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

FORM 10-Q

(Mark One)

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

FOR THE QUARTERLY PERIOD ENDED MARCH 31, 2023

☐ **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 May 4, 2023, the registrant had 306,790,214 shares of Common Stock ($0.0001 par value) outstanding.

BIONANO GENOMICS, INC.
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PART I. FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

BIONANO GENOMICS, INC.
Condensed Consolidated Balance Sheets

	(Unaudited) March 31, 2023	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	$ 4,104,000	$ 5,091,000
Investments	91,704,000	108,095,000
Accounts receivable, net	6,780,000	7,022,000
Inventory	33,113,000	29,761,000
Prepaid expenses and other current assets	6,856,000	7,329,000
Total current assets	142,557,000	157,298,000
Restricted cash	400,000	400,000
Property and equipment, net	19,050,000	18,029,000
Operating lease right-of-use assets	7,062,000	7,222,000
Finance lease right-of-use assets	3,657,000	3,707,000
Intangible assets, net	39,351,000	41,143,000
Goodwill	77,289,000	77,289,000
Other long-term assets	2,785,000	2,414,000
Total assets	$ 292,151,000	$ 307,502,000
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 15,780,000	$ 12,534,000
Accrued expenses	9,250,000	10,552,000
Contract liabilities	1,127,000	871,000
Operating lease liability	2,235,000	2,260,000
Finance lease liability	282,000	285,000
Contingent consideration	9,461,000	9,382,000
Total current liabilities	38,135,000	35,884,000
Operating lease liability, net of current portion	5,043,000	5,504,000
Finance lease liability, net of current portion	3,612,000	3,619,000
Contingent consideration, net of current portion	13,680,000	12,970,000
Long-term contract liabilities	194,000	127,000
Total liabilities	$ 60,664,000	$ 58,104,000
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, 2023 and December 31, 2022	—	—
Common stock, $0.0001 par value, 400,000,000 shares authorized at March 31, 2023 and December 31, 2022; 306,790,000 and 297,183,000 shares issued and outstanding at March 31, 2023 and December 31, 2022, respectively	31,000	30,000
Additional paid-in capital	617,960,000	599,207,000
Accumulated deficit	(385,839,000)	(348,715,000)
Accumulated other comprehensive loss	(665,000)	(1,124,000)
Total stockholders' equity	$ 231,487,000	$ 249,398,000
Total liabilities and stockholders' equity	$ 292,151,000	$ 307,502,000

See accompanying notes to the unaudited condensed consolidated financial statements

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

	Three Months Ended March 31,	
	2023	**2022**
Revenue:		
Product revenue	$ 5,447,000	$ 4,206,000
Service and other revenue	1,968,000	1,490,000
Total revenue	7,415,000	5,696,000
Cost of revenue:		
Cost of product revenue	3,858,000	3,576,000
Cost of service and other revenue	1,487,000	1,259,000
Total cost of revenue	5,345,000	4,835,000
Operating expenses:		
Research and development	13,937,000	10,527,000
Selling, general and administrative	25,976,000	20,277,000
Total operating expenses	39,913,000	30,804,000
Loss from operations	(37,843,000)	(29,943,000)
Other income (expense):		
Interest income	704,000	110,000
Interest expense	(76,000)	(77,000)
Other income (expense)	117,000	(33,000)
Total other income (expense)	745,000	—
Loss before income taxes	(37,098,000)	(29,943,000)
Benefit (provision) for income taxes	(26,000)	(9,000)
Net loss	$ (37,124,000)	$ (29,952,000)
Net loss per share, basic and diluted	$ (0.12)	$ (0.11)
Weighted-average common shares outstanding basic and diluted	302,045,000	284,613,000

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,	
	2023	2022
Net loss:	$ (37,124,000)	$ (29,952,000)
Other comprehensive income (loss):		
Unrealized gain (loss) on investment securities	423,000	(1,098,000)
Foreign currency translation adjustments	36,000	—
Other comprehensive income (loss)	$ 459,000	$ (1,098,000)
Total comprehensive loss	$ (36,665,000)	$ (31,050,000)

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, 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
Balance at January 1, 2023	297,183,000	$ 30,000	$ 599,207,000	$ (348,715,000)	$ (1,124,000)	$ 249,398,000
Stock option exercises	42,000	—	23,000	—	—	23,000
Stock-based compensation expense	—	—	3,882,000	—	—	3,882,000
Issue common stock, net of issuance costs	9,500,000	1,000	14,848,000	—	—	14,849,000
Issuance of common stock due to the vesting of restricted stock units, net of shares withheld to cover taxes	65,000	—	—	—	—	—
Net loss	—	—	—	(37,124,000)	—	(37,124,000)
Other comprehensive income (loss)	—	—	—	—	459,000	459,000
Balance at March 31, 2023	306,790,000	$ 31,000	$ 617,960,000	$ (385,839,000)	$ (665,000)	$ 231,487,000

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,	
	2023	**2022**
Operating activities:		
Net loss	$ (37,124,000)	$ (29,952,000)
Adjustments to reconcile net loss to net cash used by operating activities:		
Depreciation and amortization expense	3,190,000	2,210,000
Amortization of financing lease right-of-use asset	51,000	29,000
Amortization (accretion) of interest on securities	(82,000)	299,000
Non-cash lease expense	113,000	299,000
Net realized loss (gain) on investments	7,000	—
Stock-based compensation	3,882,000	5,102,000
Change in fair value of contingent consideration	789,000	79,000
Cost of leased equipment sold to customer	88,000	—
Changes in operating assets and liabilities:		
Accounts receivable	242,000	(640,000)
Inventory	(5,707,000)	(5,938,000)
Prepaid expenses and other current assets	471,000	(323,000)
Other assets	(372,000)	(48,000)
Accounts payable	3,017,000	(3,168,000)
Accrued expenses and contract liabilities	(978,000)	(443,000)
Net cash used in operating activities	(32,413,000)	(32,494,000)
Investing Activities:		
BioDiscovery acquisition, return of purchase consideration from escrow	—	694,000
Purchases of property and equipment	(360,000)	(150,000)
Purchase of available for sale securities	—	(14,954,000)
Sale and maturity of available for sale securities	16,888,000	47,179,000
Construction in progress	—	(832,000)
Sale of property and equipment	—	27,000
Net cash provided by investing activities	16,528,000	31,964,000
Financing activities:		
Principal payments on financing lease liability	(10,000)	(8,000)
Proceeds from sale of common stock	15,229,000	—
Offering expenses on sale of common stock	(380,000)	—
Proceeds from warrant and option exercises	23,000	15,000
Net cash provided by financing activities	14,862,000	7,000
Effect of exchange rates on cash, cash equivalents and restricted cash	36,000	—
Net decrease in cash, cash equivalents and restricted cash	(987,000)	(523,000)
Cash, cash equivalents and restricted cash at beginning of period	5,491,000	24,571,000
Cash, cash equivalents and restricted cash at end of period	$ 4,504,000	$ 24,048,000
Reconciliation of cash, cash equivalents and restricted cash reported within the unaudited condensed consolidated balance sheets to the total amounts reported on the unaudited condensed consolidated statements of cash flows		
Cash and cash equivalents	4,104,000	24,048,000
Restricted cash	400,000	—
Total cash, cash equivalents and restricted cash at end of period	4,504,000	24,048,000
Supplemental cash flow disclosures:		
Cash paid for interest	$ 76,000	$ 70,000
Cash paid for operating lease liabilities	$ 644,000	$ 217,000

Supplemental disclosure of non-cash investing and financing activities:				
Transfer of instruments and servers from property and equipment into inventory	$	—	$	544,000
Transfer of instruments and servers from inventory to property and equipment, net	$	2,356,000	$	2,056,000
Property and equipment included in accounts payable	$	230,000	$	—
Operating lease liabilities resulting from obtaining right-of-use assets	$	—	$	513,000

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 offers optical genome mapping ("OGM") solutions for applications across basic, translational and clinical research, and for other applications including bioprocessing. Through its Lineagen, Inc. (doing business as Bionano Laboratories, "Bionano Laboratories") 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 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. Through our Purigen Biosystems Inc. ("Purigen") business, we offer nucleic acid extraction and purification solutions using proprietary isotachophoresis ("ITP") technology.

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. The operating results presented in these unaudited interim condensed financial statements are not necessarily indicative of the results that may be expected for any future periods. These interim unaudited 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, 2022.

Reclassifications

Certain amounts reported in prior years have been reclassified to conform with the presentation in the current year. These reclassifications had no effect on the reported results of operations.

Liquidity and Going Concern

The Company has experienced recurring net losses from operations, negative cash flows from operating activities, and accumulated deficit since its inception and expects to continue to incur net losses into the foreseeable future. As of March 31, 2023, the Company had approximately $4.1 million in cash and cash equivalents, $91.7 million in short term investments, and working capital of $104.4 million.

The Company has an accumulated deficit of $385.8 million as of March 31, 2023. During the three months ended March 31, 2023, the Company used $32.4 million cash in operations.

Management expects operating losses and negative cash flows to continue for at least the next year as the Company continues to incur costs related to research and commercialization efforts. Management has prepared cash flows forecasts which indicate that based on the Company's expected operating losses and negative cash flows, there is substantial doubt about the Company's ability to continue as a going concern within twelve months after the date that the unaudited condensed consolidated financial statements for the three months ended March 31, 2023, are issued. Management's ability to continue as a going concern is dependent upon its ability to raise additional funding. Management's plans to raise additional capital to fulfill its operating and

capital requirements for at least 12 months include public or private equity or debt financings. However, the Company may not be able to secure such financing in a timely manner or on favorable terms, if at all.

Furthermore, if the Company issues equity securities to raise additional funds, its existing stockholders may experience dilution, and the new equity securities may have rights, preferences and privileges senior to those of the Company's existing stockholders.

The unaudited condensed consolidated financial statements have been prepared on a going concern basis, which contemplates the realization of assets and settlement of liabilities in the normal course of business, and do not include any adjustments to reflect the outcome of this uncertainty.

Significant Accounting Policies

During the three months ended March 31, 2023, 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, 2022.

Recently Adopted Accounting Pronouncements

In February 2016, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("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. For trade receivables and other instruments, entities will be required to use a new forward-looking expected loss model that generally will result in the earlier recognition of allowances for losses. For available-for-sale debt securities with unrealized losses, the losses will be recognized as allowances rather than as reductions in the amortized cost of the securities. The Company adopted ASU 2016-13 as of January 1, 2023.

The cumulative effect of applying the new credit loss standard was not material and, therefore, did not result in an adjustment to retained earnings. The adoption of this standard did not have a material impact on the Company's consolidated financial statements or related financial statement disclosures. In accordance with ASU 2016-13, the Company no longer evaluates whether its available-for-sale debt securities in an unrealized loss position are other than temporarily impaired. Instead, the Company assesses whether such unrealized loss positions are credit-related. The credit-related portion of unrealized losses, and any subsequent improvements, are recorded in other income through an allowance account. Unrealized gains and losses that are not credit-related are included in accumulated other comprehensive income.

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. The Company's potentially dilutive securities which include outstanding warrants to purchase stock, restricted stock units ("RSUs"), performance stock units ("PSUs"), 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 because all potentially dilutive securities were anti-dilutive.

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, 2023	March 31, 2022
Stock options	32,013,000	21,531,000
Unvested restricted stock	—	4,257,000
Warrants	4,356,000	4,356,000
RSUs	2,457,000	296,000
PSUs	290,000	290,000
Total	39,116,000	30,730,000

3. Revenue Recognition

Revenue by Source

	Three Months Ended March 31,	
	2023	2022
Instruments	$ 1,896,000	$ 1,596,000
Consumables	2,235,000	1,520,000
Software	1,316,000	1,090,000
Total product revenue	5,447,000	4,206,000
Service and other	1,968,000	1,490,000
Total revenue	$ 7,415,000	$ 5,696,000

The Company has revised the classification of its revenue between the categories in the table above for the March 31, 2022 statement of operations. In the March 31, 2022 statement of operations, “software” was included in “service and other.”

Revenue by Geographic Location

	Three Months Ended March 31,			
	2023		2022	
	$	%	$	%
Americas	$ 3,444,000	47 %	$ 3,328,000	58 %
EMEA	2,992,000	40 %	1,739,000	31 %
Asia Pacific	979,000	13 %	629,000	11 %
Total	$ 7,415,000	100 %	$ 5,696,000	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. EMEA consists of Europe, the Middle East, and Africa. Asia Pacific includes China, Japan, South Korea, Singapore, India and Australia. During the three months ended September 30, 2022, the Company changed the presentation of its revenues from India to be included in the Asia Pacific geographic region. Prior to the three months ended September 30, 2022, the Company had presented revenues from India in the EMEA geographic region. The impact of this change on prior period disclosures is immaterial.

For the three months ended March 31, 2023 and 2022, the United States represented 41.2% and 45.0% of total revenue, respectively. No other countries represented greater than 10% of revenue during the three months ended March 31, 2023 and 2022.

Remaining Performance Obligations

As of March 31, 2023, the estimated revenue expected to be recognized in the future related to performance obligations that are unsatisfied was approximately $1.3 million. These remaining performance obligations primarily relate to extended warranty and support and maintenance obligations. The Company expects to recognize approximately 74.9% of this amount as revenue during the remainder of 2023, 20.5% in 2024, and 4.6% in 2025 and thereafter. Warranty revenue is included in service and other revenue.

The Company recognized revenue of approximately $0.7 million and $0.3 million during the three months ended March 31, 2023 and 2022, respectively, which was included in the contract liability balance at the end of the previous year.

4. Balance Sheet Account Details

Accounts Receivable and Allowance for Credit Losses

	March 31, 2023	December 31, 2022
Accounts receivable, net:		
Accounts receivable, trade	$ 7,030,000	$ 7,315,000
Allowance for credit losses	(250,000)	(293,000)
	$ 6,780,000	$ 7,022,000

Changes to the allowance for credit losses during the three months ended March 31, 2023 were as follows:

	Allowance for Credit Losses
Balance as of January 1, 2023	$ (293,000)
Provision for expected credit loss	(5,000)
Write-offs and payments	48,000
Balance as of March 31, 2023	$ (250,000)

The Company's adoption of ASU No. 2016-13, Financial Instruments - Credit Losses, included an assessment of our aged trade receivables balances and their underlying credit risk characteristics. Our evaluation of past events, current conditions, and reasonable and supportable forecasts about the future resulted in an expectation of immaterial credit losses.

Inventory

The components of inventories are as follows:

	March 31, 2023	December 31, 2022
Inventory:		
Raw materials	$ 5,800,000	$ 5,319,000
Work in process	10,003,000	7,055,000
Finished goods	17,310,000	17,387,000
	$ 33,113,000	$ 29,761,000

Intangible Assets

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

	March 31, 2023			December 31, 2022		
	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount
Trade name	$ 2,630,000	$ (684,000)	$ 1,946,000	$ 2,630,000	$ (552,000)	$ 2,078,000
Customer relationships	4,150,000	(1,379,000)	2,771,000	4,150,000	(1,172,000)	2,978,000
Developed technology	41,600,000	(7,068,000)	34,532,000	41,600,000	(5,615,000)	35,985,000
Intangibles, net	$ 48,380,000	$ (9,131,000)	$ 39,249,000	$ 48,380,000	$ (7,339,000)	$ 41,041,000

Intangible assets not subject to amortization totaled $0.1 million at March 31, 2023 and December 31, 2022, and related to the Company's domain name.

Accrued Expenses

Accrued expenses consist of the following:

	March 31, 2023	December 31, 2022
Compensation expenses	$ 6,349,000	$ 7,002,000
Customer deposits	17,000	17,000
Taxes payable	848,000	825,000
Insurance	326,000	613,000
Professional fees and royalties	96,000	210,000
Warranty liabilities	591,000	489,000
Accrued clinical study fees	174,000	250,000
Other	849,000	1,146,000
Total	$ 9,250,000	$ 10,552,000

5. Stockholders' Equity and Stock-Based Compensation

Cowen At-the-Market Facility

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, which was amended on March 9, 2023 to decrease the maximum aggregate offering price to $200.0 million for sales made on and after the date of the amendment (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 2022, the Company sold approximately 6.6 million shares of common stock under the Cowen ATM at an average share price of $3.46 per share, and received gross proceeds of approximately $23.1 million before deducting offering costs of $0.6 million. During the first quarter of 2023, the Company sold approximately 9.5 million shares of common stock under the Cowen ATM at an average share price of $1.60 per share, and received gross proceeds of approximately $15.2 million before deducting offering costs of $0.4 million.

Stock Warrants

A summary of the Company's warrant activity during the three months ended March 31, 2023 was as follows:

	Shares of Stock under Warrants	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term	Aggregate Intrinsic Value
Outstanding at January 1, 2023	4,356,000	$ 5.96	0.76	$ 273,000
Granted	—	—	—	—
Exercised	—	—	—	—
Canceled	—	—	—	—
Outstanding at March 31, 2023	4,356,000	$ 5.96	0.52	$ 156,000

Stock Options

A summary of the Company's stock option activity during the three months ended March 31, 2023 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, 2023	24,022,000	$ 3.28	8.50	$ 2,068,000
Granted	9,121,000	1.60	—	
Exercised	(42,000)	0.55	—	25,000
Canceled	(1,088,000)	3.37	—	
Outstanding at March 31, 2023	32,013,000	$ 2.80	8.84	$ 1,147,000
Vested and exercisable at March 31, 2023	9,149,000	$ 3.56	7.89	$ 892,000

For the three months ended March 31, 2023, the weighted-average grant date fair value of stock options granted was $1.07 per share.

Stock-Based Compensation

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

	Three Months Ended March 31,	
	2023	2022
Cost of product revenue	$ 102,000	$ —
Cost of service and other revenue	44,000	—
Research and development	1,357,000	3,328,000
General and administrative	2,379,000	1,774,000
Total stock-based compensation expense	$ 3,882,000	$ 5,102,000

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,	
	2023	2022
Risk-free interest rate	4.0 %	1.9 %
Expected volatility	72.7 %	70.1 %
Expected term (in years)	6.0	6.0
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 was scheduled to vest on October 18, 2022 and one-twelfth of the Restricted Shares was scheduled to vest every three months following October 18, 2022, subject to continuous service of the key employee. The fair value of the restricted stock award was based on the market value of common stock as of the date of grant and was amortized to stock-based compensation expense over the service period.

On October 4, 2022, the restricted stock award was modified due to the change in employment status of the key employee from full time to emeritus. As a result of the modification, the restricted stock award vested in full on October 4, 2022. The award was revalued on the modification date, resulting in a modified grant date fair value of $2.04 a share ($15.8 million less than the initial grant date fair value of the award). The fair value of the modified restricted stock award was based on the market value of common stock as of the modification date.

Restricted Stock Units and Performance Stock Units

The following table summarizes RSU activity during the three months ended March 31, 2023:

	Stock Units	Weighted-Average Grant Date Fair Value per Share
Outstanding at January 1, 2023	96,000	$ 4.74
Granted	2,461,000	1.63
Released	(65,000)	4.74
Forfeited	(35,000)	1.63
Outstanding at March 31, 2023	2,457,000	$ 1.67

The total intrinsic value of the RSUs that vested during the three months ended March 31, 2023 was $0.3 million, determined as of the date of vesting. The weighted average remaining contractual term for the RSUs is 3.5 years as of March 31, 2023.

The following table summarizes PSU activity during the three months ended March 31, 2023:

	Stock Units	Weighted-Average Grant Date Fair Value per Share
Outstanding at January 1, 2023	290,000	$ 4.74
Granted	—	—
Released	—	—
Forfeited	—	—
Outstanding at March 31, 2023	290,000	$ 4.74

The weighted average remaining contractual term for the PSUs is 2.1 years as of March 31, 2023.

Executive Option Grants and RSUs

On February 15, 2023, the compensation committee of the Company’s board of directors granted various executive officers stock options to purchase an aggregate of 3.3 million shares of common stock at an exercise price of $1.63 per share, and RSUs amounting to 0.7 million shares of common stock at a grant date fair value of $1.63 per share, in each case with an effective grant date and vesting commencement date of February 15, 2023 (the “Grant Date”). These stock option grants and RSUs were issued from the 2018 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. The RSUs shall vest annually over four years beginning one year after the Grant Date, and the balance of the shares vest in a series of three successive equal annual installments measured from the first anniversary of the Grant Date, such that the RSU shall be fully vested on the four-year anniversary of the Grant Date.

Series A Preferred Stock

On April 13, 2023, the Company entered into an agreement with David Barker, the Chair of the Company's board of directors, pursuant to which the Company agreed to issue and sell one share of the Company's Series A Preferred Stock, par value $0.0001 per share for a purchase price of $100.00. The closing of the sale and purchase of the share of Series A Preferred was completed on April 13, 2023.

The share of Series A Preferred will have 3.0 billion votes, but has the right to vote only on a proposal submitted to the stockholders of the Company to adopt an amendment, or a series of alternate amendments, to the Company's Amended and Restated Certificate of Incorporation, as amended, to combine the outstanding shares of Common Stock into a smaller number of shares of Common Stock at a ratio specified in or determined in accordance with the terms of such amendment or series of alternate amendments ("Reverse Stock Split Proposal"), and will have no voting rights (i) except with respect to a Reverse Stock Split Proposal and the votes of the share of Series A Preferred are required to be cast for and against such Reverse Stock Split Proposal in the same proportion as shares of Common Stock are voted for and against such Reverse Stock Split Proposal (with any shares of Common Stock that are not voted, whether due to abstentions, broker non-votes or otherwise not counted as votes for or against a Reverse Stock Split Proposal) and (ii) unless the holders of one-third (1/3rd) of the outstanding shares of Common Stock are present and vote, in person or by proxy, at the meeting of stockholders at which a Reverse Stock Split Proposal is submitted for stockholder approval (or any adjournment thereof). The share of Series A Preferred will vote together with the Common Stock as a single class on a Reverse Stock Split Proposal. The Series A Preferred has no other voting rights, except as may be required by the General Corporation Law of the State of Delaware. The outstanding share of Series A Preferred will be redeemed in whole, but not in part, for a redemption price of $100.00, payable out of funds lawfully available therefor, (i) if such redemption is ordered by the Company's Board of Directors in its sole discretion, automatically and effective on such time and date specified by the Board of Directors in its sole discretion, or (ii) automatically immediately following the approval by the stockholders of a Reverse Stock Split Proposal.

6. Commitments and Contingencies

The Company has entered into various operating lease agreements and a finance lease agreement, primarily relating to our office, laboratory, and manufacturing space. See Note 11 – Commitments and Contingencies, subsection titled "Leases", in Part II, Item 8 of the Annual Report on Form 10-K for the year ended December 31, 2022 for information regarding the Company's lease agreements.

The future minimum payments under non-cancellable operating and finance leases as of March 31, 2023, are as follows:

	Operating Leases	Finance Lease
Remainder of 2023	$ 1,942,000	$ 242,000
2024	2,684,000	330,000
2025	2,788,000	338,000
2026	729,000	347,000
2027	255,000	356,000
Thereafter	—	5,594,000
Total future lease payments	8,398,000	7,207,000
Less: imputed interest	(1,120,000)	(3,313,000)
Total lease liabilities	$ 7,278,000	$ 3,894,000

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 unaudited condensed consolidated financial statements. An estimated loss contingency is accrued in the unaudited condensed consolidated 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 8 to our unaudited condensed consolidated financial statements for a discussion of the contingent consideration liability.

7. Acquisitions

Purigen Acquisition

In November 2022, the Company completed the acquisition of Purigen Biosystems, Inc. for approximately $32.0 million in cash and up to an aggregate of $32.0 million in cash payable based on the achievement of certain milestones. Cash of $1.2 million will be held in an escrow fund for purposes of satisfying any post-closing purchase price adjustments and indemnification claims under the Purigen Merger Agreement.

The purchase price allocation for the acquisition of Purigen 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. Per the terms of the Purigen Merger Agreement, the purchase price is still subject to adjustment for the final determination of cash, unpaid indebtedness, unpaid transaction expenses and working capital, as well for deferred and current tax assets and liabilities.

The following is the estimated purchase price for the acquisition of Purigen:

Cash	$	32,034,000
Estimated fair value of milestone consideration		12,970,000
Estimated return of cash to buyer from escrow		(90,000)
Total estimated purchase price	$	44,914,000

The total estimated purchase price was allocated to Purigen'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 & cash equivalents	$	290,000
Accounts receivable		259,000
Inventory		944,000
Prepaid expenses and other current assets		184,000
Property and equipment, net		805,000
Restricted cash		400,000
Operating lease right-of-use assets		1,636,000
Other long-term assets		533,000
Intangible assets		20,000,000
Goodwill		22,651,000
Accounts payable and other accrued liabilities		(1,152,000)
Operating lease liability (short-term and long-term)		(1,636,000)
Net assets acquired	$	44,914,000

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

Developed technology	$	18,800,000
Customer relationships		200,000
Tradename		1,000,000
Fair value of identifiable intangible assets	$	20,000,000

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 customer relationships and trade name intangibles are being amortized on a straight-line basis over their estimated useful lives of 5 years. The developed technology intangible is being amortized on a straight-line basis over its estimated useful live of 15 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 Purigen's operations with its existing operations during the fourth quarter of 2022, it is not practical or meaningful to distinguish Purigen'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 Purigen 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 Purigen 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 acquisition had taken place as of January 1, 2021.

	Three Months Ended March 31, 2022
Revenue	$ 6,220,000
Net loss	(32,048,000)
Basic and diluted net loss per share	$ (0.11)

8. 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, 2023 and December 31, 2022:

	March 31, 2023			
		Fair Value Measurement Category		
	Total Fair Value and Carrying Value on Balance Sheet	Level 1	Level 2	Level 3
Assets:				
Commercial paper	$ 15,216,000	$ —	$ 15,216,000	$ —
Corporate notes/bonds	74,500,000	—	74,500,000	—
Securities of government sponsored entities	1,988,000	—	1,988,000	—
Total investments:	$ 91,704,000	$ —	$ 91,704,000	$ —
Money market funds	$ 252,000	$ 252,000	$ —	$ —
Liabilities:				
Contingent consideration	$ 23,141,000	$ —	$ —	$ 23,141,000

	December 31, 2022			
		Fair Value Measurement Category		
	Total Fair Value and Carrying Value on Balance Sheet	Level 1	Level 2	Level 3
Assets:				
Commercial paper	$ 20,020,000	$ —	$ 20,020,000	$ —
Corporate notes/bonds	86,094,000	—	86,094,000	—
Securities of government sponsored entities	1,981,000		1,981,000	
Total investments:	$ 108,095,000	$ —	$ 108,095,000	$ —
Money market funds	$ 1,868,000	$ 1,868,000	$ —	$ —
Liabilities:				
Contingent consideration	$ 22,352,000	$ —	$ —	$ 22,352,000

Money Market Funds are classified as cash equivalents on the unaudited condensed consolidated balance sheet.

Contingent Consideration

Contingent consideration relates to the acquisitions of BioDiscovery and Purigen. The outcome of the milestone consideration for all contingent consideration liabilities is binary, meaning the milestones are either achieved or not achieved, and the only other variable factor is the timing of when the milestones are achieved. The fair value measurement of the contingent consideration liabilities is based on significant inputs not observed in the market (Level 3 inputs). These unobservable inputs represent a Level 3 measurement because they are supported by little or no market activity and reflect the Company's assumptions in measuring fair value.

The fair value of the BioDiscovery contingent consideration liability is reassessed on a quarterly basis using a probability weighted model. Assumptions used to estimate the acquisition date fair value of the contingent consideration related to the acquisition of BioDiscovery include the probability of achieving, or changes in timing, of certain milestones, and a discount rate. As of March 31, 2023 a discount rate of 3% was used. The Company determined the fair value of the BioDiscovery milestone consideration using a scenario-based technique, as the trigger for payment is event driven. The Company determined it is highly likely that the milestone related to the BioDiscovery acquisition 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 months ended March 31, 2023 was due to the passage of time.

Contingent consideration liabilities related to the Purigen milestones are related to the achievement of two independent milestones with aggregate possible milestone payments totaling $32.0 million.

The fair value of the Purigen milestones are reassessed on a quarterly basis using a probability weighted model and a Monte Carlo Simulation. Assumptions used to estimate the acquisition date fair value of the milestones using a probability weighted model include the probability of achieving, or changes in timing, of independent milestones, and a discount rate of 15%. The Company determined the fair value of this milestone consideration using a scenario-based technique, as the trigger for payment is event driven. The Company determined the likelihood of each independent milestone and used probability factors ranging from 20% to 80% which were applied to the individual payments. A Monte Carlo Simulation was performed to determine the likelihood that the milestone will be achieved and was applied to the milestone consideration payment.

Changes in estimated fair value of contingent consideration liability in the three months ended March 31, 2023 is as follows:

	Contingent Consideration Liability (Level 3 Measurement)
Balance as of January 1, 2023	$ 22,352,000
Liability recorded as a result of current period acquisition	—
Change in estimated fair value, recorded in selling, general and administrative expenses	789,000
Cash payments	—
Balance as of March 31, 2023	$ 23,141,000

Available for Sale Investments

The Company invests its excess cash in U.S. Treasury and agency securities, corporate debt securities, and commercial paper, which are classified as available-for-sale investments. These investments are carried at fair value and are included in the tables below. The Company records an allowance for credit losses when unrealized losses are due to credit-related factors. At each reporting date, the Company evaluates securities with unrealized losses to determine whether such losses, if any, are due to credit-related factors. The Company evaluates, among others, whether the Company has the intention to sell any of these investments and whether it is not more likely than not that the Company will be required to sell any of them before recovery of the amortized cost basis. Neither of these criteria were met in any period presented. The credit ratings of the securities held remain of the highest quality. Moreover, the Company continues to receive payments of interest and principal as they become due, and our expectation is that those payments will continue to be received timely. Based on this evaluation, as of March 31, 2023 and December 31, 2022, the Company determined that unrealized losses of the below securities were primarily attributable to changes in interest rates and non-credit related factors. As such, no allowances for credit losses were recorded during these periods.

As of March 31, 2023 and December 31, 2022, the Company held 17 and 16 securities, respectively, which have been in an unrealized loss position for a period of less than 12 months. As of March 31, 2023 and December 31, 2022, the Company held 19 and 24 securities, respectively, which have been in an unrealized loss position for a period of greater than 12 months.

Realized gains and losses are calculated using the specific identification method and recorded in other income (expense) in the Company's unaudited condensed consolidated statements of operations and comprehensive loss. The Company has the ability, if necessary, to liquidate any of its cash equivalents and marketable securities to meet its liquidity needs in the next 12 months.

Interest receivable as of March 31, 2023 and December 31, 2022 was $0.6 million and $0.5 million, respectively, and is recorded as a component of prepaid expenses and other current assets on the unaudited condensed consolidated balance sheets.

As of March 31, 2023, the following table summarizes the amortized cost and the unrealized gains/losses of the available for sale securities:

	Remaining Contractual Maturity (in years)	Amortized Cost	Unrealized Gains	Unrealized Losses	Aggregate Estimated Fair Value
Commercial paper	Less than 1	$ 15,259,000	$ —	$ (43,000)	$ 15,216,000
Corporate notes/bonds	Less than 1	68,739,000	—	(561,000)	68,178,000
Securities of government sponsored entities	Less than 1	1,998,000	—	(10,000)	1,988,000
Total maturity less than 1 year		$ 85,996,000	$ —	$ (614,000)	$ 85,382,000
Corporate notes/bonds	1 to 5	6,372,000	—	(50,000)	6,322,000
Total		$ 92,368,000	$ —	$ (664,000)	$ 91,704,000

As of December 31, 2022, the following table summarizes the amortized cost and the unrealized gains/losses of the available for sale securities:

	Remaining Contractual Maturity (in years)	Amortized Cost	Unrealized Gains	Unrealized Losses	Aggregate Estimated Fair Value
Commercial paper	Less than 1	$ 20,093,000	$ —	$ (73,000)	$ 20,020,000
Corporate notes/bonds	Less than 1	72,823,000	1,000	(911,000)	71,913,000
Securities of government sponsored entities	Less than 1	1,998,000	—	(16,000)	1,982,000
Total maturity less than 1 year		$ 94,914,000	$ 1,000	$ (1,000,000)	$ 93,915,000
Corporate notes/bonds	1 to 5	14,268,000	—	(88,000)	14,180,000
Total		$ 109,182,000	$ 1,000	$ (1,088,000)	$ 108,095,000

As of March 31, 2023, the following table summarizes available-for-sale securities in an unrealized loss position with no credit losses reported:

	Less Than 12 Months		12 Months or Greater		Total	
	Fair Value	Gross Unrealized Loss	Fair Value	Gross Unrealized Loss	Fair Value	Gross Unrealized Loss
Commercial paper	$ 15,216,000	$ (43,000)	$ —	$ —	$ 15,216,000	$ (43,000)
Corporate Notes/Bonds	11,687,000	(40,000)	62,813,000	(571,000)	74,500,000	(611,000)
Securities of Government Sponsored Entities	1,988,000	(10,000)	—	—	1,988,000	(10,000)
Total	$ 28,891,000	$ (93,000)	$ 62,813,000	$ (571,000)	$ 91,704,000	$ (664,000)

As of December 31, 2022, the following table summarizes available-for-sale securities in an unrealized loss position with no credit losses reported:

	Less Than 12 Months		12 Months or Greater		Total	
	Fair Value	Gross Unrealized Loss	Fair Value	Gross Unrealized Loss	Fair Value	Gross Unrealized Loss
Commercial paper	$ 20,020,000	$ (73,000)	$ —	$ —	$ 20,020,000	$ (73,000)
Corporate Notes/Bonds	9,661,000	(27,000)	74,452,000	(972,000)	84,113,000	(999,000)
Securities of Government Sponsored Entities	1,981,000	(16,000)	—	—	1,981,000	(16,000)
Total	$ 31,662,000	$ (116,000)	$ 74,452,000	$ (972,000)	$ 106,114,000	$ (1,088,000)

ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our unaudited condensed consolidated financial statements and 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, 2022 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 9, 2023. 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 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 ("OGM") solutions, diagnostic services and software. We offer OGM solutions for applications across basic, translational and clinical research, and for other applications including bioprocessing. Through our Bionano Laboratories business, we also provide diagnostic testing for patients with clinical presentations consistent with autism spectrum disorder and other neurodevelopmental disabilities. Through our BioDiscovery business, we 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. Through our Purigen business, we offer nucleic acid extraction and purification solutions using proprietary ITP technology.

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 259 as of March 31, 2023, an increase of approximately 47% from a total installed base of 176 as of March 31, 2022. Installed base represents the global number of Saphyr instruments installed at end-customer locations and therefore having the technology to process OGM.
- Sold 5,226 flowcells in the three-month period ended March 31, 2023, an increase of approximately 62% from 3,225 flowcells sold in the same quarter of 2022. 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.

Macroeconomic and Geopolitical Developments

We are subject to additional risks and uncertainties as a result of adverse geopolitical and macroeconomic developments, such as recent and potential future bank failures, the ongoing conflict between Ukraine and Russia and related sanctions, any lingering effects of COVID-19 and uncertain market conditions, including inflation and supply chain disruptions, 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. The future effects of the COVID-19 pandemic, if any, are unknown and our financial results may be negatively affected as a result. We may also experience long-term effects on the nature of the office environment and remote working, which may present strategy, operational, talent recruiting and retention and workplace culture challenges that may adversely affect our business.

During the three months ended March 31, 2023, 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, 2023 and 2022, we experienced increased costs to secure certain component parts in our products and to produce our products at our contract manufacturers. We expect these increased costs to remain high for the foreseeable future. As global economic conditions recover, business activity may not recover as quickly as anticipated, and it is not possible at this time to estimate the long-term impact that these and related events could have on our business, as the impact will depend on future developments, which are highly uncertain and cannot be predicted. For instance, product demand may be reduced due to an economic recession, a decrease in corporate capital expenditures, prolonged unemployment, rising inflation rates, labor shortages, reduction in consumer confidence, adverse geopolitical and macroeconomic developments, or any similar negative economic condition. 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 systems and consumables, which includes our instruments, and our NxClinical™ software. We currently sell our systems for research use only applications and our customers are primarily laboratories associated with academic and governmental research institutions, academic and commercial clinical laboratories, 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 reagents and chips necessary to process a sample. Sales of our NxClinical™ software, which provides customers with solutions for analysis, interpretation and reporting of genomics data, are made on a subscription basis. We generate service revenue from the sale of diagnostic testing services for those with autism spectrum disorder and other neurodevelopmental disabilities through Bionano Laboratories, as well as services performed related to customer sample evaluations using the Saphyr system. Other revenue consists of warranty and other service-based revenue, including support, repair and maintenance services.

The following table presents our revenue for the periods indicated:

	Three Months Ended March 31,	
	2023	2022
Product revenue	$ 5,447,000	$ 4,206,000
Service and other revenue	1,968,000	1,490,000
Total	$ 7,415,000	$ 5,696,000

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. EMEA consists of Europe, the Middle East, and Africa. Asia Pacific includes China, Japan, South Korea, Singapore, India and Australia.

	Three Months Ended March 31,			
	2023		2022	
	$	%	$	%
Americas	$ 3,444,000	47 %	$ 3,328,000	58 %
EMEA	2,992,000	40 %	1,739,000	31 %
Asia Pacific	979,000	13 %	629,000	11 %
Total	$ 7,415,000	100 %	$ 5,696,000	100 %

Cost of Revenue

Cost of product revenue for our systems and consumables includes raw material parts costs and associated freight, shipping and handling costs, contract manufacturing costs, salaries and other personnel costs, equipment depreciation, 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, equipment depreciation, 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, amortization expense related to acquired intangibles, and stock-based compensation for our sales and marketing, finance, legal, human resources and general management, as well as professional services, such as legal and accounting services.

Results of Operations

We have incurred losses in each year since our inception. Our net loss was $37.1 million for the three months ended March 31, 2023. As of March 31, 2023, we had an accumulated deficit of $385.8 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.

Accordingly, based on recurring losses from operations incurred since inception, the expectation of continued operating losses, and the need to raise additional capital to finance our future operations, we determined that there is substantial doubt about our ability to continue as a going concern within 12 months of this Quarterly Report on Form 10-Q.

Comparison of the Three Months Ended March 31, 2023 and 2022

The following table sets forth our results of operations for the three months ended March 31, 2023 and 2022:

	Three Months Ended March 31,		Period-to-Period Change	
	2023	2022	$	%
Revenues:				
Product revenue	$ 5,447,000	$ 4,206,000	$ 1,241,000	30 %
Service and other revenue	1,968,000	1,490,000	478,000	32 %
Total revenue	7,415,000	5,696,000	1,719,000	30 %
Cost of revenue:				
Cost of product revenue	3,858,000	3,576,000	282,000	8 %
Cost of service and other revenue	1,487,000	1,259,000	228,000	18 %
Total cost of revenue	5,345,000	4,835,000	510,000	11 %
Operating expenses:				
Research and development	13,937,000	10,527,000	3,410,000	32 %
Selling, general and administrative	25,976,000	20,277,000	5,699,000	28 %
Total operating expenses	39,913,000	30,804,000	9,109,000	30 %
Loss from operations	(37,843,000)	(29,943,000)	(7,900,000)	26 %
Other income (expenses):				
Interest income	704,000	110,000	594,000	540 %
Interest expense	(76,000)	(77,000)	1,000	(1)%
Other income (expenses)	117,000	(33,000)	150,000	(455)%
Total other income (expenses)	745,000	—	745,000	100 %
Loss before income taxes	(37,098,000)	(29,943,000)	(7,155,000)	24 %
Provision for income taxes	(26,000)	(9,000)	(17,000)	189 %
Net loss	$ (37,124,000)	$ (29,952,000)	$ (7,172,000)	24 %

Revenue

We have revised the classification of our revenue between the categories in the table above for the March 31, 2022 statement of operations to present software revenue within “product revenue”. In our March 31, 2022 statement of operations, “software” was included in “service and other revenue.”

Product revenue increased by $1.2 million, or 30%, to $5.4 million for the three months ended March 31, 2023 compared to $4.2 million for the same period in 2022. The increase in product revenue was driven by increased demand for our Saphyr OGM solutions, including an increase in instrument installed base (47%) when compared to the same period last year. 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. We expect revenue to increase as market awareness and published data of OGM utility increases, along with continued efficiencies gained in the OGM workflow through research and development, and the acquisitions of BioDiscovery and Purigen.

Service and other revenue increased by $0.5 million, or 32%, to $2.0 million for the three months ended March 31, 2023 compared to $1.5 million for the same period in 2022. The increase in service and other revenue was primarily driven by increased volume through the Bionano Laboratories sample analysis business.

Cost of Revenue, Gross Profit, and Gross Margin

	Three Months Ended March 31,		Period-to-Period Change	Period-to-Period Percentage Change
	2023	2022	2023 to 2022	2023 to 2022
Gross profit (loss):				
Product	$ 1,589,000	$ 630,000	$ 959,000	152%
Service and other	481,000	231,000	250,000	108%
Total gross profit	$ 2,070,000	$ 861,000	$ 1,209,000	140%
Gross margin:				
Product	29 %	15 %		
Service and other	24 %	16 %		
Total gross margin	28 %	15 %		

Cost of product revenue increased by $0.3 million, or 8%, to $3.9 million for the three months ended March 31, 2023, compared to $3.6 million for the three months ended March 31, 2022. The increase in cost of product revenue was due to higher sales of instruments and consumables. We anticipate similar increases in future periods as sales of our instruments and consumables grow.

Cost of service and other revenue increased $0.2 million, or 18%, to $1.5 million for the three months ended March 31, 2023, compared to $1.3 million for the three months ended March 31, 2022. The increase in cost of service and other revenue is primarily due to increased service costs on our growing installed base as well as increased costs to support the service offerings from Bionano Laboratories. We anticipate similar increases in future periods as our installed base and the number of Bionano Laboratories services grow.

Product gross profit increased $1.0 million, or 152%, to $1.6 million for the three months ended March 31, 2023, compared to $0.6 million for the three months ended March 31, 2022. The increase in gross profit was primarily due to higher sales of instruments and consumables, improvements in chip yield, and reduced scrap and quality control costs.

Service and other gross profit increased by $0.3 million, or 108%, to $0.5 million for the three months ended March 31, 2023, compared to $0.2 million for the three months ended March 31, 2022. The increase in service and other gross profit is primarily due to increased sales of services – primarily those offered by Bionano Laboratories – offset by increased costs incurred to maintain our growing installed base.

Research and Development Expenses

Research and development (“R&D”) expenses increased by $3.4 million, or 32%, to $13.9 million for the three months ended March 31, 2023 compared to $10.5 million for the same period in 2022. The increase is primarily due to an increase of $2.2 million in product development costs, an increase of $0.8 million in professional services related to research activities, and $0.6 million in software and information technology costs. Compensation costs tied to headcount, excluding stock-based compensation, increased by $1.5 million. Stock-based compensation expense decreased by $2.0 million due to the vesting of stock issued as consideration in the BioDiscovery acquisition in 2022, which primarily rolled up into R&D expense and vested in full in 2022. We anticipate that our previously planned R&D expenses will decrease for the remainder of 2023 as we implement our cash savings initiative announced May 9, 2023.

Selling, General and Administrative Expenses

Selling, general and administrative (“SG&A”) expenses increased by $5.7 million, or 28%, to $26.0 million for the three months ended March 31, 2023 compared to $20.3 million for the same period in 2022. The increase is primarily due to a $2.9 million increase in compensation expenses, of which $0.6 million relates to stock-based compensation, a $0.5 million increase in amortization of intangibles related to the acquisition of Purigen, a $1.3 million increase in professional services, a $0.6 million increase in marketing expenses, and a $0.7 million increase in the estimated fair value of the contingent consideration liabilities primarily related to the acquisition of Purigen, which rolls into SG&A expense. The increase in compensation expense is driven primarily by increased headcount. This was due to growth in our global sales, service, and back-office teams to facilitate the expanding customer base, as well as headcount additions attributed to the acquisition of Purigen. We anticipate that our previously planned SG&A expenses will decrease for the remainder of 2023 as we implement our cash savings initiative announced May 9, 2023.

Interest Income

Interest income was $0.7 million for the three months ended March 31, 2023, as compared to $0.1 million for the same period in 2022 resulting from positive returns on investments due to higher interest rates in 2023. Our total available for sale securities balance was $91.7 million as of March 31, 2023.

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 and Purigen. See Note 6 to our unaudited 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 $37.1 million and $29.9 million for the three months ended March 31, 2023 and 2022, respectively. As of March 31, 2023, we had an accumulated deficit of $385.8 million, cash and cash equivalents of $4.1 million, and available for sale investment securities of $91.7 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 and proving the utility of our offerings, expenses associated with continuing to build out our corporate infrastructure, enhancements to information technology, and expenses associated with being a public company. We expect such expenditures to continue throughout the remainder of 2023 and over the next few years.

Since our inception, we have generally incurred significant losses and negative cash flows. Based on our $4.1 million in cash and cash equivalents and $91.7 million in available for sale securities as of March 31, 2023, we anticipate our available cash balance will not be sufficient for the next twelve months from the issuance of this report. Accordingly, based on recurring losses from operations incurred since inception, our expectation of continued operating losses, our current business plan, and the need to raise additional capital to finance our future operations, we determined that there is substantial doubt about our ability to continue as a going concern within 12 months after the date that the unaudited condensed consolidated financial statements included in this Quarterly Report on Form 10-Q are issued. We plan to continue to fund our losses from operations through revenues, cash and cash equivalents on hand, sale of marketable securities and equity or debt financings. As a result, in order to continue to operate our business beyond that time, we will need to raise additional funds. Accordingly, we are actively evaluating debt and equity financing sources available to us as well as cost reduction strategies, but there can be no assurance that financing will be available on terms acceptable to us, on a timely basis, or at all, or that we are able to effectively reduce our operating expenses. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interest of our stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of common stockholders. Debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making acquisitions or capital expenditures or declaring dividends. Any disruptions to, or volatility in, the credit and financial markets or any deterioration in overall economic conditions may make any necessary debt or equity financing more difficult to obtain, more costly and/or more dilutive. If we are unable to raise additional funds through debt or equity financing or other arrangements when needed, we may be required to delay, limit, reduce or terminate our research and development activities or future commercialization efforts. Even if we raise additional capital, we may also be required to modify, delay or abandon some of our plans which could have a material adverse effect on our business, operating results and financial condition and our ability to achieve our intended business objectives. In addition, our estimate as to the sufficiency of our current cash, cash equivalents and available for sale securities, and our current operating plan are based on assumptions that may prove to be wrong, and we could deplete our capital resources sooner than we currently anticipate. See Note 1 to our unaudited condensed consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q for more information.

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,	
	2023	**2022**
Net cash provided by (used in):		
Operating activities	$ (32,413,000)	$ (32,494,000)
Investing activities	16,528,000	31,964,000
Financing activities	14,862,000	7,000

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 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. As discussed above, we anticipate our available cash balance will not be sufficient for the next twelve months from the issuance of this report. We plan to raise additional capital to fulfill our operating and capital requirements for at least 12 months through equity or debt financings, however, we may not be able to secure such financing in a timely manner or on favorable terms, if it all. We anticipate that our cash used in operating activities will decrease over the next 12 to 24 months; however, we may observe fluctuations in the cash used in operating activities on a quarterly basis to sustain the expansion of our commercial offerings.

Net cash used in operating activities was $32.4 million during the three months ended March 31, 2023 as compared to $32.5 million during the same period in 2022. The decrease in cash used in operating activities of $0.1 million was primarily attributed to increased headcount-related expenses offset by timing of invoice payments in accounts payable.

Investing Activities

Historically, our primary investing activities have consisted of capital expenditures for the purchase of capital equipment to support our expanding infrastructure, as well as the acquisitions of Lineagen, BioDiscovery and Purigen to grow our business. 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, 2023, cash provided by investing activities was $16.5 million, as compared to $32.0 million provided by investing activities during the same period in 2022. The decrease in cash provided by investing activities of $15.4 million was primarily attributed to the maturity of $16.9 million in available for sale securities during the three months ended March 31, 2023, compared to the maturity of $47.2 million in available for sale securities during the same period in 2022, which was partially offset by a purchase of $15.0 million of available for sale securities during the same period.

Financing Activities

Net cash provided by financing activities was $14.9 million during the three months ended March 31, 2023 as compared to the same period in 2022 where we had net cash provided by financing activities of $7,000, an increase of $14.9 million. During the three months ended March 31, 2023, we raised approximately $15.2 million in gross proceeds from executing sales under our at-the-market facility with Cowen and Company, LLC (“Cowen”).

Capital Resources

As of March 31, 2023, we had approximately $4.1 million in cash and cash equivalents, available for sale securities of $91.7 million, and working capital of $104.4 million.

We have in place a Sales Agreement with Cowen (the “Cowen ATM”), as amended, pursuant to which we may offer and sell from time to time up to $200.0 million of shares from the date of the amendment going forward through or to Cowen, acting as sales agent or principal. During the three months ended March 31, 2023, we sold approximately 9.5 million shares of common

stock under the Cowen ATM and received gross proceeds of approximately $15.2 million before deducting offering costs of $0.4 million.

Contingent Consideration

As part of the merger agreement related to the acquisition of BioDiscovery, we agreed to pay a milestone payment of $10.0 million in cash contingent on the achievement of a commercial milestone as set forth in the BioDiscovery agreement and plan of merger, as amended. We 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. We 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.

As part of the merger agreement related to the acquisition of Purigen, we agreed to pay two independent milestone payments up to an aggregate of $32.0 million.

The fair value of the Purigen milestones are reassessed on a quarterly basis using a probability weighted model and a Monte Carlo Simulation. We determined the fair value of this milestone consideration using a scenario-based technique, as the trigger for payment is event driven. We determined the likelihood of each independent milestone and used probability factors ranging from 20% to 80% which were applied to the individual payments. At March 31, 2023 and December 31, 2022, a Monte Carlo Simulation was performed to determine the likelihood that the milestone will be achieved and was applied to the milestone consideration payment.

Based on these valuation assumptions, the fair value of the contingent consideration liabilities was determined to be $23.1 million as of March 31, 2023, $9.5 million of which is current as of March 31, 2023.

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, 2022.

Critical Accounting Policies and Estimates

Our management's discussion and analysis of our financial condition and results of operations is based on our unaudited condensed 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 unaudited condensed consolidated 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.

As of March 31, 2023, we performed a qualitative assessment of goodwill impairment which included an evaluation of changes in industry, market and macroeconomic conditions as well as consideration of our financial performance and any significant trends. Our qualitative assessment indicated that it was not more likely than not that goodwill is impaired as of March 31, 2023. However, our stock price has significantly declined after March 31, 2023. A sustained decline in our stock price or other material changes in the significant assumptions that affect the determination of the fair value of the Company's single reporting unit may result in a goodwill impairment charge in future periods, and such charge may be material.

During the three months ended March 31, 2023, 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, 2022.

Recent Accounting Pronouncements

See Note 1 to our unaudited 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 $4.1 million in cash and cash equivalents and $91.7 million in available for sale securities as of March 31, 2023, 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.

Although we are seeing, and expect to continue to see, increased interest rates, due to our investment in highly liquid and high quality government and other debt securities as well as short-term securities, as of the date of this Quarterly Report on Form 10-Q, we do not expect anticipated changes in interest rates to have a material effect on our interest rate risk in future reporting periods. 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 $0.2 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. As a consequence of the U.S. Federal Reserve raising interest rates, the underlying risk-free interest rate we use for purposes of calculating fair value of our liabilities for acquisition-related contingent consideration has increased from our prior reporting periods, but such increase did not have a material impact on our financial statements, and we currently do not expect anticipated future changes to have a material effect in future reporting periods.

Foreign Currency Exchange Rate Risk

We conduct a portion of our business in currencies other than our U.S. dollar functional currency. Transactional exposure arises where transactions occur in currencies other than the functional currency. Transactions in foreign currencies are recorded at the exchange rate prevailing at the date of the transaction. The resulting monetary assets and liabilities are translated into the appropriate functional currency at exchange rates prevailing at the balance sheet date and the resulting gains and losses are reported in foreign currency translation adjustments in the unaudited condensed consolidated statements of comprehensive loss. Our foreign currency exposures are primarily concentrated in the British Pound, Chinese Renminbi, Euro, and Canadian dollar. We do not currently participate in material foreign exchange hedging activities.

Additionally, we have operations outside of the United States. The functional currency of each foreign subsidiary is generally the local currency. We are exposed to foreign currency exchange risk as the functional currency financial statements of foreign subsidiaries are translated to U.S. dollars. The assets and liabilities of our foreign subsidiaries having a functional currency other than the U.S. dollar are translated into U.S. dollars at the exchange rate prevailing at the balance sheet date, and at the average exchange rate for the reporting period for revenue and expense accounts. The cumulative foreign currency translation adjustment is recorded as a component of accumulated other comprehensive loss in shareholders' equity. The reported results of our foreign subsidiaries will be influenced by their translation into U.S. dollars by currency movements against the U.S. dollar. As of March 31, 2023 and December 31, 2022, we had minimal assets and liabilities denominated in foreign currencies and expect similar levels of foreign currency denomination in the next 12 months. We believe a hypothetical 10% change in foreign exchange rates as of March 31, 2023 would not have a material impact on our business, financial condition, or results of operations.

Inflation

Geopolitical and macroeconomic events, including the conflict between Ukraine and Russia and related sanctions and the recent and potential future disruptions in access to bank deposits or lending commitments due to bank failures have 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, 2023, 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, 2023 was not significantly impacted by the cost increases we experienced. While the effects of geopolitical and macroeconomic events, as well as other inflationary pressures, are highly uncertain, as of the date of this Quarterly Report on Form 10-Q, we do not expect anticipated changes in inflation to have a material effect on our business, financial condition or results of operations for future reporting periods other than the general impacts on companies due to general economic and market conditions. 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 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, 2023, 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 Exchange Act). 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, including our principal executive officer and principal financial officer, has concluded that our disclosure controls and procedures were effective as of the end of the period covered by this Quarterly Report on Form 10-Q.

Changes in Internal Control over Financial Reporting

Under the supervision and with the participation of our management, including our principal executive officer and our principal financial officer, we carried out an evaluation of any potential changes in our internal control over financial reporting during the fiscal quarter covered by this Quarterly Report on Form 10-Q. Except as described below, there were no changes in our internal control over financial reporting during the quarter ended March 31, 2023 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

In November 2022, we acquired Purigen Biosystems, Inc. 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 future capital needs are uncertain and we may require additional funding in the future to advance the commercialization of our Saphyr system, Ionic Purification 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;
- Unfavorable geopolitical and macroeconomic developments could adversely affect our business, financial condition or results of operations;
- The COVID-19 pandemic has materially affected and could continue to materially affect 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;
- 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;
- In the near term, sales of our Saphyr system, Ionic Purification system, NxClinical software, 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 and 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;
- We are subject to stringent and changing obligations related to data privacy and security. Actual or perceived failure by us or the third-party service providers upon which we rely to comply with such obligations could lead to regulatory investigations or actions; litigation; fines and penalties; disruptions of our business operations; reputational harm; loss of revenue or profits; and other adverse business consequences
- Our future success is dependent upon our ability to further penetrate our existing customer base, attract new customers and retain the customers of our acquired businesses;
- The size of the markets for our products and technologies may be smaller than we estimate, and new markets may not develop as quickly as we expect, or at all, limiting our ability to successfully sell our products and technologies.
- We are currently limited to "research use only," or RUO, with respect to many of the materials and components used in our consumable products including our assays;
- 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 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.

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 unaudited consolidated financial statements, and in the long-term, plan to further increase headcount as we expand our operations. Because 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 $37.1 million and $29.9 million, and used cash in operations of $32.4 million and $32.5 million for the three months ended March 31, 2023 and 2022, respectively. As of March 31, 2023, we had an accumulated deficit of $385.8 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 should we increase our headcount in future periods. 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 and are therefore required to comply with additional disclosure and compliance requirements. 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 OGM solutions on our Saphyr system, Ionic Purification system or successor systems;
- our successful creation of an end-to-end solution for OGM;
- the successful integration of our BioDiscovery and Purigen businesses;
- execution on our commercial and reimbursement strategy involving Bionano Laboratories;
- customer demand for current BioDiscovery software solutions, including NxClinical software, and future software solutions developed through BioDiscovery's platform;
- the position of our Purigen business in the DNA isolation space of genome analysis and customer demand for our Ionic Purification system;
- 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, 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;
- geopolitical and macroeconomic developments, such as the conflict between Ukraine and Russia and related sanctions, recent and potential future disruptions in access to bank deposits or lending commitments due to bank failures, the COVID-19 pandemic, inflation, increased cost of goods, supply chain issues, and global financial market conditions;
- 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, including our existing and recently acquired leases, 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 or expectations.

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, and to integrate such systems, processes and controls into our newly acquired businesses. 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 or integration 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 may require additional funding in the future to advance the commercialization of our Saphyr system, Ionic Purification 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 in future periods and execute potential strategic transactions. In connection with the preparation of our financial statements for the fiscal year ended December 31, 2022, we performed an analysis of our ability to continue as a going concern. We believe, based on our current business plan, that our existing cash and cash equivalents will not be sufficient for the next twelve months from the issuance of this report. Our ability to execute our operating plan depends on our ability to generate sales and obtain additional funding through equity offerings, debt financings or potential licensing and collaboration arrangements. For example, we will likely need to raise substantial additional capital 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 in future periods, 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, if applicable, in the future, loss of our status as a smaller reporting company or changes in our status from a non-accelerated filer to an accelerated filer or large accelerated filer.

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

- the cost of integrating our newly acquired businesses or of acquiring future businesses;
- 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;
- increasing interest rates;
- supply chain disruptions;

- the success of our existing distribution and marketing arrangements and our ability to enter into additional arrangements in the future;
- the effects of geopolitical or macroeconomic developments, such as the ongoing military conflict between Russia and Ukraine, related sanctions, recent and potential future disruptions in access to bank deposits or lending commitments due to bank failures and 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. In addition, we may not be able to access a portion of our existing cash, cash equivalents and investments due to market conditions such as recent and potential future disruptions in access to bank deposits or lending commitments due to bank failures.

Global economic conditions have been worsening, with disruptions to, and volatility in, the credit and financial markets in the U.S. and worldwide resulting from the effects of ongoing geopolitical or macroeconomic developments. If these conditions persist or worsen, we could experience an inability to access additional capital. 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.

If we are not able to increase the number of authorized shares of our common stock or our trading price does not increase, we may be limited in our ability to issue and sell our shares, and, as a result, our operations and financial condition may be materially and adversely affected.

We will need to seek the additional capital necessary to fund our operations through public or private equity offerings, debt financings, and collaborative and licensing arrangements. We have limited shares of our common stock currently available and authorized for issuance. Investors in prior transactions have purchased our shares of common stock or our convertible securities, such as warrants, for which we must reserve unissued shares of our common stock. If the reverse split proposal for consideration at our 2023 Annual Meeting of Stockholders is not approved, we would likely need to increase the number of authorized shares of our common stock, which requires stockholder approval, in order to issue shares of our common stock or securities convertible, exercisable or exchangeable into shares of our common stock to investors and other strategic partners, in capital raising transactions. If our trading price does not increase or if we are unable to increase the authorized shares of our common stock, we will be limited in our efforts to raise additional capital. As a result, our operations and financial condition may be materially and adversely affected.

Unfavorable geopolitical and macroeconomic developments 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, the global financial markets and adverse geopolitical and macroeconomic developments, including without limitation inflation, recent and potential future disruptions in access to bank deposits or lending commitments due to bank failures, slowing growth, rising interest rates and recession. A severe or prolonged global economic downturn could result in a variety of risks to our business. For example, inflation rates, particularly in the United States, have increased recently to levels not seen in years, and increased inflation may result in decreased demand for our products and services, increases in our operating costs (including our labor costs), prolonged unemployment, reduced liquidity and limits on our ability to access credit or otherwise raise capital on acceptable terms, if at all. In addition, the Federal Reserve has raised, and may again raise, interest rates in response to concerns about inflation, which coupled with reduced government spending and volatility in financial markets may have the effect of further increasing economic uncertainty and heightening these risks. Risks of a prolonged global economic downturn are particularly true in Europe, which is undergoing a continued severe economic crisis. A weak or declining economy, regardless of the reason for the decline, could also strain our suppliers, possibly resulting in supply disruption. For example, higher energy prices in Europe are causing an increase in cloud computing expenses, which impacts the cost for us and our partners. 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. For example, during the COVID-19 pandemic, customers that committed to order minimum quantities of consumables or to purchase our Saphyr

instrument delayed such commitments. In addition, we anticipate that ongoing disruptions in our supply chain due to lingering COVID-19 and general macroeconomic effects may 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 systems to operate our system. We have experienced supply chain disruptions, some of which have delayed shipment of products to our customers. 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.

Additionally, following the invasion of Ukraine by Russia, financial markets around the world experienced volatility. In response to the invasion, the United States, United Kingdom and European Union, along with others, imposed significant new sanctions and export controls against Russia, Russian banks and certain Russian individuals and may implement additional sanctions or take further punitive actions in the future. The full economic and social impact of the sanctions imposed on Russia (as well as possible future punitive measures that may be implemented), as well as the counter measures imposed by Russia, in addition to the ongoing military conflict between Ukraine and Russia, which could conceivably expand into the surrounding region, remains uncertain; however, both the conflict and related sanctions have resulted, and could continue to result in disruptions to trade, commerce, pricing stability, credit availability, supply chain continuity and reduced access to liquidity, in both Europe and globally, and has introduced significant uncertainty into global markets. In particular, the Russia-Ukraine conflict has contributed to rapidly rising costs of living (driven largely by higher energy prices) in Europe and other advanced economies. As the adverse effects of this conflict continue to develop and potentially spread, both in Europe and throughout the rest of the world, our customers may be negatively impacted, which in turn may cause them to delay purchasing decisions and otherwise depress the level of spend conducted by such customers for our products, technologies and services. Further, a weak or declining economy could strain our suppliers, possibly resulting in additional supply disruption. As a result, our business and results of operations may be adversely affected by the ongoing conflict between Ukraine and Russia and related sanctions, particularly to the extent it escalates to involve additional countries, further economic sanctions or wider military conflict. We have operations, as well as current and potential new customers throughout Europe. If economic conditions in Europe and other key markets for our products and technologies continue to remain uncertain or deteriorate further, we could experience adverse effects on our business, supply chain, partners or customers.

The COVID-19 pandemic has materially affected and could continue to materially affect 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, contractors, 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, or the perception of such orders, shutdowns, or other restrictions have materially affected and may continue to materially affect how we, our customers, and our suppliers are operating our businesses.

As public health directives surrounding the pandemic have relaxed, we have modified our work-from-home policies for certain employees and certain of our business practices, including reopening our offices and permitting travel and in-person events, taking into consideration government restrictions, employee safety and health risks. Our approach may vary among geographies depending on appropriate health protocols, and may change at any time. Additionally, our efforts to reopen our offices safely may not be successful, could expose our employees to health risks, and could involve additional costs or liability. To the extent our employees are exposed to or become ill with COVID-19, our ability to conduct our global and domestic operations may be impaired from time to time. For example, we experienced at various times during the pandemic the inability to visit certain customer sites to support installation of, training on or service to our OGM systems. As a result, in the past, we have had to delay instrument installations or service related visits. The COVID-19 pandemic may also have long-term effects on the nature of the office environment and remote working, which may present strategy, operational, talent recruiting and retention, worker productivity and efficiency, and workplace culture challenges that may adversely affect our business. 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.

In connection with our Bionano Laboratories 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, including due to, among other things, spread of the disease within these groups or 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 unfavorable flowcell yields in 2021 and part of 2022 and 2023. If the pandemic persists, these disruptions could reoccur.

As global economic conditions recover, business activity may not recover as quickly as anticipated or at all, and it is not possible at this time to estimate the long-term impacts that these factors could have on our business, or the global economy as a whole, as the impact will depend on future developments, which are highly uncertain and cannot be predicted. Conditions will be subject to the effectiveness of government policies, including vaccine mandates, vaccine shortages and administration rates, the emergence of new strains or variants of the virus in markets and communities where we, our customers, and our suppliers are operating our business and other factors that are not foreseeable. Any of the foregoing could adversely affect our business, financial condition and results of operations. In addition, these factors may also have the effect of heightening many of the other risks and uncertainties described in this Quarterly Report on Form 10-Q.

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

New income, sales, use, excise 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 informally titled the Tax Cuts and Jobs Act; the Coronavirus Aid, Relief, and Economic Security Act; and the Inflation Reduction 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 such legislation may affect us, and certain aspects of such legislation could be repealed or modified in future legislation. These developments, along with 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. In addition, it is uncertain if and to what extent various states will conform to federal tax legislation.

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. 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.

In addition, effective January 1, 2022, the Tax Cuts and Jobs Act eliminated the option to deduct research and development expenses for tax purposes in the year incurred and requires taxpayers to capitalize and subsequently amortize such expenses over five years for research activities conducted in the United States and over 15 years for research activities conducted outside the United States. Unless the United States Department of the Treasury issues regulations that narrow the application of this provision to a smaller subset of our research and development expenses or the provision is deferred, modified, or repealed by Congress, it could harm our future operating results by effectively increasing our future tax obligations. The actual impact of this provision will depend on multiple factors, including the amount of research and development expenses we will incur, whether we achieve sufficient income to fully utilize such deductions and whether we conduct our research and development activities inside or outside the United States.

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, 2022, we had federal and state tax net operating loss carryforwards of $463.8 million and $197.6 million, respectively. The federal tax loss carryforwards include $282.9 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 $180.9 million and state tax loss carryforwards begin to expire in 2027 and 2023, respectively, unless previously utilized. As of December 31, 2022, we also had federal and California research credit carryforwards of $9.4 million and $8.8 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 our 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, 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.

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.

Our corporate cash saving initiative and the associated headcount reduction we announced in May 2023 may not result in anticipated savings, could result in total costs and expenses that are greater than expected, could disrupt our business, and may not achieve our intended objectives.*

In May 2023, we undertook a cash savings initiative that included a reduction in force. We may not realize, in full or in part, the anticipated benefits, savings and improvements in our cost structure from our initiative due to unforeseen difficulties, delays or unexpected costs. Our initiative may also be disruptive to our operations. For example, our headcount reductions could yield unanticipated consequences and costs, such as increased difficulties in implementing our business strategy due to the loss of institutional knowledge and expertise, reduced strength of our sales force and marketing efforts, attrition beyond the intended number of employees, decreased morale among our remaining employees, and the risk that we may not achieve the anticipated benefits of the reduction in force. In addition, while certain positions have been eliminated, certain functions necessary to our operations remain, and we may be unsuccessful in distributing the duties and obligations of departed employees among our remaining employees. The reduction in workforce could also make it difficult for us to pursue, or prevent us from pursuing, new opportunities and initiatives, including restricting the strength of our sales force and marketing efforts, due to insufficient personnel, or require us to incur additional and unanticipated costs to hire new personnel to pursue such opportunities or initiatives. Moreover, employee litigation related to the headcount reduction could be costly and prevent management from fully concentrating on the business.

Our future financial performance and our ability to develop our product candidates or additional assets will depend, in part, on our ability to effectively manage future growth or restructuring, as the case may be. In addition, if we are unable to realize the anticipated benefits from our cash savings initiative, or if we experience significant adverse consequences of such initiative, our business, financial condition, and results of operations may be materially adversely affected.

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 our pre-acquisition customers, distributors or suppliers, or in the relationships of our acquired businesses with their pre-acquisition 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 with the seller(s) or third parties 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 or integrating new products, technologies and services into our commercial plan;
- 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, 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, in our acquisition of 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, and in our acquisition of Purigen, a U.S-based DNA and RNA extraction company, we paid upfront consideration of approximately $32.0 million in cash. 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. These shares vested in full on October 4, 2022.

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, the payment of cash in the Purigen acquisition reduced our cash by approximately $32.0 million, our headcount increased by more than 75 employees as a result of all three acquisitions, and we acquired new leases in each acquisition. 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, BioDiscovery and/or Purigen 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 and DNA isolation 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, 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 an 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, which we amended in March 2023 to provide for sales of up to $200.0 million going forward. 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 the fiscal year ended December 31, 2022, we sold 6.6 million shares of common stock under the Cowen ATM for gross proceeds of approximately $23.1 million before deducting offering costs. In January and February 2023, we sold approximately 9.5 million shares of common stock under the Cowen ATM for gross proceeds of approximately $15.2 million before deducting offering costs. In addition, we issued shares of our common stock in connection with our 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 12.9 million, 0.4 million and 2.2 million for our 2018 Equity Incentive Plan, as amended, 2018 Employee Stock Purchase Plan and 2020 Inducement Plan, as amended, respectively, subject to adjustment, including pursuant to automatic “evergreen” increases in certain of our plans. As of March 31, 2023, we had outstanding equity awards underlying those plans accounting for 32.0 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, 2023, our board of directors granted our executive officers options to purchase an aggregate of 3.3 million shares of our common stock, and 0.7 million restricted stock units (“RSUs”), which represented approximately 1% of our outstanding shares of common stock based on the 306.8 million shares of common stock outstanding as of May 4, 2023. 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 Bionano Laboratories 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 Bionano Laboratories business.*

Our Bionano Laboratories 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 Bionano Laboratories 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 further 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.

Geopolitical and macroeconomic developments, such as recent and potential future disruptions in access to bank deposits or lending commitments due to bank failures, 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, Ionic Purification system, NxClinical software, 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 and products and adversely affect our business and operating results.*

In the near term, we expect that our revenue from sales of our Saphyr system, Ionic Purification system, NxClinical software, consumables and OGM services will be derived primarily from sales to academic and governmental research institutions, and academic and commercial clinical laboratories, 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;
- 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, among other things, staffing, capacity, shutdowns or slowdowns of laboratories and other institutions as well as other impacts stemming from various geopolitical and macroeconomic developments, such as the conflict between Ukraine and Russia, related sanctions, recent and potential future disruptions in access to bank deposits or lending commitments due to bank failures and the COVID-19 pandemic;
- differences in budgetary cycles; and
- market acceptance of relatively new technologies, such as ours.

In addition, our operating results may fluctuate substantially due to reductions and delays in research and development expenditures by our customers. Any decrease in customers' budgets or expenditures, including impacts stemming from various geopolitical and macroeconomic developments, 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.

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;
- our ability to successfully market our Ionic Purification system through our Purigen business, and to integrate that technology in our existing ecosystem of technologies;
- 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 the Purigen acquisition in November 2022 and will need to devote time and resources in order to further develop and integrate BioDiscovery's software and technology solutions and Purigen's Ionic Purification system 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, attract new customers and retain the customers of our acquired businesses.

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 Bionano Laboratories 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. Our successes will also depend on our ability to maintain relationships with the customers of our acquired businesses. 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. We may be unsuccessful in attracting desirable sales and distribution partners. We may also be unable to enter into arrangements with such partners 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.

The size of the markets for our products and technologies may be smaller than we estimate, and new markets may not develop as quickly as we expect, or at all, limiting our ability to successfully sell our products and technologies.*

The market for our OGM-based products and technologies is evolving, making it difficult to predict with any accuracy the market opportunity for our current and future products and technologies. Our estimates of the total addressable market for our current and future products and technologies are based on a number of internal and third-party estimates and assumptions. Both our current market opportunity estimates for cytogenomics and discovery research and our potential future market opportunity estimates, including newborn screening, population genomics, neurological and cardiological risk assessment, and cell bioprocessing quality control, are forward-looking statements and are subject to significant risks and uncertainties. While these were prepared in good faith, we cannot provide assurances as to future results or events because these estimates are dependent in part on, among other things, anticipated demand for OGM instruments, complementary capabilities of OGM and NGS, and expected consumption of chips and sample prep and labeling kits. In particular, these estimates are based on current and projected selling prices for instruments and consumables, each of which is subject to change over time and may be drastically affected without warning due to matters outside of our control, including geopolitical and macroeconomic developments.

The estimates and assumptions underlying our addressable market opportunities also involve significant judgments with respect to, among other things, future economic, competitive, regulatory, market and financial conditions, as well as future customer demand, business decisions and corporate opportunities that may not be realized, and that are inherently subject to significant business, economic, competitive and regulatory risks and uncertainties, all of which are difficult to predict and many of which are outside of our control. For example, as interest rates continue to rise, our customers may be unable to deploy additional capital to purchase, or may re-prioritize their budget away from, our products and technologies. In addition, our underlying assumptions and estimates may prove to be inaccurate and our financial objectives may not be realized, and therefore our actual results may differ materially from our estimated addressable market opportunities.

Any addressable market opportunities identified in this Quarterly Report on Form 10-Q should not be construed as financial guidance and should not otherwise be relied upon as being necessarily indicative of future results, and you are cautioned not to place undue reliance on our estimated addressable opportunities. In preparing our estimated addressable opportunities, we have relied upon and assumed, without independent verification, the accuracy and completeness of certain industry and market information provided to us by third parties or through publicly available sources, which information involves assumptions and limitations, and you should not give undue weight to such information.

We are currently limited to RUO 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-Bionano Laboratories 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 in-vitro diagnostics, or IVDs, products, 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 and Ionic Purification 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, including our new Ionic Purification instruments. See the section titled "Business — Key Agreements" in our Annual Report on Form 10-K for the year ended December 31, 2022. In addition, we rely on a single contract manufacturer based in the United States 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 or chip consumables, 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 the same or a similar issue were to occur, 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 and systems could be adversely affected and our customers might instead purchase our competitors' products and systems. 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 result from various geopolitical and macroeconomic developments, such as the ongoing conflict between Ukraine and Russia or 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 with applicable regulatory authorities, 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 or recalls.

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 the three months ended March 31, 2023 and 2022, approximately 59% and 55%, respectively, of our 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. This competition has become exacerbated by the increase in employee resignations throughout the United States, which is commonly referred to as the "great resignation." We may also experience employee turnover as a result of the ongoing "great resignation." 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. Additionally, our growth depends on attracting and retaining highly-skilled personnel with the necessary technical and scientific background needed to 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. In response to competition, rising inflation rates and labor shortages, we may need to adjust employee cash compensation, which would affect our operating costs and our margins, or equity compensation, which would affect our outstanding share count, causing dilution to existing shareholders and possibly souring investor sentiment, which could in turn make it difficult to achieve our goals.

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

We are increasingly dependent upon information technology systems, infrastructure and data to operate our business. In the ordinary course of our business, we and the third parties upon which we rely collect, store, use, protect, secure, generate, transfer, dispose of, transmit, disclose, and otherwise process sensitive, proprietary, and confidential information, including intellectual property, trade secrets, financial information, and personal data (including protected health information) (collectively, "Sensitive Data"). As a result, we and the third parties upon which we rely face a variety of evolving threats including but not limited to ransomware attacks, which could cause security incidents.

Cyberattacks, malicious internet-based activity, online and offline fraud, and other similar activities threaten the confidentiality, integrity, and availability of our Sensitive Data and information technology systems, and those of the third parties upon which we rely. Such threats are prevalent and continue to rise, are becoming increasingly difficult to detect, and come from a variety of sources, including traditional computer "hackers," threat actors, personnel (such as through theft or misuse), "hacktivists," sophisticated nation-states, and nation-state-supported actors.

Some actors now engage and are expected to continue to engage in cyber-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 retaliatory 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 are 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), credential harvesting, personnel misconduct or error, ransomware attacks, supply-chain attacks, software bugs, server malfunctions, software or hardware failures, loss of data or other information technology assets, adware, telecommunications failures, earthquakes, fires, floods, and other similar threats. In particular, severe ransomware attacks, including those perpetrated by organized criminal threat actors, nation-states, and nation-state supported actors, are becoming increasingly prevalent and can lead to significant interruptions in our operations, loss of Sensitive 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.

In addition, our reliance on third-party service providers and technologies to operate critical business systems to process Sensitive Data could introduce new cybersecurity risks and vulnerabilities and other threats to our business operations. We rely on third-party service providers 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 and, as a result, we and the third parties upon which we rely face a variety of evolving threats, including but not limited to ransomware attacks, which could cause security incidents. Our ability to monitor these third parties' cybersecurity practices is limited, and these third parties may not have adequate information security measures in place. While we may be entitled to damages if our third-party service providers fail to satisfy their privacy or security-related obligations to us, any award may be insufficient to cover our damages, or we may be unable to recover such award. We may share or receive sensitive data with or from third parties. 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.

Remote work has become more common and has increased risks to our information technology systems and data, as more of our employees utilize network connections, computers and devices outside our premises or network, including working at home, while in transit, and in public locations. Additionally, past or future business transactions (such as acquisitions or integrations) could expose us to additional cybersecurity risks and vulnerabilities, as our systems and Sensitive Data could be negatively affected by vulnerabilities present in acquired or integrated entities' systems and technologies. Furthermore, we may discover security issues that were not found during due diligence of such acquired or integrated entities, and it may be difficult to integrate companies into our information technology environment and security program.

Any of the previously identified or similar threats could cause a security incident or other interruption. that could result in unauthorized, unlawful, or accidental acquisition, modification, destruction, loss, alteration, encryption, disclosure of, or access to our Sensitive Data or our information technology systems, or those of the third parties upon whom we rely. A security incident or other interruption could disrupt our ability (and that of third parties upon whom we rely) to provide our 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, or industry-standard or reasonable security measures to protect our information technology systems and Sensitive 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 take steps to detect and remediate 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, such as 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.

In addition to experiencing a security incident, third parties may gather, collect, or infer sensitive information about us from public sources, data brokers, or other means that reveals competitively sensitive details about our organization and could be used to undermine our competitive advantage or market position.

We are subject to stringent and evolving U.S. and foreign laws, regulations, rules, contractual obligations, policies and other obligations related to data privacy and security. Our actual or perceived failure to comply with such obligations could lead to regulatory investigations or actions; litigation; 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 collect, store, protect, secure, generate, transfer, dispose of, use, transmit, disclose and otherwise 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 may subject us to numerous data privacy and security obligations, such as various laws, regulations, guidance, industry standards, external and internal privacy and security policies, contractual requirements, and other obligations 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, consumer protection laws (e.g., Section 5 of the Federal Trade Commission Act), and other similar laws (e.g., wiretapping 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. For more information regarding risks associated with HIPAA, please refer to the section above that discusses risks associated with federal and state healthcare laws.

As another example, 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 and allows private litigants affected by certain data breaches to recover significant statutory damages). In addition, the California Privacy Rights Act of 2020, or the CPRA, operative January 1, 2023, expands the CCPA's requirements, including by adding a new right for individuals to correct their personal information and establishing a new regulatory agency to implement and enforce relevant laws, which could increase the risk of an enforcement action, and the CPRA applies to personal information of business representatives and employees in addition to consumers. Other states have also recently enacted data privacy laws, as well as at the federal and local levels. 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.

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, or EU GDPR, and the United Kingdom's GDPR, or UK GDPR, impose strict requirements for processing the personal data of individuals. For example, under the EU GDPR, companies may face temporary or definitive bans on data processing and other corrective actions; fines of up to 20 million euros or 4% of annual global revenue, whichever is greater; or private litigation related to the processing of personal data brought by classes of data subjects or consumer protection organizations authorized at law to represent their interests.

We may be unable to transfer personal data from Europe and other jurisdictions to the United States or other countries due to data localization requirements or limitations on cross-border data flows. Europe and other jurisdictions have enacted laws requiring data to be localized or limiting the transfer of personal data to other countries. In particular, the European Economic Area (EEA) and the United Kingdom (UK) have significantly restricted the transfer of personal data to the United States and other countries whose privacy laws it believes are inadequate. Other jurisdictions may adopt similarly stringent interpretations of their data localization and cross-border data transfer laws. Although there are currently various mechanisms that may be used to transfer personal data from the EEA and UK to the United States in compliance with law, such as the EEA and UK's standard contractual clauses, these mechanisms are subject to legal challenges, and there is no assurance that we can satisfy or rely on these measures to lawfully transfer personal data to the United States. If there is no lawful manner for us to transfer personal data from the EEA, the UK, or other jurisdictions to the United States, or if the requirements for a legally-compliant transfer are too onerous, we could face significant adverse consequences, including the interruption or degradation of our operations, the need to relocate part of or all of our business or data processing activities to other jurisdictions at significant expense, increased exposure to regulatory actions, substantial fines and penalties, the inability to transfer data and work with partners, vendors and other third parties, and injunctions against our processing or transferring of personal data necessary to operate our business. Additionally, companies that transfer personal data out of the EEA and UK to other jurisdictions, particularly to the United States, are subject to increased scrutiny from regulators, individual litigants, and activities groups. Some European regulators have ordered certain companies to suspend or permanently cease certain transfers of personal data out of Europe for allegedly violating the GDPR's cross-border data transfer limitations.

In addition, privacy advocates and industry groups have proposed, and may propose in the future, standards with which we may be legally or contractually bound to comply. For example, we may also be subject to the Payment Card Industry Data Security Standard, or PCI DSS. The PCI DSS requires companies to adopt certain measures to ensure the security of cardholder information, including using and maintaining firewalls, adopting proper password protections for certain devices and software, and restricting data access. Noncompliance with PCI-DSS can result in penalties ranging from $5,000 to $100,000 per month

by credit card companies, litigation, damage to our reputation, and revenue losses. We may also rely on vendors to process payment card data, and those vendors may be subject to PCI DSS, and our business may be negatively affected if our vendors are fined or suffer other consequences as a result of PCI DSS noncompliance.

We may also be subject to contractual obligations and policies related to data privacy and security and our efforts to comply with such obligations may not be successful. Publication of our privacy policies and other statements regarding data privacy and security may subject us to investigation or enforcement actions by regulators if those policies or statements are found to be deficient, lacking in transparency, deceptive, unfair, or misrepresentative of our practices.

Our data privacy and security obligations are quickly changing in an increasingly stringent fashion, 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) and may necessitate changes to our services, information technologies, systems, and practices and to those of any third parties on which we rely. If we or the third parties on which we rely 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 action 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 substantial changes to our business model or 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, Qiagen, and Dovetail Genomics (now part of Cantata Bio). 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 and key opinion leaders;
- innovation in product offerings;
- flexibility, scalability 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.

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 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 Bionano Laboratories 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 Bionano Laboratories 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 Bionano Laboratories diagnostic testing procedures is complex and requires substantial time and resources to collect payment.

Billing for clinical laboratory testing services in connection with our Bionano Laboratories 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 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 Bionano Laboratories diagnostic testing procedures are subject to unfavorable pricing regulations or third-party payor coverage and reimbursement policies, our business could be harmed.

Our Bionano Laboratories-related revenue depends on achieving and maintaining broad coverage and adequate reimbursement for our Bionano Laboratories 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 Bionano Laboratories 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 Bionano Laboratories 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 Bionano Laboratories 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 Bionano Laboratories 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 Bionano Laboratories products and diagnostic assays. In addition, the determinations by a third-party payor whether to cover our Bionano Laboratories 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

Bionano Laboratories 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 Bionano Laboratories 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 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.

In addition, other legislative changes have been proposed and adopted since the ACA was enacted. On August 16, 2022, President Biden signed the Inflation Reduction Act, or the IRA, into law, which among other things, extends enhanced subsidies for individuals purchasing health insurance coverage in ACA marketplaces through plan year 2025. The IRA also eliminates the coverage gap under the Medicare Part D program beginning in 2025 by significantly lowering the beneficiary maximum out-of-pocket cost and through a newly established manufacturer discount program. In addition, 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. 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. Additionally, 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;
- 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, local and foreign laws that govern the data 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, all of which are far-reaching and complex, and our failure to comply with such regulatory requirements could result in substantial penalties and have a material adverse effect on our business.

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. We have developed a global patent portfolio that includes more than 160 issued patents or allowed applications across approximately 35 patent families that are either owned or exclusively licensed. The owned and licensed patent families contain issued patents and pending applications that relate to devices, systems, and methods for macromolecular analysis, isolation and purification of molecules, genetic testing, computer software systems and reflect our active and ongoing research programs. 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 USPTO. 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.

Use of third-party open source software components in our products or our 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.

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 $3.60 on August 15, 2022 and August 12, 2022 and a low price of $0.62 on May 2, 2023. During this time, the price per share of common stock has ranged from an intra-day low of $0.60 per share to an intra-day high of $4.35 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 on Form 10-Q, 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 Bionano Laboratories 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, Ionic Purification 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;
- natural disasters, infectious diseases, conflict, including the ongoing military conflict between Russia and Ukraine and the related sanctions, civil unrest, epidemics or pandemics including COVID-19, outbreaks, resurgences or major catastrophic events;
- general political and economic conditions, including recent and potential future disruptions in access to bank deposits or lending commitments due to bank failures;
- our cost savings initiative announced in May 2023
- the announcement of the reverse stock split proposal to be voted on at our 2023 annual meeting of stockholders; 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 implement a reverse stock split, we may not achieve the intended results and the market price of our common stock may be materially and negatively impacted.*

We have submitted a proposal to our stockholders for consideration at our 2023 Annual Meeting of Stockholders to approve a series of alternate amendments to our Amended and Restated Certificate of Incorporation, as amended, to effect, at the option of our board of directors, a reverse stock split of our common stock at a ratio between 1-for-5 and 1-for-10, inclusive, as determined by our board of directors in its sole discretion. Subject to approval by our stockholders, we may file a certificate of amendment to effect the reverse split ratio chosen by our board of directors. We cannot assure you that the reverse stock split proposal will be approved by our stockholders. Further, we cannot assure you that the market price per share of our common stock after the reverse stock split is implemented, if at all, will increase in proportion to the reverse split ratio chosen by our board of directors or that we will achieve any of the other intended results of the reverse stock split, including improved marketability and liquidity of our common stock, maintaining compliance with Nasdaq listing standards and encouraging trading in our common stock by long-term investors. Accordingly, the market price and the value of your investment could be materially and negatively impacted.

The effective increase in the number of shares of our common stock available for issuance as a result of the reverse stock split, if approved and implemented, could result in further dilution to our existing stockholders and have antitakeover implications.*

The total number of authorized shares of our common stock will remain the same as before the reverse stock split discussed in the above risk factor, if approved and implemented. The reverse stock split as proposed will effectively increase the number of shares of our common stock (or securities convertible or exchangeable for our common stock) available for issuance by

decreasing the number of shares of our common stock issued and outstanding. The additional available shares would be available for issuance from time to time at the discretion of our board of directors when opportunities arise, without further stockholder action, except as may be required for a particular transaction by law, the rules of any exchange on which our securities may then be listed, or other agreements or restrictions. Any issuance of additional shares of our common stock would increase the number of outstanding shares of our common stock and (unless such issuance was pro-rata among all existing stockholders) the percentage ownership of existing stockholders would be diluted accordingly. In addition, any such issuance of additional shares of our common stock could have the effect of diluting the earnings per share and book value per share of outstanding shares of our common stock.

Additionally, such effective increase in the number of shares of our common stock available for issuance could, under certain circumstances, have anti-takeover implications. For example, without further stockholder approval, our board of directors could adopt a "poison pill" which would, under certain circumstances related to an acquisition of our securities that is not approved by the board of directors, give certain holders the right to acquire additional shares of our common stock at a low price. Our board of directors also could strategically sell shares of common stock in a private transaction to purchasers who would oppose a takeover or favor the current board of directors. Although the proposed reverse stock split has been prompted by business and financial considerations, you should be aware the proposed reverse stock split proposal could facilitate future efforts by us to deter or prevent changes in control, including transactions in which you might otherwise receive a premium for your shares over then current market prices.

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) (the "Minimum Bid Price Requirement"). As of April 24, 2023, the closing price of our common stock was $0.78. If the price of our common stock closes below $1.00 for 30 consecutive business days, we would receive notice from Nasdaq that we are not in compliance with the Minimum Bid Price Requirement.

Although we have regained compliance with Nasdaq continued listing requirements, if we fail to satisfy the Minimum Bid Price Requirement or 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.

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 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.

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.

Further, in connection with our Annual Report on Form 10-K for the period ended December 31, 2021, our independent registered public accounting firm was required to attest to the effectiveness of our internal control over financial reporting pursuant to Section 404 of the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act. As of December 31, 2022, we qualified as a “non-accelerated filer” based on the market value of our common stock held by non-affiliates as of June 30, 2022 and revenue for the fiscal year ended December 31, 2021. For as long as we are a non-accelerated filer, we will not be required to obtain an independent assessment of the effectiveness of our internal controls. An independent assessment of the effectiveness of our internal controls could detect problems that our management’s assessment might not. Consequently, if we choose not to obtain an independent assessment, there is a risk that we may not detect problems with our internal controls that otherwise might have been detected.

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 are a smaller reporting company, and the reduced reporting requirements applicable to smaller reporting companies could make our securities less attractive to investors.*

As of June 30, 2021, the market value of our common stock held by non-affiliates exceeded $700.0 million, causing us to no longer qualify as a “smaller reporting company” beginning with our first Quarterly Report on Form 10-Q for the quarterly period ended March 31, 2022. However, as of June 30, 2022, the market value of our common stock held by non-affiliates did not exceed $560.0 million and our revenue for the fiscal year ended December 31, 2021 did not exceed $100.0 million. As a result, we once again qualified as a smaller reporting company effective as of our Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2022, although we continued to be a large accelerated filer until the filing of our Annual Report on Form 10-K for the fiscal year ended December 31, 2022. Consequently, we qualify as a smaller reporting company and a non-accelerated filer for our 2023 reporting period, which allows us to take advantage of many exemptions from various reporting requirements that are applicable to other public companies that are not smaller reporting companies, including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act and reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, but we still expect to incur substantial legal and financial compliance costs. As we have chosen to avail ourselves of certain scaled disclosure requirements applicable to smaller reporting companies, the content of our disclosures may differ from period to period. We may no longer qualify as a smaller reporting company in the future should the market value of our common stock held by non-affiliates as of the end of the second quarter of any given year once again exceed $700.0 million or our revenue as of the end of any fiscal year exceed $100.0 million. There may be further variance in the content of our disclosures as we avail ourselves of certain scaled disclosure requirements if we subsequently no longer qualify as a smaller reporting company because we would be required to provide the full disclosures required of non-smaller reporting companies. We cannot predict if investors will find our securities less attractive because we rely on these exemptions, which could result in a less active trading market for our securities and increased volatility in the price of our securities.

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 the date of this Quarterly Report on Form 10-Q, we have filed registration statements on Form S-8 under the Securities Act registering the issuance of an aggregate of 52,867,200 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 General Corporation Law of the State of Delaware, 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.

Our recurring losses, negative cash flows and significant accumulated deficit have raised substantial doubt regarding our ability to continue as a going concern.

Since inception, we have experienced recurring operating losses and negative cash flows from operating activities, and have significant accumulated deficit. We expect to continue to generate operating losses and consume significant cash resources for the foreseeable future. Without additional financing, these conditions raise substantial doubt about our ability to continue as a going concern, meaning that we may be unable to continue operations for the foreseeable future or realize assets and discharge liabilities in the ordinary course of operations. As a result, our financial statements include an explanatory paragraph expressing substantial doubt about our ability to continue as a going concern. If we are unable to obtain sufficient funding, our business, prospects, financial condition and results of operations will be materially and adversely affected and we may be unable to continue as a going concern. If we are unable to continue as a going concern, we may have to liquidate our assets and may receive less than the value at which those assets are carried on our consolidated financial statements, and it is likely that investors will lose all or a part of their investment. Future reports from our independent registered public accounting firm may also contain statements expressing doubt about our ability to continue as a going concern. If we seek additional financing to fund our business activities in the future and there remains doubt about our ability to continue as a going concern, investors or other financing sources may be unwilling to provide additional funding on commercially reasonable terms or at all.

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.

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 newer 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
2.1+	First Amendment to Agreement and Plan of Merger, dated March 4, 2023, by and between the Company and Soheil Shams, as the Securityholders' Representative.
3.1 (1)	Amended and Restated Certificate of Incorporation, as amended.
3.2 (7)	Certificate of Designation of Preferences, Rights and Limitations of Series A Preferred Stock
3.3 (2)	Amended and Restated Bylaws.
3.4 (7)	Amendment to 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 (attached to the Underwriting Agreement).
4.4 (3)	Form of Warrant Certificate (included in Exhibit 4.5).
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)	Form of Warrant to Purchase Common Stock issued to Investors in October 2019 Public Offering.
4.8 (6)	Form of Warrant to Purchase Common Stock issued to Investors in April 2020 Public Offering.
10.1	Amendment No. 1 to Sales Agreement, dated March 9, 2023, by and between the Company and Cowen and Company, LLC.
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 Registration Statement on Form S-1 (File No. 333-233828), as amended.
(6) Incorporated by reference to the Registrant's Registration Statement on Form S-1 (File No. 333-237074), as amended.
(7) Incorporated by reference to the Registrant's Current Report on Form 8-K, filed with the SEC on April 14, 2023.

* 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.

+ Pursuant to Item 601(b)(10) of Regulation S-K, certain portions of this exhibit have been omitted (indicated by "[***]") because the Company has determined that the information is both not material and is the type that the Company treats as private or confidential.

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 9, 2023

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

Dated: May 9, 2023

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

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AMENDMENT NO. 1 TO

SALES AGREEMENT

March 9, 2023

This Amendment No. 1 ("**Amendment No. 1**") amends that certain Sales Agreement, dated as of March 23, 2021 (the "**Agreement**"), by and between Bionano Genomics, Inc. (the "**Company**") and Cowen and Company, LLC, as sales agent (the "**Agent**"). Defined terms used herein and not otherwise defined shall have the meaning assigned to such terms in the Agreement.

WITNESSETH THAT:

WHEREAS, Section 15 of the Agreement permits the Company and the Agent to amend the Agreement;

WHEREAS, the Company will not be a "well-known seasoned issuer" as such term is defined in Rule 405 under the Securities Act of 1933, as amended, upon the filing of the Annual Report on Form 10-K for the year ended December 31, 2022; and

WHEREAS, the Company and the Agent now desire to amend the Agreement as provided herein.

NOW, THEREFORE, in consideration of the foregoing premises and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Company and the Agent agree as follows:

1. Section 1 of the Agreement is amended by replacing the first sentence of the first paragraph with: "The Company agrees that, from time to time during the term of this Agreement, on the terms and subject to the conditions set forth herein and any Terms Agreement (defined below), it may issue and sell to or through Cowen, acting as agent and/or principal, shares (the "**Shares**") of the Company's common stock, par value $0.0001 per share (the "**Common Stock**"); *provided*, *however*, that in no event shall the Company issue or sell through Cowen such number or dollar amount of Shares that would (a) exceed the number of authorized but unissued shares of Common Stock (less shares of Common Stock issuable upon exercise, conversion or exchange of any outstanding securities of the Company or otherwise reserved from the Company's authorized capital stock), (b) exceed the number or dollar amount of shares of Common Stock permitted to be sold under Form S-3 (including General Instruction I.B.6 thereof, if applicable) or (c) exceed the number or dollar amount of shares of Common Stock for which the Company has filed a Prospectus Supplement (defined below) (the lesser of (a), (b) and (c), the "**Maximum Amount**")."

2. Section 1 of the Agreement is further amended by replacing the first sentence of the second paragraph with: "The Company has filed or will file, in accordance with the provisions of the Securities Act of 1933, as amended, and the rules and regulations thereunder (collectively, the "**Securities Act**"), with the Commission a shelf registration statement on Form S-3, including a base prospectus, relating to certain securities, including the Common Stock, to be issued from time to time by the Company, and which incorporates by reference documents that the Company has filed or will file in accordance with the provisions of the Securities Exchange Act of 1934, as amended, and the rules and regulations thereunder (collectively, the "**Exchange Act**").

3. Section 1 of the Agreement is further amended by adding the following to paragraph two immediately after the third sentence: "The Company may file one or more additional registration statements from time to time that will contain a base prospectus and related prospectus or prospectus supplement, if applicable (which shall be a Prospectus Supplement), with respect to the Shares.

4. Section 6(a) of the Agreement is amended by (i) deleting the first sentence thereof in its entirety and replacing it with "The Registration Statement has been filed, or any successor Registration Statement will

be filed, with the Commission and has been declared effective by the Commission under the Securities Act or, in the case of a successor Registration Statement, will be declared effective by the Commission under the Securities Act prior to the issuance of any Placement Notice by the Company." and (ii) deleting the fourth sentence of such section in its entirety.

5. Section 6(b) of the Agreement is amended and restated in its entirety as set forth below:

[Reserved.]

6. A new Section 20 is added to the Agreement as set forth below:

Recognition of the U.S. Special Resolution Regimes. In the event that Cowen is a Covered Entity and becomes subject to a proceeding under a U.S. Special Resolution Regime, the transfer from Cowen of this Agreement, and any interest and obligation in or under this Agreement, will be effective to the same extent as the transfer would be effective under the U.S. Special Resolution Regime if this Agreement, and any such interest and obligation, were governed by the laws of the United States or a state of the United States.

In the event that Cowen is a Covered Entity and Cowen or a BHC Act Affiliate of Cowen becomes subject to a proceeding under a U.S. Special Resolution Regime, Default Rights under this Agreement that may be exercised against Cowen are permitted to be exercised to no greater extent than such Default Rights could be exercised under the U.S. Special Resolution Regime if this Agreement were governed by the laws of the United States or a state of the United States.

For purposes of this Agreement, (A) "**BHC Act Affiliate**" has the meaning assigned to the term "affiliate" in, and shall be interpreted in accordance with, 12 U.S.C. § 1841(k); (B) "**Covered Entity**" means any of the following: (i) a "covered entity" as that term is defined in, and interpreted in accordance with, 12 C.F.R. § 252.82(b); (ii) a "covered bank" as that term is defined in, and interpreted in accordance with, 12 C.F.R. § 47.3(b); or (iii) a "covered FSI" as that term is defined in, and interpreted in accordance with, 12 C.F.R. § 382.2(b); (C) "**Default Right**" has the meaning assigned to that term in, and shall be interpreted in accordance with, 12 C.F.R. §§ 252.81, 47.2 or 382.1, as applicable; and (D) "**U.S. Special Resolution Regime**" means each of (i) the Federal Deposit Insurance Act and the regulations promulgated thereunder and (ii) Title II of the Dodd-Frank Wall Street Reform and Consumer Protection Act and the regulations promulgated thereunder.

7. References to the date of the Agreement in the form of Placement Notice included as Schedule 1 to the Agreement are hereby revised to read, "March 23, 2021, as amended by Amendment No. 1 thereto, dated March 9, 2023."

8. This Amendment No. 1 shall be deemed effective on the date first set forth above.

9. Except as amended hereby, the Agreement as now in effect is ratified and confirmed hereby in all respects. For the avoidance of doubt, this Amendment No. 1 and all of its provisions shall be deemed to be a part of the Agreement, as amended hereby. The Agreement as amended by this Amendment No. 1 constitutes the entire agreement of the parties hereto and supersedes all prior written or oral and all contemporaneous oral agreements, understandings and negotiations with respect to the subject matter hereof and thereof.

10. This Amendment No. 1 shall be governed by and construed in accordance with the internal laws of the State of New York applicable to agreements made and to be performed in such state. Any legal suit, action or proceeding arising out of or based upon this Amendment No. 1 or the transactions contemplated hereby may be instituted in the federal courts of the United States of America located in the Borough of Manhattan in the City of New York or the courts of the State of New York in each case located in the Borough of Manhattan in the City of New York (collectively, the "**Specified Courts**"), and each party irrevocably submits to the exclusive jurisdiction (except for proceedings instituted in regard to the enforcement of a judgment of any such court, as to which such jurisdiction is non-exclusive) of such courts in any such suit, action or proceeding. Service of any process, summons, notice or document by mail to such party's address set forth in the Agreement shall be effective service of process for any suit,

action or other proceeding brought in any such court. The parties irrevocably and unconditionally waive any objection to the laying of venue of any suit, action or other proceeding in the Specified Courts and irrevocably and unconditionally waive and agree not to plead or claim in any such court that any such suit, action or other proceeding brought in any such court has been brought in an inconvenient forum.

[Signature page follows.]

If the foregoing is in accordance with your understanding of our agreement, kindly sign and return to the Company the enclosed copies hereof, whereupon this instrument, along with all counterparts hereof, shall become a binding agreement in accordance with its terms.

Very truly yours,

BIONANO GENOMICS, INC.

By: /s/ R. Erik Holmlin, Ph.D.
Name: R. Erik Holmlin, Ph.D.
Title: President and Chief Executive Officer

The foregoing Amendment is hereby confirmed and accepted by the Agent in New York, New York as of the date first above written.

COWEN AND COMPANY, LLC

By: /s/ Michael Murphy
Name: Michael Murphy
Title: Managing Director

CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY [***], HAS BEEN OMITTED BECAUSE IT IS BOTH (I) NOT MATERIAL AND (II) IS THE TYPE THAT THE REGISTRANT TREATS AS PRIVATE OR CONFIDENTIAL.

Execution Version

FIRST AMENDMENT TO AGREEMENT AND PLAN OF MERGER

This First Amendment to Agreement and Plan of Merger (this "***Amendment***") is made as of March 4, 2023 (the "***Effective Date***") by and among Bionano Genomics, Inc., a Delaware corporation ("***Parent***"), and Soheil Shams, as the Securityholders' Representative ("***Securityholders' Representative***").

Recitals

A. Parent, Starship Merger Sub I, Inc., a California corporation and a wholly owned subsidiary of Parent, Starship Merger Sub II, LLC, a California limited liability company and a wholly owned subsidiary of Parent, BioDiscovery, Inc., a California corporation, and Securityholders' Representative entered into that certain Agreement and Plan of Merger, dated October 8, 2021 (the "***Agreement***");

B. Parent and Securityholders' Representative desire to amend the Agreement on the terms and subject to the conditions set forth herein; and

C. Pursuant to Section 10.1 of the Agreement, the Agreement may only be amended by an instrument in writing signed on behalf of Parent and the Securityholders' Representative after the Closing.

Agreement

Now, Therefore, in consideration of the mutual covenants and agreements of the parties hereto, and other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the parties hereto agree as follows:

1. Capitalized Terms. All capitalized terms used but not defined in this Amendment have the meanings set forth in the Agreement. From and after the date hereof, all references to the "Agreement" in the Agreement shall mean the Agreement as amended by this Amendment.

2. Amendment to the Agreement. As of the Effective Date, the defined term "Milestone" in Exhibit A of the Agreement is hereby amended and restated in its entirety as follows: "***Milestone***" shall mean [***].

3. Conflict; Ratification. In the event of any conflict between the terms of this Amendment and the terms of the Agreement, the terms of this Amendment shall control. Except as expressly provided in this Amendment, all of the terms and provisions of the Agreement are and will remain in full force and effect and are hereby ratified and confirmed by the parties hereto.

4. Limited Effect. The amendments contained herein will not be construed as an amendment to or waiver of any legal rights, other provisions of the Agreement, of any other agreement among the parties hereto, or as a waiver of or consent to any further or future action on the part of any party hereto that would require the waiver or consent of the other parties hereto.

5. Binding Effect; Governing Law; Entire Agreement. This Amendment shall be binding upon and shall inure to the benefit of the successors and permitted assigns of the parties hereto. The choice of law provisions in the Agreement remain in force and effect and govern this Amendment. This Amendment constitutes the sole and entire agreement between the parties with respect to the subject matter contained herein.

6. Counterparts. This Amendment may be executed in counterparts, each of which is deemed an original, but all of which constitute one and the same agreement. Delivery of an executed counterpart of this Amendment electronically or by facsimile shall be as effective as delivery of an original executed counterpart of this Amendment.

[Signature Page Follows]

In Witness Whereof, the parties have executed this Amendment in all applicable capacities effective as of the Effective Date.

PARENT:
Bionano Genomics, Inc.

By: /s/ R. Erik Holmlin, Ph.D.
Name: R. Erik Holmlin, Ph.D.
Title: President and Chief Executive Officer

(Signature Page to First Amendment to Agreement and Plan of Merger)

In Witness Whereof, the parties have executed this Amendment in all applicable capacities effective as of the Effective Date.

SECURITYHOLDERS' REPRESENTATIVE:

By: /s/ Soheil Shams
Name: Soheil Shams

(Signature Page to First Amendment to Agreement and Plan of Merger)

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:
    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 9, 2023

/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 9, 2023

/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, 2023, 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 9, 2023

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

Dated: May 9, 2023

/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.