laws, statutes, rules, regulations or ordinances could be interpreted, changed, modified or applied adversely to us. For example, legislation enacted in 2017 informally titled the Tax Cuts and Jobs Act, or the Tax Act, enacted many significant changes to the U.S. tax laws. Future guidance from the Internal Revenue Service and other tax authorities with respect to the Tax Act may affect us, and certain aspects of the Tax Act could be repealed or modified in future legislation. For example, the Coronavirus Aid, Relief and Economic Security Act, or the CARES Act, modified certain provisions of the Tax Act. In addition, it is uncertain if and to what extent various states will conform to the Tax Act, the CARES Act or any newly enacted federal tax legislation. Changes in corporate tax rates, the realization of net deferred tax assets relating to our operations, the taxation of foreign earnings, and the deductibility of expenses under the Tax Act or future reform legislation could have a material impact on the value of our deferred tax assets, could result in significant one-time charges, and could increase our future U.S. tax expense.

Our ability to use net operating losses and certain other tax attributes to offset future taxable income and taxes may be subject to limitations.

As of December 31, 2020, we have federal and state tax net operating loss carryforwards of $266.7 million and $114.0 million, respectively. The federal tax loss carryforwards include $102.5 million that do not expire, but utilization of such tax loss carryforwards in taxable years beginning after December 31, 2020 is limited to 80% of our taxable income. The remaining federal tax loss carryforwards of $164.2 million and state tax loss carryforwards begin to expire in 2027 and 2023, respectively, unless previously utilized. As of December 31, 2020, we also have federal and California research credit carryforwards of $5.5 million and $5.0 million, respectively. The federal research credit carryforwards begin to expire in 2027 unless previously utilized. The California research credits carry forward indefinitely.

In addition, utilization of net operating losses and research and development credit carryforwards may be subject to limitations due to ownership changes that have occurred or that could occur in the future in accordance with applicable provisions of the Internal Revenue Code of 1986, as amended, or the Code, and corresponding provisions of state law. We may have experienced one or more ownership changes in the past and we may also experience additional ownership changes in the future as a result of subsequent changes 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 or research and development credit carryforwards is materially limited, it would harm our future operating results by increasing our future tax obligations. In addition, at the state level, there may be periods during which the use of net operating loss carryforwards is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed.

U.S. taxation of international business activities or the adoption of tax reform policies could materially impact our future financial position and results of operations.

Limitations on the ability of taxpayers to claim and utilize foreign tax credits and the deferral of certain tax deductions until earnings outside of the U.S. are repatriated to the U.S., as well as changes to U.S. tax laws that may be enacted in the future, could impact the tax treatment of future foreign earnings. Should the scale of our international business activities expand, any changes in the U.S. taxation of such activities could increase our worldwide effective tax rate and harm our future financial position and results of operations.

Risks related to our business operations

If our products fail to achieve and sustain sufficient market acceptance, our revenue will be adversely affected.

Our success depends on our ability to develop and market products that are recognized and accepted as reliable, enabling and cost-effective. Most of the potential customers for our products already use expensive research systems in their laboratories that they have used for many years and may be reluctant to replace those systems with ours. Market acceptance of our systems will depend on many factors, including our ability to demonstrate to potential customers that our technology is an attractive alternative to existing technologies. Compared to some competing technologies, our technology is new and complex, and many potential customers have limited knowledge of, or experience with, our products. Prior to adopting our systems, some potential customers may need to devote time and effort to testing and validating our systems. Any failure of our systems to meet these customer benchmarks could result in potential customers choosing to retain their existing systems or to purchase systems other than ours. In addition, it is important that our gene mapping systems be perceived as accurate and reliable by the scientific and medical research community as a whole. Historically, a significant part of our sales and marketing efforts has been directed at demonstrating the advantages of our technology to industry leaders and encouraging such leaders to publish or present the results of their evaluation of our system. If we are unable to continue to motivate leading researchers to use our technology, or if such researchers are unable to achieve or unwilling to publish or present significant experimental results using our systems, acceptance and adoption of our systems will be slowed and our ability to increase our revenue would be adversely affected.

Acquisitions or joint ventures could disrupt or otherwise harm our business and may cause dilution to our stockholders.*

As part of our growth strategy, we have acquired and may continue to acquire other businesses, products or technologies as well as pursue strategic alliances, joint ventures, technology licenses or investments in complementary businesses. We may not be able to locate or make suitable acquisitions on acceptable terms, and future acquisitions may not be effectively and profitably integrated into our business. Our failure to successfully complete the integration of any business that we acquire could have an adverse effect on our prospects, business activities, cash flow, financial condition, results of operations and stock price. Integration challenges may include the following:

- disruption in our relationships with customers, distributors or suppliers as a result of such a transaction;
- unanticipated expenses and liabilities related to acquired companies;
- difficulties integrating acquired personnel, technologies, operations and legal compliance obligations into our existing business;
- diversion of management time and focus from operating our business to acquisition integration challenges;
- increases in our expenses and reductions in our cash available for operations and other uses;
- possible write-offs or impairment charges relating to acquired businesses;
- difficulties developing and marketing new products and services;
- entering markets in which we have limited or no prior experience; and
- coordinating our efforts throughout various localities and time zones.

Foreign acquisitions involve unique risks in addition to those mentioned above, including those related to integration of operations across different cultures and languages, currency risks and the particular economic, political and regulatory risks associated with specific countries. In addition, in connection with any such transactions, we may also issue equity securities, incur additional debt, assume contractual obligations or liabilities or expend significant cash. Such transactions could harm our operating results and cash position, negatively affect the price of our stock and cause dilution to our current stockholders.

Also, the anticipated benefit of any acquisition may not materialize. Future acquisitions or dispositions could result in potentially dilutive issuances of our equity securities, the incurrence of debt, contingent liabilities or amortization expenses or write-offs of goodwill, any of which could harm our financial condition. We cannot predict the number, timing or size of future joint ventures or acquisitions, or the effect that any such transactions might have on our operating results.

For example, as previously disclosed, we recently completed the acquisition of Lineagen, Inc., or Lineagen, a U.S.-based provider of proprietary molecular diagnostics services for individuals presenting with certain neurodevelopmental disorders, for aggregate consideration consisting of approximately 6,167,510 shares of our common stock (subject to adjustment for cash, accounts receivable, unpaid indebtedness, unpaid transaction expenses and certain other liabilities of Lineagen), $1.9 million in cash, and the assumption of approximately $2.9 million in certain liabilities of Lineagen, pursuant to the terms of that certain Agreement and Plan of Merger, dated as of August 21, 2020, by and among us, Alta Merger Sub, Inc., Lineagen and Michael S. Paul, Ph.D., solely in his capacity as exclusive agent and attorney-in-fact of the securityholders of Lineagen, or the Lineagen Acquisition.

The issuance of shares as consideration in the Lineagen Acquisition resulted in dilution to our existing stockholders. In addition, pursuant to the Lineagen Acquisition, headcount of our consolidated operations increased by 33 employees, which has resulted in and will continue to result in increased selling, general and administrative expenses.

Additionally, on October 18, 2021, we completed the acquisition of BioDiscovery, Inc., or BioDiscovery, a U.S.-based software company with solutions for analysis, interpretation and reporting of genomics data, where we paid upfront consideration consisting of a combination of approximately $50 million in cash and $40 million in shares of our common stock, pursuant to the terms of that certain Agreement and Plan of Merger, dated as of October 8, 2021, or the BioDiscovery Merger Agreement, by and among us, Starship Merger Sub I, Inc., Starship Merger Sub II, LLC, BioDiscovery and Soheil Shams, solely in his capacity as the securityholders' representative, or the BioDiscovery Acquisition, and together with the Lineagen Acquisition, the Recent Acquisitions. The issuance of shares as consideration in the BioDiscovery Acquisition resulted in dilution to our existing stockholders. In addition, pursuant to the BioDiscovery Acquisition, headcount of our consolidated operations increased by 24 employees, which will continue to result in increased selling, general and administrative expenses.

Although we conducted extensive business, financial and legal due diligence in connection with our evaluation of the Recent Acquisitions, our due diligence investigations may not have identified every matter that could adversely affect our business, operating results and financial condition. We may be unable to adequately address the financial, legal and operational risks introduced by the Recent Acquisitions and may have difficulty developing experience with the industry in which Lineagen and/or BioDiscovery operates. Accordingly, we cannot guarantee that the Recent Acquisitions will yield the results we have anticipated and unforeseen complexities and expenses may arise. In addition, we may not achieve the revenues, growth prospects and synergies expected from the Recent Acquisitions any such benefits we do achieve may not offset increased costs, resulting in a potential impairment of goodwill or other assets that were acquired. For future acquisitions, we may similarly be unable achieve revenue, growth prospects and synergies in a manner consistent with our expectations. Our failure to do so could adversely affect our business, operating results and financial condition.

Equity issuances in connection with strategic transactions or raising additional capital may cause dilution to our stockholders or restrict our operations.*

From time to time, we expect to finance our strategic transactions or cash needs through a combination of equity and debt financings. To the extent that we finance our strategic transactions or raise additional capital through the sale of equity or convertible debt securities, your ownership interest could be diluted and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a common stockholder. Debt financing may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends and may be secured by all or a portion of our assets.

For example, on August 13, 2020, we entered into an At Market Issuance Sales Agreement, or the Sales Agreement, with Ladenburg Thalmann & Co. Inc., as sales agent, or Ladenburg, under which we were eligible to offer and sell up to $40.0 million of shares of our common stock from time to time through Ladenburg. During the fiscal year ended December 31, 2020, we sold 27,025,384 shares of common stock under the Sales Agreement for aggregate gross proceeds of approximately $22.1 million and from January 1, 2021 through January 11, 2021, we sold 6,298,152 shares of common stock under the Sales Agreement for aggregate gross proceeds of approximately $16.9 million. On January 12, 2021, we announced the completion of an underwritten public offering of 33,368,851 shares of our common stock for gross proceeds, before deducting underwriting discounts and commissions and offering expenses, of approximately $101.8 million. Moreover, on January 25, 2021, we announced the completion of an underwritten public offering of 38,333,352 shares of our common stock for gross proceeds, before deducting underwriting discounts and commissions and offering expenses, of approximately $230.0 million. In March 2021, we entered into a new at-the-market facility, or the Cowen ATM, with Cowen and Company, LLC, or Cowen, which provides for the sale, in our sole discretion, of shares of our common stock having an aggregate offering price of up to $350.0 million through or to Cowen, acting as sales agent or principal. In August and September 2021, the Company sold 2,256,000 shares of common stock under the ATM at an average share price of $6.15 per share, and received gross proceeds of approximately $13.9 million before deducting offering costs of $0.6 million. In addition, we issued shares of our common stock in connection with the Recent Acquisitions and to our previous lender, Innovatus Life Sciences Lending Fund I, LP, in lieu of waiver fees. Any future significant sales of our capital stock would result in dilution to our current stockholders. As a result of these issuances, our investors experienced dilution of their ownership interests.

If we are unable to execute our sales and marketing strategy for our Lineagen products and services, including diagnostic assays, and are unable to gain acceptance in the market, we may be unable to generate sufficient revenue to sustain our Lineagen business.

Our Lineagen business provides molecular diagnostics services and has engaged in only limited sales and marketing activities for the diagnostic assays currently offered through our CLIA-certified laboratory. To date, the revenue generated by our Lineagen business has been insufficient to fund operations.

Although we believe that our current assays and our planned future assays represent a promising commercial opportunity, our products or assays may never gain significant acceptance in the marketplace and therefore may never generate substantial revenue or profits for us. We will need to establish a market for our products and diagnostic assays and build that market through physician education, awareness programs and the publication of clinical trial results. Gaining acceptance in medical communities requires, among other things, publications in leading peer-reviewed journals of results from studies using our current products, assays and services and/or our planned future products, assays and 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 current products, assays and services and our planned future products, assays and services.

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

- conducting clinical utility studies of such assays in collaboration with key thought leaders to demonstrate their use and value in important medical decisions such as treatment selection;
- whether our current or future partners, vigorously support our offerings;
- the success of our sales force;
- whether healthcare providers believe such diagnostic assays provide clinical utility;
- whether the medical community accepts that such diagnostic assays are sufficiently sensitive and specific to be meaningful in patient care and treatment decisions;
- our ability to continually source raw materials, shipping kits and other products that we sell or consume in our manufacturing process that are of sufficient quality and supply;
- our ability to continue to fund planned sales and marketing activities; and
- whether private health insurers, government health programs and other third-party payors will adopt our current and future assays in their guidelines, or cover such diagnostic assays and, if so, whether they will adequately reimburse us.

The COVID-19 pandemic may also increase the risk and uncertainty of the events described above and delay our development timelines. Failure to achieve widespread market acceptance of our current products, assays and services, as well as our planned future products, assays and services, would materially harm our business, financial condition and results of operations.

In the near term, sales of our Saphyr system, consumables and genome analysis services will depend on levels of research and development spending by clinical research laboratories, academic and governmental research institutions and biopharmaceutical companies, a reduction in which could limit demand for our products and adversely affect our business and operating results.

In the near term, we expect that our revenue from sales of our Saphyr system, consumables and OGM services will be derived primarily from sales to academic and governmental research institutions, as well as biopharmaceutical and contract research companies worldwide for research applications. The demand for our products will depend in part upon the research and development budgets of these customers, which are impacted by factors beyond our control, such as:

- changes in government programs that provide funding to research institutions and companies;
- macroeconomic conditions and the political climate;
- changes in the regulatory environment;
- differences in budgetary cycles; and
- market acceptance of relatively new technologies, such as ours.

For example, in March 2017, the federal government announced the intent to cut federal biomedical research funding by as much as 18%. While there has been significant opposition to these funding cuts, the uncertainty regarding the availability of research funding for potential customers may adversely affect our operating results. Our operating results may fluctuate substantially due to reductions and delays in research and development expenditures by these customers. Any decrease in customers' budgets or expenditures, or in the size, scope or frequency of capital or operating expenditures, could materially and adversely affect our business, operating results and financial condition.

The sales cycle for our systems can be lengthy and variable, which makes it difficult for us to forecast revenue and other operating results.

The sales process for our systems generally involves numerous interactions with multiple individuals within an organization, and often includes in-depth analysis by potential customers of our technology and products and a lengthy review process. Our

customers' evaluation processes often involve a number of factors, many of which are beyond our control. As a result of these factors, the capital investment required to purchase our systems and the budget cycles of our customers, the time from initial contact with a customer to our receipt of a purchase order can vary significantly. Given the length and uncertainty of our sales cycle, we have in the past experienced, and expect to in the future experience, fluctuations in our sales on a period-to-period basis. In addition, any failure to meet customer expectations could result in customers choosing to retain their existing systems, use existing assays not requiring capital equipment or purchase systems other than ours.

Our long-term results depend upon our ability to improve existing products and introduce and market new products successfully.*

Our business is dependent on the continued improvement of our existing products and our development of new products utilizing our current or other potential future technology. As we introduce new products or refine, improve or upgrade versions of existing products, we cannot predict the level of market acceptance or the amount of market share these products will achieve, if any. We cannot assure you that we will not experience material delays in the introduction of new products in the future.

Consistent with our strategy of offering new products and product refinements, we expect to continue to use a substantial amount of capital for product development and refinement. We may need additional capital for product development and refinement than is available on terms favorable to us, if at all, which could adversely affect our business, financial condition or results of operations.

We generally sell our products in industries that are characterized by rapid technological changes, frequent new product introductions and changing industry standards. If we do not develop new products and product enhancements based on technological innovation on a timely basis, our products may become obsolete over time and our revenues, cash flow, profitability and competitive position will suffer. Our success will depend on several factors, including our ability to:

- correctly identify customer needs and preferences and predict future needs and preferences;
- allocate our research and development funding to products with higher growth prospects;
- anticipate and respond to our competitors' development of new products and technological innovations;
- innovate and develop new technologies and applications, including software applications through our BioDiscovery subsidiary, and acquire or obtain rights to third-party technologies that may have valuable applications in the markets we serve;
- successfully commercialize new technologies in a timely manner, price them competitively and manufacture and deliver sufficient volumes of new products of appropriate quality on time; and
- customers' willingness to adopt new technologies.

In addition, if we fail to accurately predict future customer needs and preferences or fail to produce viable technologies, we may invest heavily in research and development of products that do not lead to significant revenue. For example, we recently completed the BioDiscovery Acquisition and will need to devote time and resources in order to further develop and integrate BioDiscovery's software and technology solutions for our current and anticipated product offerings. We may be unsuccessful in achieving our desired results or in marketing such solutions to our future customers. Even if we successfully innovate and develop new products and product enhancements, we may incur substantial costs in doing so, and our profitability may suffer.

Our ability to develop new products based on innovation can affect our competitive position and often requires the investment of significant resources. Difficulties or delays in research, development or production of new products and services or failure to gain market acceptance of new products and technologies may reduce future revenues and adversely affect our competitive position.

If we do not successfully manage the development and launch of new products, our financial results could be adversely affected.

We face risks associated with launching new products. If we encounter development or manufacturing challenges or discover errors during our product development cycle, the product launch dates of new products may be delayed. The expenses or losses associated with unsuccessful product development or launch activities or lack of market acceptance of our new products could adversely affect our business or financial condition.

Our future success is dependent upon our ability to further penetrate our existing customer base and attract new customers.

Our current customer base for our RUO products is primarily composed of academic and governmental research institutions and biopharmaceutical and contract research companies and, for our Lineagen diagnostic services, physicians and their patients. Our success will depend upon our ability to respond to the evolving needs of, and increase our market share among, existing

customers and additional potential customers, marketing new products and services as we develop them. Identifying, engaging and marketing to customers who are unfamiliar with our current products requires substantial time, expertise and expense and involves a number of risks, including:

- our ability to attract, retain and manage the sales, marketing and service personnel necessary to expand market acceptance for our technology;
- the time and cost of maintaining and growing a specialized sales, marketing and service force; and
- the fact that our sales, marketing and service force may be unable to execute successful commercial activities.

We have utilized third parties to assist with sales, distribution and customer support in certain regions of the world. There is no guarantee, when we enter into such arrangements, that we will be successful in attracting desirable sales and distribution partners. There is also no guarantee that we will be able to enter into such arrangements on favorable terms. Any failure of our sales and marketing efforts, or those of any third-party sales and distribution partners, would adversely affect our business.

We are currently limited to "research use only" with respect to many of the materials and components used in our consumable products including our assays.

Our instruments, consumable products and assays are purchased from suppliers with a restriction that they be used for research use only, or RUO. While we have focused initially on the life sciences research market and RUO products only, part of our business strategy is to expand our product line to encompass products that are intended to be used for the diagnosis of disease and precision healthcare, either alone or in collaboration with third parties. The use of our RUO products for any such diagnostic purposes would require that we obtain regulatory clearance or approval to market our products for those purposes and also that we acquire the materials and components used in such products from suppliers without an RUO restriction. There can be no assurance that we will be able to acquire these materials and components for use in diagnostic products on acceptable terms, if at all. If we are unable to do so, we would not be able to expand our non-Lineagen product offerings beyond RUO, and our business and prospects would suffer.

The FDA Guidance on "Distribution of In Vitro Diagnostic Products Labeled for Research Use Only or Investigational Use Only", or, the RUO/IUO Labeling Guidance, emphasizes that the FDA will review the totality of the circumstances when evaluating whether equipment and testing components are properly labeled as RUO. It further states that merely including a labeling statement that a product is intended for research use only will not necessarily render the device exempt from the FDA's 510(k) clearance, PMA, or other requirements, if the circumstances surrounding the distribution of the product indicate that the manufacturer intends for its product to be offered for clinical diagnostic use. These circumstances may include written or verbal marketing claims or links to articles regarding a product's performance in clinical applications, a manufacturer's provision of technical support for clinical validation or clinical applications, or solicitation of business from clinical laboratories, all of which could be considered evidence of intended uses that conflict with RUO labeling. If the FDA were to determine that our RUO products were intended for use in clinical investigation, diagnosis or treatment decisions, or that express or implied clinical or diagnostic claims were made for our RUO products, those products could be considered misbranded or adulterated under the Federal Food, Drug, and Cosmetic Act. If the FDA determines that our RUO products are being marketed for clinical diagnostic use without the required PMA or 510(k) clearance, we may be required to cease marketing our products as planned, recall the products from customers, revise our marketing plans, and/or suspend or delay the commercialization of our products until we obtain the required authorization. We also may be subject to a range of enforcement actions by the FDA, including warning or untitled letters, injunctions, civil monetary penalties, criminal prosecution, and recall and/or seizure of products, as well as significant adverse publicity.

If, in the future, we choose to commercialize our RUO products for clinical diagnostic use, we will be required to comply with the FDA's premarket review and post-market control requirements for IVDs, as may be applicable. Complying with the FDA's PMA and/or 510(k) clearance requirements may be expensive, time-consuming, and subject us to significant and/or unanticipated delays. Our efforts may never result in an approved PMA or 510(k) clearance for our products. Even if we obtain a PMA or 510(k) clearance, where required, such authorization may not be for the use or uses we believe are commercially attractive and/or are critical to the commercial success of our products. As a result, being subject to the FDA's premarket review and/or post-market control requirements for our products could materially and adversely affect our business, financial condition and results of operations.

We have limited experience in marketing and selling our products, and if we are unable to successfully commercialize our products, our business and operating results will be adversely affected.

We have limited experience marketing and selling our products. We currently sell our Saphyr system for research use only, through our direct field sales and support organizations located in North America and Europe and through a combination of our own sales force and third-party distributors in additional major markets such as Australian, China, Japan and South Korea.

The future sales of our products will depend in large part on our ability to effectively market and sell our products, successfully manage and expand our sales force, and increase the scope of our marketing efforts. We may also enter into additional distribution arrangements in the future. Because we have limited experience in marketing and selling our products, our ability to forecast demand, the infrastructure required to support such demand and the sales cycle to customers is unproven. If we do not build an efficient and effective sales force, our business and operating results will be adversely affected.

We rely on a single contract manufacturer for our optical genome mapping systems and a single contract manufacturer for our chip consumables. If either of these manufacturers should fail or not perform satisfactorily, our ability to supply these products would be negatively and adversely affected.

We currently rely on a single contract manufacturer to manufacture and supply all of our non-Lineagen instruments. See "Business–Key Agreements" in our Annual Report. In addition, we rely on a single contract manufacturer to manufacture and supply all of our chip consumables. Since our contracts with these manufacturers do not commit them to supply quantities beyond the amounts included in our purchase orders, and do not commit them to carry inventory or make available any particular quantities, these contract manufacturers may give other customers' needs higher priority than ours, and we may not be able to obtain adequate supplies in a timely manner or on commercially reasonable terms. If either of these manufacturers were to be unable to supply instruments, our business would be harmed.

In the event it becomes necessary to utilize different contract manufacturers for our non-Lineagen instruments or chip consumables, we would experience additional costs, delays and difficulties in doing so as a result of identifying and entering into an agreement with a new supplier as well as preparing such new supplier to meet the logistical requirements associated with manufacturing our units, and our business would suffer. We may also experience additional costs and delays in the event we need access to or rights under any intellectual property of these current manufacturers.

We may experience manufacturing problems or delays that could limit the growth of our revenue or increase our losses.

We may encounter unforeseen situations that would result in delays or shortfalls in our production as well as delays or shortfalls caused by our outsourced manufacturing suppliers and by other third-party suppliers who manufacture components for our products. If we are unable to keep up with demand for our products, our revenue could be impaired, market acceptance for our products could be adversely affected and our customers might instead purchase our competitors' products. Our inability to successfully manufacture our products would have a material adverse effect on our operating results.

If our laboratory facilities become damaged or inoperable or we are required to vacate our existing facilities, our ability to conduct our laboratory analysis and pursue our research and development efforts may be jeopardized.

We currently perform all research and development activities and most of our OGM services at a single laboratory facility in San Diego, California with the remaining genome analysis services at a facility we occupy at a customer's lab in Clermont-Ferrand, France. All of our molecular diagnostics services are processed at a single laboratory facility in Salt Lake City, Utah.

Our facilities and equipment could be harmed or rendered inoperable by natural or man-made disasters, including war, fire, earthquake, power loss, communications failure, terrorism, burglary, public health crises (including restrictions that may be imposed on businesses by state and local governments under stay-at-home or similar orders and mandates, such as those implemented in response to the COVID-19 pandemic) or other events, which may make it difficult or impossible for us to perform our testing services for some period of time or to receive and store samples. The inability to perform tests or to reduce the backlog of sample analysis that could develop if one or both of our facilities become inoperable, for even a short period of time, may result in the loss of revenue, loss of customers or harm to our reputation, and we may be unable to regain that revenue, those customers or repair our reputation in the future. Furthermore, integral parties in our supply chain are operating from single sites, increasing their vulnerability to natural disasters and man-made disasters or other sudden, unforeseen and severe adverse events.

In addition, the loss of our samples due to such events could limit or prevent our ability to conduct research and development analysis on existing tests as well as tests in development.

Our facilities and the equipment we use to perform our testing and research and development could be unavailable or costly and time-consuming to repair or replace. It would be difficult, time-consuming and expensive to rebuild our facilities, to locate and qualify a new facility, replace certain pieces of equipment or license or transfer our proprietary technology to a third party, particularly in light of licensure and accreditation requirements. Even in the unlikely event that we are able to find a third party with such qualifications to enable us to resume our operations, we may be unable to negotiate commercially reasonable terms.

We carry insurance for damage to our property and the disruption of our business, but this insurance may not cover all of the risks associated with damage or disruption to our business, may not provide coverage in amounts sufficient to cover our potential losses and may not continue to be available to us on acceptable terms, if at all.

We rely on a limited number of suppliers or, in some cases, one supplier, for some of our materials and components used in our products, and may not be able to find replacements or immediately transition to alternative suppliers, which could have a material adverse effect on our business, financial condition, results of operations and reputation.

We rely on limited or sole suppliers for certain reagents and other materials and components that are used in our products. While we periodically forecast our needs for such materials and enter into standard purchase orders with our suppliers, we do not have long-term contracts with many of these suppliers. If we were to lose such suppliers, there can be no assurance that we will be able to identify or enter into agreements with alternative suppliers on a timely basis on acceptable terms, if at all. An interruption in our operations, including our laboratory operations, could occur if we encounter delays or difficulties in securing these materials, or if the quality of the materials supplied do not meet our requirements, or if we cannot then obtain an acceptable substitute. The time and effort required to qualify a new supplier and ensure that the new materials provide the same or better quality results could result in significant additional costs. Any such interruption could significantly affect our business, financial condition, results of operations and reputation.

In addition, certain of the components used in our instruments are sourced from limited or sole suppliers. If we were to lose such suppliers, there can be no assurance that we will be able to identify or enter into agreements with alternative suppliers on a timely basis on acceptable terms, if at all. An interruption in our ability to sell and deliver instruments to customers could occur if we encounter delays or difficulties in securing these components, or if the quality of the components supplied do not meet specifications, or if we cannot then obtain an acceptable substitute. If any of these events occur, our business and operating results could be harmed.

Also, in order to mitigate these risks, we maintain inventories of certain supplies at higher levels than would be the case if multiple sources of supply were available. If our sales or testing volume decreases or we switch suppliers, we may hold excess supplies with expiration dates that occur before use which would adversely affect our losses and cash flow position. As we introduce any new products, we may experience supply issues as we ramp up our sales or test volume. If we should encounter delays or difficulties in securing, reconfiguring or revalidating the equipment, reagents or other materials we require for our products, our business, financial condition, results of operations and reputation could be adversely affected.

Undetected errors or defects in our products could harm our reputation, decrease market acceptance of our products or expose us to product liability claims.

Our products may contain undetected errors or defects when first introduced or as new versions or new products are released. Disruptions affecting the introduction or release of, or other performance problems with, our products may damage our customers' businesses and could harm their and our reputations. If that occurs, we may incur significant costs, the attention of our key personnel could be diverted, or other significant customer relations problems may arise. We may also be subject to warranty and liability claims for damages related to errors or defects in our products. In addition, if we do not meet industry or quality standards, if applicable, our products may be subject to recall. A material liability claim, recall or other occurrence that harms our reputation or decreases market acceptance of our products could harm our business and operating results.

If our customers develop or use our products or assays for diagnostic purposes, someone could file a product liability claim alleging that one of our products contained a design or manufacturing defect that resulted in the failure to adequately perform, leading to death or injury. In addition, the marketing, sale and use of our current or future products and assays could lead to the filing of product liability claims against us if someone alleges that our products failed to perform as designed. We may also be subject to liability for errors in the results we provide or for a misunderstanding of, or inappropriate reliance upon, the information we provide.

A product liability claim could result in substantial damages and be costly and time consuming to defend, either of which could materially harm our business or financial condition. We cannot assure investors that our product liability insurance would adequately protect our assets from the financial impact of defending a product liability claim. Any product liability claim brought against us, with or without merit, could increase our product liability insurance rates or prevent us from securing insurance coverage in the future. Additionally, any product liability lawsuit could damage our reputation, or cause current partners to terminate existing agreements and potential partners to seek other partners, any of which could impact our results of operations.

We may also initiate a correction to our existing products or assays, which could lead to increased costs and increased scrutiny by regulatory authorities and our customers regarding the quality and safety of our products or services, as well as negative publicity. The occurrence of any of these events could have an adverse effect on our business and results of operations.

Our reliance on distributors for sales of our products outside of the United States could limit or prevent us from selling our products and could impact our revenue.*

We intend to continue to grow our business internationally, and to do so we must attract additional distributors and retain existing distributors to maximize the commercial opportunity for our products. There is no guarantee that we will be successful in attracting or retaining desirable sales and distribution partners or that we will be able to enter into such arrangements on

favorable terms. Distributors may not commit the necessary resources to market and sell our products to the level of our expectations or may choose to favor marketing the products of our competitors. If current or future distributors do not perform adequately, or we are unable to enter into effective arrangements with distributors in particular geographic areas, we may not realize long-term international revenue growth. In addition, if our distributors fail to comply with applicable laws and ethical standards, including anti-bribery laws, this could damage our reputation and could have a significant adverse effect on our business and our revenues.

We expect to generate a substantial portion of our revenue internationally in the future and can become further subject to various risks relating to our international activities, which could adversely affect our business, operating results and financial condition.

During 2020 approximately 58% of our product revenue was generated from customers located outside of the U.S. We believe that a substantial percentage of our future revenue will come from international sources as we expand our overseas operations and develop opportunities in additional areas. We have limited experience operating internationally and engaging in international business involves a number of difficulties and risks, including:

- required compliance with existing and changing foreign regulatory requirements and laws;
- difficulties and costs of staffing and managing foreign operations;
- difficulties protecting or procuring intellectual property rights;
- required compliance with anti-bribery laws, such as the U.S. Foreign Corrupt Practices Act, data privacy and security requirements, labor laws and anti-competition regulations;
- export or import restrictions;
- laws and business practices favoring local companies;
- longer payment cycles and difficulties in enforcing agreements and collecting receivables through certain foreign legal systems;
- political and economic instability; and
- potentially adverse tax consequences, tariffs, customs charges, bureaucratic requirements and other trade barriers.

Historically, most of our revenue has been denominated in U.S. dollars. In the future, we may sell our products and services in local currency outside of the U.S. As our operations in countries outside of the U.S. grow, our results of operations and cash flows may be subject to fluctuations due to changes in foreign currency exchange rates, which could harm our business in the future. For example, if the value of the U.S. dollar increases relative to foreign currencies, in the absence of a corresponding change in local currency prices, our revenue could be adversely affected as we convert revenue from local currencies to U.S. dollars. If we dedicate significant resources to our international operations and are unable to manage these risks effectively, our business, operating results and financial condition will suffer.

We are subject to U.S. and foreign anti-corruption and anti-money laundering laws with respect to our operations and non-compliance with such laws can subject us to criminal and/or civil liability and harm our business.

We are subject to the U.S. Foreign Corrupt Practices Act, as amended, the U.S. domestic bribery statute contained in 18 U.S.C. § 201, the U.S. Travel Act, the USA PATRIOT Act, the United Kingdom Bribery Act 2010, and other state and national anti-bribery and anti-money laundering laws in countries in which we conduct activities. Anti-corruption laws are interpreted broadly and prohibit companies and their employees and third-party intermediaries from authorizing, promising, offering, providing, soliciting, or accepting, directly or indirectly, improper payments or benefits to or from any person whether in the public or private sector for the purpose of obtaining or retaining business or securing any other improper advantage. We rely on third-party representatives, distributors, and other business partners to support sales of our products and services and our efforts to ensure regulatory compliance. In addition, as we increase our international sales and business, we may engage with additional business partners. We can be held liable for the corrupt or other illegal activities of our employees, representatives, contractors, business partners, and agents, even if we do not explicitly authorize or have actual knowledge of such activities.

Any violations of anti-corruption and anti-money laundering 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.

We are subject to governmental export and import controls that could impair our ability to compete in international markets due to licensing requirements and subject us to liability if we are not in compliance with applicable laws.

Our products are subject to export control and import laws and regulations, including the U.S. Export Administration Regulations, U.S. Customs regulations, and various economic and trade sanctions regulations administered by the U.S. Treasury Department's Office of Foreign Assets Controls. Exports of our products must be made in compliance with these laws and regulations. If we fail to comply with these laws and regulations, we and certain of our employees could be subject to substantial civil or criminal penalties, including the possible loss of export or import privileges; fines, which may be imposed on us and responsible employees or managers; and, in extreme cases, the incarceration of responsible employees or managers.

In addition, changes in our products or changes in applicable export or import laws and regulations may create delays in the introduction and sale of our products in international markets, prevent our customers from deploying our products or, in some cases, prevent the export or import of our products to certain countries, governments or persons altogether. Any change in export or import laws and regulations, shift in the enforcement or scope of existing laws and regulations, or change in the countries, governments, persons or technologies targeted by such laws and regulations, could also result in decreased use of our products, or in our decreased ability to export or sell our products to existing or potential customers. Any decreased use of our products or limitation on our ability to export or sell our products would likely adversely affect our business, financial condition and results of operations.

If we are unable to recruit, train, retain, motivate and integrate key personnel, we may not achieve our goals.

Our future success depends on our ability to recruit, train, retain, motivate and integrate key personnel, including our recently expanded senior management team, as well as our research and development, manufacturing and sales and marketing personnel. Competition for qualified personnel is intense. Our growth depends, in particular, on attracting and retaining highly-trained sales personnel with the necessary scientific background and ability to understand our systems at a technical level to effectively identify and sell to potential new customers and develop new products. Because of the complex and technical nature of our products and the dynamic market in which we compete, any failure to attract, train, retain, motivate and integrate qualified personnel could materially harm our operating results and growth prospects.

If we cannot provide quality technical and applications support, we could lose customers and our business and prospects will suffer.

The placement of our products at new customer sites, the introduction of our technology into our customers' existing laboratory workflows and ongoing customer support can be complex. Accordingly, we need highly trained technical support personnel. Hiring technical support personnel is very competitive in our industry due to the limited number of people available with the necessary scientific and technical backgrounds and ability to understand our technology at a technical level. To effectively support potential new customers and the expanding needs of current customers, we will need to substantially expand our technical support staff. If we are unable to attract, train or retain the number of highly qualified technical services personnel that our business needs, our business and prospects will suffer.

Security breaches or other types of security incidents affecting our or our third-party service providers', consultants', or contractors' networks or systems could result in a material disruption to our services, compromise personal or sensitive information related to our business, may cause us to incur significant liabilities and adversely affect our business, results of operations, financial condition, and future prospects.*

We are increasingly dependent upon information technology systems, infrastructure and data to operate our business. In the ordinary course of our business, we collect, store, use, transmit, and otherwise process sensitive, proprietary and confidential information, including but not limited to intellectual property, proprietary business information owned or controlled by ourselves or our customers, financial information and personal information (including protected health information). The secure collection, storage, use, transmission and processing of such information is vital to our operations and business strategy. Any actual or perceived breach of our security measures or those of our third-party service providers, consultants, or contractors could adversely affect our business, operations, financial condition, and future prospects.

The procedures and controls we use to monitor cyber security threats and mitigate our exposure to such threats may not be sufficient to prevent cyber security incidents, and our internal information technology systems and those of our third-party service providers, consultants, and contractors are potentially vulnerable to breakdown or other damage or interruption from service interruptions, system malfunction, natural disasters, terrorism, war, public health crises (such as the COVID-19 global pandemic), telecommunication and electrical failures, theft as well as security breaches from inadvertent or intentional actions by our employees, contractors, consultants, business partners, and/or other third parties, or from cyber-attacks by malicious third parties (including the deployment of harmful malware, ransomware, viruses, worms, denial-of-service attacks, supply chain attacks, social engineering schemes and other means to affect service reliability and threaten the confidentiality, integrity and availability of information), which may compromise our, or our third-party service providers' consultants', or contracts' system infrastructure or lead to data leakage or misdirected payments to and from us. Ransomware attacks, including those

from organized criminal threat actors, nation-states and nation-state supported actors, are becoming increasingly prevalent and severe and can lead to significant interruptions, delays, or outages in our operations, loss of data, loss of income, significant extra expenses to restore data or systems, reputational loss and the diversion of funds. To alleviate the financial, operational and reputational impact of a ransomware attack it may be preferable to make extortion payments, but we may be unwilling or unable to do so (including, for example, if applicable laws or regulations prohibit such payments). Similarly, supply chain attacks have increased in frequency and severity, and we cannot guarantee that third parties and infrastructure in our supply chain 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 platform, systems and networks or the systems and networks of third parties that support us and our services. Despite the security controls we have in place, such attacks are very difficult to avoid. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure or acquisition of or access to information, we could incur liability and reputational damage. In addition, these incidents could result in disrupted operations, lost opportunities, misstated financial data, increased costs arising from the implementation of additional security protective measures, incident notification related costs and litigation costs.

While we have security measures in place designed to protect information and prevent data loss and other security breaches, we cannot guarantee that our, or our third-party service providers', consultants', or contractors' security measures will be sufficient to protect against unauthorized access to, or other compromise of such information. The techniques used to sabotage or to obtain unauthorized access to our products, services, platform, systems, networks and/or physical facilities in which data is stored or through which data is transmitted change frequently, and we may be unable to anticipate such techniques or implement adequate preventative measures or stop security breaches that may arise from such techniques. As a result, our safeguards and preventive measures may not be adequate to prevent current or future cyberattacks and security incidents, including security breaches that may remain undetected for extended periods of time, which can substantially increase the potential for a material adverse impact resulting from the breach.

We are also required to comply with laws, rules, industry standards, regulations, policies and contracts that may require us to maintain the security of information. In addition, we may have contractual and other legal obligations to notify relevant stakeholders of security breaches. Failure to prevent or mitigate cyberattacks could result in unauthorized access to, acquisition of or disclosure of such information, including personal information (and protected health information). Most jurisdictions have enacted laws requiring companies to notify individuals, regulatory authorities and others of security breaches involving certain types of data. In addition, our agreements with certain customers and partners may require us to notify them in the event of a security breach. Such disclosures are costly, could lead to negative publicity, may cause our customers to lose confidence in the effectiveness of our security measures and not use our services, and require us to expend significant capital and other resources to respond to and/or alleviate problems caused by the actual or perceived security breach. In addition, any costs or other liabilities related to responding to a cybersecurity event or to mitigate any identified security vulnerabilities could be significant, including costs for remediating the effects of such an event, paying a ransom, restoring data from backups, and conducting data analysis to determine what data may have been affected by the breach. In addition, our efforts to contain or remediate a security breach or any vulnerability exploited to cause a breach may be unsuccessful, and efforts and any related failures to contain or remediate them could result in interruptions, delays, loss in customer trust, harm to our reputation, and increases to our insurance coverage. For example, any such event that leads to unauthorized access, use, or disclosure of information, including personal information related to our patient samples or personnel, could harm our reputation directly, compel us to comply with federal and/or state breach notification laws and foreign law equivalents, subject us to mandatory corrective action, and otherwise subject us to liability under laws and regulations that protect the privacy and security of personal information, which could result in significant legal and financial exposure and reputational damages that could potentially have an adverse effect on our business.

We may not have adequate insurance coverage for security incidents or breaches, including fines, judgments, settlements, penalties, costs, attorney fees and other impacts that arise out of incidents or breaches. We cannot assure you that any insurance coverage will adequately cover liabilities actually incurred or that insurance will continue to be available to us on economically reasonable terms, or at all. The successful assertion of one or more large claims against us that exceeds our available insurance coverage, or results in changes to our insurance policies (including premium increases or the imposition of large deductible or co-insurance requirements), could have an adverse effect on our business. Our risks are likely to increase as we continue to expand, grow our customer base, and process, store, and transmit increasingly large amounts of confidential, proprietary and sensitive data.

We are subject to stringent and changing privacy laws, regulations and standards, as well as policies, contracts and other obligations related to data privacy and security. Our actual or perceived failure to comply with such obligations could lead to enforcement or litigation (that could result in fines or penalties), reputational harm, or other adverse business effects. *

We are or may become subject to numerous foreign and domestic laws, regulations and standards, as well as policies, contracts and other obligations regarding privacy and data security that govern the personal information and other data we may collect, store, use, or process. The regulatory framework for privacy and data protection issues is rapidly evolving and is likely to

remain uncertain for the foreseeable future. Many government bodies and agencies have adopted or are considering adopting laws and regulations regarding the collection, use, storage, destruction, and disclosure of personal information and breach notification procedures. We are also or may become required to comply with laws, rules and regulations relating to data security. Interpretation of these laws, rules and regulations in applicable jurisdictions is subject to change and may result in potentially conflicting obligations.

The federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, and their respective implementing regulations, impose requirements relating to the privacy, security and transmission of individually identifiable health information. Such laws may apply to us, our customers or our service providers. Among other things, HITECH, through its implementing regulations, makes certain of HIPAA's privacy and security standards directly applicable to business associates, defined as a person or organization, other than a member of a covered entity's workforce, that creates, receives, maintains or transmits protected health information for or on behalf of a covered entity for a function or activity regulated by HIPAA as well as their covered subcontractors. Most healthcare providers in the United States, including institutions from which we may obtain customer data, are subject to privacy and security regulations promulgated under HIPAA, as amended by HITECH. A person may be prosecuted for alleged HIPAA violations either directly or indirectly such as under aiding-and-abetting or conspiracy principles. Further, depending on the facts and circumstances, we could face substantial civil and criminal penalties and liabilities if we fail to comply with our obligations (required by law and/or contract) in our processing of such information and/or if we knowingly receive individually identifiable health information from a HIPAA-covered healthcare provider that has not satisfied HIPAA's requirements for disclosure of individually identifiable health information.

In the United States, at the state level, the California Consumer Privacy Act of 2018, or the CCPA, which took effect on January 1, 2020, gives California residents expanded rights to access and delete their personal information, opt out of certain personal information sharing, and receive detailed information about how their personal information is used. The CCPA also provides for civil penalties for violations and contains a private right of action for data breaches that is expected to increase litigation involving misuse of personal information of California residents. The CCPA may increase our compliance costs and potential liability. In addition, California voters recently approved the California Privacy Rights Act of 2020, or CPRA, which goes into effect on January 1, 2023. The CPRA is expected to, among other things, give California residents the ability to limit the use of their personal information, further restrict the use of cross-contextual advertising, establish restrictions on the retention of personal information, expand the types of data breaches subject to the CCPA's private right of action, provide for increased penalties for CPRA violations concerning California residents under the age of 16, and establish a new California Privacy Protection Agency to implement and enforce the new law. Some observers have noted that the CCPA and CPRA could mark the beginning of a trend of states adopting more stringent privacy laws in the U.S., which could further increase our compliance costs, potential liability and adversely affect our business. For example, Virginia recently passed its Consumer Data Protection Act, and Colorado recently passed the Colorado Privacy Act, both of which differ from the CPRA and become effective in 2023.

The global data protection landscape is also rapidly evolving, and we expect there will continue to be new and proposed laws, regulations, and industry standards concerning privacy, data protection, and information security. We cannot yet determine the impact that such future laws, regulations and standards may have on our business. For example, in May 2018, the European Union's General Data Protection Regulation, or the GDPR, took effect across the European Economic Area, or the EEA. Also, notwithstanding the United Kingdom's, or the UK's withdrawal from the EU, the GDPR continues to apply in substantially equivalent form in the context of the UK, UK establishments and UK-focused processing operations by operation of the so-called "UK GDPR." European data protection laws impose stringent data protection requirements and to date, have increased compliance burdens on us, including by mandating burdensome documentation requirements and granting certain rights to individuals to control how we collect, use, disclose, retain and process their personal data. The GDPR also provides for more robust regulatory enforcement and greater fines for noncompliance than previous data protection laws, including fines of up to €20 million or 4% of global annual revenue of any noncompliant company for the preceding financial year, whichever is greater as well as the potential for processing penalties that include the inability to process European personal data.

European data protection laws including the GDPR also generally prohibit the transfer of personal information from Europe to the United States and most other countries unless the parties to the transfer have implemented specific safeguards to protect the transferred personal information. The Court of Justice of the European Union, or CJEU, recently raised questions about whether the European Commission's Standard Contractual Clauses, one of the primary mechanisms used by U.S. companies to import personal information from Europe, complies with the GDPR. While the CJEU upheld the validity of Standard Contractual Clauses, the CJEU ruled that the underlying data transfers must be assessed on a case-by-case basis by the data controller to determine whether the personal information will be adequately protected. Further, the European Commission recently adopted new SCCs under the GDPR for personal data transfers outside the EEA, which may require us to expend significant resources to update our contractual arrangements and conduct personal data transfer impact assessments. At present, there are few if any viable alternatives to the Standard Contractual Clauses and, therefore, there is uncertainty regarding how to ensure that transfers of personal information from Europe to the United States comply with the GDPR. As such, any transfers by us, our customers

or our third-party service providers, of personal information from Europe may not comply with European data protection laws; may increase our exposure to the GDPR's heightened sanctions for violations of its cross-border data transfer restrictions; and may reduce demand for our services from companies subject to European data protection laws. Loss of our ability to transfer personal information from Europe may also require us to increase our data processing capabilities in those jurisdictions at significant expense. Moreover, other countries outside of Europe have enacted or are considering enacting similar cross-border data transfer restrictions and laws requiring local data residency, which could increase the cost and complexity of delivering our services and operating our business.

Further, the United Kingdom's decision to leave the EU, often referred to as Brexit, has created uncertainty about the regulation of data protection in the U.K., including with respect to whether laws or regulations will apply to us consistent with the GDPR in the future and how data transfers to and from the U.K. will be regulated. Following December 31, 2020, and the expiry of transitional arrangements between the UK and EU, the data protection obligations of the GDPR continue to apply to UK-related processing of personal data in substantially unvaried form under the so-called 'UK GDPR' (i.e., the GDPR as it continues to form part of UK law by virtue of section 3 of the EU (Withdrawal) Act 2018, as amended). However, going forward, there is increasing risk for divergence in application, interpretation and enforcement of the data protection laws as between the UK and European Economic Area, or EEA. Furthermore, the relationship between the UK and the EEA in relation to certain aspects of data protection law remains uncertain. On June 28, 2021, the European Commission issued an adequacy decision under the GDPR which allows transfers (other than those carried out for the purposes of United Kingdom immigration control) of personal data from the EEA to the United Kingdom to continue without restriction for a period of four years ending June 27, 2025. After that period, the adequacy decision may be renewed, however, only if the United Kingdom continues to ensure an adequate level of data protection. During these four years, the European Commission will continue to monitor the legal situation in the United Kingdom and could intervene at any point if the United Kingdom deviates from the level of data protection in place at the time of issuance of the adequacy decision. If the adequacy decision is withdrawn or not renewed, transfers of personal data from the EEA to the United Kingdom will require a valid 'transfer mechanism' and we may be required to implement new processes and put new agreements in place, such as SCCs, to enable transfers of personal data from the EEA to the United Kingdom to continue.

In Canada, where we may also operate or have customers, the Personal Information Protection and Electronic Documents Act, or PIPEDA and various provincial laws require that companies give detailed privacy notices to consumers, obtain consent to use personal information, with limited exceptions, allow individuals to access and correct their personal information, and report certain data breaches. In addition, Canada's Anti-Spam Legislation, or CASL, prohibits email marketing without the recipient's consent, with limited exceptions. Failure to comply with PIPEDA, CASL, or provincial privacy or data protection laws could result in significant fines or penalties or possible damage awards.

We may publish privacy policies and other documentation regarding our collection, processing, use and disclosure of personal information. Although we endeavor to comply with our published policies and other documentation, we may at times fail to do so or may be perceived to have failed to do so. Despite our efforts, we may not be successful in achieving compliance if our personnel, customers, or service providers fail to comply with our policies and documentation. Such failures can subject us to potential foreign, local, state and federal action if they are found to be deceptive, unfair, or misrepresentative of our actual practices.

Compliance with applicable privacy and data security laws and regulations and other related obligations is a rigorous and time-intensive process, and we may be required to put in place additional mechanisms to ensure compliance with our data protection obligations. These obligations may necessitate changes to our information technology systems and data practices. Any failure or perceived failure by us or third parties working on our behalf to comply with applicable laws and regulations, any privacy and data security obligations pursuant to contract, our stated privacy or security policies, or obligations to customers or other third parties may result in governmental enforcement actions (including fines, penalties, judgments, settlements, imprisonment of company officials and public censure), civil claims, litigation, damage to our brand and reputation and loss of goodwill (both in relation to existing customers and prospective customers), any of which could have a material adverse effect on our business, operations and financial performance.

The life sciences research and diagnostic markets are highly competitive. If we fail to effectively compete, our business, financial condition and operating results will suffer.

We face significant competition in the life sciences research and diagnostic markets. We currently compete with both established and early stage companies that design, manufacture and market systems and consumable supplies. We believe our principal competitors in the life sciences research and genome mapping markets include Pacific Biosciences of California, Oxford Nanopore Technologies, 10x Genomics, Genomic Vision and Dovetail Genomics. In addition, there are a number of new market entrants in the process of developing novel technologies for the life sciences research, diagnostic and screening markets.

Many of our current competitors are either publicly-traded, or are divisions of publicly-traded companies, and may enjoy a number of competitive advantages over us, including:

- greater name and brand recognition;
- substantially greater financial and human resources;
- broader product lines;
- larger sales forces and more established distributor networks;
- substantial intellectual property portfolios;
- larger and more established customer bases and relationships; and
- better established, larger scale, and lower cost manufacturing capabilities.
- We believe that the principal competitive factors in all of our target markets include:
- cost of instruments and consumables;
- accuracy, including sensitivity and specificity, and reproducibility of results;
- reputation among customers;
- innovation in product offerings;
- flexibility and ease of use; and
- compatibility with existing laboratory processes, tools and methods.

We cannot assure investors that our products will compete favorably or that we will be successful in the face of increasing competition from new products and technologies introduced by our existing competitors or new companies entering our markets. In addition, we cannot assure investors that our competitors do not have or will not develop products or technologies that currently or in the future will enable them to produce competitive products with greater capabilities or at lower costs than ours. Any failure to compete effectively could materially and adversely affect our business, financial condition and operating results.

Our application for the Paycheck Protection Program Loan, or our application for forgiveness of the Paycheck Protection Program Loan, could in the future be determined to have been impermissible or could result in damage to our reputation.

On April 17, 2020, we received loan proceeds of approximately $1.8 million, or the PPP Loan, pursuant to the Paycheck Protection Program under the "CARES Act" administered by the U.S. Small Business Administration, or the SBA. In February 2021, we applied for forgiveness of the PPP Loan, and in March 2021, the PPP Loan, including all accrued interest, was forgiven in full.

In order to apply for the PPP Loan, we were required to certify, among other things, that the current economic uncertainty made the PPP Loan request necessary to support our ongoing operations. We made this certification in good faith after analyzing, among other things, the maintenance of our workforce, our need for additional funding to continue operations, and our ability to access alternative forms of capital in the current market environment to offset the effects of the COVID-19 pandemic. Following this analysis, we believe that we satisfied all eligibility criteria for the PPP Loan, and that our receipt of the PPP Loan is consistent with the broad objectives of the CARES Act. The certification described above did not contain any objective criteria and is subject to interpretation.

On April 23, 2020, the SBA issued guidance stating that it is unlikely that a public company with substantial market value and access to capital markets will be able to make the required certification in good faith. The lack of clarity regarding loan eligibility under the Paycheck Protection Program has resulted in significant media coverage and controversy with respect to public companies applying for and receiving loans. If, despite our good-faith belief that given our circumstances we satisfied all eligibility requirements for the PPP Loan, we are later determined to have violated any applicable laws or regulations that may apply to us in connection with the PPP Loan or it is otherwise determined that we were ineligible to receive the PPP Loan, we may be required to repay the PPP Loan in its entirety and/or be subject to additional penalties, which could also result in adverse publicity and damage to our reputation. Should we be audited or reviewed by federal or state regulatory authorities as a result of filing an application for forgiveness of the PPP Loan or otherwise, such audit or review could result in the diversion of management's time and attention and legal and reputational costs. If we were to be audited or reviewed and receive an adverse determination or finding in such audit or review, we could be required to return the full amount of the PPP Loan. Any of these events could have a material adverse effect on our business, results of operations and financial condition.

Unfavorable global economic conditions could adversely affect our business, financial condition or results of operations.

Our results of operations could be adversely affected by general conditions in the global economy and in the global financial markets. A severe or prolonged global economic downturn could result in a variety of risks to our business, including our ability to raise additional capital when needed on acceptable terms, if at all. This is particularly true in Europe, which is undergoing a continued severe economic crisis. A weak or declining economy could also strain our suppliers, possibly resulting in supply disruption. Any of the foregoing could harm our business and we cannot anticipate all of the ways in which the current economic climate and financial market conditions could adversely impact our business.

The United Kingdom's referendum to leave the European Union or "Brexit," has and may continue to cause disruptions to capital and currency markets worldwide. The full impact of the Brexit decision, however, remains uncertain. A process of negotiation will determine the future terms of the United Kingdom's relationship with the European Union. During this period of negotiation, our results of operations and access to capital may be negatively affected by interest rate, exchange rate and other market and economic volatility, as well as regulatory and political uncertainty. Brexit may also have a detrimental effect on our suppliers and manufacturers, which would, in turn, adversely affect our financial condition.

Legal, political and economic uncertainty surrounding the exit of the U.K., from the European Union, or EU, may be a source of instability in international markets, create significant currency fluctuations, adversely affect our operations or intended operations in the U.K. and pose additional risks to our business, revenue, financial condition and results of operations.

Nearly 4% of our sales in fiscal year 2020 came from the United Kingdom. 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. will be subject to a transition period until December 31, 2020, or the Transition Period, during which EU rules will continue to apply. Negotiations between the U.K. and the EU are expected to continue in relation to the customs and trading relationship between the U.K. and the EU following the expiry of the Transition Period.

The uncertainty concerning the U.K's legal, political and economic relationship with the EU after the Transition Period may be a source of instability in the international markets, create significant currency fluctuations, and/or otherwise adversely affect trading agreements or similar cross-border co-operation arrangements (whether economic, tax, fiscal, legal, regulatory or otherwise).

These developments, or the perception that any of them could occur, have had, and may continue to have, a significant adverse effect on global economic conditions and the stability of global financial markets, and could significantly reduce global market liquidity and limit the ability of key market participants to operate in certain financial markets. In particular, it could also lead to a period of considerable uncertainty in relation to the U.K. financial and banking markets, as well as on the regulatory process in Europe. Asset valuations, currency exchange rates and credit ratings may also be subject to increased market volatility.

If the U.K. and the EU are unable to negotiate acceptable trading and customs terms or if other EU Member States pursue withdrawal, barrier-free access between the U.K. and other EU Member States or among the European Economic Area overall could be diminished or eliminated. The long-term effects of Brexit will depend on any agreements (or lack thereof) between the U.K. and the EU and, in particular, any arrangements for the U.K. to retain access to EU markets after the Transition Period.

Such a withdrawal from the EU is unprecedented, and it is unclear how the U.K's access to the European single market for goods, capital, services and labor within the EU, or single market, and the wider commercial, legal and regulatory environment, will impact our business. Any current or planned future operations in the U.K. as well as in other countries in the EU and European Economic Area, or EEA, could be disrupted by Brexit, particularly if there is a change in the U.K's relationship to the single market.

Brexit has caused, and may continue to create, volatility in global stock markets and regional and global economic uncertainty particularly in the United Kingdom financial and banking markets. Weakening of economic conditions or economic uncertainties tend to harm our business. There may continue to be economic uncertainty surrounding the consequences of Brexit which could adversely impact customer confidence resulting in customers reducing their spending budgets on our solutions, which could adversely affect our business, revenue, financial condition and results of operations.

Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware and the federal district courts of the United States of America 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 other 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 United States of America 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 nevertheless 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 contained 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 adversely affect our results of operations and financial condition.

Risks related to government regulation and diagnostic product reimbursement

If the FDA determines that our RUO products are medical devices or if we seek to market our RUO products for clinical diagnostic or health screening use, we will be required to obtain regulatory clearance(s) or approval(s), and may be required to cease or limit sales of our then marketed products, which could materially and adversely affect our business, financial condition and results of operations. Any such regulatory process would be expensive, time-consuming and uncertain both in timing and in outcome.

Our RUO products are focused on the life sciences research market. This includes laboratories associated with academic and governmental research institutions, as well as pharmaceutical, biotechnology and contract research companies. Accordingly, our products are labeled as "Research Use Only," or RUO, and are not intended for diagnostic use. While we have focused initially on the life sciences research market and RUO products only, our strategy is to expand our product line to encompass products that are intended to be used for the diagnosis of disease, either alone or in collaboration with third parties (such as our collaboration with Berry Genomics). Such in-vitro diagnostic, or IVD, products will be subject to regulation by the FDA as medical devices, or comparable international agencies, including requirements for regulatory clearance or approval of such products before they can be marketed. If the FDA were to determine that our products are intended for clinical use or if we decided to market our products for such use, we would be required to obtain FDA 510(k) clearance or premarket approval in order to sell our products in a manner consistent with FDA laws and regulations. Such regulatory approval processes or clearances are expensive, time-consuming and uncertain; our efforts may never result in any approved premarket approval application, or PMA, or 510(k) clearance for our products; and failure by us or a collaborator to obtain or comply with such approvals and clearances could have an adverse effect on our business, financial condition or operating results.

IVD products may be regulated as medical devices by the FDA and comparable international agencies and may require either clearance from the FDA following the 510(k) pre-market notification process or PMA from the FDA, in each case prior to marketing. If we or our collaborators are required to obtain a PMA or 510(k) clearance for products based on our technology, we or they would be subject to a substantial number of additional requirements for medical devices, including establishment registration, device listing, Quality Systems Regulations which cover the design, testing, production, control, quality assurance, labeling, packaging, servicing, sterilization (if required), and storage and shipping of medical devices (among other activities), product labeling, advertising, recordkeeping, post-market surveillance, post-approval studies, adverse event reporting, and correction and removal (recall) regulations. One or more of the products we or a collaborator may develop using our technology may also require clinical trials in order to generate the data required for PMA approval. Complying with these requirements may be time-consuming and expensive. We or our collaborators may be required to expend significant resources to ensure ongoing compliance with the FDA regulations and/or take satisfactory corrective action in response to enforcement action, which may have a material adverse effect on the ability to design, develop, and commercialize products using our technology as planned. Failure to comply with these requirements may subject us or a collaborator to a range of enforcement actions, such as warning letters, injunctions, civil monetary penalties, criminal prosecution, recall and/or seizure of products, and revocation of marketing authorization, as well as significant adverse publicity. If we or our collaborators fail to obtain, or experience

significant delays in obtaining, regulatory approvals for IVD products, such products may not be able to be launched or successfully commercialized in a timely manner, or at all.

Laboratory developed tests, or LDTs, are a subset of IVD tests that are designed, manufactured and used within a single laboratory. Our Lineagen diagnostic services are provided as LDTs. The FDA maintains that LDTs are medical devices and has for the most part exercised enforcement discretion for most LDTs. A significant change in the way that the FDA regulates any LDTs that we, our collaborators or our customers market or develop using our technology could affect our business. If the FDA requires laboratories to undergo premarket review and comply with other applicable FDA requirements in the future, the cost and time required to commercialize an LDT will increase substantially, and may reduce the financial incentive for us to continue to offer our Lineagen genetic diagnostic services or for our customer laboratories to develop LDTs, which could reduce demand for our RUO instruments and our other products. In addition, if the FDA were to change the way that it regulates LDTs to require that we undergo pre-market review or comply with other applicable FDA requirements before we can sell our RUO instruments or our other products to clinical cytogenetics laboratories, our ability to sell our RUO instruments and other products to this addressable market would be delayed, thereby impeding our ability to penetrate this market and generate revenue from sales of our instruments and our other products.

Failure to comply with applicable FDA requirements could subject us to misbranding or adulteration allegations under the Federal Food, Drug, and Cosmetic Act. We could be subject to a range of enforcement actions, including warning letters, injunctions, civil monetary penalties, criminal prosecution, and recall and/or seizure of products, as well as significant adverse publicity. In addition, changes to the current regulatory framework, including the imposition of additional or new regulations, could arise at any time during the development or marketing of our products, which may negatively affect our ability to obtain or maintain FDA or comparable regulatory approval of our products, if required.

Foreign jurisdictions have laws and regulations similar to those described above, which may adversely affect our ability to market our products as planned in such countries. The number and scope of these requirements are increasing. As in the U.S., the cost and time required to comply with regulatory requirements may be substantial, and there is no guarantee that we will obtain the necessary authorization(s) required to make our products commercially viable. As a result, the imposition of foreign requirements may also have a material adverse effect on the commercial viability of our operations.

We expect to rely on third parties in conducting any required future studies of diagnostic products that may be required by the FDA or other regulatory authorities, and those third parties may not perform satisfactorily.

We do not have the ability to independently conduct clinical trials or other studies that may be required to obtain FDA and other regulatory clearance or approval for future diagnostic products. Accordingly, we expect that we would rely on third parties, such as clinical investigators, consultants, and collaborators to conduct such studies if needed. Our reliance on these third parties for clinical and other development activities would reduce our control over these activities. If these third parties do not successfully carry out their contractual duties or regulatory obligations or meet expected deadlines, if the third parties need to be replaced or if the quality or accuracy of the data they obtain is compromised, we may not be able to obtain regulatory clearance or approval.

Billing for our Lineagen diagnostic testing procedures is complex and requires substantial time and resources to collect payment.

Billing for clinical laboratory testing services in connection with our Lineagen diagnostic services is complex, time-consuming and expensive. Depending on the billing arrangement and applicable law, we bill various payors, including Medicare, Medicaid, private insurance companies, private healthcare institutions, and patients, all of which have different billing requirements. We generally bill third-party payors for our diagnostic testing services and pursue reimbursement on a case-by-case basis where pricing contracts are not in place. To the extent laws or contracts require us to bill patient co-payments or co-insurance, we must also comply with these requirements. We may also face increased risk in our collection efforts, including potential write-offs of accounts receivable and long collection cycles, which could adversely affect our business, results of operations and financial condition.

Several factors make the billing process complex, including:

- differences between the billing rates and reimbursement rates for our products;
- compliance with complex federal and state regulations related to billing government healthcare programs, including Medicare, Medicaid and TRICARE;
- risk of government audits related to billing;
- disputes among payors as to which party is responsible for payment;
- differences in coverage and information and billing requirements among payors, including the need for prior authorization and/or advanced notification;

- the effect of patient co-payments or co-insurance and our ability to collect such payments from patients;
- changes to billing codes used for our products;
- changes to requirements related to our current or future clinical studies, including our registry studies, which can affect eligibility for payment;
- ongoing monitoring provisions of LCDs for our products, which can affect the circumstances under which a claim would be considered medically necessary;
- incorrect or missing billing information; and
- the resources required to manage the billing and claims appeals process.

We use standard industry billing codes, known as Current Procedural Terminology, or CPT, codes, to bill for our diagnostic testing services. If these codes were to change, there is a risk of an error being made in the claim adjudication process. Such errors can occur with claims submission, third-party transmission or in the processing of the claim by the payor. Claim adjudication errors may result in a delay in payment processing or a reduction in the amount of the payment we receive.

As we introduce new products, we may need to add new codes to our billing process as well as our financial reporting systems. Failure or delays in effecting these changes in external billing and internal systems and processes could negatively affect our collection rates, revenue and cost of collecting.

Additionally, our billing activities require us to implement compliance procedures and oversight, train and monitor our employees, and undertake internal audits to evaluate compliance with applicable laws and regulations as well as internal compliance policies and procedures. When payors deny our claims, we may challenge the reason, low payment amount or payment denials. Payors also conduct external audits to evaluate payments, which add further complexity to the billing process. If the payor makes an overpayment determination, there is a risk that we may be required to return all or some portion of prior payments we have received.

Additionally, the Patient Protection and Affordable Care Act of 2010, as amended by the Health Care and Education Reconciliation Act of 2010, collectively the ACA, requires providers and suppliers to report and return any overpayments received from government payors under the Medicare and Medicaid programs within 60 days of identification. Failure to identify and return such overpayments exposes the provider or supplier to liability under federal false claims laws. These billing complexities, and the related uncertainty in obtaining payment for our products, could negatively affect our revenue and cash flow, our ability to achieve sustained profitability, and the consistency and comparability of our results of operations.

If our Lineagen diagnostic testing procedures are subject to unfavorable pricing regulations or third-party payor coverage and reimbursement policies, our business could be harmed.

Our Lineagen-related revenue depends on achieving and maintaining broad coverage and adequate reimbursement for our Lineagen products and diagnostic assays from third-party payors, including both government and commercial third-party payors. If third-party payors do not provide coverage of, or do not provide adequate reimbursement for, a substantial portion of the list price of our Lineagen products and diagnostic assays, we may need to seek additional payment from the patient beyond any co-payments and deductibles, which may adversely affect demand for our Lineagen products and diagnostic assays. Coverage determinations by a third-party payor may depend on a number of factors, including, but not limited to, a third-party payor's determination of whether our products or services are appropriate, medically necessary or cost-effective. If we are unable to provide third-party payors with sufficient evidence of the clinical utility and validity of our Lineagen products and diagnostic assays, they may not provide coverage, or may provide limited coverage, which will adversely affect our revenues and our ability to succeed.

Since each third-party payor makes its own decision as to whether to establish a policy to cover our Lineagen products and diagnostic assays, enter into a contract with us and set the amount it will reimburse for a product, these negotiations are a time-consuming and costly process, and they do not guarantee that the third-party payor will provide coverage or adequate reimbursement for our Lineagen products and diagnostic assays. In addition, the determinations by a third-party payor whether to cover our Lineagen products and diagnostic assays and the amount it will reimburse for them are often made on an indication-by-indication basis.

In cases where there is no coverage policy or we do not have a contracted rate for reimbursement as a participating provider, the patient is typically responsible for a greater share of the cost of the product, which may result in further delay of our revenue, increase our collection costs or decrease the likelihood of collection.

Our claims for reimbursement from third-party payors may be denied upon submission, and we may need to take additional steps to receive payment, such as appealing the denials. Such appeals and other processes are time-consuming and expensive, and may not result in payment. Third-party payors may perform audits of historically paid claims and attempt to recoup funds years after the funds were initially distributed if the third-party payors believe the funds were paid in error or determine that our

Lineagen products and diagnostic assays were medically unnecessary. If a third-party payor audits our claims and issues a negative audit finding, and we are not able to overturn the audit findings through appeal, the recoupment may result in a material adverse effect on our revenue. Additionally, in some cases commercial third-party payors for whom we are not a participating provider may elect at any time to review claims previously paid and determine the amount they paid was too much. In these situations, the third-party payor will typically notify us of their decision and then offset whatever amount they determine they overpaid against amounts they owe us on current claims. We cannot predict when, or how often, a third-party payor might engage in these reviews and we may not be able to dispute these retroactive adjustments.

Additionally, coverage policies and third-party payor reimbursement rates may change at any time. Therefore, even if favorable coverage and reimbursement status is attained, less favorable coverage policies and reimbursement rates may be implemented in the future that may adversely affect the coverage and reimbursement of our Lineagen products and diagnostic assays.

If diagnostic procedures that are enabled by our Saphyr technology are subject to unfavorable pricing regulations or third-party payor coverage and reimbursement policies, our business could be harmed.

Currently, our Saphyr product is for research use only, but clinical laboratories may acquire our instrumentation through a capital purchase or capital lease and use the Saphyr and direct label stain chemistry to create their own potentially reimbursable products, such as laboratory developed tests for in vitro diagnostics. Our customers may generate revenue for these testing services by seeking the necessary approval of their product from the FDA or the Centers for Medicare & Medicaid Services, or CMS, along with coverage and reimbursement from third-party payors, including government health programs and private health plans. 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 such third-party payors.

In the U.S., molecular testing laboratories have multiple options for reimbursement coding, but we expect that the primary codes used will be the genomic sequencing procedure codes, or GSPs. The American Medical Association, or AMA, added GSPs to its clinical laboratory fee schedule in 2015. In addition, CMS recently issued a coverage determination providing for the reimbursement of next-generation sequencing for certain cancer diagnostics using an FDA-approved in vitro diagnostic test. Private health plans often follow CMS coverage and reimbursement guidelines to a substantial degree, and it is difficult to predict what CMS will decide with respect to the coverage and reimbursement of any products our customers try to commercialize.

In Europe, coverage for molecular diagnostic testing is varied. Countries with statutory health insurance (e.g., Germany, France, The Netherlands) tend to be more progressive in technology adoption with favorable reimbursement for molecular diagnostic testing. In countries such as the United Kingdom with tax-based insurance, adoption and reimbursement for molecular diagnostic testing is not uniform and is influenced by local budgets.

Ultimately, coverage and reimbursement of new products is uncertain, and whether laboratories that use our instruments to develop their own products will attain coverage and adequate reimbursement is unknown. In the U.S., 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. We cannot be sure that coverage will be available for any diagnostic tests based on our technology, and, if coverage is available, the level of payments. Reimbursement may impact the demand for those tests. If coverage and reimbursement is not available or is available only to limited levels, our customers may not be able to successfully commercialize any tests for which they receive marketing authorization.

Healthcare legislative or regulatory reform measures may have a negative impact on our business and results of operations.*

In March 2010, the ACA became law. The ACA is a sweeping law intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add new transparency requirements for the healthcare and health insurance industries, impose new taxes and fees on the health industry and impose additional health policy reforms. For example, the ACA contained a 2.3% excise tax on certain entities that manufacture or import medical devices offered for sale in the U.S., with limited exceptions, which has been permanently eliminated as part of the 2020 spending package.

There have been executive, judicial and Congressional challenges to certain aspects of the ACA. For example, 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. On June 17, 2021 the U.S. Supreme Court dismissed a challenge on procedural grounds that argued the ACA was unconstitutional in its entirety because the "individual mandate" was repealed by Congress. Thus, the ACA will remain in effect in its current form. In addition, other legislative changes have been proposed and adopted since the ACA was enacted. For

example, on April 1, 2014, the Protecting Access to Medicare Act of 2014, or PAMA, was signed into law, which, among other things, significantly altered the payment methodology under the Medicare Clinical Laboratory Fee Schedule, or CLFS. PAMA requires certain laboratories performing clinical diagnostic laboratory tests to report to CMS the amounts paid by private payors for laboratory tests. Such reporting has been subject to numerous delays. Beginning on January 1, 2018, CMS has begun using reported private payor pricing to periodically revise payment rates under the CLFS.

We expect that the ACA, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and additional downward pressure on the price that we or our collaborators will receive for any cleared or approved product. Based on a recent executive order, the Biden administration expressed its intent to pursue certain policy initiatives to reduce drug prices. Further, it is possible that additional governmental action is taken in response to the COVID-19 pandemic. Any reduction in payments from Medicare or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent our customers from successfully commercializing any tests for which they receive approval, which could prevent us from being able to generate revenue and attain profitability.

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

We are subject to the Clinical Laboratory Improvement Amendment of 1988, or CLIA, which is a federal law regulating clinical laboratories that perform testing on specimens derived from humans for the purpose of providing information for the diagnosis, prevention or treatment of disease. Our clinical laboratory is located in Utah and must be certified under CLIA in order for us to perform testing on human specimens. CLIA is intended to ensure the quality and reliability of clinical laboratories in the United States by mandating specific standards in the areas of personnel qualifications, administration, and participation in proficiency testing, patient test management, quality control, quality assurance and inspections. We have a current certificate of compliance under CLIA to perform cytogenetics. To renew this certificate, we are subject to survey and inspection every two years. Moreover, CLIA inspectors may make periodic inspections of our clinical laboratory outside of the renewal process. The failure to comply with CLIA requirements can result in enforcement actions, including the revocation, suspension, or limitation of our CLIA certificate of compliance, as well as a directed plan of correction, state on-site monitoring, civil money penalties, civil injunctive suit and/or criminal penalties. We must maintain CLIA compliance and certification to be eligible to bill for assays provided to Medicare beneficiaries. If we were to be found out of compliance with CLIA program requirements and subjected to sanctions, our business and reputation could be harmed. Even if it were possible for us to bring our laboratory back into compliance, we could incur significant expenses and potentially lose revenue in doing so.

We hold laboratory licenses from the states of California, Pennsylvania, and Maryland, to test specimens from patients in those states or received from ordering physicians in those states. Other states may have similar requirements or may adopt similar requirements in the future. Finally, we may be subject to regulation in foreign jurisdictions if we seek to expand international distribution of our assays outside the United States.

If we were to lose our CLIA certification or state laboratory licenses, whether as a result of a revocation, suspension or limitation, we would no longer be able to offer our assays, which would limit our revenues and harm our business. If we were to lose, or fail to obtain, a license in any other state where we are required to hold a license, we would not be able to test specimens from those states. If we were to lose our CAP accreditation, our reputation for quality, as well as our business, financial condition and results of operations, could be significantly and adversely affected.

We are subject to federal and state healthcare fraud and abuse laws and other federal and state laws applicable to our business activities, including our marketing practices. If we are unable to comply, or have not complied, with such laws, we could face substantial penalties.

Our operations are subject to various federal and state fraud and abuse laws, including, without limitation, the federal and state anti-kickback statutes and false claims laws. These laws may impact, among other things, our sales and marketing and education programs, and our financial and business relationships with health care professionals. The laws that may affect our ability to operate include, but are not limited to:

- the federal Anti-Kickback Statute, or the AKS, which prohibits, among other things, any person or entity from knowingly and willfully soliciting, receiving, offering or paying any remuneration, directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, order or recommendation of an item or service reimbursable, in whole or in part, under a federal healthcare program, such as the Medicare and Medicaid programs. The term ‘‘remuneration’’ has been broadly interpreted to include anything of value. There are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution, however these are drawn narrowly. Additionally, 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 ACA

codified case law that a claim including items or services resulting from a violation of the AKS constitutes a false or fraudulent claim for purposes of the federal False Claims Act, or the FCA;

- the Stark Law, which prohibits a physician from making a referral for certain designated health services covered by the Medicare or Medicaid program, including laboratory and pathology services, if the physician or an immediate family member of the physician has a financial relationship with the entity providing the designated health services and prohibits that entity from billing, presenting or causing to be presented a claim for the designated health services furnished pursuant to the prohibited referral, unless an exception applies;
- federal civil and criminal false claims laws and civil monetary penalty laws, such as the FCA, which can be enforced by private citizens through civil qui tam actions, prohibits individuals or entities from, among other things, knowingly presenting, or causing to be presented false, fictitious or fraudulent claims for payment or approval by the federal government, including federal health care programs, such as Medicare and Medicaid, and knowingly making, using or causing to be made or used a false record or statement material to a false or fraudulent claim, or knowingly making a false statement to improperly avoid, decrease or conceal an obligation to pay money to the federal government;
- the Eliminating Kickbacks in Recovery Act of 2018, or EKRA, prohibits payments for referrals to recovery homes, clinical treatment facilities, and laboratories. EKRA's reach extends beyond federal health care programs to include private insurance (i.e., it is an "all payor" statute). For purposes of EKRA, the term "laboratory" is defined broadly and without reference to any connection to substance use disorder treatment. The law includes a limited number of exceptions, some of which closely align with corresponding federal Anti-Kickback Statute exceptions and safe harbors, and others that materially differ;
- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which, among other things, imposes criminal liability for executing or attempting to execute a scheme to defraud any healthcare benefit program, including private third-party payors, knowingly and willfully embezzling or stealing from a healthcare benefit program, willfully obstructing a criminal investigation of a healthcare offense, and knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement or representation, in connection with the delivery of or payment for healthcare benefits, items or services. Like the AKS, 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 the Health Information Technology for Economic and Clinical Health Act, or HITECH, and their implementing regulations, which imposes privacy, security and breach reporting obligations with respect to individually identifiable health information upon entities subject to the law, such as health plans, healthcare clearinghouses and certain healthcare providers, known as covered entities, and their respective business associates, individuals or entities that perform services for them that involve individually identifiable health information as well as their covered subcontractors;
- state laws that prohibit other specified practices, such as billing physicians for tests that they order or providing tests at no or discounted cost to induce physician or patient adoption; insurance fraud laws; 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 third-party payors employing, exercising control over or splitting professional fees with licensed professionals in violation of state laws prohibiting fee splitting or the corporate practice of medicine and other professions; and
- federal and state consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers;
- the prohibition on reassignment of Medicare claims, which, subject to certain exceptions, precludes the reassignment of Medicare claims to any other party;
- state and foreign law equivalents of each of the above federal laws, such as anti-kickback and false claims laws, that may impose similar or more prohibitive restrictions, and may apply to items or services reimbursed by any non-governmental third-party payors, including private insurers; and
- federal, state and foreign laws that govern the privacy and security of health information or personally identifiable information in certain circumstances, including state health information privacy and data breach notification laws which govern the collection, use, disclosure, and protection of health-related and other personal information, many of which differ from each other in significant ways and often are not pre-empted by HIPAA, thus complicating compliance efforts.

As a clinical laboratory, our business practices may face additional scrutiny from government regulatory agencies such as the Department of Justice, the U.S. Department of Health and Human Services Office of Inspector General, or OIG, and CMS.

Certain arrangements between clinical laboratories and referring physicians have been identified in fraud alerts issued by the OIG as implicating the AKS. 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.

We have entered into consulting and scientific advisory board arrangements, speaking arrangements and clinical research agreements with physicians and other healthcare providers, including some who could influence the use of our products. Although we believe that these have been structured in compliance with applicable laws, because of the complex and far-reaching nature of these laws, regulatory agencies may view these transactions as prohibited arrangements that must be restructured, or discontinued, or for which we could be subject to other significant penalties. We could be adversely affected if regulatory agencies interpret our financial relationships with providers who may influence the ordering of and use of our products to be in violation of applicable laws.

Ensuring that our business arrangements with third parties comply with applicable healthcare laws and regulations is costly. If our operations are found to be in violation of any of these laws, we may be subject to significant penalties, including, without limitation, civil, criminal, and administrative penalties, damages, fines, disgorgement, the curtailment or restructuring of our operations, exclusion from participation in federal and state healthcare programs, additional integrity oversight and reporting obligations, imprisonment, contractual damages, and reputational harm, any of which could adversely affect our ability to operate our business and our results of operations. If any of the physicians or other healthcare providers or entities with whom we do business is found to be not in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs.

Additionally, sales of our products outside of the U.S. will subject us to similar foreign regulatory requirements.

Risks Related to Intellectual Property

If we are unable to protect our intellectual property, it may reduce our ability to maintain any technological or competitive advantage over our competitors and potential competitors, and our business may be harmed.

We rely on patent protection as well as trademark, copyright, trade secret and other intellectual property rights protection and contractual restrictions to protect our proprietary technologies, all of which provide limited protection and may not adequately protect our rights or permit us to gain or keep any competitive advantage. As of October 28, 2021, we (directly or through our wholly owned subsidiary Lineagen, Inc.) were the assignee or assignee-applicant of 21 granted U.S. patents and 17 pending U.S. patent applications. We also were the assignee-applicant of approximately 94 pending patent applications and granted patents in particular jurisdictions outside the U.S. If we fail to protect and/or maintain our intellectual property, third parties may be able to compete more effectively against us, we may lose our technological or competitive advantage, and/or we may incur substantial litigation costs in our attempts to recover or restrict use of our intellectual property.

We cannot assure investors that any of our currently pending or future patent applications will result in granted patents, and we cannot predict how long it will take for such patents to issue, if at all. It is possible that, for any of our patents that have issued or that may issue in the future, our competitors may design their products or services around our patented technologies. Further, we cannot assure investors that other parties will not challenge any patents granted to us, or that courts or regulatory agencies will hold our patents to be valid, enforceable, and/or infringed. We cannot guarantee investors that we will be successful in defending challenges made against our patents and patent applications. Any successful third-party challenge or challenges to our patents could result in the unenforceability or invalidity of such patents, or such patents being interpreted narrowly and/or in a manner adverse to our interests. Our ability to establish or maintain a technological or competitive advantage over our competitors and/or market entrants may be diminished because of these uncertainties. For these and other reasons, our intellectual property may not provide us with any competitive advantage. For example:

- we or our licensors might not have been the first to make the inventions claimed or disclosed by our pending patent applications or issued patents;
- we or our licensors might not have been the first to file patent applications for these inventions. To determine the priority of these inventions, we may have to participate in interference proceedings or derivation proceedings declared by the U.S. Patent and Trademark Office, or the USPTO, which could result in substantial cost to us, and could possibly result in a loss or narrowing of patent rights. No assurance can be given that our or our licensors' patent applications or granted patents will have priority over any other patent or patent application involved in such a proceeding, or will be held valid as an outcome of the proceeding;
- other parties may independently develop similar or alternative products and technologies or duplicate any of our products and technologies, which can potentially impact our market share, revenue, and goodwill, regardless of whether intellectual property rights are successfully enforced against these other parties;

- it is possible that our owned or licensed pending patent applications will not result in granted patents, and even if such pending patent applications issue as patents, they may not provide intellectual property protection of commercially viable products or product features, may not provide us with any competitive advantages, or may be challenged and invalidated by third parties, patent offices, and/or the courts;
- we may be unaware of or unfamiliar with prior art and/or interpretations of prior art that could potentially impact the validity or scope of our patents or pending patent applications, or patent applications that we intend to file;
- we take efforts and enter into agreements with employees, consultants, collaborators, and, as applicable, advisors to confirm ownership and chain of title in intellectual property rights. However, an inventorship or ownership dispute could arise that may permit one or more third parties to practice or enforce our intellectual property rights, including possible efforts to enforce rights against us;
- we may elect not to maintain or pursue intellectual property rights that, at some point in time, may be considered relevant to or enforceable against a competitor;
- we may not develop additional proprietary products and technologies that are patentable, or we may develop additional proprietary products and technologies that are not patentable;
- the patents or other intellectual property rights of others may have an adverse effect on our business; and
- we apply for patents relating to our products and technologies and uses thereof, as we deem appropriate. However, we or our representatives or their agents may fail to apply for patents on important products and technologies in a timely fashion or at all, or we or our representatives or their agents may fail to apply for patents in potentially relevant jurisdictions.

To the extent our intellectual property offers inadequate protection, or is found to be invalid or unenforceable, we would be exposed to a greater risk of direct or indirect competition. If our intellectual property does not provide adequate coverage of our competitors' products or services, our competitive position could be adversely affected, as could our business.

Further, to the extent that computation methods implemented by software included in our products are not protected by our patents, our dependence on copyright and trade secret protection may not provide adequate protection. In addition, the Supreme Court's ruling *Alice Corporation Pty. Ltd. v. CLS Bank International*, has narrowed the scope of patent protection available for computational methods in certain circumstances.

The measures that we use to protect the security of our intellectual property and other proprietary rights may not be adequate, which could result in the loss of legal protection for, and thereby diminish the value of, such intellectual property and other rights.

In addition to pursuing patents on our technologies, we also rely upon trademarks, trade secrets, copyrights and unfair competition laws, as well as license agreements and other contractual provisions, to protect our intellectual property and other proprietary rights. Despite these measures, any of our intellectual property rights could be challenged, invalidated, circumvented or misappropriated. In addition, we take steps to protect our intellectual property and proprietary technologies by entering into confidentiality agreements and intellectual property assignment agreements with our employees, consultants, corporate partners and, when needed, our advisors. Such agreements may not be enforceable or may not provide meaningful protection for our trade secrets and/or other proprietary information in the event of unauthorized use or disclosure or other breaches of the agreements, and we may not be able to prevent such unauthorized disclosure. Moreover, if a party having an agreement with us has an overlapping or conflicting obligation to a third-party, our rights in and to certain intellectual property could be undermined. Monitoring unauthorized and inadvertent disclosure is difficult, and we do not know whether the steps we have taken to prevent such disclosure are, or will be, adequate. If we were to enforce a claim that a third-party had illegally obtained and was using our trade secrets, it would be expensive and time consuming, the outcome would be unpredictable, and any remedy may be inadequate. In addition, courts outside the U.S. may be less willing to protect trade secrets.

In addition, competitors could purchase our products and attempt to replicate and/or improve some or all of the competitive advantages we derive from our development efforts, willfully infringe our intellectual property rights, design their products around our protected technologies or develop their own competitive technologies that fall outside of our intellectual property rights. If our intellectual property does not adequately protect our market share against competitors' products, services and methods, our competitive position could be adversely affected, as could our business.

We have rights in some intellectual property that has been discovered through government funded programs and thus is subject to federal regulations such as "march-in" rights, certain reporting requirements, and a preference for U.S. industry. Compliance with such regulations may limit our exclusive rights, subject us to expenditure of resources with respect to reporting requirements, and limit our ability to contract with non-U.S. manufacturers.

Some of the intellectual property rights assigned to us and/or in-licensed to us have been generated through the use of U.S. government funding and are therefore subject to certain federal regulations. For example, all of the intellectual property rights licensed to us under our license agreement with Princeton University have been generated using U.S. government funds. As a result, the U.S. government has certain rights to intellectual property embodied in our current or future products pursuant to the Bayh-Dole Act of 1980. These U.S. government rights in certain inventions developed under a government-funded program include a non-exclusive, non-transferable, irrevocable worldwide license to use inventions for any governmental purpose. In addition, the U.S. government has the right to require us to grant exclusive, partially exclusive, or non-exclusive licenses to any of these inventions to a third-party if the government determines that: (i) adequate steps have not been taken to commercialize the invention; (ii) government action is necessary to meet public health or safety needs; or (iii) government action is necessary to meet requirements for public use under federal regulations (also referred to as "march-in rights"). The U.S. government also has the right to take title to these inventions if we fail, or the applicable licensor fails, to disclose the invention to the government, elect title, and file an application to register the intellectual property within specified time limits. In addition, the U.S. government may acquire title to these inventions in any country in which a patent application is not filed within specified time limits. Intellectual property generated under a government funded program is also subject to certain reporting requirements, compliance with which may require us, or the applicable licensor, to expend substantial resources. In addition, the U.S. government requires that any products embodying the subject invention or produced through the use of the subject invention be manufactured substantially in the U.S. The manufacturing preference requirement can be waived if the owner of the intellectual property can show that reasonable but unsuccessful efforts have been made to grant licenses on similar terms to potential licensees that would be likely to manufacture substantially in the U.S. or that, under the circumstances, domestic manufacture is not commercially feasible. This preference for U.S. manufacturing may limit our ability to license the applicable patent rights on an exclusive basis under certain circumstances.

If we enter into future arrangements involving government funding, and we make or license inventions that result from such funding, intellectual property rights to such discoveries may be subject to the applicable provisions of the Bayh-Dole Act. To the extent any of our current or future intellectual property is generated through the use of U.S. government funding, the provisions of the Bayh-Dole Act may similarly apply. Any exercise by the government of certain of its rights could harm our competitive position, business, financial condition, results of operations and prospects.

We depend on technology that is licensed to us by Princeton University. Any loss of our rights to this technology could prevent us from selling our products.

Some technology that relates to analysis of nucleic acids is licensed exclusively to us from Princeton University, or Princeton. We do not own the patents that underlie this license. Our rights to use this technology and employ the inventions claimed in the licensed patents are subject to the continuation of and compliance with the terms of the license. Our principal obligations under our license agreement with Princeton are as follows:

- royalty payments;
- annual maintenance fees;
- using commercially reasonable efforts to develop and sell a product using the licensed technology and developing a market for such product;
- paying and/or reimbursing fees related to prosecution, maintenance and enforcement of patent rights; and
- providing certain reports.

If we breach any of these obligations, Princeton may have the right to terminate or modify the license, which could result in our being unable to develop, manufacture and sell our products or a competitor gaining access to the relevant technology. Termination or certain modifications of our license agreement with Princeton would have a material adverse effect on our business.

In addition, we are a party to a number of other agreements that include licenses to intellectual property, including non-exclusive licenses. We may need to enter into additional license agreements in the future. Our business could suffer, for example, if any current or future licenses terminate, if the licensors fail to abide by the terms of the license, 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.

As we have done previously, we may need or may choose to obtain licenses and/or acquire intellectual property rights from third parties to advance our research or begin commercialization of our current or future products or services, and we cannot

provide any assurances that third-party patents do not exist that might be enforced against our current or future products or services in the absence of such a license. We may fail to obtain any of these licenses or intellectual property rights on commercially reasonable terms. Even if we are able to obtain a license, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. In that event, we may be required to expend significant time and resources to develop or license replacement technology. If we are unable to do so, we may be unable to develop or commercialize the affected products or services, which could materially harm our business and the third parties owning such intellectual property rights could seek either an injunction prohibiting our sales, or, with respect to our sales, an obligation on our part to pay royalties and/or other forms of compensation.

Licensing of intellectual property is important to our business and involves complex legal, business and scientific issues. Disputes may arise between us and our licensors regarding intellectual property subject to a license agreement, including:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- whether and the extent to which our technologies and processes infringe any intellectual property of the licensor that is not subject to the licensing agreement;
- whether to take action to enforce any intellectual property rights against an allegedly infringing product or process of a third-party;
- our right to sublicense patent and other rights to third parties;
- our diligence obligations with respect to the use of licensed technology in relation to our development and commercialization of our products and services, and what activities satisfy those diligence obligations; and
- the ownership of inventions and know-how, such as intellectual property resulting from the joint creation or use of intellectual property by our licensors and us and our partners.

If disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on acceptable terms, we may be unable to successfully develop and commercialize the affected product or service, or the dispute may have an adverse effect on our results of operation.

In addition to agreements pursuant to which we in-license intellectual property, we may in the future grant licenses under our intellectual property, or sell certain intellectual property. Like in-licenses, out-licenses can be complex and disputes may arise between us and our licensees, such as the types of disputes described above. Moreover, licensees may breach their obligations, or we may be exposed to liability due to our failure or alleged failure to satisfy our obligations. Any such occurrence could have an adverse effect on our business.

If we or any of our partners is sued for infringing intellectual property rights of third parties, it would be costly and time consuming, and an unfavorable outcome in that litigation could have a material adverse effect on our business.

Our success also depends on our ability to develop, manufacture, market and sell our products and perform our services without infringing the proprietary rights of third parties. Numerous U.S. and foreign-issued patents and pending patent applications owned by third parties exist in the fields in which we are developing manufacturing, marketing and selling products and performing services. As part of a business strategy to impede our successful commercialization and entry into new markets, competitors may allege that our products and/or services infringe their intellectual property rights.

We could incur substantial costs and divert the attention of our management and technical personnel in defending ourselves against claims of infringement made by third parties. Any adverse ruling by a court or administrative body, or perception of an adverse ruling, may have a material adverse impact on our ability to conduct our business and our finances. Moreover, third parties making claims against us may be able to obtain injunctive relief against us, which could block our ability to offer one or more products or services and could result in a substantial award of damages against us. In addition, since we sometimes indemnify customers, collaborators or licensees, we may have additional liability in connection with any infringement or alleged infringement of third-party intellectual property. Intellectual property litigation can be very expensive, and we may not have the financial means to defend ourselves or our customers, collaborators and licensees.

Because patent applications can take many years to issue, there may be pending applications, some of which are unknown to us, that may result in issued patents upon which our products, services or proprietary technologies may infringe. Moreover, we may fail to identify issued patents of relevance or incorrectly conclude that an issued patent is invalid or not infringed any of our products, services or proprietary technologies. There is a substantial amount of litigation involving patents and other intellectual property rights in our industry. If a third-party claims that we or any of our licensors, customers or collaboration partners infringe upon a third-party’s intellectual property rights, we may have to:

- seek to obtain licenses that may not be available on commercially reasonable terms, if at all;

- abandon any product or service alleged or held to infringe, or redesign our products or processes to avoid potential assertion of infringement;
- pay substantial damages including, in exceptional cases, treble damages and attorneys' fees, which we may have to pay if a court decides that the product or proprietary technology at issue infringes upon or violates the third-party's rights;
- pay substantial royalties or fees for, or grant cross-licenses to, our technology; or
- defend litigation or administrative proceedings that may be costly whether we win or lose, and which could result in a substantial diversion of our financial and management resources.

We may be involved in lawsuits to protect or enforce our patents or the patents of our licensors, which could be expensive, time-consuming and unsuccessful.

Competitors may infringe our patents or the patents we license in. In the event of infringement or unauthorized use, we may file one or more infringement lawsuits, which can be expensive and time-consuming. An adverse result in any such litigation proceedings could put one or more of our patents at risk of being invalidated, being found to be unenforceable, and/or being interpreted narrowly and could put our patent applications at risk of not issuing and/or could impact the validity or enforceability positions of our other patents or those we license. 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.

Most of our competitors are larger than we are and have substantially greater resources. They are, therefore, likely to be able to sustain the costs of complex patent litigation longer than we could. In addition, the uncertainties associated with litigation could have a material adverse effect on our ability to raise the funds necessary to continue our operations, continue our internal research programs, in-license needed technology, pursue, obtain or maintain intellectual property rights, or enter into development partnerships that would help us bring our products or services to market.

In addition, patent litigation can be very costly and time-consuming. An adverse outcome in such litigation or proceedings may expose us or any of our future development partners to loss of our proprietary position, expose us to significant liabilities, or require us to seek licenses that may not be available on commercially acceptable terms, if at all.

Our issued patents could be found invalid or unenforceable if challenged in court or at the Patent Office or other administrative agency, which could have a material adverse impact on our business.

If we or any of our partners were to initiate legal proceedings against a third-party to enforce a patent related to one of our products or services, the defendant in such litigation could counterclaim that our patent is invalid and/or unenforceable. In patent litigation in the U.S., defendant counterclaims alleging invalidity and/or unenforceability are commonplace, as are validity challenges by the defendant against the subject patent or other patents before the USPTO. 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, failure to meet the written description requirement, indefiniteness, and/or failure to disclose the best mode or to claim patent eligible subject matter. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent intentionally withheld material information from the USPTO, or made a misleading statement, during prosecution. Additional grounds for an unenforceability assertion include an allegation of misuse or anticompetitive use of patent rights, and an allegation of incorrect inventorship with deceptive intent. Third parties may also raise similar claims before the USPTO even outside the context of litigation. The outcome is unpredictable following legal assertions of invalidity and unenforceability. With respect to the validity question, for example, we cannot be certain that no invalidating prior art existed of which we and the patent examiner were unaware during prosecution. These assertions may also be based on information known to us or the Patent Office. If a defendant or third-party were to prevail on a legal assertion of invalidity and/or unenforceability, we would lose at least part, and perhaps all, of the claims of the challenged patent. Such a loss of patent protection would or could have a material adverse impact on our business.

We may be subject to claims that our employees, consultants or independent contractors have wrongfully used or disclosed alleged trade secrets of their other clients or former employers to us, and/or that their other clients or former employers allegedly have rights in our intellectual property, which could subject us to costly litigation.

As is common in the life sciences industry, we engage the services of consultants and independent contractors to assist us in the development of our products and services. Many of these consultants and independent contractors were previously employed at, or may have previously or may be currently providing consulting or other services to, universities or other technology, biotechnology or pharmaceutical companies, including our competitors or potential competitors. We may become subject to claims that our company, a consultant or an independent contractor inadvertently or otherwise used or disclosed trade secrets or other information proprietary to their former employers or their former or current clients. We may similarly be subject to claims stemming from similar actions of an employee, such as one who was previously employed by another company, including a competitor or potential competitor. We may become subject to claims that one or more current or former employees, consultants, advisors, or independent contractors of ours owns rights in our intellectual property and/or has assigned or is under an obligation to assign rights in our intellectual property to another party. This may include a competitor of ours. If a competitor has rights in our patents, the competitor or a licensee or related entity of the competitor may be able to make, use, sell, import, and/or export the patented technology without liability to us under our patents or the patents we license. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to our management team. If we were not successful, we could lose valuable intellectual property rights.

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

We generally enter into confidentiality and intellectual property assignment agreements with our employees, consultants, contractors, and, as applicable, advisors. These agreements generally provide that inventions conceived by the party in the course of rendering services to us will be our exclusive property. However, those agreements may not be honored and may not effectively assign or may be alleged to ineffectively assign intellectual property rights to us. For example, even if we have a consulting agreement in place with an academic advisor pursuant to which such academic advisor is required to assign any inventions developed in connection with providing services to us, such academic advisor may not have the right to assign such inventions to us, as it may conflict with his or her obligations to assign all such intellectual property to his or her employing institution.

In addition, we sometimes enter into agreements where we provide services to third parties, such as customers. Under such circumstances, our agreements may provide that certain intellectual property that we conceive in the course of providing those services is assigned to the customer. In those cases, we may not be able to use that particular intellectual property in, for example, our work for other customers without a license.

We may not be able to protect our intellectual property rights throughout the world, which could materially and negatively affect our business.

Filing, prosecuting, maintaining, and defending patents on current and future products and services 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. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the U.S. Consequently, regardless of whether we are able to prevent third parties from practicing our inventions in the U.S., we may not be able to prevent third parties from practicing our inventions in all countries outside the U.S., or from selling or importing products made using our inventions in and into the U.S. or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not pursued and obtained patent protection to develop their own products or services, and further, may export otherwise infringing products to territories where we have patent protection, but enforcement is not as strong as it is in the U.S. These products or services may compete with our products or services and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing. Even if we pursue and obtain issued patents in particular jurisdictions, our patent claims or other intellectual property rights may not be effective or sufficient to prevent third parties from so competing. 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.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing 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 or marketing of competing products or services in violation of our proprietary rights generally. 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, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing, and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful.

Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license and may adversely impact our business.

In addition, we and our partners also face the risk that our products or components thereof are imported, reimported, or exported into markets with relatively higher prices from markets with relatively lower prices, which would result in a decrease of sales and any payments we receive from the affected market. Recent developments in U.S. patent law have made it more difficult to stop these and related practices based on theories of patent infringement.

Changes in patent laws or patent jurisprudence could diminish the value of patents in general, thereby impairing our ability to protect our products.

As is the case with other life science industry companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents involve both technological complexity and legal complexity. Therefore, obtaining and enforcing patents is costly, time-consuming and inherently uncertain. In addition, the America Invents Act, or the AIA, became effective on March 16, 2013.

An important change introduced by the AIA is that the U.S. transitioned to a "first-to-file" system for deciding which party should be granted a patent when two or more patent applications are filed by different parties claiming the same invention. A third-party that files a patent application in the USPTO after that date but before us could therefore be awarded a patent claiming or disclosing an invention of ours even if we had made the invention before it was made by the third-party. This will require us to be cognizant going forward of the time from invention to filing of a patent application, but circumstances could prevent us from promptly filing patent applications on our inventions. Additionally, there can be a trade-off between obtaining an earlier filing date, and waiting to obtain additional data and/or further refine a patent application. In some circumstances, the effects of a decision to pursue an earlier filing or a later filing will not be known until prior art or third-party activities are subsequently discovered, such as by the USPTO or by a third-party seeking to challenge patent rights. These circumstances may apply, for example, to patent applications prepared and filed around the time of the implementation of the AIA, or with a priority application that preceded the implementation of the AIA.

Among some of the other changes introduced by the AIA are changes that limit where a patent holder may file a patent infringement suit and providing additional opportunities for third parties to challenge an issued patent in the USPTO. This applies to all of our owned and in-licensed U.S. patents, even those issued before March 16, 2013. Because of a lower standard for evidence in USPTO proceedings compared to the standard for evidence in U.S. federal courts necessary to invalidate a patent claim, a third-party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a court action. Accordingly, a third-party may try to use the USPTO procedures to invalidate our patent claims that would not have been invalidated if first challenged by the third-party in court. The AIA and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents. In addition, the contours of the laws under the AIA are subject to further judicial interpretation and/or legislative changes.

Additionally, the U.S. Supreme Court has ruled on several patent cases in recent years, such as *Impression Products, Inc. v. Lexmark International, Inc.*, *Association for Molecular Pathology v. Myriad Genetics, Inc*., *Mayo Collaborative Services v. Prometheus Laboratories, Inc.* and *Alice Corporation Pty. Ltd. v. CLS Bank International*, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. In addition to increasing uncertainty with our ability to obtain patents in the future, this combination of events has created uncertainty as to the value of patents, once obtained, including patents in the molecular biology analysis and diagnostic space in particular. Depending on decisions by the U.S. Congress, the federal courts, and the USPTO, the laws and regulations governing patents could change in unpredictable ways that could weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future.

Obtaining and maintaining our 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 process. There are situations in which noncompliance can result in abandonment or lapse of a patent or patent application, resulting in partial or complete 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. In some cases, our licensors may be responsible for these payments, thereby decreasing our control over compliance with these requirements.

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 registered or unregistered trademarks or trade names may be challenged, infringed, circumvented or declared generic or determined to be infringing other marks. We may not be able to protect our rights to these trademarks and trade names, which we need to build name recognition by potential partners or customers in our markets of interest. At times, competitors may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. In addition, there could be potential trade name or trademark infringement claims brought by owners of other registered trademarks. Over the long term, if we are unable to establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively and our business may be adversely affected.

We may use third-party open source software components in future products, and failure to comply with the terms of the underlying open source software licenses could restrict our ability to sell such products.

While our current products do not contain any software tools licensed by third-party authors under "open source" licenses, we may choose to use open source software in future products. Use and distribution of open source software may entail greater risks than use of third-party commercial software, as open source licensors generally do not provide warranties or other contractual protections regarding infringement claims or the quality of the code. Some open source licenses may contain requirements that we make available source code for modifications or derivative works we create based upon the type of open source software we use. If we combine our proprietary software with open source software in a certain manner, we could, under certain open source licenses, be required to release the source code of our proprietary software to the public. This would allow our competitors to create similar products with less development effort and time, and ultimately could result in a loss of product sales.

Although we intend to monitor any use of open source software to avoid subjecting our products to conditions, we do not intend, the terms of many open source licenses have not been interpreted by U.S. courts, and there is a risk that any such licenses could be construed in a way that could impose unanticipated conditions or restrictions on our ability to commercialize our products. Moreover, we cannot assure investors that our processes for controlling our use of open source software in our products will be effective. If we are held to have breached the terms of an open source software license, we could be required to seek licenses from third parties to continue offering our products on terms that are not economically feasible, to re-engineer our products, to discontinue the sale of our products if re-engineering could not be accomplished on a timely basis, or to make generally available, in source code form, our proprietary code, any of which could adversely affect our business, operating results, and financial condition.

We use third-party software that may be difficult to replace or cause errors or failures of our products that could lead to lost customers or harm to our reputation.

We use software licensed from third parties in our products. In the future, this software may not be available to us on commercially reasonable terms, or at all. Any loss of the right to use any of this software could result in delays in the production of our products until equivalent technology is either developed by us, or, if available, is identified, obtained and integrated, which could harm our business. In addition, any errors or defects in third-party software or other third-party software failures could result in errors or defects or cause our products to fail, which could harm our business and be costly to correct. Many of these providers attempt to impose limitations on their liability for such errors, defects or failures, and, if enforceable, we may have additional liability to our customers or third-party providers that could harm our reputation and increase our operating costs.

We intend to maintain our relationships with third-party software providers and to seek software from such providers that does not contain any errors or defects. Any failure to do so could adversely impact our ability to deliver reliable products to our customers and could harm our results of operations.

Numerous factors may limit any potential competitive advantage provided by our intellectual property rights.

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations, and may not adequately protect our business, provide a barrier to entry against our competitors or potential competitors, or permit us to maintain our competitive advantage. Moreover, if a third-party has intellectual property rights that cover or impact our use of our technologies, we may not be able to fully use or extract value from our intellectual property rights. For example:

- others may be able to develop and/or use technologies that are similar to our technologies or aspects of our technologies but that does not cover the claims of any our patents or patents that may issue from our patent applications or those we license;
- we or the licensor of our licensed-in patents might not have been the first to make the inventions disclosed and/or claimed in a pending patent application that we own or license;

- we or the licensor of our licensed-in patents might not have been the first to file patent applications disclosing and/or claiming an invention;
- others may independently develop similar or alternative technologies without infringing our or our licensors' intellectual property rights;
- pending patent applications that we own or license may not lead to issued patents or may not result in the claims that we want (for example, as to the scope of issued claims, if any);
- patents, if issued, that we own or license may not provide us with any competitive advantages, or may be held invalid or unenforceable, as a result of legal challenges by our competitors or other third parties;
- third parties may compete with us in jurisdictions where we do not pursue and obtain patent protection;
- we may not be able to obtain and/or maintain necessary or useful licenses on reasonable terms or at all;
- third parties may assert an ownership interest in our intellectual property and, if successful, such disputes may preclude us from exercising exclusive rights over that intellectual property;
- we may not be able to maintain the confidentiality of our trade secrets or other proprietary information;
- we may not develop or in-license additional proprietary technologies that are patentable; and
- the patents or other intellectual property of others may have an adverse effect on our business.

Should any of these events occur, they could significantly harm our business and results of operations.

Risks Related to Ownership of our Securities

The price of our securities may be volatile, and you could lose all or part of your investment.

The trading price of our securities is likely to be highly volatile and could be subject to wide fluctuations in response to various factors, some of which are beyond our control, including limited trading volume. In addition to the factors discussed in this Part I, Item 1A Risk Factors and elsewhere in our Annual Report, these factors include:

- our commercial progress in marketing and selling our genome analysis systems, including sales and revenue trends;
- changes in laws or regulations applicable to our systems;
- adverse developments related to our laboratory facilities;
- increased competition in the diagnostics services industry;
- the failure to obtain and/or maintain coverage and adequate reimbursement for our Lineagen products and diagnostic assays and patients' willingness to pay out-of-pocket in the absence of such coverage and adequate reimbursement;
- the failure of our customers to obtain and/or maintain coverage and adequate reimbursement for their services using our Saphyr systems;
- adverse developments concerning our manufacturers and suppliers;
- our inability to establish future collaborations;
- additions or departures of key scientific or management personnel;
- introduction of new testing services offered by us or our competitors;
- announcements of significant acquisitions, strategic partnerships, joint ventures or capital commitments by us or our competitors;
- our ability to effectively manage our growth;
- the size and growth, if any, of our targeted markets;
- actual or anticipated variations in quarterly operating results;
- our cash position;
- our failure to meet the estimates and projections of the investment community or that we may otherwise provide to the public;
- publication of research reports about us or our industry or positive or negative recommendations or withdrawal of research coverage by securities analysts;

- changes in the market valuations of similar companies;
- overall performance of the equity markets;
- issuances of debt or equity securities;
- sales of our securities by us or our stockholders in the future;
- trading volume of our securities;
- changes in accounting practices;
- ineffectiveness of our internal controls;
- disputes or other developments relating to proprietary rights, including our ability to adequately protect our proprietary rights in our technologies;
- significant lawsuits, including patent or stockholder litigation;
- general political and economic conditions; and
- other events or factors, many of which are beyond our control.

In addition, the stock market in general, and diagnostic and biotechnology companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. Broad market and industry factors may negatively affect the market price of our securities, regardless of our actual operating performance. In the past, securities class action litigation has often been instituted against companies following periods of volatility in the market price of a company's securities. This type of litigation, if instituted, could result in substantial costs and a diversion of management's attention and resources, which would harm our business, operating results or financial condition.

If we are not able to comply with the applicable continued listing requirements or standards of The Nasdaq Capital Market, Nasdaq could delist our common stock.

Our ability to publicly or privately sell equity securities and the liquidity of our common stock could be adversely affected if we are delisted from The Nasdaq Capital Market or if we are unable to transfer our listing to another stock market. In order to maintain this listing, we must satisfy minimum financial and other continued listing requirements and standards, including a requirement to maintain a minimum bid price of our common stock of $1.00 per share.

For example, in a letter dated April 22, 2020, or the Notice, we were notified by the Nasdaq Stock Market LLC, or Nasdaq, that for 30 consecutive trading days preceding the date of the Notice, the bid price of our common stock had closed below the $1.00 per share minimum required for continued listing on The Nasdaq Capital Market pursuant to Nasdaq Listing Rule 5550(a)(2), or the Minimum Bid Price Requirement. Under Nasdaq Listing Rule 5810(c)(3)(A), we had 180 calendar days following the date of the Notice to regain compliance with the Minimum Bid Price Requirement, and due to extraordinary market conditions, Nasdaq determined to toll the compliance period for the Minimum Bid Price Requirement through September 30, 2020, or the Tolling Period. As a result, the compliance Period ended on December 28, 2020, or the Compliance Period, instead of October 20, 2020. Nasdaq subsequently granted us an extension until June 28, 2021 to regain compliance with the Minimum Bid Price Requirement.

On January 13, 2021, Nasdaq notified us that it had regained compliance with the Minimum Bid Price Requirement because the closing bid price of our common stock had been at least $1.00 per share or greater from December 29, 2020 to January 12, 2021. Although we have regained compliance with Nasdaq, if we fail to satisfy another Nasdaq requirement for continued listing, Nasdaq staff could provide notice that our common stock may become subject to delisting. In such event, Nasdaq rules permit us to appeal the decision to reject our proposed compliance plan or any delisting determination to a Nasdaq Hearings Panel. Accordingly, there can be no guarantee that we will be able to maintain our Nasdaq listing. If our common stock is delisted by Nasdaq, it could lead to a number of negative implications, including an adverse effect on the price of our common stock, increased volatility in our common stock, reduced liquidity in our common stock, the loss of federal preemption of state securities laws and greater difficulty in obtaining financing. In addition, delisting of our common stock could deter broker-dealers from making a market in or otherwise seeking or generating interest in our common stock, could result in a loss of current or future coverage by certain sell-side analysts and might deter certain institutions and persons from investing in our securities at all. Delisting could also cause a loss of confidence of our customers, collaborators, vendors, suppliers and employees, which could harm our business and future prospects.

If our common stock is delisted by Nasdaq, our common stock may be eligible to trade on the OTC Bulletin Board, OTC-QB or another over-the-counter market. Any such alternative would likely result in it being more difficult for us to raise additional capital through the public or private sale of equity securities and for investors to dispose of or obtain accurate quotations as to

the market value of, our common stock. In addition, there can be no assurance that our common stock would be eligible for trading on any such alternative exchange or markets. Moreover, if our common stock is delisted, it may come within the definition of "penny stock" under the Exchange Act, which imposes additional sales practice requirements on broker-dealers who sell securities to persons other than established customers and accredited investors. For example, we and/or broker-dealers are required to make a special suitability determination for purchases of such securities and must receive a purchaser's written consent to the transaction prior to any purchase. Additionally, unless exempt, prior to a transaction involving a penny stock, the penny stock rules require the delivery of a disclosure schedule prescribed by the SEC relating to the penny stock market. The broker-dealer must also disclose the commissions payable to the broker-dealer, current quotations for the securities and, if the broker-dealer is the sole market-maker for the security, the fact that they are the sole market-maker and their presumed control over the market. Finally, monthly statements disclosing recent price information on the limited market in penny stocks must be sent to holders of such penny stocks. These requirements may reduce trading activity in the secondary market for our common stock and may impact the ability or willingness of broker-dealers to sell our securities which could limit the ability of stockholders to sell their securities in the public market and limit our ability to attract and retain qualified employees or raise additional capital in the future.

We have never paid dividends and we do not intend to pay dividends on our capital stock.*

We have never declared or paid any cash dividend on our capital stock. We currently anticipate that we will retain future earnings for the development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. Any determination to pay dividends in the future will be at the discretion of our board of directors and will depend upon results of operations, financial condition, contractual restrictions, restrictions imposed by applicable law and other factors our board of directors deems relevant. Accordingly, realization of a gain on your investment will depend on the appreciation of the price of our securities, which may never occur.

Our principal stockholders and management own a significant percentage of our stock and will be able to exert significant control over matters subject to stockholder approval.

Our executive officers, directors and 5% stockholders and their affiliates currently beneficially own a significant percentage of our outstanding voting stock. These stockholders may be able to determine all matters requiring stockholder approval. For example, these stockholders may be able to control elections of directors, amendments of our organizational documents, or approval of any merger, sale of assets or other major corporate transaction. This may prevent or discourage unsolicited acquisition proposals or offers for our securities that you may feel are in your best interest as one of our stockholders.

We are an emerging growth company, and the reduced reporting requirements applicable to emerging growth companies could make our securities less attractive to investors.*

We are an emerging growth company, as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act. For as long as we continue to be an emerging growth company, we may take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies, including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation in our Annual Report and our periodic reports and proxy statements and exemptions from the requirements of holding nonbinding advisory votes on executive compensation and stockholder approval of any golden parachute payments not previously approved. We can remain an emerging growth company until the earlier of (1) the last day of the fiscal year (a) ending December 31, 2023, which is the end of the fiscal year following the fifth anniversary of the closing of our initial public offering, (b) in which we have total annual gross revenue of at least $1.07 billion, or (c) in which we are deemed to be a large accelerated filer, which means the market value of our common stock that is held by non-affiliates exceeds $700.0 million as of the prior June 30th, and (2) the date on which we have issued more than $1.0 billion in non-convertible debt during the prior three-year period. Even after we no longer qualify as an emerging growth company, we may still qualify as a "smaller reporting company" which would allow us to take advantage of many of the same exemptions from disclosure requirements including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act and reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements. We cannot predict if investors will find our securities less attractive because we may rely on these exemptions, which could result in a less active trading market for our securities and increased volatility in the price of our securities.

Under the JOBS Act, emerging growth companies can also delay adopting new or revised accounting standards that have different effective dates for public and private companies until those standards apply to private companies. We have elected to use this extended transition period. As a result of this election, our timeline to comply with these standards will in many cases be delayed as compared to other public companies that are not eligible to take advantage of this election or have not made this election. Therefore, our financial statements may not be comparable to those of companies that comply with the public company effective dates for these standards.

In addition, if we cease to be an emerging growth company, we will no longer be able to use the extended transition period for complying with new or revised accounting standards. As a result, changes in rules of U.S. generally accepted accounting principles or their interpretation, the adoption of new guidance or the application of existing guidance to changes in our business could significantly affect our financial position and results of operations.

As of June 30, 2021, the market value of our common stock held by non-affiliates exceeded $700.0 million. As a result, we will be a large accelerated filer and thus will cease to be an emerging growth company effective December 31, 2021. Additionally,, we will no longer qualify as a smaller reporting company beginning with our first Quarterly Report on Form 10-Q for the quarterly period ending March 31, 2022.

We have identified material weaknesses in our internal control over financial reporting. If our internal control over financial reporting is not effective, we may not be able to accurately report our financial results or file our periodic reports in a timely manner, which may cause adverse effects on our business and may cause investors to lose confidence in our reported financial information and may lead to a decline in our stock price.

We are subject to the reporting requirements of the Securities Exchange Act of 1934, as amended, or the Exchange Act, the Sarbanes-Oxley Act and the rules and regulations of Nasdaq. The Sarbanes-Oxley Act requires, among other things, that we maintain effective disclosure controls and procedures and internal controls over financial reporting. Internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements in accordance with accounting principles generally accepted in the U.S. Effective internal control over financial reporting is necessary for us to provide reliable financial reports in a timely manner.

For the year ended December 31, 2020, we concluded there was a material weakness in our internal control environment over financial reporting because we did not have a sufficient number of resources to support the growth and complexity of our financial reporting requirements. This material weakness contributed to a material weakness in our control activities based on the criteria set forth in the 2013 Framework. Specifically, the design of certain controls did not adequately provide appropriate segregation of duties. The failure to maintain appropriate segregation of duties had a pervasive impact and as such, this deficiency resulted in a risk that could have impacted all financial statement account balances and disclosures. The material weaknesses did not result in any identified material misstatements to our financial statements, and there were no changes to previously released financial results.

In an attempt to remediate the material weaknesses, we have (i) engaged an external consulting firm to assist with our internal accounting functions and further enhance our internal controls, which has increased the number of personnel involved in financial reporting and (ii) we are in the process of hiring additional qualified individuals that will increase the number of personnel involved in financial reporting and the control environment. However, we cannot assure you that these efforts will remediate our material weakness in a timely manner, or at all.

If we are unable to remediate the material weaknesses described above, or if we or our independent registered public accounting firm are otherwise unable to conclude that our internal control over financial reporting is effective we could lose investor confidence in the accuracy and completeness of our financial reports, the market price of our securities could decline, and we could be subject to sanctions or investigations by Nasdaq, the Securities and Exchange Commission, or the SEC, or other regulatory authorities. Failure to remedy any material weakness in our internal control over financial reporting, or to implement or maintain other effective control systems required of public companies, could also restrict our future access to the capital markets.

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

We have designed our disclosure controls and procedures to reasonably assure 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 or internal 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. Accordingly, because of the inherent limitations in our control system, misstatements due to error or fraud may occur and not be detected.

Based on the evaluation of our disclosure controls and procedures as of December 31, 2020, we concluded that, as of such date, our disclosure controls and procedures were not effective at a reasonable assurance level as a result of the material weakness that existed in our internal control over financial reporting, as described above. Although we are implementing certain measures to address such material weakness, as described above, we cannot assure you that these efforts will successfully remediate our material weakness in a timely manner, or at all.

We have begun to incur significant increased costs as a result of operating as a public company, and our management will be required to devote substantial time to compliance initiatives.*

As a newly public company, we have incurred significant legal, accounting and other expenses that we did not incur as a private company. We are subject to the reporting requirements of the Securities Exchange Act of 1934, as amended, which require, among other things, that we file with the SEC annual, quarterly and current reports with respect to our business and financial condition. In addition, the Sarbanes-Oxley Act, as well as rules subsequently adopted by the SEC and Nasdaq to implement provisions of the Sarbanes-Oxley Act, impose significant requirements on public companies, including requiring establishment and maintenance of effective disclosure and financial controls and changes in corporate governance practices. Further, in July 2010, the Dodd-Frank Wall Street Reform and Consumer Protection Act, or the Dodd-Frank Act, was enacted. There are significant corporate governance and executive-compensation-related provisions in the Dodd-Frank Act that require the SEC to adopt additional rules and regulations in these areas. Recent legislation permits emerging growth companies to implement many of these requirements over a longer period and up to five years from the pricing of our initial public offering. We intend to take advantage of this new legislation, but cannot assure you that we will not be required to implement these requirements sooner than planned and thereby incur unexpected expenses. As of June 30, 2021, the market value of our common stock held by non-affiliates exceeded $700.0 million. Consequently, we will be a large accelerated filer and will therefore cease to be an emerging growth company effective December 31, 2021. As a result of this transition, we will be subject to certain disclosure and compliance requirements that apply to other public companies but did not previously apply to us due to our status as an emerging growth company and expect to incur additional legal and financial compliance costs as a result. Stockholder activism, the current political environment and the current high level of government intervention and regulatory reform may lead to substantial new regulations and disclosure obligations, which may lead to additional compliance costs and impact the manner in which we operate our business in ways we cannot currently anticipate.

We expect the rules and regulations applicable to public companies will continue to substantially increase our legal and financial compliance costs and to make some activities more time-consuming and costly. If these requirements divert the attention of our management and personnel from other business concerns, they could have a material adverse effect on our business, financial condition and results of operations. The increased costs will decrease our net income or increase our consolidated net loss, and may require us to reduce costs in other areas of our business or increase the prices of our products or services. For example, these rules and regulations to make it more difficult and more expensive for us to obtain director and officer liability insurance and we are required to incur substantial costs to maintain the same or similar coverage. We cannot predict or estimate the amount or timing of additional costs we may incur to respond to these requirements. The impact of these requirements also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, our board committees or as executive officers.

A significant portion of our total outstanding shares are restricted from immediate resale but may be sold into the market in the near future. This could cause the market price of our common stock to drop significantly, even if our business is doing well.*

Sales of a substantial number of shares of our common stock in the public market could occur at any time, subject to the restrictions and limitations described below. If our stockholders sell, or the market perceives that our stockholders intend to sell, substantial amounts of our common stock in the public market, the market price of our common stock could decline significantly. All of our outstanding shares of common stock are available for sale in the public market, subject only to the restrictions of Rule 144 under the Securities Act in the case of our affiliates.

In addition, as of September 30, 2021, we have filed registration statements on Form S-8 under the Securities Act registering the issuance of an aggregate of 21,104,867 shares of common stock subject to options or other equity awards issued or reserved for future issuance under our equity incentive plans. Shares registered under these registration statements on Form S-8 are available for sale in the public market subject to vesting arrangements and exercise of options, the lock-up agreements described above and the restrictions of Rule 144 in the case of our affiliates.

Anti-takeover provisions under our charter documents and Delaware law could delay or prevent a change of control which could limit the market price of our securities and may prevent or frustrate attempts by our security holders to replace or remove our current management.

Our amended and restated certificate of incorporation and amended and restated bylaws, contain provisions that could delay or prevent a change of control of our company or changes in our board of directors that our stockholders might consider favorable. Some of these provisions include:

- a board of directors divided into three classes serving staggered three-year terms, such that not all members of the board will be elected at one time;
- a prohibition on stockholder action through written consent, which requires that all stockholder actions be taken at a meeting of our stockholders;

- a requirement that special meetings of stockholders be called only by the chairman of the board of directors, the chief executive officer, the president or by a majority of the total number of authorized directors;
- advance notice requirements for stockholder proposals and nominations for election to our board of directors;
- a requirement that no member of our board of directors may be removed from office by our stockholders except for cause and, in addition to any other vote required by law, upon the approval of not less than two-thirds of all outstanding shares of our voting stock then entitled to vote in the election of directors;
- a requirement of approval of not less than two-thirds of all outstanding shares of our voting stock to amend any bylaws by stockholder action or to amend specific provisions of our certificate of incorporation; and
- the authority of the board of directors to issue preferred stock on terms determined by the board of directors without stockholder approval and which preferred stock may include rights superior to the rights of the holders of common stock.

In addition, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporate Law, which may prohibit certain business combinations with stockholders owning 15% or more of our outstanding voting stock. These anti-takeover provisions and other provisions in our amended and restated certificate of incorporation and amended and restated bylaws could make it more difficult for stockholders or potential acquirers to obtain control of our board of directors or initiate actions that are opposed by the then-current board of directors and could also delay or impede a merger, tender offer or proxy contest involving our company. These provisions could also discourage proxy contests and make it more difficult for you and other stockholders to elect directors of your choosing or cause us to take other corporate actions you desire. Any delay or prevention of a change of control transaction or changes in our board of directors could cause the market price of our securities to decline.

An active trading market for our common stock may not be sustained.

Our shares of common stock began trading on The Nasdaq Capital Market on September 21, 2018. Given the limited trading history of our common stock, there is a risk that an active trading market for our shares will not be sustained, which could put downward pressure on the market price of our common stock and thereby affect the ability of our stockholders to sell their shares.

General Risk Factors

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

The trading market for our securities will depend in part on the research and reports that securities or industry analysts publish about us or our business. As a newly public company, we have only limited research coverage on our company by equity research analysts. If securities or industry analysts elect not to initiate or continue to provide coverage of our company, the trading price for our securities would likely be negatively impacted. If one or more of the analysts who covers us downgrades our securities or publishes inaccurate or unfavorable research about our business, the price of our securities may decline. If one or more of these analysts ceases coverage of our company or fails to publish reports on us regularly, demand for our securities could decrease, which might cause the price of our securities and trading volume to decline.

Future sales of substantial amounts of our common stock, or the possibility that such sales could occur, could adversely affect the market price of our common stock.

Future sales in the public market of shares of our common stock, including shares issued upon exercise of our outstanding stock options, or the perception by the market that these sales could occur, could lower the market price of our common stock or make it difficult for us to raise additional capital.

Our business could be negatively affected as a result of actions of activist stockholders, and such activism could impact the trading value of our securities.

Stockholders may, from time to time, engage in proxy solicitations or advance stockholder proposals, or otherwise attempt to effect changes and assert influence on our board of directors and management. Activist campaigns that contest or conflict with our strategic direction or seek changes in the composition of our board of directors could have an adverse effect on our operating results and financial condition. A proxy contest would require us to incur significant legal and advisory fees, proxy solicitation expenses and administrative and associated costs and require significant time and attention by our board of directors and management, diverting their attention from the pursuit of our business strategy. Any perceived uncertainties as to our future direction and control, our ability to execute on our strategy, or changes to the composition of our board of directors or senior management team arising from a proxy contest could lead to the perception of a change in the direction of our business or instability which may result in the loss of potential business opportunities, make it more difficult to pursue our strategic

initiatives, or limit our ability to attract and retain qualified personnel and business partners, any of which could adversely affect our business and operating results. If individuals are ultimately elected to our board of directors with a specific agenda, it may adversely affect our ability to effectively implement our business strategy and create additional value for our stockholders. We may choose to initiate, or may become subject to, litigation as a result of the proxy contest or matters arising from the proxy contest, which would serve as a further distraction to our board of directors and management and would require us to incur significant additional costs. In addition, actions such as those described above could cause significant fluctuations in our stock price based upon temporary or speculative market perceptions or other factors that do not necessarily reflect the underlying fundamentals and prospects of our business.

Securities class action litigation could divert our management's attention and harm our business and could subject us to significant liabilities.

The stock markets have from time to time experienced significant price and volume fluctuations that have affected the market prices for the equity securities of life sciences and biotechnology companies. These broad market fluctuations may cause the market price of our ordinary shares to decline. In the past, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for us because biotechnology and biopharma companies have experienced significant stock price volatility in recent years. Even if we are successful in defending claims that may be brought in the future, such litigation could result in substantial costs and may be a distraction to our management and may lead to an unfavorable outcome that could adversely impact our financial condition and prospects.

ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

Not applicable

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
3.1 (1)	Amended and Restated Certificate of Incorporation, as amended.
3.2 (1)	Amended and Restated Bylaws.
4.1 (2)	Form of Common Stock Certificate
4.5 (2)	Form of Warrant to Purchase Series D-1 Preferred Stock issued to Midcap Financial Trust.
4.6 (2)	Form of Warrant to Purchase Common Stock Issued to Underwriters.
4.7 (2)	Form of Warrant Certificate (included in Exhibit 4.8).
4.8 (2)	Form of Warrant Agent Agreement by and between the Registrant and American Stock Transfer & Trust Company LLC, as warrant agent.
4.9 (3)	Form of Warrant to Purchase Common Stock for Service Providers.
4.11 (4)	Registration Rights Agreement, dated March 14, 2019, between the Company and Aspire Capital Fund, LLC.
4.12 (4)	Registration Rights Agreement, dated March 14, 2019, by and among the Company and the Innovatus Investors.
4.13 (5)	Form of Warrant to Purchase Common Stock issued to Investors in October 2019 Public Offering.
4.14 (6)	Form of Warrant to Purchase Common Stock issued to Investors in April 2020 Public Offering.
10.1	Non-Employee Director Compensation Policy, as Amended.
31.1*	Certification of Principal Executive Officer pursuant to Rules 13a-14(a) and 15d-14(a) promulgated under the Securities Exchange Act of 1934, as amended.
31.2*	Certification of Principal Financial Officer pursuant to Rules 13a-14(a) and 15d-14(a) promulgated under the Securities Exchange Act of 1934, as amended.
32.1*	Certification of Principal Executive Officer and Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS	Inline XBRL Instance Document—the instance document does not appear in the Interactive Data File as its XBRL tags are embedded within the Inline XBRL document.
101.SCH	Inline XBRL Taxonomy Extension Schema Document.
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document.
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document.
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document.
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document.
104	Cover Page Interactive Data File (formatted in Inline XBRL and contained in Exhibit 101)

(1) Incorporated by reference to the Registrant's Annual Report on Form 10-K, filed with the SEC on March 23, 2021.
(2) Incorporated by reference to the Registrant's Registration Statement on Form S-1 (File No. 333-225970), as amended.
(3) Incorporated by reference to the Registrant's Current Report on Form 8-K, filed with the SEC on November 21, 2018.
(4) Incorporated by reference to the Registrant's Current Report on Form 8-K, filed with the SEC on March 14, 2019.
(5) Incorporated by reference to the Registrant's Registration Statement on Form S-1 (File No. 333-233828), as amended.
(6) Incorporated by reference to the Registrant's Registration Statement on Form S-1 (File No. 333-237074), as amended.

* This certification is deemed not filed for purpose of section 18 of the Exchange Act or otherwise subject to the liability of that section, nor shall it be deemed incorporated by reference into any filing under the Securities Act or the Exchange Act.

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.

BIONANO GENOMICS, INC.

Dated: November 4, 2021

By: /s/ R. Erik Holmlin, Ph.D.
R. Erik Holmlin, Ph.D.
President and Chief Executive Officer
(Principal Executive Officer)

Dated: November 4, 2021

By: /s/ Christopher Stewart
Christopher Stewart
Chief Financial Officer
(Principal Financial and Accounting Officer)

BIONANO GENOMICS, INC.

NON-EMPLOYEE DIRECTOR COMPENSATION POLICY

Each member of the Board of Directors (the "***Board***") who is not also serving as an employee of or consultant to Bionano Genomics, Inc. (the "***Company***") or any of its subsidiaries (each such member, an "***Eligible Director***") will receive the compensation described in this policy for his or her Board service. An Eligible Director may decline all or any portion of his or her compensation by giving notice to the Company prior to the date cash may be paid or equity awards are to be granted, as the case may be. This policy may be amended at any time in the sole discretion of the Board or the Compensation Committee of the Board.

Annual Cash Compensation

The annual cash compensation amount set forth below is payable to Eligible Directors in equal quarterly installments, payable in arrears on the last day of each fiscal quarter in which the service occurred. If an Eligible Director joins the Board or a committee of the Board at a time other than effective as of the first day of a fiscal quarter, each annual retainer set forth below will be pro-rated based on days served in the applicable fiscal year, with the pro-rated amount paid for the first fiscal quarter in which the Eligible Director provides the service and regular full quarterly payments thereafter. All annual cash fees are vested upon payment.

1. Annual Board Service Retainer:

    a. All Eligible Directors: $40,000

    b. Chairman of the Board Service Retainer (in addition to Eligible Director Service Retainer): $20,000

2. Annual Committee Chair Service Retainer:

    a. Chairman of the Audit Committee: $20,000

    b. Chairman of the Compensation Committee: $15,000

    c. Chairman of the Nominating and Corporate Governance Committee: $10,000

3. Annual Committee Member Service Retainer (not applicable to Committee Chairs):

a. Member of the Audit Committee: $10,000

b. Member of the Compensation Committee: $7,500

c. Member of the Nominating and Corporate Governance Committee: $5,000

Equity Compensation

The equity compensation set forth below will be granted under the Company's 2018 Equity Incentive Plan, as amended (the "***Plan***"), subject to the approval of the Plan by the Company's stockholders. All stock options granted under this policy will be nonstatutory stock options, with an exercise price per share equal to 100% of the Fair Market Value (as defined in the Plan) of the underlying common stock of the Company (the "***Common Stock***") on the date of grant, and a term of ten years from the date of grant (subject to earlier termination in connection with a termination of service as provided in the Plan, provided that upon a termination of service other than for death, disability or cause, the post-termination exercise period will be 12 months from the date of termination).

1. Initial Grant: For each Eligible Director who is first elected or appointed to the Board following the Effective Date, on the date of such Eligible Director's initial election or appointment to the Board (or, if such date is not a market trading day, the first market trading day thereafter), the Eligible Director will be automatically, and without further action by the Board or Compensation Committee of the Board, granted a stock option to purchase Common Stock with an aggregate Black-Scholes option value of $247,500 (the "***Initial Grant***"). The shares subject to each Initial Grant will vest in equal monthly installments over a three year period such that the option is fully vested on the third anniversary of the date of grant, subject to the Eligible Director's Continuous Service (as defined in the Plan) through each such vesting date and will vest in full upon a Change in Control (as defined in the Plan).

2. Annual Grant: On the date of each annual stockholder meeting of the Company held after the Effective Date, each Eligible Director who continues to serve as a non-employee member of the Board following such stockholder meeting will be automatically, and without further action by the Board or Compensation Committee of the Board, granted a stock option to purchase Common Stock with an aggregate Black-Scholes option value of $165,000 (the "***Annual Grant***"). The shares subject to the Annual Grant will vest in equal monthly installments over the 12 months following the date of grant, provided that the Annual Grant will in any case be fully vested on the date of Company's next annual stockholder meeting, subject to the Eligible Director's Continuous Service (as defined in the Plan) through such vesting date and will vest in full upon a Change in Control (as defined in the Plan).

Amended effective as of August 17, 2021

Exhibit 31.1

CERTIFICATION

I, R. Erik Holmlin, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Bionano Genomics, Inc., a Delaware corporation (the "registrant");
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.

Dated: November 4, 2021

/s/ R. Erik Holmlin, Ph.D.

R. Erik Holmlin, Ph.D.
President and Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION

I, Christopher Stewart, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Bionano Genomics, Inc., a Delaware corporation (the "registrant");
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:
    (i) 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;
    (ii) 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;
    (iii) 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
    (iv) 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):
    (i) 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
    (ii) 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.

Dated: November 4, 2021

/s/ Christopher Stewart

Christopher Stewart

Chief Financial Officer

(Principal Financial and Accounting Officer)

Exhibit 32.1

CERTIFICATION

Pursuant to the requirement set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, (the "Exchange Act") and 18 U.S.C. Section 1350 as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, R. Erik Holmlin, Chief Executive Officer of Bionano Genomics, Inc., a Delaware corporation (the "Company") and Christopher Stewart, Chief Financial Officer of the Company, each hereby certifies that, to the best of his knowledge:

1. The Company's Quarterly Report on Form 10-Q for the period ended September 30, 2021, as filed with the Securities and Exchange Commission on the date hereof (the "Periodic Report"), and to which this Certification is attached as Exhibit 32.1, fully complies with the requirements of Section 13(a) or Section 15(d) of the Exchange Act; and

2. The information contained in the Periodic Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: November 4, 2021

/s/ R. Erik Holmlin, Ph.D.
R. Erik Holmlin, Ph.D.
President and Chief Executive Officer
(Principal Executive Officer)

Dated: November 4, 2021

/s/ Christopher Stewart
Christopher Stewart
Chief Financial Officer
(*Principal Financial and Accounting Officer*)

This certification accompanies and is being "furnished" with the Periodic Report, shall not be deemed "filed" by the Company for purposes of Section 18 of the Exchange Act, or otherwise subject to liability under that Section and shall not be deemed to be incorporated by reference into any filing of the Company under the Securities Act of 1933, as amended, or the Exchange Act, whether made before or after the date of the Periodic Report, irrespective of any general incorporation language contained in such filing.