Table of Contents

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 MARCH 31, 2022

☐ **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 April 28, 2022, the registrant had 289,697,045 shares of Common Stock ($0.0001 par value) outstanding.

BIONANO GENOMICS, INC.
TABLE OF CONTENTS

PART I. FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

BIONANO GENOMICS, INC.
Condensed Consolidated Balance Sheets

	(Unaudited) March 31, 2022	December 31, 2021
Assets		
Current assets:		
Cash and cash equivalents	$ 24,048,000	$ 24,571,000
Investments	192,420,000	226,041,000
Accounts receivable, net of allowance for doubtful accounts of $463,000 and $690,000 as of March 31, 2022 and December 31, 2021, respectively	5,514,000	4,934,000
Inventory	16,268,000	12,387,000
Prepaid expenses and other current assets	4,110,000	4,481,000
Total current assets	242,360,000	272,414,000
Property and equipment, net	12,661,000	10,318,000
Operating lease right-of-use assets	6,817,000	6,691,000
Finance lease right-of-use assets, related party	3,897,000	3,926,000
Intangible assets, net	25,424,000	26,842,000
Goodwill	56,254,000	56,160,000
Other long-term assets	798,000	749,000
Total assets	$ 348,211,000	$ 377,100,000
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 6,590,000	$ 9,696,000
Accrued expenses	8,936,000	9,694,000
Contract liabilities	1,107,000	684,000
Operating lease liability	1,730,000	1,467,000
Finance lease liability, related party	296,000	299,000
Total current liabilities	18,659,000	21,840,000
Operating lease liability, net of current portion	5,451,000	5,288,000
Finance lease liability, net of current portion, related party	3,638,000	3,642,000
Contingent consideration	9,145,000	9,066,000
Long-term contract liabilities	133,000	146,000
Total liabilities	37,026,000	39,982,000
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 March 31, 2022 and December 31, 2021	—	—
Common stock, $0.0001 par value, 400,000,000 shares authorized at March 31, 2022 and December 31, 2021; 289,688,000 and 289,602,000 shares issued and outstanding at March 31, 2022 and December 31, 2021, respectively	29,000	29,000
Additional paid-in capital	558,864,000	553,747,000
Accumulated deficit	(246,071,000)	(216,119,000)
Accumulated other comprehensive loss	(1,637,000)	(539,000)
Total stockholders' equity	311,185,000	337,118,000
Total liabilities and stockholders' equity	$ 348,211,000	$ 377,100,000

See accompanying notes to the unaudited condensed consolidated financial statements

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

	Three Months Ended March 31,	
	2022	**2021**
Revenue:		
Product revenue	$ 3,116,000	$ 2,049,000
Service and other revenue	2,580,000	1,119,000
Total revenue	5,696,000	3,168,000
Cost of revenue:		
Cost of product revenue	3,576,000	1,513,000
Cost of service and other revenue	1,259,000	612,000
Total cost of revenue	4,835,000	2,125,000
Operating expenses:		
Research and development	10,527,000	2,678,000
Selling, general and administrative	20,277,000	9,528,000
Total operating expenses	30,804,000	12,206,000
Loss from operations	(29,943,000)	(11,163,000)
Other income (expense):		
Interest income	110,000	65,000
Interest expense	(77,000)	(603,000)
Gain on forgiveness of Paycheck Protection Program loan	—	1,775,000
Other income (expense)	(33,000)	(15,000)
Total other income (expense)	—	1,222,000
Loss before income taxes	(29,943,000)	(9,941,000)
Benefit (provision) for income taxes	(9,000)	(6,000)
Net loss	$ (29,952,000)	$ (9,947,000)
Net loss per share, basic and diluted	$ (0.11)	$ (0.04)
Weighted-average common shares outstanding basic and diluted	284,613,000	263,939,000

See accompanying notes to the unaudited condensed consolidated financial statements.

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

	Three Months Ended March 31,	
	2022	**2021**
Net Loss:	$ (29,952,000)	$ (9,947,000)
Unrealized (loss) on investment securities	(1,098,000)	—
Comprehensive Loss	$ (31,050,000)	$ (9,947,000)

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, 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
Balance at January 1, 2022	289,602,000	$ 29,000	$ 553,747,000	$ (216,119,000)	$ (539,000)	$ 337,118,000
Stock option exercises	21,000	—	15,000	—	—	15,000
Stock-based compensation expense	—	—	5,102,000	—	—	5,102,000
Issuance of common stock due to the vesting of restricted stock units, net of shares withheld to cover taxes	65,000	—	—	—	—	—
Net loss	—	—	—	(29,952,000)	—	(29,952,000)
Other comprehensive loss	—	—	$ —	—	(1,098,000)	(1,098,000)
Balance at March 31, 2022	289,688,000	$ 29,000	$ 558,864,000	$ (246,071,000)	$ (1,637,000)	$ 311,185,000

See accompanying notes to the unaudited condensed consolidated financial statements

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

	Three Months Ended March 31,	
	2022	**2021**
Operating activities:		
Net loss	$ (29,952,000)	$ (9,947,000)
Adjustments to reconcile net loss to net cash used by operating activities:		
Depreciation and amortization expense	2,210,000	448,000
Amortization of financing lease right-of-use asset	29,000	—
Amortization of interest on securities	299,000	—
Non-cash lease expense	299,000	—
Non-cash interest expense	—	315,000
Stock-based compensation	5,102,000	371,000
Change in fair value of contingent consideration	79,000	—
Gain on forgiveness of PPP Loan	—	(1,775,000)
Changes in operating assets and liabilities:		
Accounts receivable	(640,000)	783,000
Inventory	(5,938,000)	(961,000)
Prepaid expenses and other current assets	(371,000)	(1,049,000)
Accounts payable	(3,168,000)	(1,045,000)
Accrued expenses and contract liabilities	(443,000)	(1,044,000)
Net cash used in operating activities	(32,494,000)	(13,904,000)
Investing Activities:		
BioDiscovery acquisition, return of purchase consideration from escrow	694,000	—
Purchases of property and equipment	(150,000)	(24,000)
Purchase of available for sale securities	(14,954,000)	—
Sale and maturity of available for sale securities	47,179,000	—
Construction in progress	(832,000)	—
Sale of property and equipment	27,000	—
Net cash provided by / (used in) investing activities	31,964,000	(24,000)
Financing activities:		
Principal payments of financing lease liability	(8,000)	—
Proceeds from sale of common stock	—	328,635,000
Offering expenses on sale of common stock	—	(825,000)
Proceeds from warrant and option exercises	15,000	9,726,000
Net cash provided by financing activities	7,000	337,536,000
Net increase in cash and cash equivalents	(523,000)	323,608,000
Cash and cash equivalents at beginning of period	24,571,000	38,449,000
Cash and cash equivalents at end of period	$ 24,048,000	$ 362,057,000
Supplemental cash flow disclosures:		
Cash paid for interest	$ 70,000	$ 287,000
Cash paid for operating lease liabilities	$ 217,000	$ 206,000
Supplemental disclosure of non-cash investing and financing activities:		
Transfer of instruments and servers from inventory to property and equipment, net	$ 2,056,000	$ 1,240,000
Operating Lease Liabilities resulting from obtaining right-of-use assets	$ 513,000	$ 2,013,000
Forgiveness of PPP Loan	$ —	$ 1,775,000
Offering costs in accounts payable	$ —	$ 324,000
Warrant exercise pursuant to cashless exercise	$ —	$ 129,000

See accompanying notes to the unaudited condensed consolidated financial statements

BIONANO GENOMICS, INC.
NOTES TO CONDENSED CONSOLIDATED 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, LLC. ("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, 2021.

Liquidity

As of March 31, 2022, the Company had approximately $24.0 million in cash and cash equivalents, $192.4 million in available for sale investment securities, and working capital of $223.7 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, the Company applied for forgiveness of its 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.

The Company believes its available cash, cash equivalents, and available for sale securities will be sufficient to fund operations, obligations as they become due and capital investments for at least the next 12 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. If restrictions related to COVID-19 persist, the Company could see additional supply chain disruptions that impact its ability to produce its products and may cause the Company to make strategic determinations regarding, among other things, the cost and quality of the components and supplies it acquires. The Company may also see negative effects on study enrollment in its ongoing or future studies. At various times throughout the pandemic, the Company has been unable to visit certain customer sites to support installation or service of its OGM systems. The Company's manufacturing partners, suppliers, and customers, have implemented similar operational reductions. Despite reporting an increase in revenue for the three months ended March 31, 2022 when compared to the same period in 2021, the Company experienced supply chain constraints that negatively impacted the Company's first quarter 2022 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.

During the three months ended March 31, 2022, the Company experienced supply chain challenges, which it largely attributes to the COVID-19 pandemic. While the COVID-19 pandemic did not prevent the Company from operating its business during the three months ended March 31, 2022, it experienced increased cost to secure certain component parts in its products and to produce its products at its contract manufacturers.

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. Further, the travel restrictions on the Company's business have limited its ability to support its global and domestic operations, including providing installation and training and customer service, which has and may continue to slow the pace of its commercial strategy, sales and marketing efforts. These negative effects could have a material impact on the Company's operations, business, earnings, and liquidity.

Significant Accounting Policies

During the three months ended March 31, 2022, 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, 2021.

Recently Issued But Not Yet Adopted Accounting Pronouncements

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.

Recently Adopted Accounting Pronouncements

In February 2016, the Financial Accounting Standards Board issued Accounting Standards Update 2016-02, "Leases (Topic 842)" ("ASC 842") which requires lessees to recognize leases on the balance sheet and disclose key information about leasing arrangements. ASC 842 establishes a right-of-use model that requires a lessee to recognize a ROU asset and lease liability on the balance sheet for all leases with a term longer than 12 months. ASC 842 also requires disclosures to meet the objective of enabling users of financial statements to assess the amount, timing, and uncertainty of cash flows arising from leases. The standard was adopted on January 1, 2021, as the Company lost its status as an Emerging Growth Company effective December 31, 2021, and therefore was required to adopt the standard for the year ending December 31, 2021, using the modified retrospective method. Under this transition method, the Company recognized and measured leases that existed at the adoption date in the consolidated balance sheet as of January 1, 2021. In connection with the adoption of ASC 842, the Company elected the package of practical expedients requiring no reassessment of whether any expired or existing contracts contain leases, the lease classification of any expired or existing leases, or initial direct costs for any existing leases. The Company also made accounting policy elections not to apply the recognition requirements under ASC 842 to any short-term leases and to account for each separate lease and associated non-lease components as a single lease component for all the Company's leases. The adoption of this new accounting standard resulted in increased qualitative and quantitative disclosures regarding the amount, timing, and uncertainty of cash flows arising from leases. For further details, see Note 7, Commitments and Contingencies. The adoption of the new standard did not materially impact the Company's consolidated results of operations.

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's adoption of this accounting standard on January 1, 2022, did not have a material impact on the Company's consolidated financial statements and related disclosures.

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 share equivalents are only included when their effect is dilutive. Pre-funded warrants from the Company's follow-on offering have been treated as if they were common shares outstanding on the date of issuance. The Company's potentially dilutive securities which include outstanding warrants to purchase stock and outstanding stock options under the Company's equity incentive plans have been excluded from the computation of diluted net loss per share as they would be anti-dilutive to the net loss per share. Restricted stock is treated as outstanding for accounting purposes. For all periods presented, there is no difference in the number of shares used to calculate basic and diluted shares outstanding due to the Company's net loss position.

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):

	March 31, 2022	March 31, 2021
Stock options	21,531,000	5,126,000
Unvested restricted stock	4,257,000	
Warrants	4,356,000	4,411,000
RSUs	296,000	—
PSUs	290,000	—
Total	30,730,000	9,537,000

3. Revenue Recognition

Revenue by Source

	Three Months Ended March 31,	
	2022	2021
Instruments	$ 1,596,000	$ 882,000
Consumables	1,520,000	1,167,000
Total product revenue	3,116,000	2,049,000
Service and other	2,580,000	1,119,000
Total revenue	$ 5,696,000	$ 3,168,000

Revenue by Geographic Location

	Three Months Ended March 31,			
	2022		2021	
	$	%	$	%
Americas	$ 3,328,000	58 %	$ 1,498,000	47 %
EMEIA	1,739,000	31 %	1,587,000	50 %
Asia Pacific	629,000	11 %	83,000	3 %
Total	$ 5,696,000	100 %	$ 3,168,000	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. Americas consists of North America and South America. 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 March 31, 2022 and 2021, the United States represented 45.0% and 44.8% of total revenue, respectively. No other countries represented greater than 10% of revenue during the three months ended March 31, 2022 and 2021.

Remaining Performance Obligations

As of March 31, 2022, the estimated revenue expected to be recognized in the future related to performance obligations that are unsatisfied was approximately $1.2 million. These remaining performance obligations primarily relate to extended warranty and support and maintenance obligations. The Company expects to recognize approximately 75.8% of this amount as revenue during the remainder of 2022, 20.9% in 2023, and 3.3% in 2024 and thereafter. Warranty revenue is included in service and other revenue.

The Company recognized revenue of approximately $0.3 million and $0.2 million during the three months ended March 31, 2022 and 2021, respectively, which was included in the contract liability balance at the end of the previous year.

4. Balance Sheet Account Details

Accounts Receivable

	March 31, 2022	December 31, 2021
Accounts receivable, net:		
Accounts receivable, trade	$ 5,977,000	$ 5,624,000
Less allowance for doubtful accounts	(463,000)	(690,000)
	$ 5,514,000	$ 4,934,000

Inventory

The components of inventories are as follows:

	March 31, 2022	December 31, 2021
Inventory:		
Raw materials	$ 1,139,000	$ 745,000
Finished goods	15,129,000	11,642,000
	$ 16,268,000	$ 12,387,000

Intangible Assets

Intangible assets that are subject to amortization consisted of the following for the periods presented:

	March 31, 2022			December 31, 2021		
	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount
Trade name	$ 1,630,000	$ (290,000)	$ 1,340,000	$ 1,630,000	$ (210,000)	$ 1,420,000
Customer relationships	3,950,000	(576,000)	3,374,000	3,950,000	(378,000)	3,572,000
Developed technology	22,800,000	(2,090,000)	20,710,000	22,800,000	(950,000)	21,850,000
Intangibles, net	$ 28,380,000	$ (2,956,000)	$ 25,424,000	$ 28,380,000	$ (1,538,000)	$ 26,842,000

Accrued Expenses

Accrued expenses consist of the following:

	March 31, 2022	December 31, 2021
Compensation expenses	$ 3,946,000	$ 4,529,000
Goods received not invoiced	1,238,000	1,073,000
Customer deposits	979,000	826,000
Taxes payable	685,000	677,000
Insurance	389,000	1,011,000
Professional fees and royalties	218,000	288,000
Warranty liabilities	175,000	175,000
Other	1,306,000	1,115,000
Total	$ 8,936,000	$ 9,694,000

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”). 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 three months ended March 31, 2021.

Innovatus Loan and Security Agreement

In May 2021, the outstanding term loan with Innovatus (“Innovatus LSA”) was paid in full, including all accrued interest, the end of term fee, and a prepayment fee for a total of approximately $17.0 million. Interest expense recognized during the three months ended March 31, 2021 totaled approximately $0.6 million.

6. Stockholders’ Equity and Stock-Based Compensation

Follow-on Public Offerings

On January 12, 2021 and January 25, 2021, the Company completed an underwritten public offering of 33.4 million and 38.3 million shares of common stock, respectively. The price to the public in the offerings on January 12, 2021 and January 15,

2021 was $3.05 and $6.00 per share, respectively. The net proceeds to the Company from the offerings, after deducting the underwriting discounts and commissions and other offering expenses, were $101.5 million and $229.6 million, respectively.

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 million of the Company's securities, including up to $40 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 2020 through January 2021, the Company sold approximately 27.0 million shares of common stock under the Ladenburg ATM and received net proceeds of $38.0 million after deducting aggregate offering costs. 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 approximately 2.3 million 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. There were no sales of common stock under the Cowen ATM from January 1, 2022 to March 31, 2022.

Stock Warrants

A summary of the Company's warrant activity during the three months ended March 31, 2022 was as follows:

	Shares of Stock under Warrants	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term	Aggregate Intrinsic Value
Outstanding at January 1, 2022	4,356,000	$ 5.96	1.76	$ 785,000
Granted	—	—	—	—
Exercised	—	—	—	—
Canceled	—	—	—	—
Outstanding at March 31, 2022	4,356,000	$ 5.96	1.76	$ 785,000

Stock Options

A summary of the Company's stock option activity during the three months ended March 31, 2022 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, 2022	12,765,000	$ 4.97	8.9	$ 7,891,000
Granted	9,691,000	2.19	—	—
Exercised	(21,000)	0.79	—	32,000
Canceled	(904,000)	5.73	—	—
Outstanding at March 31, 2022	21,531,000	$ 3.69	9.11	$ 10,131,000
Vested and exercisable at March 31, 2022	4,018,000	$ 3.66	7.88	$ 3,972,000

For the three months ended March 31, 2022, the weighted-average grant date fair value of stock options granted was $1.39 per share.

Stock-Based Compensation

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

	Three Months Ended March 31,	
	2022	2021
Research and development	$ 3,328,000	$ 81,000
General and administrative	1,774,000	290,000
Total stock-based compensation expense	$ 5,102,000	$ 371,000

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 March 31,	
	2022	2021
Risk-free interest rate	1.9 %	0.7 %
Expected volatility	70.1 %	79.3 %
Expected term (in years)	6.0	6.1
Expected dividend yield	0.0 %	0.0 %

Restricted Stock

Restricted Stock

A restricted stock award in the amount of 5.0 million shares with a grant date fair value of $5.20 a share was granted as part of the acquisition of BioDiscovery. One-third of the Restricted Shares will vest on October 18, 2022 and one-twelfth of the Restricted Shares shall vest every three months following October 18, 2022, subject to continuous service of a key employee. The weighted average remaining contractual term for the restricted stock is 2.6 years as of March 31, 2022. The fair value of the restricted stock award is based on the market value of common stock as of the date of grant and is amortized to expense over the respective vesting period or the service period.

Restricted Stock Units and Performance Stock Units

The following table summarizes restricted share unit (“RSU”) activity during the three months ended March 31, 2022:

	Stock Units	Weighted-Average Grant Date Fair Value per Share
Outstanding at January 1, 2022	361,000	$ 4.74
Granted	—	—
Released	(65,000)	4.74
Forfeited	—	—
Outstanding at March 31, 2022	296,000	$ 4.74

The total intrinsic value of the RSUs that vested was $0.3 million during the three months ended March 31, 2022, determined as of the date of vesting. The weighted average remaining contractual term for the RSUs is 1.1 years as of March 31, 2022.

The following table summarizes performance share unit (“PSU”) activity during the quarter ended March 31, 2022:

	Stock Units	Weighted-Average Grant Date Fair Value per Share
Outstanding at January 1, 2021	290,000	$ 4.74
Granted	—	—
Released	—	—
Forfeited	—	—
Outstanding at March 31, 2022	290,000	$ 4.74

The weighted average remaining contractual term for the PSUs is 3.1 years as of March 31, 2022.

Executive Option Grants

On February 15, 2022, the compensation committee of the Company's board of directors granted various executive officers stock options to purchase an aggregate of 4.3 million shares of common stock at an exercise price of $2.18 a share, in each case with an effective grant date and vesting commencement date of February 15, 2022 (the "Grant Date"). These stock option grants were issued from the 2018 Stock Plan. The shares subject to the option shall vest monthly over 48 months beginning on the one-month anniversary of the Grant Date, such that the option shall be fully vested and exercisable on the four-year anniversary of the Grant Date.

7. Commitments and Contingencies

The Company discounts its lease payments using its incremental borrowing rate as of the commencement of the lease. The Company has determined a weighted-average discount rate of 7.1% as of March 31, 2022 and December 31, 2021.

The operating lease right-of-use asset and operating lease liability as of March 31, 2022 and December 31, 2021 are as follows:

	March 31, 2022	December 31, 2021
Operating lease right-of-use assets	$ 6,817,000	$ 6,691,000
Operating lease liability		
Current	1,730,000	1,467,000
Non-current	5,451,000	5,288,000
Total operating lease liability	$ 7,181,000	$ 6,755,000

For the three months ended March 31, 2022, the Company recorded $0.5 million in expense related to operating leases, including amortized tenant improvement allowances. For the three months ended March 31, 2021, the Company recorded $0.2 million in expense related to operating leases, including amortized tenant improvement allowances.

The finance lease right-of-use asset and finance lease liability as of March 31, 2022 and December 31, 2021 are as follows:

	March 31, 2022	December 31, 2021
Finance lease right-of-use assets	$ 3,897,000	$ 3,926,000
Finance lease liability		
Current	296,000	299,000
Non-current	3,638,000	3,642,000
Total finance lease liability	$ 3,934,000	$ 3,941,000

For the three months ended March 31, 2022, the Company recorded $0.1 million in expense related to its finance lease. The Company did not hold a finance lease as of March 31, 2021.

The future minimum payments under non-cancellable operating and finance leases as of March 31, 2022, are as follows:

	Operating Leases	Finance Lease
Remainder of 2022	$ 1,538,000	$ 236,000
2023	2,149,000	322,000
2024	2,219,000	330,000
2025	2,305,000	338,000
2026	232,000	347,000
Thereafter	—	5,949,000
Total future lease payments	8,443,000	7,522,000
Less: imputed interest	(1,262,000)	(3,588,000)
Total lease liabilities	$ 7,181,000	$ 3,934,000

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.

Contingent Consideration

See Note 9 to our condensed consolidated financial statements for a discussion of the contingent consideration liability.

8. Acquisitions

BioDiscovery Acquisition

In October 2021, the Company completed the acquisition of BioDiscovery, LLC, for a combination of approximately $52.3 million in cash, $40.0 million in shares of Company common stock, and $10.0 million in cash payable based on the achievement of certain milestones. Of the $40.0 million in shares of Company common stock, approximately $26.0 million is subject to vesting based on continuous service. See Note 6 to our condensed consolidated financial statements for a discussion of the restricted stock vesting terms and accounting treatment.

The purchase price allocation for the acquisition of BioDiscovery is preliminary and subject to revision as additional information about the fair value of assets and liabilities becomes available. As permitted under ASC 805, the Company is allowed a measurement period, which may not exceed one year, in which to complete its accounting for the acquisition. During the first quarter of 2022, the Company recorded an increase to the value of acquired contract liabilities in the amount of $94,000, with the offset recorded to goodwill. The purchase price is still subject to adjustment for the final determination of deferred and current tax assets and liabilities.

The following is the purchase price for the acquisition of BioDiscovery:

Cash	$ 52,291,000
Estimated fair value of milestone consideration	$ 9,000,000
Return of cash to buyer from escrow	$ (694,000)
Shares of common stock issued as consideration	2,723,000
Stock price per share on closing date	$ 5.20
Value of estimated common stock consideration	$ 14,159,000
Total purchase price	$ 74,756,000

The total purchase price was allocated to BioDiscovery's tangible and identifiable intangible assets acquired and liabilities assumed based on their estimated fair values as of the acquisition date, with the excess recorded as goodwill, as follows:

Cash and cash equivalents	$	3,205,000
Accounts receivable		1,782,000
Right-of-use assets		3,987,000
Other assets		213,000
Intangible assets		26,800,000
Goodwill		49,081,000
Accounts payable and other accrued liabilities		(193,000)
Right-of-use liabilities (short-term and long-term)		(3,987,000)
Deferred tax liability		(5,777,000)
Contract liabilities		(355,000)
Net assets acquired	$	74,756,000

The acquisition date fair values of identifiable intangible assets acquired are as follows:

Customer relationships	$	3,000,000
Developed technology		22,800,000
Tradename		1,000,000
Fair value of identifiable intangible assets	$	26,800,000

The Company uses the income approach to derive the fair value of the identified intangible assets acquired. This approach calculates fair value by estimating future cash flows attributable to the assets and then discounting these cash flows to a present value using a risk-adjusted discount rate.

The developed technology, customer relationships and trade name intangibles are both being amortized on a straight-line basis over their estimated useful lives of five years. Straight-line amortization was determined to be materially consistent with the pattern of expected use of the intangible assets.

As the Company began integrating BioDiscovery's operations with its existing operations during the fourth quarter of 2021, it is not practical or meaningful to distinguish BioDiscovery's expenses or net income or loss from that of the combined operations.

Pro forma Financial Information

The unaudited pro forma financial information in the table below summarizes the combined results of operations for the Company and BioDiscovery as if the companies had been combined as of the beginning of the year prior to the acquisition. These amounts have been calculated after applying the Company's accounting policies and adjusting the results of BioDiscovery to reflect the additional amortization that would have been charged assuming the fair value adjustments to intangible assets had been applied at the beginning of the year prior to the acquisition. The following 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 acquisitions had taken place as of January 1, 2020.

		Three Months Ended March 31,
		2021
Revenue	$	4,154,000
Net loss		(11,159,000)
Basic and diluted net loss per share	$	(0.04)

9. Investments and 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 as of March 31, 2022 and December 31, 2021:

	March 31, 2022			
		Fair Value Measurement Category		
	Total Fair Value and Carrying Value on Balance Sheet	Level 1	Level 2	Level 3
Assets:				
Commercial Paper	$ 75,642,000	$ —	$ 75,642,000	$ —
Corporate Notes/Bonds	116,778,000	—	116,778,000	—
Total Investments:	$ 192,420,000	$ —	$ 192,420,000	$ —
Money Market Funds	$ 7,700,000	$ 7,700,000	$ —	$ —
Liabilities:				
Contingent consideration	$ 9,145,000	$ —	$ —	$ 9,145,000

	December 31, 2021			
		Fair Value Measurement Category		
	Total Fair Value and Carrying Value on Balance Sheet	Level 1	Level 2	Level 3
Assets:				
Commercial Paper	$ 100,860,000	$ —	$ 100,860,000	$ —
Corporate Notes/Bonds	125,181,000	—	125,181,000	—
Total Investments:	$ 226,041,000	$ —	$ 226,041,000	$ —
Money Market Funds	$ 11,126,000	$ 11,126,000	$ —	$ —
Liabilities:				
Contingent consideration	$ 9,066,000			$ 9,066,000

Money Market Funds are classified as cash equivalents on the balance sheet. As of March 31, 2022 and December 31, 2021, the Company held 51 and 57 securities in an unrealized loss position, respectively. None of the Company's available for sale investment securities were in a material unrealized loss position at March 31, 2022 or December 31, 2021. As such, the Company has not recognized any impairment in its financial statements related to its available for sale investment securities.

The fair value of the contingent consideration liability is reassessed on a quarterly basis using the income approach. Assumptions used to estimate the acquisition date fair value of the contingent consideration include the probability of achieving certain milestones and a discount rate of 3%. The fair value measurement of the contingent consideration is based on significant inputs not observed in the market (Level 3 inputs). The Company determined the fair value of the milestone consideration using a scenario-based technique, as the trigger for payment is event driven. The outcome of the milestone consideration is binary, meaning the milestone is either achieved or not achieved, and the only other variable factor is the timing of when the milestone is achieved. The Company determined it is highly likely that the milestone will be achieved and therefore used a 95% probability factor which is applied to the $10.0 million milestone consideration. The change in fair value of the contingent consideration during the three month period ended March 31, 2022 was due to the passage of time.

Changes in estimated fair value of contingent consideration liability in the three months ended March 31, 2022 is as follows:

	Contingent Consideration Liability (Level 3 Measurement)
Balance as of January 1, 2021	$ 9,066,000
Liability recorded as a result of current period acquisition	—
Change in estimated fair value, recorded in selling, general and administrative expenses	79,000.00
Cash payments	—
Balance as of March 31, 2022	$ 9,145,000

As of March 31, 2022, 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	$ 75,922,000	$ (280,000)	$ 54,179,000	$ (370,000)
Due after one year through five years	—	—	63,956,000	(987,000)
Total	$ 75,922,000	$ (280,000)	$ 118,135,000	$ (1,357,000)

As of December 31, 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 loss	Amortized Cost	Unrealized loss
Less than 1 year	$ 100,929,000	$ (69,000)	$ 41,173,000	$ (61,000)
Due after one year through five years	—	—	84,478,000	(409,000)
Total	$ 100,929,000	$ (69,000)	$ 125,651,000	$ (470,000)

Included in interest income for the three-month period ended March 31, 2022 was interest income related to the Company's available for sale securities of $0.1 million. 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.

10. Related Party Transactions

Through the acquisition of BioDiscovery in October 2021, the Company inherited a building lease with a landlord owned by BioDiscovery's former Director and Chief Executive Officer, who is now the Company's Chief Informatics Officer. The Company recorded $0.1 million in finance lease costs related to this lease for the three-month period ended March 31, 2022.

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, 2021 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 1, 2022. 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 provide diagnostic testing for patients with clinical presentations consistent with autism spectrum disorder and other neurodevelopmental disabilities. Through our BioDiscovery, LLC, 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 $30.0 million and $9.9 million for the three months ended March 31, 2022, and 2021 respectively. As of March 31, 2022, we had an accumulated deficit of $246.1 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

Commercial Adoption of Offerings for Saphyr

In executing on our commercialization strategy, we expanded the utilization of our Saphyr® system and:

- Grew our installed base to 176 as of March 31, 2022, an increase of approximately 64% from a total installed base of 107 as of March 31, 2021. Installed base represents the global number of Saphyr instruments installed at end-customer locations and therefore having the technology to process OGM.
- Sold 3,225 flowcells in the three-month period ended March 31, 2022, an increase of approximately 24% over the 2,603 flowcells sold during the same quarter of 2021. The Saphyr cartridge is the consumable that packages nanochannel arrays for DNA linearization. In its current form, the Saphyr cartridge has two configurations one with two flowcells per cartridge and the other with three flowcells per cartridge. Flowcells sold refers to the units of genome mapping consumables used for analyzing one genome, purchased by customers to process optical genome mapping.
- We analyzed 329 samples in our Saphyr service lab during the quarter ended March 31, 2022, compared to 227 samples analyzed in the same quarter in 2021.

COVID-19 Overview

We are 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 our business and financial results. We closely monitor and comply with various applicable guidelines and legal requirements in the jurisdictions in which we operate, 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. If restrictions related to COVID-19 persist, we could see additional supply chain disruptions that impact our ability to produce our products and may cause us to make strategic determinations regarding, among other things, the cost and quality of the components and supplies we acquire. We may also see negative effects on enrollment in our ongoing or future clinical studies . At various times throughout the pandemic, we have been unable to visit certain customer sites to support installation or service our OGM systems. Our manufacturing partners, suppliers, and customers, have implemented similar operational reductions. This overall reduction in activity has contributed to a decrease in sales which negatively impacted the Company's financial results in the first quarter of 2022. We expect these challenges to persist while the COVID-19 pandemic continues. The future effects of COVID-19 are unknown and our financial results may continue to be negatively affected in the future.

During the three months ended March 31, 2022, we experienced supply chain challenges, which we largely attribute to the COVID-19 pandemic. While the COVID-19 pandemic did not prevent us from operating our business during the three months ended March 31, 2022, we experienced increased cost to secure certain component parts in our products and to produce our products at our contract manufacturers.

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. Further, the travel restrictions on our business have limited our ability to support our global and domestic operations, including providing installation and training and customer service, which has and may continue to slow the pace of our commercial strategy, sales and marketing efforts. These negative effects could have a material impact on our operations, business, earnings, and liquidity.

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 laboratories associated with academic and governmental research institutions, as well as pharmaceutical, biotechnology and contract research companies. In addition, we provide instruments to certain customers under our reagent rental program, under which we provide an instrument to customers at no cost and the customers agree to purchase minimum quantities of consumables. 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 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. We also generate service and product revenue through BioDiscovery's NxClincial™ software, which provides customers with solutions for analysis, interpretation and reporting of genomics data. Other revenue consists of warranty and other service-based revenue.

The following table presents our revenue for the periods indicated:

	Three Months Ended March 31,	
	2022	2021
Product revenue	$ 3,116,000	$ 2,049,000
Service and other revenue[1]	2,580,000	1,119,000
Total	$ 5,696,000	$ 3,168,000

[1] Includes $1.2 million of revenue generated from BioDiscovery during the three months ended March 31, 2022.

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

	Three Months Ended March 31,			
	2022		2021	
	$	%	$	%
Americas	$ 3,328,000	58 %	$ 1,498,000	47 %
EMEIA	1,739,000	31 %	1,587,000	50 %
Asia Pacific	629,000	11 %	83,000	3 %
Total	$ 5,696,000	100 %	$ 3,168,000	100 %

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 and other 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, stock-based compensation for our sales and marketing, amortization expense related to acquired intangible assets, 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 March 31, 2022 and 2021

The following table sets forth our results of operations for the three months ended March 31, 2022 and 2021:

	Three Months Ended March 31,		Period-to-Period Change	
	2022	2021	$	%
Revenues:				
Product revenue	$ 3,116,000	$ 2,049,000	$ 1,067,000	52 %
Service and other revenue	2,580,000	1,119,000	1,461,000	131 %
Total revenue	5,696,000	3,168,000	2,528,000	80 %
Cost of revenue:				
Cost of product revenue	3,576,000	1,513,000	2,063,000	136 %
Cost of other revenue	1,259,000	612,000	647,000	106 %
Total cost of revenue	4,835,000	2,125,000	2,710,000	128 %
Operating expenses:				
Research and development	10,527,000	2,678,000	7,849,000	293 %
Selling, general and administrative	20,277,000	9,528,000	10,749,000	113 %
Total operating expenses	30,804,000	12,206,000	18,598,000	152 %
Loss from operations	(29,943,000)	(11,163,000)	(18,780,000)	168 %
Other income (expenses):				
Interest income	110,000	65,000	45,000	69 %
Interest expense	(77,000)	(603,000)	526,000	(87)%
Gain on forgiveness of Paycheck Protection Program Loan	—	1,775,000	(1,775,000)	(100)%
Other income (expenses)	(33,000)	(15,000)	(18,000)	120 %
Total other income (expenses)	—	1,222,000	(1,222,000)	(100)%
Loss before income taxes	(29,943,000)	(9,941,000)	(20,002,000)	201 %
Provision for income taxes	(9,000)	(6,000)	(3,000)	50 %
Net loss	$ (29,952,000)	$ (9,947,000)	$ (20,005,000)	201 %

Revenue

Total revenue increased by $2.5 million, or 80%, to $5.7 million for the three months ended March 31, 2022 compared to $3.2 million for the same period in 2021. The increase in product sales was driven by increased demand for our Saphyr OGM solutions, including increased instrument (64%) and flowcell units sold (24%) when compared to the same period last year, despite the supply chain challenges posed by COVID-19. The increased demand for our reagent rental program continues to drive a significant portion of the increase in consumable sales. We believe increased demand for our OGM systems was primarily driven by increased market awareness and additional published data demonstrating the utility of OGM, which we expect to continue as market awareness and published data, while not immune, can be influenced despite the negative effects of COVID-19. The increase in service and other revenue was primarily driven by $1.2 million in revenues generated by our BioDiscovery subsidiary, which was acquired in October 2021.

Cost of Revenue

Total cost of revenue increased by $2.7 million, or 128%, to $4.8 million for the three months ended March 31, 2022 compared to $2.1 million for the same period in 2021. Cost of product revenue increased primarily due to increased instrument and flowcell sales volume, but was also negatively impacted by unfavorable flowcell yields in the production cycle, which is in part attributable to COVID-19. Our gross margins for the three months ended March 31, 2022 were affected by the unfavorable flowcell yields in the production cycle which led to increased scrap and quality control costs during the first quarter of 2022. If we are unable to solve the unfavorable flowcell yield issue, it could lead to lower gross margins in future periods. Cost of service and other revenue increased primarily due to increased maintenance and service costs on our increased installed base, as well as increased service expenses related to our laboratory services.

Research and Development Expenses

Research and development, or R&D, expenses increased by $7.8 million, or 293%, to $10.5 million for the three months ended March 31, 2022 compared to $2.7 million for the same period in 2021. The increase is primarily due to a $6.2 million increase in compensation expenses, of which $3.2 million relates to stock-based compensation expense, and an increase of $1.4 million in product development costs. The increase in compensation expense is primarily driven by a 178% increase in R&D headcount. We anticipate future additions to our development teams as well as continued increases to our product development costs and, thus, future increases to R&D expenses.

We expect R&D expenses to increase in the remainder of 2022 relative to 2021 as we have added headcount in order to support our efforts to develop more scalable and efficient manufacturing workflows, expand the utility of Saphyr, and develop the next versions of OGM products – including integration of OGM data into our NxClinical software. We expect that stock based compensation will continue to drive a significant portion of the increase in expense in the remainder of 2022 as a result of the stock issued as consideration in the BioDiscovery acquisition, which primarily rolls up into R&D expense.

Selling, General and Administrative Expenses

Selling, general and administrative expenses increased by $10.7 million, or 113%, to $20.3 million for the three months ended March 31, 2022 compared to $9.5 million for the same period in 2021. The increase is primarily due to a $5.8 million increase in compensation expenses, of which $1.5 million relates to stock-based compensation, a $1.3 million increase in amortization of intangibles related to the acquisition of BioDiscovery, a $1.2 million increase in marketing expenses, a $0.8 million increase in software and information technology costs, and a $0.6 million increase in other headcount-related expenses. The increase in compensation expense is driven primarily by a 173% increase in selling, general and administrative headcount. This is due to organic headcount additions to our global sales and back-office teams to support world-wide product distribution, as well as headcount additions attributed to the acquisition of BioDiscovery. We anticipate headcount additions to our global sales and back-office teams in the coming 12 months. Other headcount-related expenses included the cost of recruiting, temporary employment, and facilities expenses incurred in order to support increased product demand.

We expect selling, general, and administrative expenses to increase in the remainder of 2022 due to our continuing investment in growing and supporting our customer base. We expect stock based compensation to continue to drive a significant portion of the increase in expense in the remainder of 2022 due to stock option awards issued to senior-level fourth quarter 2021 hires as well as annual refresher grants issued to executives and non-executives in February 2022.

Interest Expense

Interest expense decreased by $0.5 million, or 87%, to $0.08 million for the three months ended March 31, 2022 compared to $0.6 million for the same period in 2021, driven by us paying off the outstanding principal balance of our outstanding term loan with Innovatus (“Innovatus LSA”). The Innovatus LSA was outstanding for all of the three month period ended March 31, 2021.

Interest Income

Interest income was $0.1 million for the three months ended March 31, 2022, as compared to $65,000 for the same period in 2021 resulting from positive returns on investments. Our total available for sale securities balance was $192.4 million as of March 31, 2022.

Gain on forgiveness of Paycheck Protection Program loan

A gain on forgiveness of our Paycheck Protection Program loan, or PPP Loan, of $1.8 million was recognized during the three months ended March 31, 2021 in connection with the forgiveness of the PPP Loan, including all accrued interest in full.

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 financings. 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. Revenue from our commercial operations has increased due to increased demand for our product offerings and our acquisition of revenue-positive BioDiscovery. See Note 6 to our condensed consolidated financial statements for a discussion of our recent equity activity included elsewhere in this Quarterly Report on Form 10-Q for more information. We incurred net losses of $30.0 million and $9.9 million for the three months ended March 31, 2022 and 2021, respectively. As of March 31, 2022, we had an accumulated deficit of $246.1 million, cash and cash equivalents of $24.0 million, and available for sale investment securities of $192.4 million.

Future Capital Requirements

We expect that our near and longer-term liquidity requirements will consist of working capital and general corporate expenses associated with the growth of our business, including, without limitation, expenses associated with scaling up our operations and continuing to increase our manufacturing capacity, sales and marketing expense, increasing market awareness of our products and services to target customers, instrument placements with customers via the reagent rental sales strategy, additional research and development expenses associated with expanding our offerings, expenses associated with continuing to build out our corporate infrastructure and expenses associated with being a public company. Our short-term capital expenditure needs relate primarily to the ongoing build out of our manufacturing and research facilities, service lab and service-related capabilities, research and development expenses related to current and future product offerings, and enhancements to information technology. We expect such expenditures to continue throughout 2022.

Cash Flows

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

	Three Months Ended March 31,	
	2022	**2021**
Net cash provided by (used in):		
Operating activities	$ (32,494,000)	$ (13,904,000)
Investing activities	31,964,000	(24,000)
Financing activities	7,000	337,536,000

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. We anticipate our use of cash in operating activities to increase in the next 12 to 24 months due to anticipated increases in headcount and ongoing support of our growing operations, including, R&D operations. As discussed below, we anticipate our available cash balance will be sufficient to fund those increases in cash used in operating activities for at least the next 12 months, but we may consider funding those increases or increases beyond the next 12 months with the methods discussed in the section below entitled “Capital Resources.”

Net cash used in operating activities was $32.5 million during the three months ended March 31, 2022 as compared to $13.9 million during the same period in 2021. The increase in cash used in operating activities of $18.6 million was primarily attributed to an incremental headcount growth of 174% compared to our headcount as of March 31, 2021.

Investing Activities

Historically, our primary investing activities have consisted of capital expenditures for the purchase of capital equipment to support our expanding infrastructure, the acquisitions of Lineagen and BioDiscovery to grow our business, and purchases of available for sale investment securities. We expect to continue to incur additional costs for capital expenditures related to these efforts in future periods. During the three months ended March 31, 2022, cash provided by investing activities was $32.0 million for the three months ended March 31, 2022, cash compared to the same period in 2021 where we had a cash outflow of $0.02 million, a net increase of $32.0 million. This increase is primarily attributed to the sale of $47.2 million in available for sale securities.

Financing Activities

Net cash provided by financing activities was $7,000 during the three months ended March 31, 2022 as compared to the same period in 2021 where we had net cash provided by financing activities of $337.5 million, a decrease of $337.5 million. During the three months ended March 31, 2021, we raised approximately $328.6 million in gross proceeds from executing two follow-on offerings and sales under our at-the-market facilities with Landenburg and Cowen. We did not have similar fundraising activity in the three months ended March 31, 2022.

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 March 31, 2022, we had approximately $24.0 million in cash and cash equivalents, available for sale securities of $192.4 million, and working capital of $223.7 million.

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 Market Issuance Sales Agreement, with Ladenburg Thalmann & Co. Inc. acting as sales agent (the "Ladenburg ATM"). During October 2020 through January 2021, we sold 27.0 million shares of common stock under the Ladenburg ATM and received net proceeds of $38.0 million after deducting aggregate offering costs. We terminated the Ladenburg ATM in March 2021.

On January 12, 2021, we completed an underwritten public offering of 33.4 million shares of our common stock, including 4.4 million shares of our 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 $2.87 per share. The gross proceeds to us 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 U.S. Securities and Exchange Commission, or 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 future 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 pursuant to our shelf registration statement of 38.3 million shares of our common stock, including 5.0 million shares of our 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 to us 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 2.3 million 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. There were no sales of common stock under the Cowen ATM from January 1, 2022 to March 31, 2022.

We believe that our cash, cash equivalents, and available for sale securities will be sufficient to fund our planned operations, obligations as they become due and capital investments for at least the next twelve months. This estimate is based on our current business plan. This estimate does not reflect any additional expenditures resulting from potential acquisitions or strategic transactions. We have based these estimates on assumptions that may prove to be wrong, and we could use our available capital resources sooner than we currently expect. See Note 1 to our condensed consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q for more information.

Contingent Consideration

As part of the merger agreement related to the acquisition of BioDiscovery, the Company agreed to pay a milestone payment of $10.0 million in cash contingent on the achievement of a commercial milestone within eighteen months of the acquisition date. The Company determined the fair value of the milestone consideration using a scenario-based technique, as the trigger for payment is event driven. The outcome of the milestone consideration is binary, meaning the milestone is either achieved or not achieved, and the only other variable factor is the timing of when the milestone is achieved. The Company determined it is highly likely that the milestone will be achieved and therefore used a 95% probability factor which is applied to the $10.0 million milestone consideration. Based on these valuation assumptions, the fair value of the milestone consideration was determined to be $9.1 million as of March 31, 2022.

Contractual Obligations

There were no material changes to our contractual obligations from those disclosed in the Company's Annual Report on Form 10-K for the year ended December 31, 2021.

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. These accounting principles require us to make certain estimates, judgments and assumptions that affect the reported amounts of assets and liabilities as of the date of the financial statements, as well as the reported amounts of revenues and expenses during the periods presented. We have discussed the development, selection and disclosure of the accounting estimates with our audit committee. We believe that the estimates, judgments and assumptions are reasonable based upon information available to us at the time that these estimates, judgments and assumptions are made. To the extent there are material differences between these estimates, judgments or assumptions and actual results, our financial statements will be affected. Historically, revisions to our estimates have not resulted in a material change to our financial statements.

During the three months ended March 31, 2022, there have been no changes to our critical accounting policies and estimates as described in our Annual Report on Form 10-K for the fiscal year ended December 31, 2021.

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

We have operations both within the United States and internationally, and we are exposed to market risks in the ordinary course of business. These risks primarily relate to interest rates, foreign currency exchange rates and inflation.

Interest Rate Risk

We had approximately $24.0 million in cash and cash equivalents and $192.4 million in available for sale securities as of March 31, 2022, which include highly liquid, investment grade debt securities. Such interest-bearing instruments are exposed to a certain degree of interest rate risk. The primary objective of our investment activities is to preserve principal while at the same time maximizing yields without significantly increasing risk. We do not enter into investments for trading or speculative purposes and have not used any derivative financial instruments to manage our interest rate risk exposure. To achieve this objective, we invest in highly liquid and high-quality government and other debt securities. To minimize our exposure due to adverse shifts in interest rates, we invest primarily in short-term securities. Due to the short holding period of our investments and the nature of our investments, a hypothetical change of 100 basis points would have approximately a $0.9 million impact on our investments.

Our liabilities for acquisition-related contingent consideration, which is adjusted to fair value each reporting period, is also impacted by changes in interest rates. The risk-free interest rate used to estimate our weighted average cost of capital is a component of the discount rate used to calculate the present value of future cash flows due upon the achievement of certain milestones. As a result, any changes in the underlying risk-free interest rate could result in material changes to the fair value of such liabilities and could materially impact the amount of non-cash expense (or income) recorded each reporting period.

Foreign Currency Exchange Rate Risk

We conduct a portion of our business in currencies other than our U.S. dollar functional currency. These transactions give rise to monetary assets and liabilities that are denominated in currencies other than the U.S. dollar. The value of these monetary assets and liabilities are subject to changes in currency exchange rates from the time the transactions are originated until settlement in cash. Our foreign currency exposures are primarily concentrated in the British Pound, Chinese Renminbi, Euro, and Canadian dollar. Both realized and unrealized gains or losses on the value of these monetary assets and liabilities are included in the determination of net income. We do not currently participate in material foreign exchange hedging activities. As of March 31, 2022 and December 31, 2021, we had minimal assets and liabilities denominated in foreign currencies. We believe a hypothetical 10% change in foreign exchange rates as of March 31, 2022 would not have a material impact on our business, financial condition, or results of operations.

Inflation

The COVID-19 pandemic has contributed to supply chain challenges, which we believe have resulted in inflation headwinds, particularly increased logistical costs and raw material prices. During the three months ended March 31, 2022, we experienced increased costs to secure certain component parts in our products and to produce our products at our contract manufacturers. However we do not believe that inflation has had a material effect on our business, financial condition or results of operations, other than its impact on the general economy, as our cost of revenue for the three months ended March 31, 2022 was not significantly impacted by the cost increases we experienced. If our costs were to become subject to significant inflationary pressures, we may not be able to fully offset such higher costs through price increases. Our inability or failure to do so could harm our business, financial condition or results of operations.

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 March 31, 2022, 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 this assessment, our management has concluded that our disclosures controls and procedures were effective as of March 31, 2022.

Changes in Internal Control over Financial Reporting

Except as described below, there were no changes in our internal control over financial reporting during the quarter ended March 31, 2022 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

On October 2021, we acquired BioDiscovery LLC. We are in the process of integrating the internal controls of the acquired business into our overall system of 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 and our other filings with the SEC before making investment decisions regarding our securities.

- We are an early-commercial-stage company and have a limited commercial history, which may make it difficult to evaluate our current business and predict our future performance;
- 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 makes our future operating results difficult to predict and could cause the market price of our securities to decline substantially;
- 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. As a result, in some cases we have had to delay instrument installations or service-related visits.
- Our future capital needs are uncertain and we may require additional funding in the future to advance the commercialization of Saphyr system, NxClinical software and our other products, technologies, 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;
- Acquisitions, joint ventures and other strategic transactions could disrupt or otherwise harm our business and may cause dilution to our stockholders;

- If our products or technologies fail to achieve and sustain sufficient market acceptance, our revenue will be adversely affected;
- 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, the NxClinical software, our 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 technologies, products and adversely affect our business and operating results;
- If we do not successfully manage the development and launch of new products and technologies, 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 or may decline regardless of our operating performance, 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 on Form 10-K.

Risks related to our financial condition and need for additional capital

We are an early commercial-stage company and have a limited commercial-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, especially when combined with the other risk factors listed in this section, makes predictions about our future success or viability subject to significant uncertainty. In particular, we have significantly increased our headcount through recent acquisitions of other businesses and the expansion of our sales, marketing and research and development teams, which has increased our operating costs in a manner not historically reflected in our consolidated financial statements, and plan to further increase headcount as we expand our operations. Our business model has evolved over time, and combined with our recent acquisitions, this has impacted the composition and concentration of our revenues, which we expect to continue to change with any future acquisitions and further expansion of our operations. These changes, among others, may make it difficult to evaluate our current business, assess our future performance relative to prior performance and accurately predict our future performance. We have encountered in the past, and will continue to encounter in the future, risks and difficulties frequently experienced by early commercial-stage companies, including those associated with scaling up our infrastructure, increasing the size of our organization and integrating acquired businesses. If we do not address these risks successfully, or if our assumptions regarding these risks and uncertainties are incorrect or change over time, our results of operations could differ materially from our expectations and our business, financial condition and results of operations could be materially and adversely affected.

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.*

Since our inception, we have incurred recurring net losses. We incurred net losses of $30.0 million and $9.9 million, and used cash in operations of $32.5 million and $13.9 million for the three months ended March 31, 2022 and 2021, respectively. As of March 31, 2022, we had an accumulated deficit of $246.1 million. We cannot predict if we will be profitable 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 the expansion of our commercial organization, research and development efforts and capital expenditures, among other things. Our recent acquisitions have increased our expenses and we expect that any future acquisitions of businesses, assets, products or technologies will further increase our expenses, which may result in additional losses. We also expect significant increases in our stock-based compensation expense in future periods, reflecting higher stock option valuations as a public company and the issuance of additional equity awards due to increased headcount. In addition, we incur significant legal, accounting and other expenses as a result of being a public company, especially as we no longer qualify as an emerging growth company or a smaller reporting company and are therefore required to comply with additional disclosure and compliance requirements, subject to a transition period. These factors, among others, will make it hard for us to achieve and sustain profitability. We may also incur significant losses in the future for a number of other reasons, many of which are beyond our control, including the level of market acceptance of our products, the introduction of competitive products and technologies, our future product development efforts, our market penetration and our margins, as well as the other risks described below.

Our quarterly and annual operating results and cash flows have fluctuated in the past and might continue to fluctuate, which makes our future operating results difficult to predict and 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 and 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 other periods. 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, alone or together, may cause fluctuations in our quarterly and annual operating results include:

- adoption of our optical genome mapping solutions on our Saphyr system or successor systems;
- the successful integration of our Lineagen and BioDiscovery businesses;
- execution on our commercial and reimbursement strategy involving Lineagen;
- customer demand for current BioDiscovery software solutions, including NxClinical software, and future software solutions developed through BioDiscovery’s platform;
- the timing of customer orders and payments and our ability to recognize revenue;
- the rate of utilization of consumables by our customers;
- reductions in or other difficulties relating to staffing, capacity, shutdowns or slowdowns of laboratories and other institutions in our customer base, as well as other impacts stemming from the COVID-19 pandemic or other similar factors, such as reduced or delayed investment in new technologies or spending on products, technologies or consumables;
- differences in purchasing patterns across our customer base, including potential differences in consumables spending between earlier adopters of our technologies and more recent customers and variances in rates of increase of consumables spending following new technology purchases, some of which may be compounded by impacts of the COVID-19 pandemic;
- our ability to successfully integrate new personnel, technology and other assets that we may acquire into our company;
- the timing of the introduction of new systems, products, technologies, system and product enhancements and services;
- changes in governmental funding of life sciences research and development or other changes that impact budgets, budget cycles or seasonal or other spending patterns of our customers;
- future accounting pronouncements or changes in our accounting policies; and

- the outcome of any current or future litigation or governmental investigations involving us or other third parties with whom we do business.

In addition, a significant portion of our operating expenses are 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. This variability and unpredictability caused by factors such as those described above and elsewhere in this section could also result in our failing to meet the expectations of industry or financial analysts or investors for any period. If our revenue or operating results fall below the expectations of analysts or investors or below any guidance we may provide, or if the guidance we provide is below the expectations of analysts or investors, the price of our securities could decline substantially. Such a stock price decline could occur even when we have met or exceeded any previously publicly stated guidance.

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, technologies and services. As additional products and technologies 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 technologies, 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, technologies 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 system, NxClinical software, and our other products, technologies 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 of cash in order to continue the commercialization of our products and technologies, fund our research and development programs, expand headcount and execute potential strategic transactions. Although we raised $384.7 million of gross proceeds during 2021, we may need to raise additional funding, or we may seek additional capital due to favorable market conditions or strategic considerations, even if we believe we have sufficient funds for our current or future operating plans. Such funding may mean the sale of common or preferred equity or convertible debt securities, entry into one or more credit facilities or another form of third-party funding, or seeking other debt financing. We may also consider raising additional capital in the future to expand our business, to pursue strategic investments, to take advantage of financing opportunities, or for other reasons, including to:

- expand our sales and marketing efforts to further commercialize our products, technologies and services and address competitive developments;
- expand our research and development efforts to improve our existing products, technologies and services and develop and launch new products, technologies and services, particularly if any of our products, technologies 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;
- pursue a regulatory path with the FDA, or a regulatory body outside the United States, to market our existing RUO products or new products utilized for diagnostic purposes;

- lease additional facilities or build-out existing facilities as we continue to grow our employee headcount, inventory and research and development;
- further expand our operations outside the United States;
- enter into collaboration arrangements, if any, or in-license products and technologies;
- acquire or invest in complimentary businesses or assets;
- add operational, financial and management information systems; and
- cover increased costs incurred as a result of continued operation as a public company, including costs resulting from our no longer qualifying as an emerging growth company and a smaller reporting company and becoming a large accelerated filer.

Our future funding requirements will be influenced by many factors, including:

- market acceptance of our products, technologies and services, and the variability in costs to achieve such acceptance;
- the cost and timing of establishing additional sales, marketing and distribution capabilities;
- the cost of our research and development activities;
- our ability to satisfy any outstanding or future debt obligations;
- the success of our existing distribution and marketing arrangements and our ability to enter into additional arrangements in the future;
- the effects of the ongoing military conflict between Russia and Ukraine and the related sanctions imposed against Russia;
- the effects of the COVID-19 pandemic; and
- the effect of competing technological and market developments.

The various ways we could raise additional capital carry potential risks. 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. Any equity or debt securities we issue could provide for rights, preferences, or privileges senior to those of holders of our common stock. 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 technologies and products. We also may have to reduce marketing, customer support or other resources devoted to our products or technologies 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 securities 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 evolving effects of the COVID-19 pandemic and government measures taken in response have had significant impacts, both direct and indirect, on businesses and commerce, as significant reductions in business-related activities have occurred, supply chains have been disrupted, manufacturing and clinical development activities have been curtailed or suspended and enrollment in studies has been limited or made more difficult. Continued remote work policies, quarantines, shelter-in-place and similar government orders, shutdowns or other restrictions on the conduct of business operations related to the effects of the COVID-19 pandemic have materially affected and may continue to materially affect how we, our customers, and our suppliers are operating our businesses.

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. 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, namely in sales and marketing and product delivery, including providing installation and training and customer service, which has and may continue to slow the pace of our commercial strategy. For example, we experienced at various times during the pandemic the inability to visit certain customer sites to support installation or service our OGM systems. In addition, 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 economies and financial markets globally, which may negatively affect demand for our products, technologies 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 have delayed 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, while many of our employees have been vaccinated, we do not know if vaccination will remain effective against further COVID-19 variants such as the Delta and Omicron variants. To the extent our employees are exposed to or become ill with COVID-19, our ability to conduct our operations may be impaired from time to time.

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 securities even after the outbreak of COVID-19 has subsided due to, among other things, unforeseen adverse impacts on us or our third-party manufacturers, vendors and customers. Such a recession could also cause product demand to be reduced, a decrease in corporate capital expenditures, prolonged unemployment, reduction in consumer confidence and similar negative economic conditions.

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 studies involving our tests, negatively affect enrollment in our ongoing or future studies, cause us to make strategic determinations regarding, among other things, the cost and quality of the components and supplies we acquire, and have a material adverse effect on our business, financial condition and results of operations. For example, COVID-19 related disruptions to the global supply chain created challenges in getting sufficient components and raw materials for production of our OGM systems and consumables, as well as resulted, at least in part, in the unfavorable flowcell yields. If the pandemic persists, these disruptions could reoccur or persist.

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, have disrupted our supply chain and affected 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.

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 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.

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. In addition, the Biden administration and Congress have proposed various changes to the U.S. federal tax regime. Certain of these proposals include, among other things, eliminating or modifying some of the provisions enacted in the Tax Act, a significant increase in the corporate income tax rate, a new alternative minimum tax on book income and changes in the taxation of non-U.S. income. While these proposals have not yet been enacted and it is unclear whether these proposals or similar changes will ultimately ever be enacted, the passage of any legislation as a result of these proposals or any other future changes in U.S. tax laws 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. Moreover, should the scale of our international business activities expand, any changes in the U.S. taxation of such activities or any other changes in applicable non-U.S. tax laws could increase our worldwide effective tax rate and harm our future financial position and results of operations.

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, 2021, we have federal and state tax net operating loss carryforwards of $341.1 million and $158.4 million, respectively. The federal tax loss carryforwards include $176.8 million that do not expire, but utilization of such tax loss carryforwards is limited to 80% of our taxable income. The remaining federal tax loss carryforwards of $164.3 million and state tax loss carryforwards begin to expire in 2027 and 2023, respectively, unless previously utilized. As of December 31, 2021, we also have federal and California research credit carryforwards of $6.7 million and $6.1 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 United States 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 United States taxation of such activities could increase our worldwide effective tax rate and harm our future financial position and results of operations.

If our estimates or judgments relating to our critical accounting policies are based on assumptions that change or prove to be incorrect, our results of operation could fall below our publicly announced guidance or the expectations of securities analysts and investors, resulting in a decline in the market price of our securities.

The preparation of financial statements in conformity with generally accepted accounting principles in the United States, or GAAP, requires management to make estimates and assumptions that affect the amounts reported in our financial statements and accompanying notes. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets, liabilities, equity, revenue and expenses that are not readily apparent from other sources. If our assumptions underlying our estimates and judgements relating to our critical accounting policies change or if actual circumstances differ from our

assumptions, estimates or judgements, our operating results may be adversely affected and could fall below our publicly announced guidance or the expectations of securities analysts and investors, resulting in a decline in the market price of our securities.

Risks related to our business operations

Acquisitions, joint ventures and other strategic transactions 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 or assets. 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 or assets 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 or assets;
- disputes with the seller(s) of any acquired companies or assets or litigation resulting from acquired companies or assets;
- 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 or assets;
- difficulties developing and marketing new products, technologies 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 in a dilutive manner, 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. For example, in connection with our acquisition of Lineagen, Inc., or Lineagen, a U.S.-based provider of proprietary molecular diagnostics services for individuals presenting with certain neurodevelopmental disorders, we issued 6.2 million shares of our common stock, and in our acquisition of BioDiscovery, LLC, or BioDiscovery, a U.S.-based software company with solutions for analysis, interpretation and reporting of genomics data, we paid upfront consideration consisting of a combination of approximately $52.3 million in cash and 2.7 million shares of our common stock. In connection with the acquisition of BioDiscovery, we issued an additional 5.0 million shares of our common stock subject to vesting based on continued service of a key employee. The issuances of shares in connection with the Lineagen and BioDiscovery acquisitions resulted in dilution to our existing stockholders, the payment of cash in the BioDiscovery acquisition reduced our cash by approximately $52.3 million and our headcount increased by more than 50 employees as a result of both acquisitions. Accordingly, in addition to transaction costs, these acquisitions have increased our operating expenses, further increasing our net losses. We cannot predict the number, timing or size of any future strategic transactions, or the effect that any such transactions might have on our operating results.

Although we conducted extensive business, financial and legal due diligence in connection with our evaluation of our recent acquisitions, our due diligence investigations may not have identified every matter that could adversely affect our business, operating results and financial condition, and such investigations may have identified matters that, in the opinion of our management based on information available at the time, bore an acceptable level of risk that they, individually or in the aggregate, might or might not adversely affect our business, operating results or financial condition. We may be unable to adequately address the financial, legal and operational risks introduced by our recent acquisitions and may have difficulty developing experience with the industries in which Lineagen and/or BioDiscovery operate. Accordingly, we cannot guarantee that our 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 these recent acquisitions, and any

such benefits we do achieve may not offset our increased costs, resulting in a potential impairment of goodwill or other assets that were acquired. For any future acquisitions, we may similarly be unable to 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.

If our products or technologies 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 and technologies that are recognized and accepted as reliable, enabling and cost-effective. Most of the potential customers for our products and technologies 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 and technologies. 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. The scientific community is comprised of a small number of early adopters and key opinion leaders who significantly influence the rest of the community. Historically, a significant part of our sales and marketing efforts has been directed at demonstrating the advantages of our technology to industry leaders, including those key opinion 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. We also run the risk that researchers may produce publications or presentations with findings that are negative about our technologies or systems, and that such findings may be due to factors outside of our control, which may also slow acceptance and adoption of our systems and adversely affect our ability to increase our revenue.

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 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. In the first half of the fiscal year ended December 31, 2021, we sold approximately 6.3 million shares of common stock through Ladenburg for aggregate gross proceeds of approximately $16.9 million and exhausted our capacity under this sales agreement. In January 2021, we completed two underwritten public offerings pursuant to which we issued an aggregate of approximately 71.7 million shares of our common stock for gross proceeds, before deducting underwriting discounts and commissions and offering expenses, of approximately $331.8 million. In March 2021, we entered into a new at-the-market facility 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, we sold 2.3 million shares of common stock through Cowen for gross proceeds of approximately $13.9 million before deducting offering costs. In addition, we issued shares of our common stock in connection with our recent acquisitions of Lineagen and BioDiscovery. Any future significant sales of our capital stock or strategic transactions in which we use equity as consideration would result in further dilution to our current stockholders. As a result of these issuances, our investors experienced dilution of their ownership interests.

The issuance of shares under awards granted under existing or future employee equity benefit plans may cause immediate and substantial dilution to our existing stockholders.*

In order to provide persons who have a responsibility for our management and/or growth with additional incentive, to increase their proprietary interest in our success, and to support and increase our ability to attract and retain individuals of exceptional talent, we maintain multiple equity incentive plans. The total number of shares of our common stock available for the grant of awards under these plans is 11.9 million, 0.4 million and 0.7 million for our 2018 Equity Incentive Plan, as amended, 2018 Employee Stock Purchase Plan and 2020 Inducement Plan, respectively, subject to adjustment, including pursuant to automatic “evergreen” increases in certain of our plans. As of March 31, 2022, we had outstanding equity awards underlying those plans accounting for 11.2 million underlying shares. We may also adopt one or more additional employee equity benefit plans in the

future. The issuance of shares under an employee equity benefit plan may result in substantial dilution to the interests of other stockholders. For example on February 15, 2022, our Board of Directors granted our executive officers options to purchase an aggregate of 4.3 million shares of our common stock, which represented approximately 1% of our outstanding shares of common stock based on the 289.7 million shares of common stock outstanding as of April 28, 2022. Accordingly, the issuance of shares under current or future employee equity benefit plans will have the effect of further diluting the proportionate equity interest and voting power of holders of our common stock.

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, the NxClinical software, our consumables and our 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 technologies and adversely affect our business and operating results.*

In the near term, we expect that our revenue from sales of our Saphyr system, NxClinical software, 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 and technologies 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;

- scientists' and customers' opinions of the utility of new products, technologies or services
- reductions in or other difficulties relating to staffing, capacity, shutdowns or slowdowns of laboratories and other institutions as well as other impacts stemming from the COVID-19 pandemic;
- differences in budgetary cycles; and
- market acceptance of relatively new technologies, such as ours.

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, including impacts stemming from the COVID-19 pandemic, the ongoing military conflict between Russia and Ukraine and the related sanctions imposed against Russia, 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 technologies and introduce and market new products and technologies successfully.

Our business is dependent on the continued improvement of our existing products and technologies and our development of new products and technologies utilizing our current or other potential future technology. As we introduce new products or technologies or refine, improve or upgrade versions of existing products or technologies, we cannot predict the level of market acceptance or the amount of market share these products or technologies will achieve, if any. We cannot assure you that we will not experience material delays in the introduction of new products or technologies 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 and technologies in industries that are characterized by rapid technological changes, frequent new product and technology introductions and changing industry standards. If we do not develop new products and technologies and product and technology enhancements based on technological innovation on a timely basis, our products and technologies 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 and technologies 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 and technologies that do not lead to significant revenue. For example, we completed the BioDiscovery Acquisition in October 2021 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 technologies and product and technological enhancements, we may incur substantial costs in doing so, and our profitability may suffer.

Our ability to develop new products and technologies 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, technologies 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 and technologies, our financial results could be adversely affected.

We face risks associated with launching new products and technologies. If we encounter development or manufacturing challenges or discover errors during our product or technology development cycle, the launch dates of new products and technologies may be delayed. The expenses or losses associated with unsuccessful product and technology development or launch activities or lack of market acceptance of our new products and technologies 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 products and technologies 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, technologies and services as we develop them. Identifying, engaging and marketing to customers who are unfamiliar with our current products and technologies 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, could 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 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 RUO 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 technologies, and if we are unable to successfully commercialize our products and technologies, our business and operating results will be adversely affected.*

We have limited experience marketing and selling our products and technologies. We currently sell our Saphyr system for RUO, 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 Australia, China, Japan and South Korea.

The future sales of our products and technologies will depend in large part on our ability to effectively market and sell our products and technologies, 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 and technologies, 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 OGM-based instruments. See "Business — Key Agreements" in this Quarterly 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 OGM-based 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 have experienced manufacturing problems or delays that could limit the growth of our revenue or increase our losses.*

We have encountered situations that resulted in delays or shortfalls caused by our outsourced manufacturing suppliers and by other third-party suppliers who manufacture components for our products. We have been negatively impacted by unfavorable flowcell yields in the production cycle. If we are unable to solve for the yield issue, it could lead to lower gross margins in future periods. 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 or technologies could harm our reputation, decrease market acceptance of our products or technologies or expose us to product liability claims.

Our products or technologies may contain undetected errors or defects when first introduced or as new versions or new products or technologies are released. Disruptions affecting the introduction or release of, or other performance problems with, our products or technologies 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 or technologies. 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 or technologies 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 2021 approximately 54% of our product revenue was generated from customers located outside of the United States. 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. For sales made to customers outside of the United States, we may sell our products and services in local currency outside of the United States. As our operations in countries outside of the United States 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 and technologies. Because of the complex and technical nature of our products and technologies 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.

If our information systems or data or those of third parties upon which we rely, are or were compromised, we could experience adverse consequences resulting from such compromise, including but not limited to regulatory investigations or actions; litigation; fines and penalties; disruptions of our business operations; reputational harm; loss of revenue or profits; loss of customers or sales; and other adverse consequences.*

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, disclose, and otherwise process sensitive, proprietary, and confidential information, including intellectual property, trade secrets, financial information, and personal data (including

protected health information). We may rely upon third-party service providers and technologies to operate critical business systems to process confidential and personal data in a variety of contexts, including, without limitation, third-party providers of cloud-based infrastructure, encryption and authentication technology, employee email, content delivery to customers, and other functions. Our ability to monitor these third parties' cybersecurity practices is limited, and these third parties may not have adequate information security measures in place. We may share or receive sensitive data with or from third parties.

Cyberattacks, malicious internet-based activity, and online and offline fraud are prevalent and continue to increase. Moreover, these threats are becoming increasingly difficult to detect, and they come from a variety of sources. In addition to traditional computer "hackers," threat actors, personnel (such as through theft or misuse), sophisticated nation-states, and nation-state-supported actors now engage and are expected to continue to engage in attacks, including without limitation nation-state actors for geopolitical reasons and in conjunction with military conflicts and defense activities. During times of war and other major conflicts, including as a result of the ongoing military conflict between Russia and Ukraine and the related sanctions imposed against Russia, we and the third parties upon which we rely may be vulnerable to a heightened risk of these attacks, including cyber-attacks that could materially disrupt our systems and operations, supply chain, and ability to produce, sell and distribute our goods and services. We and the third parties upon which we rely may be subject to a variety of evolving threats, including but not limited to social-engineering attacks (such as through phishing attacks), malicious code (such as viruses and worms), malware (including as a result of advanced persistent threat intrusions), denial-of-service attacks (such as credential stuffing), personnel misconduct or error, ransomware attacks, supply-chain attacks, software bugs, server malfunctions, software or hardware failures, loss of data or other information technology assets, adware, telecommunications failures, earthquakes, fires, floods, and other similar threats. Ransomware attacks, including those perpetrated by organized criminal threat actors, nation-states, and nation-state supported actors, are becoming increasingly prevalent and severe and can lead to significant interruptions in our operations, loss of data and income, reputational harm, and diversion of funds. Extortion payments may alleviate the negative impact of a ransomware attack, but we may be unwilling or unable to make such payments due to, for example, applicable laws or regulations prohibiting such payments. Similarly, supply chain attacks have increased in frequency and severity, and we cannot guarantee that third parties and infrastructure in our supply chain or our third-party partners' supply chains have not been compromised or that they do not contain exploitable defects or bugs that could result in a breach of or disruption to our information technology systems (including our software) or the third-party information technology systems that support us and our services. The COVID-19 pandemic and our remote workforce also poses increased risks to our information technology systems and data, as more of our personnel work from home, utilizing network connections outside our premises. Future business transactions (such as acquisitions or integrations) could expose us to additional cybersecurity risks and vulnerabilities, as our systems could be negatively affected by vulnerabilities present in acquired or integrated entities' systems and technologies.

Any of the previously identified or similar threats could cause a security incident or other interruption. A security incident or other interruption could result in unauthorized, unlawful, or accidental acquisition, modification, destruction, loss, alteration, encryption, disclosure of, or access to data. A security incident or other interruption could disrupt our ability (and that of third parties upon whom we rely) to provide our products, software and services. We may expend significant resources or modify our business activities in an effort to protect against security incidents. Certain data privacy and security obligations may require us to implement and maintain specific security measures, industry-standard, or reasonable security measures to protect our information technology systems and data.

While we have implemented security measures designed to protect against security incidents, there can be no assurance that these measures will be effective. We may be unable in the future to detect vulnerabilities in our information technology systems (including our software) because such threats and techniques change frequently, are often sophisticated in nature, and may not be detected until after a security incident has occurred. Despite our efforts to identify and remediate vulnerabilities, if any, in our information technology systems (including our software), our efforts may not be successful. Further, we may experience delays in developing and deploying remedial measures designed to address any such identified vulnerabilities.

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

Our contracts may not contain limitations of liability, and even where they do, there can be no assurance that limitations of liability in our contracts are sufficient to protect us from liabilities, damages, or claims related to our data privacy and security obligations. We cannot be sure that our insurance coverage, if any, will be adequate or sufficient to protect us from or to

mitigate liabilities arising out of our privacy and security practices, that such coverage will continue to be available on commercially reasonable terms or at all, or that such coverage will pay future claims.

We are subject to stringent and changing obligations related to data privacy and security. Our actual or perceived failure to comply with such obligations could lead to regulatory investigations or actions; litigation; fines and penalties; disruption of our business operations; reputational harm; loss of revenue or profits; loss of customers or sales; and other adverse business consequences.

In the ordinary course of business, we process personal data (including protected health information) and other sensitive information, including proprietary and confidential business data, trade secrets, and intellectual property. Our data processing activities subject us to numerous data privacy and security obligations, such as various laws, regulations, guidance, industry standards, external and internal privacy and security policies, contracts, and other obligations that govern the processing of personal data by us and on our behalf.

In the United States, federal, state, and local governments have enacted numerous data privacy and security laws, including data breach notification laws, personal data privacy laws, and consumer protection laws. For example, 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 specific requirements relating to the privacy, security, and transmission of individually identifiable health information. 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 clinical laboratories and institutions from which we may obtain customer data, are subject to privacy and security regulations promulgated under HIPAA, as amended by HITECH. Further, 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) under HIPAA.

In the United States, at the state level, the California Consumer Privacy Act of 2018, or the CCPA, imposes obligations on businesses to which it applies. These obligations include, but are not limited to, providing specific disclosures in privacy notices and affording California residents certain rights related to their personal data. The CCPA allows for statutory fines for noncompliance (up to $7,500 per violation). The California Privacy Rights Act of 2020, or the CPRA, which takes effect January 1, 2023, is anticipated to expand the CCPA's obligations on businesses. For example, the CPRA establishes a new California Privacy Protection Agency to implement and enforce relevant laws, which could increase the risk of an enforcement action. Other states have also recently enacted data privacy laws. For example, Virginia passed the Consumer Data Protection Act, and Colorado passed the Colorado Privacy Act, both of which differ from the CPRA and take effect in 2023. If we become subject to new state-level data privacy laws, the risk of enforcement action against us could increase because we may become subject to additional obligations, and the number of individuals or entities that can initiate actions against us may increase (including individuals, via a private right of action, and state actors). Data privacy and security laws have been proposed at the federal, state, and local levels in recent years, which, if passed, could further complicate compliance efforts.

Outside the United States, an increasing number of laws, regulations, and industry standards apply to data privacy and security. For example, the European Union's General Data Protection Regulation ("EU GDPR"), and the United Kingdom's GDPR ("UK GDPR") impose strict requirements for processing the personal data of individuals. For example, under the EU GDPR, government regulators may impose temporary or definitive bans on data processing, as well as fines of up to 20 million euros or 4% of annual global revenue, whichever is greater. Further, individuals may initiate litigation related to our processing of their personal data. In Canada, the Personal Information Protection and Electronic Documents Act ("PIPEDA") and various related provincial laws, as well as Canada's Anti-Spam Legislation ("CASL"), may apply to our operations. In addition, privacy advocates and industry groups have proposed, and may propose in the future, standards with which we are legally or contractually bound to comply.

Certain jurisdictions have enacted data localization laws and cross-border personal data transfer laws. For example, absent appropriate safeguards or other circumstances, the EU GDPR generally restricts the transfer of personal data to countries outside of the EEA, such as the United States, which the European Commission does not consider to provide an adequate level of data privacy and security. The European Commission released a set of "Standard Contractual Clauses" ("SCCs") that are designed to be a valid mechanism by which entities can transfer personal data out of the EEA to jurisdictions that the European Commission has not found to provide an adequate level of protection. Currently, these SCCs are a valid mechanism to transfer personal data outside of the EEA. However, the SCCs require parties that rely on them to comply with additional obligations, such as conducting transfer impact assessments to determine whether additional security measures are necessary to protect personal data. Moreover, due to potential legal challenges, there exists some uncertainty regarding whether the SCCs will remain a valid mechanism for transfers of personal data out of the EEA. Laws in Switzerland and the UK similarly restrict

transfers of personal data outside of those jurisdictions to countries such as the United States that do not provide an adequate level of personal data protection. In addition to European restrictions on cross-border transfers of personal data, other countries, such as China and Brazil, have enacted or are considering similar cross-border personal data transfer laws and local personal data residency laws, any of which could increase the cost and complexity of doing business. If we cannot implement a valid compliance mechanism for cross-border data transfers, we may face increased exposure to regulatory actions, substantial fines, and injunctions against processing or transferring personal data from Europe or elsewhere. The inability to import personal data to the United States could significantly and negatively impact our business operations, including by limiting our ability to collaborate with parties that are subject to European and other data privacy and security laws or by requiring us to increase our personal data processing capabilities and infrastructure in Europe and/or elsewhere at significant expense.

Our data privacy and security obligations are quickly changing, creating some uncertainty as to the effective future legal framework. Additionally, these obligations may be subject to differing applications and interpretations, which may be inconsistent or in conflict among jurisdictions. Preparing for and complying with these obligations requires us to devote significant resources (including, without limitation, financial and time-related resources). These obligations may necessitate changes to our information technologies, systems, and practices and to those of any third parties on which we rely. Although we endeavor to comply with all applicable data privacy and security obligations, we may at times fail (or be perceived to have failed) to do so. Moreover, despite our efforts, our personnel or third parties upon which we rely may fail to comply with such obligations, which could negatively impact our business operations and compliance posture. For example, any failure by a third-party processor to comply with applicable law, regulations, or contractual obligations could result in adverse effects, including inability to operate our business and proceedings against us by governmental entities or others. If we fail, or are perceived to have failed, to address or comply with data privacy and security obligations, we could face significant consequences. These consequences may include, but are not limited to, government enforcement actions (e.g., investigations, fines, penalties, audits, inspections, and similar); litigation (including class-related claims); additional reporting requirements and/or oversight; bans on processing personal data; orders to destroy or not use personal data; and imprisonment of company officials. Any of these events could have a material adverse effect on our reputation, business, or financial condition, including but not limited to, loss of customers; interruptions or stoppages in our business operations; inability to process personal data or to operate in certain jurisdictions; limited ability to develop or commercialize our products; expenditure of time and resources to defend any claim or inquiry; adverse publicity; or revision or restructuring of our operations.

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 PacBio, Oxford Nanopore Technologies, 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 or technologies 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 or technologies 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.

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.

In addition, the conflict between Russia and Ukraine and the related sanctions imposed against Russia could lead to disruption, instability and volatility in global markets and industries that could negatively impact our operations. The U.S. government and other governments in jurisdictions in which we operate have imposed sanctions and export controls against Russia and Russian interests and threatened additional sanctions and controls. The impact of these measures, as well as potential responses to them by Russia, is currently unknown and they could adversely affect our business, supply chain, partners or customers.

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.

If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could have a material adverse effect on the success of our business.

We, and any the third parties with access to our facilities, are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Each of our operations involve the use of hazardous and flammable materials, including chemicals and biological and radioactive materials. Our operations also produce hazardous waste. We generally contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury from these

materials. We could be held liable for any resulting damages in the event of contamination or injury resulting from the use of hazardous materials by us or the third parties with whom we contract, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties. Although we maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials, this insurance may not provide adequate coverage against potential liabilities. We do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us in connection with our storage or disposal of biological, hazardous or radioactive materials. We do not have any insurance for liabilities arising from medical or hazardous materials. In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. Compliance with applicable environmental laws and regulations is expensive, and these current or future laws and regulations may impair our research, development and commercialization efforts, which could harm our business, prospects, financial condition or results of operations. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

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 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 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 United

States, 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 system is for RUO, 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 United States, 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 United States, 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 United States, 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. Based on current law, between January 1, 2023 and March 31, 2023, applicable laboratories will be required to report on data collected during January 1, 2019 and June 30, 2019. This data will be utilized to determine 2024 to 2026 CLFS rates.

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. Congress is considering additional health reform measures. 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, co-payments, 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 data, 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 United States 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 April 30, 2022, we (directly or through our wholly owned subsidiaries Lineagen, Inc and BioDiscovery, LLC) were the assignee of 28 granted U.S. patents or allowed U.S. patent applications and 21 pending U.S. patent applications. We also were the assignee of approximately 97 pending patent applications and granted patents in particular jurisdictions outside the United States. 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, technologies 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 to 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, technologies 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 or technologies 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 in 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 United States may be less willing to protect trade secrets.

In addition, competitors could purchase our products or technologies 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 or technologies 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 or technologies, 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 United States. 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 United States 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 technologies 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 technologies 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, technologies 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, technologies 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 technologies 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, technologies 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, technologies or services, the defendant in such litigation could counterclaim that our patent is invalid and/or unenforceable. In patent litigation in the United States, 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, technologies 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, technologies and services in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States can be less extensive than those in the United States. 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 United States. Consequently, regardless of whether we are able to prevent third parties from practicing our inventions in the United States, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not pursued and obtained patent protection to develop their own products, technologies or services, and further, may export otherwise infringing products or technologies to territories where we have patent protection, but enforcement is not as strong as it is in the United States. These products, technologies or services may compete with our products, technologies 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, technologies 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 or technologies.*

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 United States 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 or technologies, and failure to comply with the terms of the underlying open source software licenses could restrict our ability to sell such products or technologies.

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 has been and may in the future be volatile or may decline regardless of our operating performance, and you could lose all or part of your investment.*

Our stock price has been and may continue to be volatile. The daily closing market price for our common stock has varied significantly in the last 12 months, ranging between a high price of $8.40 on June 7, 2021 and a low price of $1.63 on April 27, 2022 and April 28, 2022. During this time, the price per share of common stock has ranged from an intra-day low of $1.50 per share to an intra-day high of $9.12 per share.

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 risk factors discussed in this section and elsewhere in our Quarterly 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;
- changes in the structure or funding of research at academic and governmental research institutions, as well as pharmaceutical, biotechnology and contract research companies, including changes that would affect their ability to purchase our products, consumables and technologies;
- 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 or our NxClinical software;
- 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, dispositions, 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;
- the failure or discontinuation of any of our product development and research programs;
- actual or anticipated variations in quarterly operating results;
- our cash position;
- our failure to meet the estimates and projections of the investment community and securities analysts or that we may otherwise provide to the public;
- publication of research reports about us or our industries 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;
- data breaches of our company, providers, vendors or customers;
- regulatory or legal developments in the United States and other countries;
- 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;
- natural disasters, infectious diseases, conflict, including the ongoing military conflict between Russia and Ukraine and the related sanctions imposed against Russia, civil unrest, epidemics or pandemics including COVID-19, outbreaks, resurgences or major catastrophic events; and
- other events or factors, many of which are beyond our control.

In addition, the stock market in general, and the market for life science technology companies in particular (including companies in the diagnostic, genomic and biotechnology related sectors), 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. Because of the volatility of our stock price, we may become the target of securities litigation in the future. 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 the Company's common stock of $1.00 per share.

In the past, we have failed to comply with the 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.

Although we have regained compliance with Nasdaq continued listing requirements, 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. We cannot assure you that such an event will not happen and, if it does, that we will be able to regain compliance. 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.

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

If we fail to maintain effective internal control over financial reporting, 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 United States. Effective internal control over financial reporting is necessary for us to provide reliable financial reports in a timely manner. The rules governing the standards that must be met for our management to assess our internal control over financial reporting are complex and require significant documentation, testing and possible remediation.

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 and was therefore considered a material weakness. 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, and as of December 31, 2021, we concluded that as of such date our controls and procedures were effective at a reasonable assurance level due to the implementation of remediation measures that we undertook.

Although we were able to remediate our prior material weakness, we cannot assure you that we will not experience future material weaknesses or that we will be able to successfully remediate any such material weakness in a timely manner or at all. If our independent registered public accounting firm is subsequently 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 SEC or other regulatory authorities and we could be subject to shareholder litigation. 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 control over financial reporting, 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.

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

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. As of June 30, 2021, the market value of our common stock held by non-affiliates exceeded $700.0 million. Consequently, we are a large accelerated filer and ceased to be an emerging growth company effective December 31, 2021. As a result of this transition, we are subject to certain disclosure and compliance requirements that apply to other public companies but did not previously apply to us due to our previous 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, especially as we no longer qualify as an emerging growth company or a smaller reporting company and are therefore required to comply with additional, costly disclosure and compliance requirements, subject to a transition period. 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, technologies 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 March 31, 2022, we have filed registration statements on Form S-8 under the Securities Act registering the issuance of an aggregate of 36,796,518 shares of common stock subject to options or other equity awards issued or reserved for future issuance under our equity incentive plans. We also intend to file future registration statements on Form S-8 under the Securities Act registering the issuance of additional shares of common stock as the number of shares that may be issued under certain employee equity benefit plans automatically increase due to "evergreen" provisions. 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 (2)	Amended and Restated Bylaws.
4.1 (3)	Form of Common Stock Certificate
4.2 (3)	Form of Warrant to Purchase Series D-1 Preferred Stock issued to Midcap Financial Trust.
4.3 (3)	Form of Warrant to Purchase Common Stock Issued to Underwriters.
4.4 (3)	Form of Warrant Certificate (included in Exhibit 4.8).
4.5 (3)	Form of Warrant Agent Agreement by and between the Registrant and American Stock Transfer & Trust Company LLC, as warrant agent.
4.6 (4)	Form of Warrant to Purchase Common Stock for Service Providers.
4.7 (5)	Registration Rights Agreement, dated March 14, 2019, by and among the Company and the Innovatus Investors.
4.8 (6)	Form of Warrant to Purchase Common Stock issued to Investors in October 2019 Public Offering.
4.9 (7)	Form of Warrant to Purchase Common Stock issued to Investors in April 2020 Public Offering.
10.1 (8)	Fifth Amendment to the Lease by and between the Registrant and The Irvine Company, LLC, dated January 12, 2022.
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 Current Report on Form 8-K, filed with the SEC on August 24, 2018.
(3) Incorporated by reference to the Registrant's Registration Statement on Form S-1 (File No. 333-225970), as amended.
(4) Incorporated by reference to the Registrant's Current Report on Form 8-K, filed with the SEC on November 21, 2018.
(5) Incorporated by reference to the Registrant's Current Report on Form 8-K, filed with the SEC on March 14, 2019.
(6) Incorporated by reference to the Registrant's Registration Statement on Form S-1 (File No. 333-233828), as amended.
(7) Incorporated by reference to the Registrant's Registration Statement on Form S-1 (File No. 333-237074), as amended.
(8) Incorporated by reference to the Registrant's Annual Report on Form 10-K, filed with the SEC on March 1, 2022.

* 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: May 5, 2022

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

Dated: May 5, 2022

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

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: May 5, 2022

/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: May 5, 2022

/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 March 31, 2022, 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: May 5, 2022

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

Dated: May 5, 2022

/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.