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

FORM 10-Q

(Mark One)

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

FOR THE QUARTERLY PERIOD ENDED SEPTEMBER 30, 2024

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

(State or Other Jurisdiction of Incorporation or Organization)

26-1756290

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

**9540 Towne Centre Drive, Suite 100,
San Diego, CA**

(Address of Principal Executive Offices)

92121

(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

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes No

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, 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	<input type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input checked="" type="checkbox"/>	Smaller reporting company	<input checked="" type="checkbox"/>
		Emerging growth company	<input type="checkbox"/>

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

As of November 6, 2024, the registrant had 101,993,225 shares of Common Stock (\$0.0001 par value) outstanding.

BIONANO GENOMICS, INC.
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PART I. FINANCIAL INFORMATION**ITEM 1. FINANCIAL STATEMENTS****BIONANO GENOMICS, INC.
Condensed Consolidated Balance Sheets**

	(Unaudited) September 30, 2024	December 31, 2023
Assets		
Current assets:		
Cash and cash equivalents	\$ 8,794,000	\$ 17,948,000
Investments	3,160,000	48,823,000
Accounts receivable, net	5,316,000	9,319,000
Inventory	14,323,000	22,892,000
Prepaid expenses and other current assets	4,387,000	6,019,000
Restricted investments	11,000,000	35,117,000
Total current assets	46,980,000	140,118,000
Restricted cash, net of current portion	400,000	400,000
Property and equipment, net	19,995,000	23,345,000
Operating lease right-of-use assets	2,833,000	5,633,000
Finance lease right-of-use assets	3,351,000	3,503,000
Intangible assets, net	11,045,000	33,974,000
Other long-term assets	2,758,000	7,431,000
Total assets	\$ 87,362,000	\$ 214,404,000
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	8,700,000	10,384,000
Accrued expenses	5,883,000	8,089,000
Contract liabilities	1,195,000	783,000
Operating lease liability	1,956,000	2,163,000
Finance lease liability	263,000	272,000
Purchase option liability (at fair value)	—	8,534,000
Convertible debentures and High Trail notes payable (at fair value)	14,953,000	69,803,000
Total current liabilities	32,950,000	100,028,000
Operating lease liability, net of current portion	1,730,000	3,590,000
Finance lease liability, net of current portion	3,551,000	3,585,000
Contingent consideration	—	10,890,000
Long-term contract liabilities	263,000	154,000
Total liabilities	\$ 38,494,000	\$ 118,247,000
Commitments and contingencies (Note 7)		
Stockholders' equity:		
Preferred stock, \$0.0001 par value; 10,000,000 shares authorized at September 30, 2024 and December 31, 2023; no shares issued and outstanding at September 30, 2024 and December 31, 2023	—	—
Common stock, \$0.0001 par value, 400,000,000 shares authorized at September 30, 2024 and December 31, 2023; 88,468,000 and 45,752,000 shares issued and outstanding at September 30, 2024 and December 31, 2023, respectively	9,000	5,000
Additional paid-in capital	720,425,000	677,337,000
Accumulated deficit	(673,100,000)	(581,208,000)
Accumulated other comprehensive income	1,534,000	23,000
Total stockholders' equity	\$ 48,868,000	\$ 96,157,000
Total liabilities and stockholders' equity	\$ 87,362,000	\$ 214,404,000

See accompanying notes to the unaudited condensed consolidated financial statements.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Revenue:				
Product revenue	\$ 6,021,000	\$ 6,456,000	\$ 19,359,000	\$ 18,512,000
Service and other revenue	52,000	2,862,000	3,254,000	6,883,000
Total revenue	6,073,000	9,318,000	22,613,000	25,395,000
Cost of revenue:				
Cost of product revenue	14,251,000	5,105,000	23,858,000	13,714,000
Cost of service and other revenue	268,000	1,464,000	1,792,000	4,553,000
Total cost of revenue	14,519,000	6,569,000	25,650,000	18,267,000
Operating expenses:				
Research and development	4,717,000	13,785,000	21,329,000	42,331,000
Selling, general and administrative	9,464,000	24,896,000	40,109,000	77,809,000
Goodwill impairment	—	77,280,000	—	77,280,000
Intangible assets and other long-lived assets impairment	19,504,000	—	19,951,000	—
Restructuring costs	1,770,000	—	7,616,000	—
Total operating expenses	35,455,000	115,961,000	89,005,000	197,420,000
Loss from operations	(43,901,000)	(113,212,000)	(92,042,000)	(190,292,000)
Other income (expense):				
Interest income	376,000	730,000	1,876,000	2,122,000
Other income (expense)	(697,000)	(45,000)	(1,694,000)	(334,000)
Total other income (expense)	(321,000)	685,000	182,000	1,788,000
Loss before income taxes	(44,222,000)	(112,527,000)	(91,860,000)	(188,504,000)
Provision for income taxes	(24,000)	(39,000)	(32,000)	(98,000)
Net loss	\$ (44,246,000)	\$ (112,566,000)	\$ (91,892,000)	\$ (188,602,000)
Net loss per share, basic and diluted	\$ (0.52)	\$ (3.22)	\$ (1.34)	\$ (5.85)
Weighted-average common shares outstanding basic and diluted	85,870,000	35,001,000	68,748,000	32,246,000

See accompanying notes to the unaudited condensed consolidated financial statements.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Net loss:	\$ (44,246,000)	\$ (112,566,000)	\$ (91,892,000)	\$ (188,602,000)
Other comprehensive income (loss):				
Unrealized gain on investment securities	10,000	227,000	12,000	1,014,000
Change in fair value attributable to instrument-specific credit risk	1,503,000	—	1,503,000	—
Foreign currency translation adjustments	24,000	(10,000)	(4,000)	17,000
Other comprehensive income	\$ 1,537,000	\$ 217,000	\$ 1,511,000	\$ 1,031,000
Total comprehensive loss	<u>\$ (42,709,000)</u>	<u>\$ (112,349,000)</u>	<u>\$ (90,381,000)</u>	<u>\$ (187,571,000)</u>

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 Income (Loss)	Total Stockholders' Equity (Deficit)
	Shares	Amount				
Balance at January 1, 2023	29,718,000	\$ 3,000	\$ 599,234,000	\$ (348,715,000)	\$ (1,124,000)	\$ 249,398,000
Stock option exercises	4,000	—	23,000	—	—	23,000
Stock-based compensation expense	—	—	3,882,000	—	—	3,882,000
Issue common stock, net of issuance costs	950,000	—	14,848,000	—	—	14,848,000
Issuance of common stock due to the vesting of restricted stock units, net of shares withheld to cover taxes	7,000	—	—	—	—	—
Net loss	—	—	—	(37,124,000)	—	(37,124,000)
Other comprehensive income	—	—	—	—	459,000	459,000
Balance at March 31, 2023	30,679,000	\$ 3,000	\$ 617,987,000	\$ (385,839,000)	\$ (665,000)	\$ 231,486,000
Stock option exercises	—	—	1,000	—	—	1,000
Stock-based compensation expense	—	—	3,932,000	—	—	3,932,000
Issue common stock, net of issuance costs	2,552,000	—	17,802,000	—	—	17,802,000
Issuance of common stock due to the vesting of restricted stock units, net of shares withheld to cover taxes	(6,000)	—	—	—	—	—
Issue stock for employee stock purchase plan	15,000	—	92,000	—	—	92,000
Net loss	—	—	—	(38,912,000)	—	(38,912,000)
Other comprehensive income	—	—	—	—	355,000	355,000
Balance at June 30, 2023	33,240,000	\$ 3,000	\$ 639,814,000	\$ (424,751,000)	\$ (310,000)	\$ 214,756,000
Stock-based compensation expense	—	—	3,992,000	—	—	3,992,000
Issue common stock, net of issuance costs	2,109,000	—	12,661,000	—	—	12,661,000
Issue stock for warrant exercises	—	—	—	—	—	—
Issuance of common stock due to the vesting of restricted stock units, net of shares withheld to cover taxes	—	—	(61,000)	—	—	(61,000)
Net loss	—	—	—	(112,566,000)	—	(112,566,000)
Other comprehensive income	—	—	—	—	217,000	217,000
Balance at September 30, 2023	35,349,000	\$ 3,000	\$ 656,406,000	\$ (537,317,000)	\$ (93,000)	\$ 118,999,000
Balance at January 1, 2024	45,752,000	\$ 5,000	\$ 677,337,000	\$ (581,208,000)	\$ 23,000	\$ 96,157,000
Stock-based compensation expense	—	—	3,015,000	—	—	3,015,000
Issue common stock, net of issuance costs	11,787,000	1,000	15,059,000	—	—	15,060,000
Net loss	—	—	—	(31,422,000)	—	(31,422,000)
Other comprehensive income (loss)	—	—	—	—	(39,000)	(39,000)
Balance at March 31, 2024	57,539,000	\$ 6,000	\$ 695,411,000	\$ (612,630,000)	\$ (16,000)	\$ 82,771,000
Stock-based compensation expense	—	—	2,583,000	—	—	2,583,000
Issue common stock, net of issuance costs	11,025,000	1,000	11,181,000	—	—	11,182,000

Issue stock for warrant exercises	2,197,000	—	2,000	—	—	2,000
Issue stock for employee stock purchase plan	15,000	—	10,000	—	—	10,000
Net loss	—	—	—	(16,224,000)	—	(16,224,000)
Other comprehensive income	—	—	—	—	13,000	13,000
Balance at June 30, 2024	<u>70,776,000</u>	<u>\$ 7,000</u>	<u>\$ 709,187,000</u>	<u>\$ (628,854,000)</u>	<u>\$ (3,000)</u>	<u>\$ 80,337,000</u>
Stock option exercises	—	—	—	—	—	—
Stock-based compensation expense	—	—	2,202,000	—	—	2,202,000
Issue common stock, net of issuance costs	11,865,000	1,000	9,034,000	—	—	9,035,000
Issue stock for warrant exercises	5,813,000	1,000	2,000	—	—	3,000
Issuance of common stock due to the vesting of restricted stock units, net of shares withheld to cover taxes	14,000	—	—	—	—	—
Net loss	—	—	—	(44,246,000)	—	(44,246,000)
Other comprehensive income	—	—	—	—	1,537,000	1,537,000
Balance at September 30, 2024	<u>88,468,000</u>	<u>\$ 9,000</u>	<u>\$ 720,425,000</u>	<u>\$ (673,100,000)</u>	<u>\$ 1,534,000</u>	<u>\$ 48,868,000</u>

See accompanying notes to the unaudited condensed consolidated financial statements.

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

	Nine Months Ended September 30,	
	2024	2023
Operating activities:		
Net loss	\$ (91,892,000)	\$ (188,602,000)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization expense	11,624,000	10,112,000
Goodwill impairment	—	77,280,000
Inventory write-offs	7,231,000	—
Amortization of financing lease right-of-use asset	153,000	153,000
Accretion of interest on securities	(1,176,000)	(309,000)
Non-cash lease expense	(2,000)	38,000
Gain on lease modification	(73,000)	—
Net realized loss on investments	18,000	23,000
Stock-based compensation	7,800,000	11,806,000
Change in fair value of contingent consideration	(10,890,000)	2,528,000
Change in fair value of convertible debentures, convertible notes payable and option liability	(6,988,000)	—
Loss on issuance of convertible debentures	1,890,000	—
Gain on High Trail extinguishment	(3,965,000)	—
Impairment of internal-use software	1,293,000	—
Loss on intangible assets and other long-lived assets impairment	17,850,000	—
Loss on ROU asset impairment	808,000	—
Loss on property and equipment disposal	1,404,000	—
Cost of leased equipment sold to customer	361,000	88,000
Changes in operating assets and liabilities:		
Accounts receivable	4,006,000	(1,646,000)
Inventory	(3,521,000)	(3,819,000)
Prepaid expenses and other current assets	339,000	1,376,000
Other assets	4,677,000	(7,798,000)
Accounts payable	(1,679,000)	2,401,000
Accrued expenses and contract liabilities	(1,686,000)	967,000
Net cash used in operating activities	<u>(62,418,000)</u>	<u>(95,402,000)</u>
Investing Activities:		
Purigen acquisition, return of purchase consideration from escrow	—	96,000
Purchases of property and equipment	(103,000)	(946,000)
Purchase of available for sale securities	(214,323,000)	(4,485,000)
Sale and maturity of available for sale securities	285,268,000	84,866,000
Net cash provided by investing activities	<u>70,842,000</u>	<u>79,531,000</u>
Financing activities:		
Principal payments on financing lease liability	(43,000)	(34,000)
Proceeds from sale of common stock and warrants	37,712,000	46,411,000
Offering expenses on sale of common stock and warrants	(2,438,000)	(1,161,000)
Proceeds from sale of common stock under employee stock purchase plan	10,000	92,000
Proceeds from warrant and option exercises	4,000	23,000
Proceeds from issuance of convertible debentures	18,000,000	—
Payments on High Trail Notes	(61,001,000)	—
Payments on convertible debentures	(3,000,000)	—
Debt issuance costs on sale of convertible debentures	(1,444,000)	—

Payments of retirement fees for redemption of High Trail Notes	(5,375,000)	—
Net cash (used in)/provided by financing activities	(17,575,000)	45,331,000
Effect of exchange rates on cash, cash equivalents and restricted cash	(3,000)	17,000
Net decrease in cash, cash equivalents and restricted cash	(9,154,000)	29,477,000
Cash, cash equivalents and restricted cash at beginning of period	18,348,000	5,491,000
Cash, cash equivalents and restricted cash at end of period	<u>\$ 9,194,000</u>	<u>\$ 34,968,000</u>
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	8,794,000	34,568,000
Restricted cash	400,000	400,000
Total cash, cash equivalents and restricted cash at end of period	<u>\$ 9,194,000</u>	<u>\$ 34,968,000</u>
Supplemental cash flow disclosures:		
Cash paid for interest	\$ 10,136,000	\$ 221,000
Cash paid for operating lease liabilities	\$ 2,126,000	\$ 1,938,000
Supplemental disclosure of non-cash investing and financing activities:		
Transfer of instruments and servers from inventory to property and equipment, net	\$ 5,023,000	\$ 7,112,000
Property and equipment included in accounts payable	\$ —	\$ 434,000

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. The Company offers a platform-agnostic software solution, which integrates next-generation sequencing, microarray and OGM 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. The Company also offers nucleic acid extraction and purification solutions using proprietary isotachopheresis (“ITP”) technology. Through its Bionano Laboratories, (“Bionano Laboratories”) business, the Company also provides OGM-based diagnostic testing services.

Reverse Stock Split

On August 4, 2023, the Company filed a Certificate of Amendment to its Amended and Restated Certificate of Incorporation with the Secretary of State of the State of Delaware to effect a reverse stock split of all issued and outstanding shares of the Company’s common stock at a ratio of 1-for-10. The reverse stock split did not change the par value or the authorized number of shares of the Company’s common stock. The accompanying consolidated financial statements and notes to the consolidated financial statements present the retroactive effect of the reverse stock split on the Company’s common stock and per share amounts for all periods presented.

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, 2023.

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 September 30, 2024, the Company had approximately \$8.8 million in cash and cash equivalents, \$3.2 million in short-term investments and \$11.4 million in restricted cash and investments. The amount we are required to hold as restricted cash or investments is equal to the lesser of (a) \$11.0 million and (b) the then outstanding principal balance of the Debentures (as defined in Note 5 (Debt) below).

As of September 30, 2024 the Company had \$17.0 million of principal outstanding under the Debentures (see Note 5 (Debt)) and an accumulated deficit of \$673.1 million. During the nine months ended September 30, 2024, the Company used \$62.4 million of 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 product development 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 nine months ended September 30, 2024, 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, and if the Company is

unable to raise sufficient additional capital in the very near term, it may need to further curtail or cease operations and seek protection by filing a voluntary petition for relief under the United States Bankruptcy Code.

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 and nine months ended September 30, 2024, there were no material 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, 2023.

Restructuring

The Company's restructuring expense consists primarily of actions taken in May and October 2023 (the "2023 Workforce Reductions") and March and September 2024 (the "2024 Workforce Reductions") in order to reduce costs and improve operations and manufacturing efficiency. Severance-related costs were accounted for as a one-time termination benefit communicated by period end without an additional service component, so the charge represents the total amount expected to be incurred. As a result of reducing facility costs and discretionary spending unrelated to headcount and combined with the cost savings from the 2023 Workforce Reductions and 2024 Workforce Reductions, such plans are intended to decrease expenses and maintain a streamlined organization to support its business.

In connection with the Company's restructuring initiatives, the Company entered into a lease termination agreement on February 28, 2024 with the landlord for the facility in Salt Lake City that resulted in a one-time termination fee of approximately \$0.2 million in the third quarter of 2024. The Company continued to lease the property through June 2024. The Company accounted for the lease amendment as a lease modification and recorded a gain of \$0.1 million during the three months ended March 31, 2024.

On March 1, 2024, and September 4, 2024, the Company's board of directors approved restructuring plans, including reductions in force, that it expects to reduce the Company's annualized operating expenses. The 2024 Workforce Reductions were incremental to the 2023 Workforce Reductions. As part of the 2024 Workforce Reductions, the Company reduced its overall headcount by approximately 120 and 83 employees in March and September, respectively. The Company has substantially completed the reduction in force from the 2024 Workforce Reductions as of October 4, 2024. In addition, as of September 30, 2024, Bionano Laboratories has phased out the offering of certain testing services related to neurodevelopmental disorders, including autism spectrum disorders, and other disorders of childhood development. The Company may also incur additional costs not currently contemplated due to events that may occur as a result of, or that are associated with, the reduction in force. See Note 7 (Commitments and Contingencies) for additional information.

Impairment of In-Process Internal-Use Software

In-process internal-use software or cloud computing arrangements are reviewed for impairment if indicators of potential impairment exist. In September 2024, Bionano announced a change in its business strategy to focus on driving utilization and adoption of OGM from the Company's existing installed base, with less emphasis on new placements of the Company's OGM systems, which resulted in a change in the manner in which the Company's in-process internally developed software would be used; therefore, it became probable that the software would not be placed into service. The Company fully impaired the project, and recorded a loss of \$1.3 million included in intangible assets and other long-lived assets impairments on the unaudited condensed consolidated statement of operations during the three and nine months ended September 30, 2024. No impairment loss to the Company's internal-use software was recorded during the same period in 2023. The Company's in-process internal-use software was recorded in prepaid expenses and other current assets on the unaudited condensed consolidated balance sheets.

Impairment of Long-Lived Assets (including Finite-Lived Intangible Assets)

Long-lived assets are reviewed for impairment if indicators of potential impairment exist. If the Company identifies a change in the circumstances related to its long-lived assets, such as property and equipment and intangible assets (other than goodwill), that indicates the carrying value of any such asset may not be recoverable, the Company will perform an impairment analysis. A long-lived asset (other than goodwill) is not recoverable when the undiscounted cash flows expected to be generated by the asset (or asset group) are less than the asset's carrying amount. Any required impairment loss would be measured as the amount

by which the asset's carrying value exceeds its fair value, and would be recorded as a reduction in the carrying value of the related asset and a charge to operating expense.

During the three months ended March 31, 2024, the Company experienced a triggering event as a result of the restructuring initiatives announced in March 2024 that required an evaluation of its non-OGM Bionano Laboratories asset group for impairment. The Company performed a recoverability test and concluded that the non-OGM Bionano Laboratories long-lived assets were not recoverable; therefore, the Company measured the impairment loss and fully impaired the intangible assets acquired through the acquisition of Lineagen, consisting of its trade name and customer relationship intangible assets. The Company recognized an impairment loss of \$0.4 million during the three months ended March 31, 2024.

During the three months ended September 30, 2024, the Company experienced a triggering event and identified indicators of impairment in all of its asset groups as a result of the restructuring initiatives and change in business strategy announced in September 2024. The Company assessed the recoverability of each asset group and concluded the legacy OGM Bionano and Purigen asset groups were not recoverable. Therefore, the Company was required to perform an impairment analysis to determine the fair value of the legacy OGM Bionano and Purigen asset groups as further described below.

The Company evaluated the fair value of the finite-lived assets of the legacy OGM Bionano asset group. The Company evaluated the fair value of the reagent rental instruments based on expected sales price and recorded an impairment loss of \$2.6 million. The estimates and assumptions used in the assessment of the reagent rental instrument impairments represent Level 2 measurements because they are supported by quoted prices for similar assets in markets where trading occurs. The impairment loss associated with these reagent rental instruments was recorded to cost of product revenue in the Company's unaudited condensed consolidated statement of operations. Underperforming assets that were subject to impairment are included in the install base.

The Company evaluated the fair value of the finite-lived intangible assets of the Purigen asset group, consisting of the Purigen trade name, customer relationships and developed technology, as well as the operating lease right-of-use asset and related office equipment and leasehold improvements. To estimate the fair value of the intangible assets, the Company utilized the discounted cash flow method to estimate the fair value of the asset group. The Company identified that no projected after-tax cash flows would be generated from the Purigen intangible assets and that the cost to maintain and sell the Purigen products exceeded the expected revenue to be generated from the asset group. The carrying value of the Purigen intangible assets therefore exceeded its fair value and the Company recorded an impairment loss of \$17.3 million for the intangible assets. The Company estimated the fair value of the right-of-use asset and related office equipment and leasehold improvements for the Pleasanton, California facility and recorded an impairment loss of \$0.8 million. The fair value of the right-of-use asset and related office equipment and leasehold improvements was estimated using the discounted future cash flow methods, which includes estimates and assumptions for future sublease rental rates that reflect current sublease market conditions as well as discount rates. The Company also recorded \$0.1 million of leasehold improvements and office equipment impairments related to the Pleasanton, California facility. The estimates and assumptions used in the assessment of intangible assets, right-of-use assets and related office equipment and leasehold improvement impairments represent Level 3 measurements because they are supported by little or no market activity and reflect the Company's assumptions in measuring fair value. The impairment losses were recognized in intangible assets and other long-lived assets impairment in the unaudited condensed consolidated statement of operations.

No impairment losses were recorded during the three or nine months ended September 30, 2023.

Inventories

The Company reviews its inventories for classification purposes. The value of inventories not expected to be realized in cash, sold or consumed during the next 12 months are classified as non-current within other long-term assets. As of September 30, 2024, \$2.0 million of inventories were included in other long-term assets.

During the three months ended September 30, 2024, the Company recorded a \$7.2 million write-off of its Saphyr instrument spare parts and other obsolete inventory as a result of the Company's restructuring initiatives and change in business strategy announced in September 2024.

Loss on disposal of property and equipment

Loss on disposal of property and equipment includes the net book value of assets that have been abandoned or retired and consists primarily of our leasehold improvements, furniture, equipment and fixtures that were abandoned and disposed of in the normal course of business. We recorded a loss on disposal of property and equipment of \$1.4 million as of September 30, 2024.

Change in depreciable lives of property and equipment

The Company reviews the estimated useful life of its fixed assets on an ongoing basis. This review indicated that the actual lives of the Company's Saphyr and Stratys instruments were longer than the estimated useful lives used for depreciation purposes in the Company's unaudited condensed consolidated financial statements. As a result, effective January 1, 2024, the Company changed its estimates of the useful lives of the Company's Saphyr and Stratys instruments to better reflect the

estimated period during which these assets will remain in service. The estimated useful lives of the Company's Saphyr and Stratys instruments were increased from 5 to 7 years. The effect of this change in estimate reduced depreciation expense by \$0.5 million for the fiscal year 2024.

Recent Accounting Pronouncements

In November 2024, the FASB issued ASU 2024-03, *Income Statement - Reporting Comprehensive Income - Expense Disaggregation Disclosures (Subtopic 220-40): Disaggregation of Income Statement Expenses*, which requires additional disclosure about specific expense categories in the notes to financial statements. The amendments are effective for fiscal years beginning after December 15, 2026, and for interim periods within fiscal years beginning after December 15, 2027. Early adoption is permitted. The amendments should be applied either prospectively to financial statements issued for reporting periods after the effective date of this ASU or retrospectively to any or all prior periods presented in the financial statements. The Company is currently evaluating the impact of this accounting standard update on the Company's consolidated financial statements and related disclosures.

In November 2023, the FASB issued Accounting Standards Update, or ASU, 2023-07, *Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures*, which updates reportable segment disclosure requirements primarily through enhanced disclosures about significant segment expenses. The amendments are effective for fiscal years beginning after December 15, 2023, and for interim periods within fiscal years beginning after December 15, 2024. Early adoption is permitted. The amendments should be applied retrospectively to all prior periods presented in the financial statements. The Company is currently evaluating this ASU to determine its impact on the Company's consolidated financial statements and related disclosures.

In December 2023, the FASB issued ASU 2023-09, *Income Taxes (Topic 740): Improvement to Income Tax Disclosures* to enhance the transparency and decision usefulness of income tax disclosures. Two primary enhancements related to this ASU include disaggregating existing income tax disclosures relating to the effective tax rate reconciliation and income taxes paid. ASU 2023-09 is effective for annual periods beginning after December 15, 2024 on a prospective basis. Early adoption is permitted. The Company is currently evaluating the impact of this accounting standard update on the Company's consolidated financial statements and related disclosures.

2. Net Loss Per Share

Basic net loss per share is calculated by dividing the net loss by the weighted-average number of common shares outstanding for the period. The Pre-Funded Warrants (as defined below) issued in the April 2024 Registered Direct Offering and the July 2024 Registered Direct Offering (each as defined below) were exercised in full and included in the weighted-average number of common shares outstanding (See Note 6 (Stockholder's Equity and Stock-Based Compensation) for further information). 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 common warrants to purchase common 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. 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):

	September 30, 2024	September 30, 2023
Stock options	3,782,000	3,527,000
Warrants	65,456,000	40,000
Convertible debentures into common stock	8,500,000	—
RSUs	413,000	266,000
PSUs	29,000	29,000
Total	<u>78,180,000</u>	<u>3,862,000</u>

3. Revenue Recognition

Revenue by Source

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Instruments	\$ 1,419,000	\$ 2,338,000	\$ 5,293,000	\$ 6,684,000
Consumables	3,333,000	2,476,000	9,366,000	7,664,000
Software	1,269,000	1,642,000	4,700,000	4,164,000
Total product revenue	6,021,000	6,456,000	19,359,000	18,512,000
Service and other	52,000	2,862,000	3,254,000	6,883,000
Total revenue	\$ 6,073,000	\$ 9,318,000	\$ 22,613,000	\$ 25,395,000

Revenue by Geographic Location

	Three Months Ended September 30,				Nine Months Ended September 30,			
	2024		2023		2024		2023	
	\$	%	\$	%	\$	%	\$	%
Americas	\$ 2,537,000	42 %	\$ 5,346,000	57 %	\$ 10,613,000	47 %	\$ 13,103,000	52 %
EMEA	2,764,000	46 %	2,686,000	29 %	9,521,000	42 %	8,426,000	33 %
Asia Pacific	772,000	13 %	1,286,000	14 %	2,479,000	11 %	3,866,000	15 %
Total	\$ 6,073,000	100 %	\$ 9,318,000	100 %	\$ 22,613,000	100 %	\$ 25,395,000	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.

For the three months ended September 30, 2024 and 2023, the United States represented 32.3% and 51.2% of total revenue, respectively. For the nine months ended September 30, 2024 and 2023, the United States represented 38.3% and 44.2% of total revenue, respectively. For the nine months ended September 30, 2023, China represented 10.3% of total revenue. No other countries represented greater than 10% of total revenue during the three and nine months ended September 30, 2024 and 2023.

Remaining Performance Obligations

As of September 30, 2024, the estimated revenue expected to be recognized in the future related to performance obligations that are unsatisfied was approximately \$1.5 million. These remaining performance obligations primarily relate to extended warranty, support and maintenance obligations, as well as obligations related to software under hosting arrangements. The Company expects to recognize approximately 38.3% of this amount as revenue during the remainder of 2024, 48.0% in 2025, and 13.7% in 2026 and thereafter. Warranty revenue is included in service and other revenue.

The Company recognized revenue of approximately \$0.6 million and \$0.2 million during the three months ended September 30, 2024 and 2023, respectively, which was included in the contract liability balance at the end of the year preceding each period, and revenue of approximately \$1.3 million and \$1.3 million during the nine months ended September 30, 2024 and 2023, respectively, which was included in the contract liability balance at the end of the year preceding each period.

4. Balance Sheet Account Details

Accounts Receivable and Allowance for Credit Losses

	September 30, 2024	December 31, 2023	December 31, 2022
Accounts receivable, net:			
Accounts receivable, trade	\$ 5,520,000	\$ 9,802,000	\$ 7,315,000
Allowance for credit losses	(204,000)	(483,000)	(293,000)
	<u>\$ 5,316,000</u>	<u>\$ 9,319,000</u>	<u>\$ 7,022,000</u>

Changes to the allowance for credit losses during the nine months ended September 30, 2024 and 2023 were as follows:

	Allowance for Credit Losses
Balance as of January 1, 2023	\$ (293,000)
Provision for expected credit loss	(98,000)
Write-offs	37,000
Balance as of September 30, 2023	<u>\$ (354,000)</u>
Balance as of January 1, 2024	\$ (483,000)
Provision for expected credit loss	(9,000)
Write-offs	288,000
Balance as of September 30, 2024	<u>\$ (204,000)</u>

The Company's analysis 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:

	September 30, 2024	December 31, 2023
Inventory:		
Raw materials	\$ 3,601,000	\$ 7,567,000
Work in process	3,583,000	9,790,000
Finished goods	9,097,000	10,245,000
	<u>\$ 16,281,000</u>	<u>\$ 27,602,000</u>
Inventories current	\$ 14,323,000	\$ 22,892,000
Inventories non-current (included in other long-term assets)	\$ 1,958,000	\$ 4,710,000

Intangible Assets

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

	September 30, 2024			December 31, 2023		
	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount
Trade name	\$ 1,000,000	\$ (592,000)	\$ 408,000	\$ 2,630,000	\$ (1,078,000)	\$ 1,552,000
Customer relationships	3,000,000	(1,775,000)	1,225,000	4,150,000	(2,002,000)	2,148,000
Developed technology	22,800,000	(13,490,000)	9,310,000	41,600,000	(11,428,000)	30,172,000
Intangibles, net	<u>\$ 26,800,000</u>	<u>\$ (15,857,000)</u>	<u>\$ 10,943,000</u>	<u>\$ 48,380,000</u>	<u>\$ (14,508,000)</u>	<u>\$ 33,872,000</u>

Intangible assets not subject to amortization totaled \$0.1 million at September 30, 2024 and December 31, 2023, and related to the Company's domain name. See Note 1 (Organization and Basis of Presentation) for further discussion on the impairment charges impacting the Company's intangible assets in the period.

Accrued Expenses

Accrued expenses consist of the following:

	September 30, 2024	December 31, 2023
Compensation expenses*	\$ 4,007,000	\$ 5,030,000
Customer deposits	17,000	17,000
Taxes payable	1,008,000	1,099,000
Insurance	16,000	512,000
Professional fees and royalties	496,000	387,000
Warranty liabilities	254,000	391,000
Accrued clinical study fees	10,000	138,000
Other	75,000	515,000
Total	<u>\$ 5,883,000</u>	<u>\$ 8,089,000</u>

*Compensation expenses include restructuring costs of \$1.0 million as of September 30, 2024. Refer to Note 7 (Commitments and Contingencies).

5. Debt

JGB Debentures

On May 24, 2024, the Company entered into a securities purchase agreement with certain accredited investors (the “Holders”) and JGB Collateral LLC, as collateral agent for the Holders, for the sale by the Company in a private placement (the “JGB Debentures Offering”) of:

- 2.25 million shares (the “Shares”) of the Company’s common stock, par value \$0.0001 per share (“Common Stock”), and
- Senior Secured Convertible Debentures in the aggregate principal amount of \$20.0 million (the “Debentures”), for an aggregate purchase price of \$18.0 million.

The closing of the JGB Debentures Offering occurred on May 24, 2024. In connection with the closing of the JGB Debentures Offering, the Company received net proceeds of approximately \$16.6 million, after payment of placement agent fees, and other offering expenses. The Company used the proceeds received to fully redeem the outstanding balance due under the High Trail Note of approximately \$17.6 million, as amended (see “High Trail Agreement & Amendment” below).

Debentures

The Debentures have an aggregate face value of \$20.0 million and were issued with an original issue discount of \$2.0 million. The Debentures mature on May 24, 2026, and have an interest rate of 11% per annum payable monthly on the last business day of each calendar month. As of September 30, 2024, the Company has paid the Holders \$0.8 million in interest, which is included in the change in fair value within other income (expense), net.

The Company recorded the Debentures at their fair value at issuance of \$19.9 million, per the fair value option under ASC 825 (refer to Note 8 (Investments and Fair Value Measurements)) and they will be measured on a recurring basis and adjusted through other income and expense, net. The Shares were recorded at \$0 in common stock and additional paid in capital, which represents the residual amount after allocation of proceeds to the Debentures at fair value. The Company recognized an initial loss on the issuance of the Debentures of \$1.9 million for the difference between the fair value of the Debentures and proceeds from the transaction, which is recorded in other income (expense) on the unaudited condensed consolidated statement of operations. The Company incurred debt issuance costs of \$1.4 million related to the JGB Debentures Offering, which was charged to interest expense and recorded in other income (expense) on the unaudited condensed consolidated statement of operations.

On July 24, 2024, the Holders of the Debentures requested that the Company redeem up to \$1.0 million per calendar month of its Debentures. The table below shows the amount of potential redemptions each year until the maturity of the Debentures. As of September 30, 2024, the Company has paid the Holders \$3.0 million in principal redemptions.

2024	\$	3,000,000
2025		12,000,000
2026		2,000,000
Total	\$	<u>17,000,000</u>

The Company may redeem the Debentures, subject to certain Equity Conditions (as defined in the Debentures), at any time by paying an amount equal to the entire outstanding principal amount of the Debenture, plus all accrued and unpaid interest, plus the applicable Company Redemption Premium (as defined in the Debentures, the “Premium”) plus any other amounts due and payable under the Debentures. The Premium is an amount equal to 112% of the principal amount of the Debenture if the redemption is prior to the first anniversary of the original issue date, or 106% of the principal amount of the Debenture if the redemption is on or after the first anniversary of the original issue date. No partial redemptions by the Company are permitted.

At the election of the holder, each Debenture is convertible, in whole or in part, at any time and from time to time at a conversion price of \$2.00 per share of common stock. The conversion price is subject to adjustment for stock dividends, stock splits, and certain other corporate events. Notwithstanding the foregoing, the Company will not effect any conversion under the Debentures to the extent that such conversion would cause the holder’s beneficial ownership of the Company’s common stock to exceed 4.99% (or 9.99% at the election of the holder) of the Company’s issued and outstanding common stock.

Under the Debentures, the Company must at all times maintain a cash or restricted investments balance equal to the lesser of (a) \$11.0 million and (b) the then outstanding principal balance of the Debentures, in a blocked account. In addition, for as long as any portion of the Debentures remain outstanding, the Company is generally restricted from: incurring indebtedness; granting or suffering liens on any of its property or assets; amending its organizational documents; repurchasing any of its securities; paying dividends; selling, disposing, licensing or leasing its assets other than in the ordinary course; and other customary restrictive covenants. The Debentures also set forth certain customary events of default after which the Debentures may be

declared immediately due and payable, including certain types of bankruptcy or insolvency events of default involving the Company and its subsidiaries, and in the event of a change of control or fundamental transaction as defined in the Debentures.

As of September 30, 2024 the Company had \$17.0 million of principal outstanding under the Debentures reported at fair value of \$15.0 million (refer to Note 8 (Investments and Fair Value Measurements), for fair value measurements and additional discussion) and activity broken out as follows:

	Debentures
Principal balance, January 1, 2024	\$ —
Issuance of convertible debentures	20,000,000
Less:	
Conversions	—
Redemption payments of principal	(3,000,000)
Debentures principal balance, September 30, 2024	<u>\$ 17,000,000</u>

High Trail Agreement & Amendment

On February 27, 2024, the Company entered into a letter agreement with High Trail and an amendment to the Registered Note (the “High Trail Amendment”) which provided for, among other things, the following:

- Reduction of the minimum available liquidity covenant from \$50.0 million to \$25.0 million;
- Reduction of the restricted cash covenant from \$35.0 million to the amount equal to the sum of (i) the outstanding principal amount of the senior secured convertible notes payable due 2025 (the “High Trail Registered Notes”) plus (ii) approximately \$0.7 million, which will be further reduced as the remaining principal on the High Trail Registered Notes are retired;
- Cancellation of the March 2024 partial redemption payment and delay of the April 2024 partial redemption payment;
- Redemption of the outstanding \$17.0 million balance of the privately placed senior secured convertible notes payable due 2025 (the “High Trail Private Placement Notes”) at a redemption price of 115% for a total redemption payment of approximately \$19.6 million;
- Redemption of approximately \$10.7 million of the High Trail Registered Notes at a redemption price of 115% for a total redemption payment of approximately \$12.3 million; and
- Increase of \$1.0 million to the Retirement Fee (as defined in the Notes) of the High Trail Private Placement Notes to \$3.2 million payable concurrently with redemptions of the Initial Private Placement Note.

Immediately following the redemptions above, there was approximately \$24.3 million in aggregate principal amount of the High Trail Registered Notes outstanding.

High Trail Redemption Agreement

On May 23, 2024, in connection with the JGB Debentures Offering, the Company entered into a redemption agreement with High Trail (the “HT Agreement”). Pursuant to the HT Agreement, the Company agreed to redeem the entire outstanding principal amount of \$15.3 million under the High Trail Note at a redemption price of 115% for a total redemption payment of \$17.6 million (the “Redemption Payment”). Upon High Trail’s receipt of the Redemption Payment on May 24, 2024, the High Trail Note and related Option were cancelled. In addition, the Company agreed to pay High Trail a retirement fee of \$2.2 million and to reimburse High Trail for all of its reasonable and documented out-of-pocket expenses incurred with the release and termination of security interests relating to the High Trail Note.

The Company recognized a loss on the extinguishment of the High Trail Note of \$1.1 million, and a gain on the extinguishment of the Purchase Option (as defined in Note 7 (Commitments and Contingencies) below) of \$5.1 million, for a net gain of \$4.0 million, which is recorded in other income (expense) on the unaudited condensed consolidated statement of operations.

As of September 30, 2024, the Company had no principal outstanding under the High Trail Note (refer to Note 8 (Investments and Fair Value Measurements), for fair value measurements and additional discussion) and activity broken out as follows:

Principal balance, January 1, 2024	\$	61,000,000
Less:		
Conversions		—
Partial redemption of principal		18,000,000
Redemption payment of principal		43,000,000
Total	\$	—

In addition to redeeming \$15.3 million and \$27.7 million of the principal outstanding under the High Trail Note on May 24, 2024, and March 1, 2024, respectively, for an aggregate principal redemption of \$43.0 million at the aggregate Redemption Price of \$49.5 million, the Holders redeemed \$4.5 million each of principal on January 1, 2024, February 1, 2024, April 20, 2024, and May 1, 2024, for an aggregate principal redemption of \$18.0 million at an aggregate Repayment Price of \$20.7 million. Under the terms of the High Trail Notes, the Holders had the option to redeem a portion of the Notes not to exceed \$4.5 million principal on the first day of each month beginning November 1, 2023, at the Repayment Price. The April 2024 payment was delayed to April 20, 2024, under the High Trail Amendment as discussed above.

Other Income (Expense), Net

The following is a summary of the charges included within other income (expense), net on the unaudited condensed consolidated statement of operations:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Debt issuance costs on sale of convertible debenture	\$ —	\$ —	\$ (1,444,000)	\$ —
Other interest expense	(68,000)	(71,000)	(262,000)	(221,000)
Changes in estimated fair value, interest and redemption payments on High Trail Notes and convertible debentures	(630,000)	—	(1,485,000)	—
Other expense	1,000	26,000	(578,000)	(113,000)
Gain on High Trail extinguishment	—	—	3,965,000	—
Loss on issuance of convertible debentures	—	—	(1,890,000)	—
Total other income (expense)	\$ (697,000)	\$ (45,000)	\$ (1,694,000)	\$ (334,000)

6. Stockholders' Equity and Stock-Based Compensation

Reverse Stock Split

On August 4, 2023, the Company completed a reverse stock split of its outstanding shares of common stock pursuant to which every 10 shares of issued and outstanding common stock were exchanged for one share of common stock. No fractional shares were issued in the reverse stock split. Instead, the Company paid cash (without interest) equal to such fraction multiplied by \$5.90 per share (a price equal to the average of the closing sales prices of the common stock on The Nasdaq Capital Market during regular trading hours for the five consecutive trading days immediately preceding August 4, with such average closing sales prices being adjusted to give effect to a Reverse Stock Split). All share and per share amounts included within these condensed consolidated financial statements have been retrospectively adjusted to reflect the reverse stock split.

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. During the nine months ended September 30, 2024, the Company sold approximately 14.2 million shares of common stock under the Cowen ATM at an average share price of \$1.25 per share, and received gross proceeds of approximately \$17.7 million before deducting offering costs of \$0.4 million.

In October 2024, the Company sold approximately 3.6 million shares of common stock under the Cowen ATM at an average share price of \$0.34 per share, and received gross proceeds of approximately \$1.2 million before deducting offering costs of approximately \$31,000.

Stock Warrants

A summary of the Company's warrant activity during the nine months ended September 30, 2024 was as follows:

	Shares of Stock under Warrants	Weighted- Average Exercise Price	Weighted- Average Remaining Contractual Term	Aggregate Intrinsic Value
Outstanding at January 1, 2024	21,696,000	\$ 4.38	4.78	\$ —
Granted	51,770,000	0.56	—	—
Exercised	(8,010,000)	—	—	—
Canceled	—	—	—	—
Outstanding at September 30, 2024	65,456,000	\$ 1.89	1.94	\$ —

Stock Options

A summary of the Company's stock option activity during the nine months ended September 30, 2024 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, 2024	3,268,000	\$ 24.79	7.80	\$ 3,000
Granted	1,904,000	0.92	—	—
Exercised	—	—	—	—
Canceled	(1,390,000)	17.12	—	—
Outstanding and expected to vest at September 30, 2024	3,782,000	\$ 15.59	7.66	\$ —
Vested and exercisable at September 30, 2024	1,729,000	\$ 25.72	6.42	\$ —

For the three months ended September 30, 2024, the weighted-average grant date fair value of stock options granted was \$0.44 per share. For the nine months ended September 30, 2024, the weighted-average grant date fair value of stock options granted was \$0.67 per share.

Stock-Based Compensation

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Cost of product revenue	\$ 82,000	\$ 139,000	\$ 244,000	\$ 395,000
Cost of service and other revenue	—	48,000	94,000	136,000
Research and development	445,000	1,249,000	1,730,000	\$ 3,907,000
General and administrative	1,675,000	2,556,000	5,732,000	7,368,000
Total stock-based compensation expense	\$ 2,202,000	\$ 3,992,000	\$ 7,800,000	\$ 11,806,000

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Risk-free interest rate	3.8 %	4.3 %	4.3 %	4.0 %
Expected volatility	85.7 %	78.9 %	86.2 %	75.2 %
Expected term (in years)	6.1	6.1	5.7	5.9
Expected dividend yield	0.0 %	0.0 %	0.0 %	0.0 %

Restricted Stock Units and Performance Stock Units

The following table summarizes RSU activity during the nine months ended September 30, 2024:

	Stock Units	Weighted-Average Grant Date Fair Value per Share
Outstanding at January 1, 2024	239,000	\$ 16.30
Granted	407,000	0.93
Released	(69,000)	12.28
Forfeited	(164,000)	6.15
Outstanding at September 30, 2024	413,000	\$ 4.44

The total fair value of the RSUs that vested during the nine months ended September 30, 2024 was \$0.8 million, determined as of the date of vesting. The weighted average remaining contractual term for the RSUs is 3.3 years as of September 30, 2024.

The following table summarizes PSU activity during the nine months ended September 30, 2024:

	Stock Units	Weighted-Average Grant Date Fair Value per Share
Outstanding at January 1, 2024	29,000	\$ 47.40
Granted	—	—
Released	—	—
Forfeited	—	—
Outstanding at September 30, 2024	29,000	\$ 47.40

During the year ended December 31, 2023, the Company reassessed the implicit service period on its performance-based stock units relative to specified revenue targets and determined that the performance conditions were met from an accounting perspective, but subject to certain certifications and approval from the Compensation Committee; therefore, the remaining

expense was accelerated as of December 31, 2023. As a result of the accelerated vesting terms, the weighted average remaining contractual term for the PSUs is 0 years as of September 30, 2024.

Registered Direct Offerings

On April 4, 2024, the Company entered into a securities purchase agreement (the “April 2024 Purchase Agreement”) with certain institutional investors, pursuant to which the Company agreed to issue and sell, in a registered direct offering priced at-the-market consistent with the rules of the Nasdaq Stock Market (the “April 2024 Registered Direct Offering”): (i) an aggregate of approximately 6.5 million shares of the Company’s common stock, (ii) pre-funded warrants to purchase up to an aggregate of approximately 2.2 million shares of common stock (the “April Pre-Funded Warrants”), and (iii) warrants to purchase up to approximately 8.7 million shares of common stock (the “April Purchase Warrants”). The combined purchase price of each share of common stock and accompanying April Purchase Warrant is \$1.15 per share. The combined purchase price of each April Pre-Funded Warrant and accompanying April Purchase Warrant is \$1.14 (equal to the combined purchase price per share of common stock and accompanying April Purchase Warrant, minus \$0.001). The gross proceeds to the Company from the April 2024 Registered Direct Offering was \$10.0 million. The Company received net proceeds of \$9.3 million after deducting placement agent fees and other offering expenses of \$0.7 million payable by the Company.

Each April Purchase Warrant is exercisable for one share of common stock at an exercise price of \$1.02 per share. The Purchase Warrants are immediately exercisable as of the date of issuance of April 8, 2024, and will expire on the five-year anniversary of the date of issuance. The April Pre-Funded Warrants are offered in lieu of shares of common stock and provide that the holder may not exercise any portion of an April Pre-Funded Warrant to the extent that immediately prior to or after giving effect to such exercise the holder would own more than 4.99% (or, at the election of the holder, 9.99%) of the Company’s outstanding common stock immediately following the consummation of the April 2024 Registered Direct Offering. Each April Pre-Funded Warrant is exercisable for one share of common stock at an exercise price of \$0.001 per share. The April Pre-Funded Warrants are immediately exercisable and were exercised in full at the time of closing.

On July 4, 2024, the Company entered into a securities purchase agreement (the “July 2024 Purchase Agreement”) with certain institutional investors, pursuant to which the Company agreed to issue and sell, (i) in a registered direct offering priced at-the-market consistent with the rules of the Nasdaq Stock Market (the “July 2024 Registered Direct Offering”): (a) an aggregate of 11.7 million shares of the Company’s common stock, and (b) pre-funded warrants to purchase up to an aggregate of approximately 5.8 million shares of common stock (the “July Pre-Funded Warrants”), and (ii) in a concurrent private placement (the “Private Placement” and together with the July 2024 Registered Direct Offering, the “July 2024 Offering”), Series A warrants to purchase up to an aggregate of approximately 17.5 million shares of common stock (the “Series A Warrants”) and Series B warrants to purchase up to an aggregate of approximately 17.5 million shares of common stock (the “Series B Warrants”, and together with the Series A Warrants, the “July Purchase Warrants”). Each share of common stock and each July Pre-Funded Warrant sold pursuant to the July 2024 Purchase Agreement will be accompanied by one Series A Warrant and one Series B Warrant. The combined purchase price of each share of common stock and accompanying July Purchase Warrants is \$0.571 per share. The combined purchase price of each July Pre-Funded Warrant and accompanying July Purchase Warrants is \$0.571 (equal to the combined purchase price per share of common stock and accompanying July Purchase Warrants, minus \$0.001). The gross proceeds to the Company from the July 2024 Offering was approximately \$10.0 million (excluding up to \$20.0 million of aggregate gross proceeds that may be received in the future upon the cash exercise of the July Purchase Warrants issued in the Private Placement which is contingent upon the July Stockholder Approval described below), before deducting placement agent fees and other offering expenses payable by the Company. The Company received net proceeds of \$9.3 million after deducting placement agent fees and other offering expenses of \$0.7 million payable by the Company.

Each July Purchase Warrant is exercisable for one share of common stock at an exercise price of \$0.571 per share beginning on the effective date of stockholder approval of the issuance of the shares of common stock upon exercise of the July Purchase Warrants (the “July Stockholder Approval”). The Series A Warrants will expire on the earlier of (i) the 24-month anniversary of the July Stockholder Approval and (ii) 60 days following the later of (a) the date of the public announcement of the occurrence of a medical administrative contractor (including, without limitation, Molecular Diagnostic Services), issuing a final local coverage determination for optical genome mapping for hematological malignancies and (b) the date of the July Stockholder Approval. The Series B Warrants will expire on the earlier of (i) the five-year anniversary of the July Stockholder Approval and (ii) six months following the later of (a) the date of the public announcement of the occurrence of the Company receiving clearance from the U.S. Food and Drug Administration for an optical genome mapping system for any indication and (b) the date of the July Stockholder Approval. Each July Pre-Funded Warrant is exercisable for one share of common stock at an exercise price of \$0.001 per share. The July Pre-Funded Warrants were immediately exercisable and were exercised in full as of September 30, 2024.

The Company adjourned its reconvened Special Meeting of Stockholders originally held on October 2, 2024 and subsequently adjourned to October 30, 2024 (the “Special Meeting”) because a quorum was not present at the time of the reconvened meeting. The Special Meeting will reconvene on November 27, 2024 to seek stockholder approval for the issuance of the shares of common stock upon exercise of the July Purchase Warrants.

On October 30, 2024, the Company entered into a securities purchase agreement (the “October 2024 Purchase Agreement”) with certain institutional investors, pursuant to which the Company agreed to issue and sell, in a registered direct offering priced at-the-market consistent with the rules of the Nasdaq Stock Market (the “October 2024 Offering”): (i) an aggregate of approximately 9.9 million shares (the “Shares”) of the Company’s common stock, (ii) Series C warrants to purchase up to an aggregate of approximately 9.9 million shares of the Company’s common stock (the “Series C Warrants”) and (iii) Series D warrants to purchase up to an aggregate of approximately 9.9 million shares of the Company’s common stock (the “Series D Warrants”, and together with the Series C Warrants, the (“October Purchase Warrants”). Each share of common stock sold pursuant to the October 2024 Purchase Agreement will be accompanied by one Series C Warrant to purchase one share of common stock and one Series D Warrant to purchase one share of common stock. The Shares and the October Purchase Warrants are immediately separable and will be issued separately. The combined purchase price of each Share and accompanying October Purchase Warrants is \$0.304 per share. The gross proceeds to the Company from the October 2024 Offering were approximately \$3.0 million (excluding up to approximately \$6.0 million of aggregate gross proceeds that may be received in the future upon the cash exercise of the October Purchase Warrants, which is contingent upon the October Stockholder Approval described below), before deducting placement agent fees and other offering expenses payable by the Company.

Each October Purchase Warrant is exercisable for one share of common stock at an exercise price of \$0.304 per share beginning on the effective date of stockholder approval of the issuance of the shares of common stock upon exercise of the October Purchase Warrants (the “October Stockholder Approval”). The Series C Warrants will expire on the five-year anniversary of the October Stockholder Approval. The Series D Warrants will expire on the 18-month anniversary of the October Stockholder Approval.

7. 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, 2023 for information regarding the Company’s lease agreements.

The future minimum payments under non-cancellable operating and finance leases as of September 30, 2024, are as follows:

	Operating Leases	Finance Lease
Remainder of 2024	\$ 628,000	\$ 83,000
2025	2,608,000	338,000
2026	545,000	346,000
2027	254,000	356,000
2028	—	365,000
Thereafter	—	5,230,000
Total future lease payments	4,035,000	6,718,000
Less: imputed interest	(349,000)	(2,904,000)
Total lease liabilities	<u>\$ 3,686,000</u>	<u>\$ 3,814,000</u>

Restructuring

The 2024 Workforce Reductions described in Note 1 (Organization and Basis of Presentation) resulted in total restructuring charges of approximately \$5.6 million, comprised primarily of severance payments and wages for the 60-day notice period in accordance with the California Worked Adjustment and Retraining Notification (WARN) Act.

The following is a summary of restructuring charges associated with the reduction in force for the three and nine months ended September 30, 2024 including severance and other exit related costs:

	Three Months Ended September 30,	Nine Months Ended September 30,
	2024	2024
Severance	\$ 1,050,000	\$ 5,475,000
Lease related expenses	—	374,000
Other	720,000	1,767,000
Total restructuring charges including in operating expenses	<u>\$ 1,770,000</u>	<u>\$ 7,616,000</u>
COGS restructuring	<u>\$ 139,000</u>	<u>\$ 157,000</u>
Total restructuring charges	<u><u>\$ 1,909,000</u></u>	<u><u>\$ 7,773,000</u></u>

The following restructuring liability activity was recorded in connection with the reductions in force for the nine months ended September 30, 2024 included within accrued expenses on the unaudited condensed consolidated financial statements:

Accrued restructuring as of January 1, 2024	\$ 83,000
Restructuring charges incurred during the period	7,773,000
Cash payments	<u>(6,828,000)</u>
Accrued restructuring as of September 30, 2024	<u><u>\$ 1,028,000</u></u>

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 (Investments and Fair Value Measurements) for a discussion of the contingent consideration liability.

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 September 30, 2024 and December 31, 2023:

September 30, 2024

	Total Fair Value and Carrying Value on Balance Sheet	Fair Value Measurement Category		
		Level 1	Level 2	Level 3
Assets:				
U.S. treasuries	3,160,000	—	3,160,000	—
Total investments:	\$ 3,160,000	\$ —	\$ 3,160,000	\$ —
Money market funds classified as cash equivalents	\$ 6,430,000	\$ 6,430,000	\$ —	\$ —
U.S. treasuries classified as restricted investments	11,000,000	—	11,000,000	—
Total restricted investments:	\$ 11,000,000	\$ —	\$ 11,000,000	\$ —
Liabilities:				
Convertible notes payable	\$ 14,953,000	\$ —	\$ —	\$ 14,953,000

December 31, 2023

	Total Fair Value and Carrying Value on Balance Sheet	Fair Value Measurement Category		
		Level 1	Level 2	Level 3
Assets:				
Corporate notes/bonds	14,360,000	—	14,360,000	—
U.S. treasuries	34,463,000	—	34,463,000	—
Total investments:	\$ 48,823,000	\$ —	\$ 48,823,000	\$ —
Money market funds classified as cash equivalents	\$ 9,752,000	\$ 9,752,000	\$ —	\$ —
Commercial paper classified as restricted investments	5,432,000	—	5,432,000	—
U.S. treasuries classified as restricted investments	29,685,000	—	29,685,000	—
Total restricted investments:	\$ 35,117,000	\$ —	\$ 35,117,000	\$ —
Liabilities:				
Contingent consideration	\$ 10,890,000	\$ —	\$ —	\$ 10,890,000
Convertible notes payable	\$ 69,803,000	\$ —	\$ —	\$ 69,803,000
Purchase option liability	\$ 8,534,000	\$ —	\$ —	\$ 8,534,000

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 BioDiscovery milestone consideration was paid in full in 2023.

Contingent consideration liabilities related to the Purigen acquisition are related to the achievement of two independent milestones with aggregate possible milestone payments totaling \$32.0 million. As of September 30, 2024, the Company concluded that the probability of achievement of the two independent milestones was 0% which resulted in a reduction in the contingent consideration liability to zero. The fair value of the Purigen contingent consideration as of December 31, 2023 was \$10.9 million.

The fair value of the Purigen milestones were reassessed on a quarterly basis using a probability weighted model and a Monte Carlo Simulation. Assumptions used to estimate the fair value of the milestones using a probability weighted model include the probability of achieving independent milestones, anticipated payment date and a discount rate of 13.2% as of December 31, 2023. The Company determined the likelihood of each milestone payment which is then applied to the individual payments over the five-year milestone terms. The probability factors as of December 31, 2023 ranged from 9% to 49%.

For the second milestone, a Monte Carlo Simulation was performed to determine the likelihood that the milestone will be achieved to determine the milestone consideration payment. Assumptions include the projected units, revenue discount rates of 7% and discount rates of 13.2% as of December 31, 2023.

JGB Convertible debentures payable, High Trail convertible notes payable and purchase option liability

As of September 30, 2024, the fair value of the JGB convertible debentures maturing in 2026, which were issued on May 24, 2024, was estimated using a scenario-based analysis using a 66.7% probability attributed to a going concern scenario and 33.3% attributed to a dissolution scenario. For the going concern scenario, the fair value was estimated using a lattice model, consistent with previous periods. The key input assumptions utilized in the going concern scenario are summarized in the table below:

	September 30, 2024	December 31, 2023
Expected volatility	100.00 %	80.20 %
Risk-free interest rate	3.81 %	4.92 %
Term to maturity (years)	1.41	0.80
Debt discount rate	19.80 %	17.11 %
Equity discount rate	3.81 %	4.92 %

The September 30, 2024 assumptions in the table above reflect the JGB convertible debentures payable. For December 31, 2023, the table reflects a weighted average of assumptions based on the fair value of the convertible notes payable from the High Trail Agreement (refer to Note 5 (Debt)).

The volatility is based on an analysis of the Company and its peers' historical stock price, the risk-free rate is based on US treasury yields, the equity discount rate is based on term-specific US treasury yields, and the debt discount rate is based on the Company's credit rating.

In the dissolution scenario, the fair value of the JGB convertible debentures was estimated based on an expected recovery rate of 75% considering certain restricted cash allocable to principal redemption repayments. The key input assumptions utilized in the dissolution scenario are summarized in the table below:

	September 30, 2024
Risk-free interest rate	4.33 %
Expected term to repayment (years)	0.50
Dissolution discount rate	21.19 %

The risk-free rate is based on US treasury yields; the expected term to repayment is based on management's best estimate calculated by reducing the outstanding principal balance of the debentures as of September 30, 2024 from the \$11.0 million in restricted cash and investments; and the dissolution discount rate is based on an analysis of comparable yields for debt instruments with similar credit ratings.

In connection with the High Trail Notes, the purchaser was granted an option (the "Purchase Option") which expired on the maturity date of the High Trail Notes to purchase up to an additional \$25.0 million aggregate principal amount of private placement notes (the "Subsequently Purchased Notes") and warrants (refer to Note 5 (Debt)). The estimated fair value of the Purchase Option as of the valuation date was assessed as the difference in the aggregate indicated value of the Subsequently Purchased Notes and the consideration to be paid upon exercising the option which was estimated to be \$8.5 million at December 31, 2023. The outstanding amount of the High Trail Notes was redeemed on May 24, 2024, and the Purchase Option rights no longer exist.

The terms used to estimate the fair value of the Subsequently Purchased Notes and warrant underlying the Purchase Option liability (the "Subsequently Purchased Warrants") as of December 31, 2023 are as follows:

	Subsequently Purchased Notes	Subsequently Purchased Warrants
	December 31, 2023	December 31, 2023
Expected volatility	80.20 %	66.20 %
Risk-free interest rate	4.46 %	3.80 %
Term to maturity (years)	1.50	5.00
Dividend yield	— %	— %
Exercise price	—	\$3.19
Debt discount rate	16.60 %	— %
Equity discount rate	4.46 %	— %

Changes in estimated fair value of contingent consideration liability, convertible debentures payable, convertible notes payable and option liability in the nine months ended September 30, 2024 are as follows:

	Contingent Consideration Liability (Level 3 Measurement)	Convertible Debentures Payable (Level 3 Measurement)	Convertible Notes Payable (Level 3 Measurement)	Option Liability (Level 3 Measurement)
Balance as of January 1, 2024	\$ 10,890,000	\$ —	\$ 69,803,000	\$ 8,534,000
Issuance of convertible debentures payable, convertible notes payable and option	—	19,890,000	—	—
Change in estimated fair value, recorded in selling, general and administrative expenses	(10,890,000)	—	—	—
Change in estimated fair value, recorded in other income (expense), net	—	(434,000)	(4,524,000)	(3,474,000)
Change in fair value attributable to instrument-specific credit risk recorded in other comprehensive income (loss)	—	(1,503,000)	—	—
Cash payments	—	—	(61,000,000)	—
Cash payments on redemptions	—	(3,000,000)	(5,374,000)	—
(Gain)/loss on extinguishment of High Trail	—	—	1,095,000	(5,060,000)
Balance as of September 30, 2024	<u>\$ —</u>	<u>\$ 14,953,000</u>	<u>\$ —</u>	<u>\$ —</u>

We evaluated the change in fair value attributable to instrument-specific credit risk as the excess of the total change in fair value over the change in fair value attributable to changes in the valuation model described above and determined that the total change in fair value of \$1.5 million for the three months ended September 30, 2024 was attributable to instrument-specific credit risk which is recorded in other comprehensive income (loss).

Changes in estimated fair value of contingent consideration liability in the nine months ended September 30, 2023 is as follows:

	Contingent Consideration Liability (Level 3 Measurement)
Balance as of January 1, 2023	\$ 22,352,000
Change in estimated fair value, recorded in selling, general and administrative expenses	2,528,000
Balance as of September 30, 2023	<u>\$ 24,880,000</u>

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 September 30, 2024 and December 31, 2023, 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 September 30, 2024 and December 31, 2023, the Company held 2 and 15 securities, respectively, which have been in an unrealized loss position for a period of less than 12 months. As of September 30, 2024 and December 31, 2023, the Company held 0 and 2 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.

During the nine months ended September 30, 2024, the Company sold 18 of its available for sale securities and received proceeds of \$33.3 million. During the nine months ended September 30, 2024, the Company recognized an immaterial loss in other income relating to the maturity of its securities. Amounts are reclassified out of accumulated other comprehensive income into earnings using the specific identification method.

Interest receivable as of September 30, 2024 was immaterial and as of December 31, 2023 was \$0.3 million. Interest receivable is recorded as a component of prepaid expenses and other current assets on the unaudited condensed consolidated balance sheets.

As of September 30, 2024, the following table summarizes the amortized cost and the unrealized gains (losses) of the available for sale securities presented within investments:

	Remaining Contractual Maturity (in years)	Amortized Cost	Unrealized Gains	Unrealized Losses	Aggregate Estimated Fair Value
U.S. treasuries	Less than 1	3,160,000	—	—	3,160,000
Total maturity less than 1 year		<u>\$ 3,160,000</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 3,160,000</u>

As of September 30, 2024, the following table summarizes the amortized cost and the unrealized gains (losses) of the available for sale securities presented within restricted investments:

	Remaining Contractual Maturity (in years)	Amortized Cost	Unrealized Gains	Unrealized Losses	Aggregate Estimated Fair Value
U.S. treasuries	Less than 1	10,998,000	2,000	—	11,000,000
Total maturity less than 1 year		<u>\$ 10,998,000</u>	<u>\$ 2,000</u>	<u>\$ —</u>	<u>\$ 11,000,000</u>

As of December 31, 2023, the following table summarizes the amortized cost and the unrealized gains (losses) of the available for sale securities presented within investments:

	Remaining Contractual Maturity (in years)	Amortized Cost	Unrealized Gains	Unrealized Losses	Aggregate Estimated Fair Value
Corporate notes/bonds	Less than 1	\$ 14,369,000	\$ —	\$ (9,000)	\$ 14,360,000
U.S. treasuries	Less than 1	34,459,000	4,000	—	34,463,000
Total maturity less than 1 year		\$ 48,828,000	\$ 4,000	\$ (9,000)	\$ 48,823,000

As of December 31, 2023, the following table summarizes the amortized cost and the unrealized gains (losses) of the available for sale securities presented within restricted investments:

	Remaining Contractual Maturity (in years)	Amortized Cost	Unrealized Gains	Unrealized Losses	Aggregate Estimated Fair Value
Commercial paper	Less than 1	\$ 5,435,000	\$ —	\$ (3,000)	\$ 5,432,000
U.S. treasuries	Less than 1	29,682,000	5,000	(2,000)	29,685,000
Total maturity less than 1 year		\$ 35,117,000	\$ 5,000	\$ (5,000)	\$ 35,117,000

As of September 30, 2024, the following table summarizes available-for-sale securities in an unrealized loss position:

	Less Than 12 Months		12 Months or Greater		Total	
	Fair Value	Gross Unrealized Loss	Fair Value	Gross Unrealized Loss	Fair Value	Gross Unrealized Loss
U.S. treasuries	3,160,000	—	—	—	3,160,000	—
Total	\$ 3,160,000	\$ —	\$ —	\$ —	\$ 3,160,000	\$ —

As of September 30, 2024, the available-for-sale securities listed as restricted investments in an unrealized loss position was zero.

As of December 31, 2023, the following table summarizes available-for-sale securities in an unrealized loss position:

	Less Than 12 Months		12 Months or Greater		Total	
	Fair Value	Gross Unrealized Loss	Fair Value	Gross Unrealized Loss	Fair Value	Gross Unrealized Loss
Corporate Notes/Bonds	\$ 2,362,000	\$ (5,000)	\$ 10,001,000	\$ (4,000)	\$ 12,363,000	\$ (9,000)
Total	\$ 2,362,000	\$ (5,000)	\$ 10,001,000	\$ (4,000)	\$ 12,363,000	\$ (9,000)

As of December 31, 2023, the following table summarizes available-for-sale securities listed as restricted investments in an unrealized loss position:

	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	\$ 5,432,000	\$ (3,000)	\$ —	\$ —	\$ 5,432,000	\$ (3,000)
U.S. treasuries	11,789,000	(2,000)	—	—	11,789,000	(2,000)
Total	\$ 17,221,000	\$ (5,000)	\$ —	\$ —	\$ 17,221,000	\$ (5,000)

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 for the three and nine months ended September 30, 2024 ("Quarterly Report") and the audited consolidated financial statements and notes thereto as of and for the year ended December 31, 2023 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 for the year ended December 31, 2023, ("Annual Report"), filed with the Securities and Exchange Commission, ("SEC"), on March 5, 2024. 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 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, expected savings including from restructuring initiatives, projected cash runway, prospects and plans, expected growth in sales of instruments and consumables, installed bases and provision of clinical services, 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 under Part II, Item 1A. Risk Factors in this Quarterly Report and in our other 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. We offer a platform-agnostic software solution, which integrates next-generation sequencing, microarray and OGM 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. The Company also offers nucleic acid extraction and purification solutions using proprietary isotachopheresis ITP technology. Through our Bionano Laboratories business, we also provide OGM-based diagnostic testing services.

Recent Highlights

Commercial Adoption of Offerings for OGM Systems

In executing on our commercialization strategy, we expanded the utilization of our OGM systems and:

- Grew our installed base to 368 as of September 30, 2024, an increase of approximately 22% from a total installed base of 301 as of September 30, 2023. Installed base represents the global number of OGM instruments installed at end-customer locations and therefore having the technology to process OGM.
- Sold 7,835 flowcells in the three-month period ended September 30, 2024, an increase of approximately 27% from 6,176 flowcells sold in the same quarter of 2023. Sold 22,249 flowcells in the nine-month period ended September 30, 2024, an increase of approximately 20% from 18,464 flowcells sold in the same period of 2023. The OGM cartridge is the consumable that packages nanochannel arrays for DNA linearization. In its current form, the OGM cartridge can comprise - one, two or three flowcells per cartridge. Flowcells sold refers to the units of genome mapping consumables used for analyzing one genome, purchased by customers to process samples for 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 in the Middle East, related sanctions, and any effects of global pandemics and uncertain market conditions, including inflation and supply chain disruptions, which could continue to have a material impact on our business and financial results. For example, we are

anticipating a potential protracted slowdown in our Asia Pacific business due to funding headwinds in the region, which are negatively impacting these manufacturing partners who are reliant on government funding, and are awaiting approval from the NMPA.

We closely monitor and comply with various applicable guidelines and legal requirements in the jurisdictions in which we operate. In the past, we have experienced supply chain challenges, attributable to such adverse geopolitical and macroeconomic developments including increased costs to secure certain component parts in our products and to produce our products at our contract manufacturers. During the nine months ended September 30, 2024, we did not experience material increases in our supply chain costs, but we may experience such increases in future fiscal periods. We expect our 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, high 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.

Recent Developments

In March 2024 and September 2024, we announced restructuring plans that aim to reduce annualized operating expenses by approximately \$35.0 to \$40.0 million starting in the second half of 2024, and by an additional \$25.0 million to \$30.0 million beginning in the fourth quarter of 2024, respectively. As part of the plans, we reduced our overall headcount by approximately 120 and 83 employees, respectively. The Company has substantially completed the reductions in force as of September 30, 2024. In addition, as of September 30, 2024, we have phased out the offering by Bionano Laboratories of certain testing services related to neurodevelopmental disorders, including autism spectrum disorders and other disorders of childhood development. These measures were incremental to the cost saving initiatives previously announced in May 2023 and October 2023. See Note 7 (Commitments and Contingencies) to our unaudited condensed consolidated financial statements included elsewhere in this Quarterly Report for additional information.

As part of the plans we have also made a change in our business strategy and refocused our efforts on the current installed base of OGM systems with less emphasis on new placements of OGM systems and more emphasis on ensuring customers are able to maximize their utilization of the OGM systems.

Financial Overview

Revenue

We generate product revenue from sales of our OGM and Ionic® Purification systems and consumables, which includes our instruments, and our VIA™ software. At the end of July 2023 we began installations of VIA software as a replacement to NxClinical software. Like NxClinical, VIA has a simple integrated workflow for visualization, interpretation and reporting of NGS and microarray data. VIA additionally incorporates OGM data to that workflow creating a standard software tool for use across molecular pathology and cytogenomics applications. 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 at no cost under our reagent rental program, 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 VIA software, which provides customers with solutions for analysis, interpretation and reporting of genomic data, are made on a subscription basis. We generate service revenue from the sale of diagnostic testing services through Bionano Laboratories, as well as services performed related to customer sample evaluations using an OGM system. Other revenue consists of warranty and other service-based revenue, including support, repair and maintenance services. We anticipate that our change in business strategy to focus on driving utilization and adoption of OGM from our existing installed base, with less emphasis on new placements of our OGM systems would slow the pace of our revenue growth when compared to historical growth rates. We expect service and other revenue to continue to decrease over the remainder of 2024 as a result of phasing out Bionano Laboratories offerings.

The following table presents our revenue for the periods indicated:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Product revenue	\$ 6,021,000	\$ 6,456,000	\$ 19,359,000	\$ 18,512,000
Service and other revenue	52,000	2,862,000	3,254,000	6,883,000
Total	\$ 6,073,000	\$ 9,318,000	\$ 22,613,000	\$ 25,395,000

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 September 30,				Nine Months Ended September 30,			
	2024		2023		2024		2023	
	\$	%	\$	%	\$	%	\$	%
Americas	\$ 2,537,000	42 %	\$ 5,346,000	57 %	\$ 10,613,000	47 %	\$ 13,103,000	52 %
EMEA	2,764,000	46 %	2,686,000	29 %	9,521,000	42 %	8,426,000	33 %
Asia Pacific	772,000	13 %	1,286,000	14 %	2,479,000	11 %	3,866,000	15 %
Total	\$ 6,073,000	100 %	\$ 9,318,000	100 %	\$ 22,613,000	100 %	\$ 25,395,000	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. Our research and development efforts have focused primarily on the tasks required to support development and commercialization of 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 \$44.2 million and \$91.9 million for the three and nine months ended September 30, 2024, respectively. As of September 30, 2024, we had an accumulated deficit of \$673.1 million.

While we have implemented restructuring plans in March and September 2024, we expect to continue to incur significant expenses and operating losses as we:

- continue our sales and marketing efforts to maintain sales of our existing products;
- continue research and development efforts to improve our existing products;
- enter into collaboration arrangements, if any;
- maintain 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 after the date that the financial statements included in this Quarterly Report are issued.

We will continue to seek to raise additional capital, but without sufficient additional financing in the very near term we will not be able to continue as a going concern. If we are unable to continue as a going concern, we may have to reorganize or liquidate our business and may receive less than the value at which those assets are carried on our consolidated financial statements, and investors may lose all or a part of their investment. The board of directors (the "Board") has established a strategy committee to work with the Company and outside advisors in evaluating our options and considering alternatives that we believe will maximize stakeholder value, including any of the following or a combination thereof: debt financing, equity investments, combinations with other companies, or the sale of all or part of the company. There can be no assurances that any transactions will be available to us or completed and if we are not able to raise sufficient additional capital in the very near term to fund our operation, we may seek relief available under applicable insolvency laws. We do not intend to make further announcements regarding this process unless and until the Board approves a specific transaction or otherwise determines that further disclosure is appropriate.

Comparison of the Three Months Ended September 30, 2024 and 2023

The following table sets forth our results of operations for the three months ended September 30, 2024 and 2023:

	Three Months Ended September 30,		Period-to-Period Change	
	2024	2023	\$	%
Revenues:				
Product revenue	\$ 6,021,000	\$ 6,456,000	\$ (435,000)	(7)%
Service and other revenue	52,000	2,862,000	(2,810,000)	(98)%
Total revenue	<u>6,073,000</u>	<u>9,318,000</u>	<u>(3,245,000)</u>	<u>(35)%</u>
Cost of revenue:				
Cost of product revenue	14,251,000	5,105,000	9,146,000	179 %
Cost of service and other revenue	268,000	1,464,000	(1,196,000)	(82)%
Total cost of revenue	<u>14,519,000</u>	<u>6,569,000</u>	<u>7,950,000</u>	<u>121 %</u>
Operating expenses:				
Research and development	4,717,000	13,785,000	(9,068,000)	(66)%
Selling, general and administrative	9,464,000	24,896,000	(15,432,000)	(62)%
Goodwill impairment	—	77,280,000	(77,280,000)	(100)%
Intangible assets and other long-lived assets impairment	19,504,000	—	19,504,000	100 %
Restructuring costs	1,770,000	—	1,770,000	100 %
Total operating expenses	<u>35,455,000</u>	<u>115,961,000</u>	<u>(80,506,000)</u>	<u>(69)%</u>
Loss from operations	<u>(43,901,000)</u>	<u>(113,212,000)</u>	<u>69,311,000</u>	<u>(61)%</u>
Other income (expenses):				
Interest income	376,000	730,000	(354,000)	(48)%
Other income (expenses)	(697,000)	(45,000)	(652,000)	1,449 %
Total other income (expenses)	<u>(321,000)</u>	<u>685,000</u>	<u>(1,006,000)</u>	<u>(147)%</u>
Loss before income taxes	<u>(44,222,000)</u>	<u>(112,527,000)</u>	<u>68,305,000</u>	<u>(61)%</u>
Provision for income taxes	<u>(24,000)</u>	<u>(39,000)</u>	<u>15,000</u>	<u>(38)%</u>
Net loss	<u>\$ (44,246,000)</u>	<u>\$ (112,566,000)</u>	<u>\$ 68,320,000</u>	<u>(61)%</u>

Revenue

Product revenue decreased by \$0.4 million, or 7%, to \$6.0 million for the three months ended September 30, 2024 compared to \$6.5 million for the same period in 2023. The decrease in product revenue was driven by a \$0.9 million or 39% decrease in instrument revenue, a \$0.4 million or 23% decrease in software revenue, and partially offset by an increase of \$0.9 million or 35% in consumables revenue. In September 2024 Bionano announced a change in its business strategy which would allow the company to become a more capital-efficient business. Our focus is on driving utilization and adoption of OGM from our

existing installed base, with less emphasis on new placements of our OGM systems. We anticipate that this change in strategy would slow the pace of our revenue growth when compared to historical growth rates.

Service and other revenue decreased by \$2.8 million, or 98%, to \$0.1 million for the three months ended September 30, 2024 when compared to the same period in 2023 which is the result of discontinuing sales of certain clinical service offerings from Bionano Laboratories effective March 2024. We expect service and other revenue to continue to decrease over the remainder of 2024 as a result of phasing out these offerings.

Cost of Revenue

Cost of product revenue increased by 179%, to \$14.3 million for the three months ended September 30, 2024, compared to \$5.1 million for the three months ended September 30, 2023. The increase in cost of product revenue was primarily due to \$9.8 million in total expenses recognized to write-off excess Saphyr instrument spare parts and other obsolete inventory for \$7.2 million, as well as dispose of reagent rentals that were underutilized for \$2.6 million. We expect cost of product revenue to fluctuate with the volume of product sales.

Cost of service and other revenue decreased by \$1.2 million, or 82%, to \$0.3 million for the three months ended September 30, 2024, compared to \$1.5 million for the three months ended September 30, 2023. The decrease in cost of service and other revenue was primarily due to discontinuing sales of certain clinical service offerings from Bionano Laboratories effective March 2024. We expect cost of service and other revenue to decrease over the remainder of 2024 as a result of our decision to phase out certain clinical service offerings from Bionano Laboratories.

Gross Profit, and Gross Margin

	Three Months Ended September 30,		Period-to-Period Change	Period-to-Period Percentage Change
	2024	2023	2024 to 2023	2024 to 2023
Gross profit (loss):				
Product	\$ (8,230,000)	\$ 1,351,000	\$ (9,581,000)	(709)%
Service and other	(216,000)	1,398,000	(1,614,000)	(115)%
Total gross profit	<u>\$ (8,446,000)</u>	<u>\$ 2,749,000</u>	<u>\$ (11,195,000)</u>	<u>(407)%</u>
Gross margin:				
Product	(137)%	21 %		
Service and other	(415)%	49 %		
Total gross margin	<u>(139)%</u>	<u>30 %</u>		

Product gross profit decreased by \$9.6 million, or 709%, to \$8.2 million for the three months ended September 30, 2024, compared to \$1.4 million for the three months ended September 30, 2023. The decrease in product gross profit was primarily due to \$9.8 million in total expenses recognized to write-off excess Saphyr instrument spare parts and other obsolete inventory for \$7.2 million as well as dispose of reagent rentals that were underutilized for \$2.6 million. We expect cost of product revenue to fluctuate with the volume of product sales.

Service and other gross profit decreased by \$1.6 million, or 115%, to \$0.2 million for the three months ended September 30, 2024, compared to \$1.4 million for the three months ended September 30, 2023. The decrease in service and other gross profit was impacted by a \$0.5 million write-down of aged receivables tied to discontinued clinical service offerings from Bionano Laboratories. The write-down was treated as a reversal of revenue. We expect service and other gross profit to decrease over the remainder of 2024 as a result of our decision to phase out certain clinical service offerings from Bionano Laboratories.

Research and Development Expenses

Research and development (“R&D”) expenses decreased by \$9.1 million, or 66%, to \$4.7 million for the three months ended September 30, 2024 compared to \$13.8 million for the same period in 2023. The decrease was partially due to decreases of \$4.6 million in salaries, wages and benefits driven by headcount reductions announced throughout 2023 and 2024, and of \$2.6 million in professional and consulting fees including decreases in costs incurred to support clinical research studies, Stratys development, foundry expenses, and cloud computing. We also reduced our internal consumption of inventory, materials and supplies by \$1.4 million. We anticipate that R&D expenses will decrease for the remainder of 2024 as a result of our cost saving initiatives announced in March and September 2024.

Selling, General and Administrative Expenses

Selling, general and administrative (“SG&A”) expenses decreased by \$15.4 million, or 62%, to \$9.5 million for the three months ended September 30, 2024 compared to \$24.9 million for the same period in 2023. The decrease was primarily due to a \$6.3 million decrease in salaries, wages and benefits driven by headcount reductions announced throughout 2023 and 2024, a \$6.1 million decrease in the gain/loss recorded on fair value of the contingent consideration due for BioDiscovery and Purigen milestones, a \$3.2 million decrease in professional and consulting fees which is primarily marketing, software and legal expenses, and \$0.6 million decrease in travel and entertainment. We anticipate that SG&A expenses will decrease for the remainder of 2024 as a result of our restructuring initiatives announced in March and September 2024.

Goodwill impairment

Goodwill of \$77.3 million was fully impaired during the three months ended September 30, 2023.

Intangible assets and other long-lived assets impairment

The Company recognized a \$19.5 million loss on intangible assets and other long-lived assets impairment during the three months ended September 30, 2024 due to our restructuring initiatives and change in business strategy. The Company recognized no additional impairment losses during the three months ended September 30, 2023. See Note 1 (Organization and Basis of Presentation) to our unaudited condensed consolidated financial statements included elsewhere in this Quarterly Report for further discussion on the impairment charges that were recorded during the quarter.

Restructuring Costs

Restructuring costs were \$1.8 million for the three months ended September 30, 2024, as a result of our cost saving initiatives announced in March and September 2024. We had no expenses that were classified as restructuring costs during the same period in 2023.

Interest Income

Interest income was \$0.4 million for the three months ended September 30, 2024, as compared to \$0.7 million for the same period in 2023. The decrease is the result of a reduction in investments offset by higher returns.

Other income (expense)

Other income (expense) was \$0.7 million for the three months ended September 30, 2024, as compared to \$45,000 for the same period in 2023. The increase is primarily driven by an increase in the change in fair value (net gain) of \$0.6 million for the convertible debentures. See Note 5 (Debt) to our unaudited condensed consolidated financial statements included elsewhere in this Quarterly Report for further discussion on debt transactions that took effect during the year.

Comparison of the Nine Months Ended September 30, 2024 and 2023

The following table sets forth our results of operations for the nine months ended September 30, 2024 and 2023:

	Nine Months Ended September 30,		Period-to-Period Change	
	2024	2023	\$	%
Revenues:				
Product revenue	\$ 19,359,000	\$ 18,512,000	\$ 847,000	5 %
Service and other revenue	3,254,000	6,883,000	(3,629,000)	(53)%
Total revenue	22,613,000	25,395,000	(2,782,000)	(11)%
Cost of revenue:				
Cost of product revenue	23,858,000	13,714,000	10,144,000	74 %
Cost of service and other revenue	1,792,000	4,553,000	(2,761,000)	(61)%
Total cost of revenue	25,650,000	18,267,000	7,383,000	40 %
Operating expenses:				
Research and development	21,329,000	42,331,000	(21,002,000)	(50)%
Selling, general and administrative	40,109,000	77,809,000	(37,700,000)	(48)%
Goodwill impairment	—	77,280,000	(77,280,000)	(100)%
Intangible assets and other long-lived assets impairment	19,951,000	—	19,951,000	100 %
Restructuring costs	7,616,000	—	7,616,000	100 %
Total operating expenses	89,005,000	197,420,000	(108,415,000)	(55)%
Loss from operations	(92,042,000)	(190,292,000)	98,250,000	(52)%
Other income (expenses):				
Interest income	1,876,000	2,122,000	(246,000)	(12)%
Other income (expenses)	(1,694,000)	(334,000)	(1,360,000)	407 %
Total other income (expenses)	182,000	1,788,000	(1,606,000)	(90)%
Loss before income taxes	(91,860,000)	(188,504,000)	96,644,000	(51)%
Provision for income taxes	(32,000)	(98,000)	66,000	(67)%
Net loss	\$ (91,892,000)	\$ (188,602,000)	\$ 96,710,000	(51)%

Revenue

Product revenue increased by \$0.8 million, or 5%, to \$19.4 million for the nine months ended September 30, 2024, compared to \$18.5 million for the same period in 2023. The increase in product revenue was driven by a \$1.7 million or 22% increase in sales of consumables and an increase of \$0.5 million or 13% of software, partially offset by a \$1.4 million or 21% decrease in instrument sales. In September 2024, we announced a change in its business strategy which would allow the company to become a more capital-efficient business. Our focus is on driving utilization and adoption of OGM from our existing installed base, with less emphasis on new placements of our OGM systems. We anticipated that this change in strategy would slow the pace of our revenue growth when compared to historical growth rates.

Service and other revenue decreased by \$3.6 million or 53% for the nine months ended September 30, 2024, compared to the same period in 2023 which is the result of discontinuing sales of certain clinical service offerings from Bionano Laboratories effective March 2024. Such clinical service offerings from Bionano Laboratories contributed \$1.7 million in revenues for the nine months ended September 30, 2024 compared to \$5.1 million for the same period in 2023. We expect service and other revenue to continue to decrease over the remainder of 2024 as a result of phasing out these offerings.

Cost of Revenue

Cost of product revenue increased by \$10.1 million, or 74%, to \$23.9 million for the nine months ended September 30, 2024, compared to \$13.7 million for the same period in 2023. The increase in cost of product revenue was due to higher sales of consumables offset by lower sales of instruments. In addition, during the three months ended September 30, 2024, \$9.8 million in total expenses recognized to write-off excess Saphyr instrument spare parts and other obsolete inventory for \$7.2 million as well as dispose of reagent rentals that were underutilized for \$2.6 million. We expect cost of product revenue to fluctuate with the volume of product sales.

Cost of service and other revenue decreased by \$2.8 million, or 61%, to \$1.8 million for the nine months ended September 30, 2024, compared to \$4.6 million for the same period in 2023. The decrease in cost of service and other revenue was primarily due to discontinuing sales of certain clinical service offerings from Bionano Laboratories effective March 2024. We expect cost of service and other revenue to decrease over the remainder of 2024 as a result of our decision to phase out certain clinical service offerings from Bionano Laboratories.

Gross Profit, and Gross Margin

	Nine Months Ended September 30,		Period-to-Period Change	Period-to-Period Percentage Change
	2024	2023	2024 to 2023	2024 to 2023
Gross profit (loss):				
Product	\$ (4,499,000)	\$ 4,798,000	\$ (9,297,000)	(194)%
Service and other	1,462,000	2,330,000	(868,000)	(37)%
Total gross profit	\$ (3,037,000)	\$ 7,128,000	\$ (10,165,000)	(143)%
Gross margin:				
Product	(23)%	26 %		
Service and other	45 %	34 %		
Total gross margin	(13)%	28 %		

Product gross profit decreased by \$9.3 million, or 194%, to \$4.5 million for the nine months ended September 30, 2024, compared to \$4.8 million for the same period in 2023. The decrease in product gross profit was primarily due to \$9.8 million in total expenses recognized to write-off excess Saphyr instrument spare parts and other obsolete inventory for \$7.2 million as well as dispose of reagent rentals that were underutilized for \$2.6 million.

Service and other gross profit decreased by \$0.9 million, or 37%, to \$1.5 million for the nine months ended September 30, 2024, compared to \$2.3 million for the same period in 2023. The decrease in service and other gross profit was primarily due to discontinuing sales of certain clinical service offerings from Bionano Laboratories effective March 2024. We expect service and other gross profit to decrease over the remainder of 2024 as a result of our decision to phase out certain clinical service offerings from Bionano Laboratories.

Research and Development Expenses

R&D expenses decreased by \$21.0 million, or 50%, to \$21.3 million for the nine months ended September 30, 2024 compared to \$42.3 million for the same period in 2023. The decrease was partially due to decreases of \$11.1 million in salaries, wages and benefits driven by headcount reductions announced throughout 2023 and 2024 and \$6.2 million in professional and consulting fees, including decreases in costs incurred to support clinical research studies, Stratys development, foundry expenses, and cloud computing. Lastly, we reduced information technology and rent and facility costs by \$0.6 million, and we reduced our internal consumption of inventory, materials and supplies by \$2.5 million. We anticipate that R&D expenses will decrease for the remainder of 2024 as a result of our cost saving initiatives announced in March and September 2024.

Selling, General and Administrative Expenses

SG&A expenses decreased by \$37.7 million, or 48%, to \$40.1 million for the nine months ended September 30, 2024 compared to \$77.8 million for the same period in 2023. The decrease was primarily due to a \$16.1 million decrease in salaries, wages and benefits driven by headcount reductions announced in 2023 and 2024, a \$13.4 million decrease in the gain/loss recorded on fair value of the contingent consideration due for Purigen and BioDiscovery milestones, a \$7.4 million decrease in professional and consulting fees which is primarily marketing, software, and legal expenses, and a \$1.7 million decrease in travel and entertainment. We anticipate that SG&A expenses will decrease for the remainder of 2024 as a result of our cost saving initiatives announced in March and September 2024.

Goodwill impairment

Goodwill of \$77.3 million was fully impaired during the nine months ended September 30, 2023.

Intangible assets and other long-lived assets impairment

The Company recognized \$20.0 million in impairment losses on intangible assets and other long-lived assets during the nine months ended September 30, 2024 due to our restructuring initiatives and change in business strategy. The Company recognized no additional impairment losses during the nine months ended September 30, 2023. See Note 1 (Organization and Basis of Presentation) to our unaudited condensed consolidated financial statements included elsewhere in this Quarterly Report for further discussion on the impairment charges that were recorded during the quarter.

Restructuring Costs

Restructuring costs were \$7.6 million for the nine months ended September 30, 2024, as a result of our cost saving initiatives announced in March and September 2024. We had no expenses that were classified as restructuring costs during the same period in 2023.

Interest Income

Interest income was \$1.9 million for the nine months ended September 30, 2024, as compared to \$2.1 million for the same period in 2023. The decrease is the result of a reduction in investments offset by higher returns.

Other income (expense)

Other expense was \$1.7 million for the nine months ended September 30, 2024 compared to \$0.3 million for the same period in 2023. The decrease was driven by a net gain on the extinguishment of the High Trail Note and Purchase Option of \$4.0 million, offset by a loss recorded on the issuance of the JGB Debentures of \$1.9 million, an increase in the change in fair value (net gain) of \$2.0 million for the convertible notes, purchase option, and convertible debentures, and an increase in interest expense of \$1.5 million. See Note 5 (Debt) to our unaudited condensed consolidated financial statements included elsewhere in this Quarterly Report for further discussion on debt transactions that took effect during the year.

Liquidity and Capital Resources

Since our inception, we have incurred recurring net losses from operations, negative cash flows from operating activities and accumulated deficit. We have primarily generated cash flows from sales of equity securities and debt financings. We incurred net losses of \$91.9 million and \$188.6 million for the nine months ended September 30, 2024 and 2023, respectively. As of September 30, 2024, we had an accumulated deficit of \$673.1 million, cash and cash equivalents of \$8.8 million, \$11.4 million in restricted cash and short-term investments of \$3.2 million. In connection with the Debentures (as defined below), the amount we are required to hold as restricted cash or restricted investments is equal to the lesser of (a) \$11.0 million and (b) the then outstanding principal balance of the Debentures.

Sources of Liquidity and Capital Resources

In the nine months ended September 30, 2024, we incurred negative cash flows from operating activities of \$62.4 million. We anticipate that future sources of liquidity will principally come from sales of common stock and other equity instruments, borrowings from credit facilities and revenue from our commercial operations. See Note 6 (Stockholder's Equity and Stock-Based Compensation) to our unaudited condensed consolidated financial statements included elsewhere in this Quarterly Report for a discussion of our recent equity activity for more information.

On October 13, 2023, we completed a registered offering (the "October 2023 Registered Offering") of senior secured convertible notes payable due 2025 (the "High Trail Registered Notes") and warrants (the "Registered Warrants") and a concurrent private placement (the "October 2023 Private Placement" and together with the October 2023 Registered Offering, the "October 2023 Offering") of senior secured convertible notes payable due 2025 (the "High Trail Private Placement Notes" and, together with the High Trail Registered Notes, the "High Trail Notes") and warrants (the "Private Placement Warrants" and, together with the Registered Warrants, the "Warrants") and received net proceeds from the sale of the High Trail Notes and the Registered Warrants of approximately \$75.6 million, after deducting the offering expenses and placement agent fees.

On February 27, 2024, we entered into a letter agreement (the "Letter Agreement") and an Amendment to the Registered Notes (the "Amendment"), with the purchaser of the High Trail Registered Notes which provided reduction (i) of the minimum liquidity covenant from \$50.0 million, and (ii) of the restricted cash covenant from \$35.0 million, to the amount equal to the sum of (iii) the outstanding principal amount of the High Trail Registered Notes plus (iv) approximately \$0.7 million, which will be further reduced as the remaining principal on the High Trail Registered Notes are retired. We also redeemed the outstanding \$17.0 million of the High Trail Private Placement Notes for a redemption payment of approximately \$19.6 million and a retirement fee of \$3.2 million paid concurrently and \$10.7 million of the High Trail Registered Notes for a redemption payment of approximately \$12.3 million.

On March 1, 2024, we redeemed \$27.7 million aggregate principal amount of the High Trail Notes at a redemption price of 115% of the outstanding principal (the “Repayment Price”) or \$31.8 million, and for the period January 1, 2024 through May 1, 2024, redeemed an additional \$18.0 million aggregate principal amount of the High Trail Notes at the holders’ option at the Repayment Price for an aggregate of \$20.7 million.

On May 24, 2024, we entered into a securities purchase agreement with certain accredited investors (the “Holders”) and JGB Collateral LLC, as collateral agent for the Holders, for the sale by the Company in a private placement (the “JGB Debentures Offering”) of:

- 2.25 million shares (the “Shares”) of the Company’s common stock, par value \$0.0001 per share (“Common Stock”), and
- Senior Secured Convertible Debentures in the aggregate principal amount of \$20.0 million (the “Debentures”), for an aggregate purchase price of \$18.0 million.

The closing of the JGB Debentures Offering occurred on May 24, 2024. In connection with the closing of the JGB Debentures Offering, the Company received net proceeds of approximately \$16.6 million, after payment of placement agent fees, and other offering expenses. The Company used the proceeds received to fully redeem the outstanding balance due under the High Trail Note of approximately \$17.6 million, as amended (see further discussion below).

On May 23, 2024, in connection with the JGB Debentures Offering, the Company entered into a redemption agreement with High Trail (“HT Agreement”). Pursuant to the HT Agreement, the Company agreed to redeem the entire outstanding principal amount of \$15.3 million under the High Trail Note at a redemption price of 115% for a total redemption payment of \$17.6 million (the “Redemption Payment”). Upon High Trail’s receipt of the Redemption Payment on May 24, 2024, the High Trail Note and related Option were cancelled. In addition, the Company agreed to pay High Trail a retirement fee of \$2.2 million and to reimburse High Trail for all of its reasonable and documented out-of-pocket expenses incurred with the release and termination of security interests relating to the High Trail Note.

As of September 30, 2024, the Company reported \$15.0 million of Debentures at fair value, which is classified as current on the unaudited condensed consolidated balance sheet. Through September 30, 2024, the Company paid \$0.8 million in interest and \$3.0 million in principal redemption amounts on the Debentures. As of September 30, 2024, the Company may be required to redeem up to \$3.0 million of principal and expects to pay an additional \$0.4 million in interest on the Debentures in the fourth quarter of 2024.

See Note 5 (Debt) to our unaudited condensed consolidated financial statements included elsewhere in this Quarterly Report for further information.

On April 4, 2024, we entered into a securities purchase agreement (the “April Purchase Agreement”) with certain institutional investors, pursuant to which we agreed to issue and sell, in a registered direct offering priced at-the-market consistent with the rules of the Nasdaq Stock Market (the “April 2024 Registered Direct Offering”): (i) an aggregate of 6.5 million shares of common stock, (ii) pre-funded warrants to purchase up to an aggregate of 2.2 million shares of common stock and (iii) warrants to purchase up to 8.7 million shares of common stock. The combined purchase price of each share of common stock and accompanying warrant was \$1.15 per share. The combined purchase price of each pre-funded warrant and accompanying warrant was \$1.14 (equal to the combined purchase price per share of common stock and accompanying warrant, minus \$0.001). We received gross proceeds from the April 2024 Registered Direct Offering of approximately \$10.0 million, before deducting placement agent fees and other offering expenses of \$0.7 million.

On July 4, 2024, we entered into a securities purchase agreement (the “July 2024 Purchase Agreement”) with certain institutional investors, pursuant to which we agreed to issue and sell, (i) in a registered direct offering priced at-the-market consistent with the rules of the Nasdaq Stock Market (the “July 2024 Registered Direct Offering”): (a) an aggregate of 11.7 million shares of our common stock, and (b) pre-funded warrants to purchase up to an aggregate of 5.8 million shares of Common Stock, and (ii) in a concurrent private placement (the “Private Placement” and together with the Registered Direct Offering, the “July 2024 Offering”), Series A warrants to purchase up to an aggregate of 17.5 million shares of Common Stock (the “Series A Warrants”) and Series B warrants to purchase up to an aggregate of 17.5 million shares of Common Stock (the “Series B Warrants”), and together with the Series A Warrants, the “Purchase Warrants”). Each share of Common Stock and each Pre-Funded Warrant sold pursuant to the Purchase Agreement will be accompanied by one Series A Warrant and one Series B Warrant. The combined purchase price of each share of Common Stock and accompanying Purchase Warrants is \$0.571 per share. The combined purchase price of each Pre-Funded Warrant and accompanying Purchase Warrants is \$0.571 (equal to the combined purchase price per share of Common Stock and accompanying Purchase Warrants, minus \$0.001). We received gross proceeds from the July 2024 Offering of approximately \$10.0 million (excluding up to \$20.0 million of aggregate gross proceeds that may be received in the future upon the cash exercise of the Purchase Warrants issued in the Private Placement which is contingent upon stockholder approval), before deducting placement agent fees and other offering expenses of \$0.7 million.

On October 30, 2024, the Company entered into a securities purchase agreement (the “October 2024 Purchase Agreement”) with certain institutional investors, pursuant to which the Company agreed to issue and sell, in a registered direct offering priced at-the-market consistent with the rules of the Nasdaq Stock Market (the “October 2024 Offering”): (i) an aggregate of approximately 9.9 million shares (the “Shares”) of the Company’s common stock, (ii) Series C warrants to purchase up to an aggregate of approximately 9.9 million shares of the Company’s common stock (the “Series C Warrants”) and (iii) Series D warrants to purchase up to an aggregate of approximately 9.9 million shares of the Company’s common stock (the “Series D Warrants”, and together with the Series C Warrants, the “October Purchase Warrants”). Each share of common stock sold pursuant to the October 2024 Purchase Agreement will be accompanied by one Series C Warrant to purchase one share of common stock and one Series D Warrant to purchase one share of common stock. The Shares and the October Purchase Warrants are immediately separable and will be issued separately. The combined purchase price of each Share and accompanying October Purchase Warrants is \$0.304 per share. The gross proceeds to the Company from the October 2024 Offering are expected to be approximately \$3.0 million (excluding up to approximately \$6.0 million of aggregate gross proceeds that may be received in the future upon the cash exercise of the October Purchase Warrants, which is contingent upon stockholder approval), before deducting placement agent fees and other offering expenses payable by the Company.

Based on our current business plans, we will continue to require additional capital in the very near term to fund our operating expenses and capital expenditure requirements, or we may need to further curtail or cease operations and seek protection by filing a voluntary petition for relief under the United States Bankruptcy Code. If this were to occur, the value available to our various stakeholders, including our creditors and stockholders, is uncertain and trading prices for our securities may bear little or no relationship to the actual recovery, if any, by holders of our securities in bankruptcy proceedings, if any. This estimate assumes the inclusion of the amount equal to the outstanding principal amount of the Debentures. Our existing cash and cash equivalents and short-term investments, will not be sufficient for us to achieve cash-flow break even and we expect to need to seek additional capital.

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, restructuring and advisory fees, and expenses associated with being a public company. We expect such expenditures to continue throughout the balance of 2024.

As of September 30, 2024, we had \$8.8 million in cash and cash equivalents, \$3.2 million in short-term investments and \$11.4 million in restricted cash and investments. The amount we are required to hold as restricted cash or restricted investments is equal to the lesser of (a) \$11.0 million and (b) the then outstanding principal balance of the Debentures. Based on recurring losses from operations incurred since inception and the expectation of continued operating losses, we anticipate our available cash balance will not be sufficient to operate our business for the next twelve months from the issuance of this Quarterly Report. Accordingly, we determined that there is substantial doubt about our ability to continue as a going concern within 12 months after the date that the financial statements included in this Quarterly Report are issued. In order to continue to operate our business beyond that time, we will need to raise substantial additional capital. 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 short-term investments and our current operating plan as discussed above 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 (Organization and Basis of Presentation) to our unaudited condensed consolidated financial statements included elsewhere in this Quarterly Report for more information. If we are unable to continue as a going concern, we may have to reorganize or liquidate our business and may receive less than the value at which those assets are carried on our consolidated financial statements, and investors may lose all or a part of their investment. The Board has established a strategy committee to work with the Company and outside advisors in evaluating our options and considering alternatives that we believe will maximize stakeholder value, including any of the following or a combination thereof: debt financing, equity investments, combinations with other companies, or the sale of all or part of the company. There can be no assurances that any transactions will be available to us or completed and if we are not able to raise sufficient additional capital in the very near term to fund our operation, we may seek relief available under applicable insolvency laws. We do not intend to make further announcements regarding this process unless and until the Board approves a specific transaction or otherwise determines that further disclosure is appropriate.

Cash Flows

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

	Nine Months Ended September 30,	
	2024	2023
Net cash provided by (used in):		
Operating activities	\$ (62,418,000)	\$ (95,402,000)
Investing activities	70,842,000	79,531,000
Financing activities	(17,575,000)	45,331,000

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 expect to seek 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 at all, and if we are unable to raise sufficient additional capital in the very near term, we may need to further curtail or cease operations and seek protection by filing a voluntary petition for relief under the United States Bankruptcy Code. See Note 5 (Debt) to our unaudited condensed consolidated financial statements included elsewhere in this Quarterly Report for a discussion of our recent debt financing. Our recent restructuring activities are anticipated to reduce the cash used in operating activities over the next 12 months; however, our financial condition may result in certain additional restructuring or advisory expenses which may result in our corporate expenditures increasing, potentially materially, and we may observe fluctuations in the cash used in operating activities on a quarterly basis to sustain our current commercial offerings.

Net cash used in operating activities was \$62.4 million during the nine months ended September 30, 2024 as compared to \$95.4 million during the same period in 2023. The decrease in cash used in operating activities of \$33.0 million was primarily attributed to a decrease in our net loss and a decrease in cash used for inventory purchases over that time, consistent with the cost saving initiatives that were initiated in May of 2023

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 nine months ended September 30, 2024, cash provided by investing activities was \$70.8 million, as compared to \$79.5 million provided by investing activities during the same period in 2023. The decrease in cash provided by investing activities of \$8.7 million was primarily attributed to the maturity of \$285.3 million in available for sale securities which was offset by a purchase of available for sale securities of \$214.3 million during the nine months ended September 30, 2024, compared to the maturity of \$84.9 million in available for sale securities offset by a purchase of \$4.5 million of available for sale securities during the same period in 2023.

Financing Activities

Net cash used in financing activities was \$17.6 million during the nine months ended September 30, 2024 as compared to net cash provided by financing activities of \$45.3 million during the same period in 2023, a decrease of \$62.9 million. During the nine months ended September 30, 2024, the Company made principal payments of \$61.0 million and payments on debt extinguishment costs of \$5.4 million towards the High Trail convertible notes payable which was offset by approximately \$18.0 million in gross proceeds from the issuance of the JGB convertible debentures and \$37.7 million in gross proceeds from executing sales under our at-the-market facility with Cowen and Company, LLC (“Cowen”) as compared to \$46.4 million during the same period in 2023.

Capital Resources

As of September 30, 2024, we had approximately \$8.8 million in cash and cash equivalents, \$3.2 million in short-term investments, \$11.4 million in restricted cash and restricted investments and working capital of \$14.0 million. The amount we are required to hold as restricted cash or restricted investments is equal to the lesser of (a) \$11.0 million and (b) the then outstanding principal balance of the Debentures.

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 nine months ended September 30, 2024, we sold approximately 14.2 million shares of common stock under the Cowen ATM and received gross proceeds of approximately \$17.7 million before deducting offering costs of \$0.4 million.

Contingent 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 is reassessed on a quarterly basis using a probability weighted model and a Monte Carlo Simulation. We determined the fair value of the milestone consideration using a scenario-based technique, as the trigger for payment is event driven. For the second milestone, we performed a Monte Carlo Simulation to determine the likelihood that

the milestone will be achieved and was applied to the milestone consideration payment. As of September 30, 2024, the Company concluded that the probability of achievement of the two independent milestones was 0% which resulted in a reduction in the contingent consideration liability to zero.

Contractual Obligations

There were no material changes to our contractual obligations from those disclosed in the Company's Annual Report.

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.

Change in Accounting Estimates

The Company reviews the estimated useful life of its fixed assets on an ongoing basis. This review indicated that the actual lives of the Company's Saphyr and Stratys instruments were longer than the estimated useful lives used for depreciation purposes in the Company's unaudited condensed consolidated financial statements. We first assessed several qualitative and quantitative factors as part of our review including an analysis of the product life cycle, continued product support, customer commitments, technical durability, and compatibility of the Company's Saphyr and Stratys instruments.

As described further in Note 1, (Organization and Basis of Presentation) to our unaudited condensed consolidated financial statements included elsewhere in this Quarterly Report, effective January 1, 2024, the Company changed its estimates of the useful lives of the Company's Saphyr and Stratys instruments to better reflect the estimated period during which these assets will remain in service.

During the nine months ended September 30, 2024, there have been no changes to our critical accounting policies and estimates as described in our Annual Report.

Recent Accounting Pronouncements

See Note 1 (Organization and Basis of Presentation) to our unaudited condensed consolidated financial statements included elsewhere in this Quarterly Report 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 \$8.8 million in cash and cash equivalents, \$3.2 million in short-term investments and \$11.4 million in restricted cash and investments as of September 30, 2024, 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. The amount we are required to hold as restricted cash or restricted investments is equal to the lesser of (a) \$11.0 million and (b) the then outstanding principal balance of the Debentures.

Although we have seen 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 an immaterial impact on our investments.

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 September 30, 2024 and December 31, 2023, 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 September 30, 2024 would not have a material impact on our business, financial condition, or results of operations.

Inflation

Geopolitical and macroeconomic events, including the conflicts between Ukraine and Russia and related sanctions, conflicts in the Middle East, 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. In prior periods, 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 and nine months ended September 30, 2024 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 September 30, 2024, 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.

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. There were no changes in our internal control over financial reporting during the quarter ended September 30, 2024 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

None.

ITEM 1A. RISK FACTORS

RISK FACTOR SUMMARY

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

- We have incurred recurring net losses since we were formed and expect to incur losses in the future. We cannot be certain that we will ever achieve or sustain profitability;
- Our recurring losses, negative cash flows and significant accumulated deficit have raised substantial doubt regarding our ability to continue as a going concern. We will need to raise additional capital, which may not be available on acceptable terms, if at all, to fund our existing operations. If we are unable to raise sufficient additional capital in the very near term, we will be required to further curtail our operations, liquidate or otherwise dispose of assets, wind-down or cease operations entirely. In these circumstances, investors may not receive full value, or any value, for their investment;
- Our corporate cash saving initiatives and the associated headcount reductions we announced in May 2023, October 2023 and March 2024 could disrupt our business, and may not achieve our intended objectives;
- 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;
- 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 OGM systems, Ionic Purification system, VIA 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;
- The terms of the Debentures and the Debenture Purchase Agreement restrict our current and future operations. Upon an event of default under the Debentures, we may not be able to make any accelerated payments under the Debentures or our other permitted indebtedness;
- Unfavorable geopolitical and macroeconomic developments could adversely affect our business, financial condition or results of operations;
- 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 OGM systems, Ionic Purification system, VIA 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;
- 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;
- We are subject to stringent and evolving U.S. and foreign laws, regulations, and rules, contractual obligations, industry standards, policies and other obligations related to data privacy and security. Our actual or perceived failure to comply with such obligations could lead to regulatory investigations or actions; litigation (including class claims) and mass

arbitration demands; fines and penalties; disruption of our business operations; reputational harm; loss of revenue or profits; loss of customers or sales; and other adverse business consequences;

- If the U.S. Food and Drug Administration, or FDA, ends enforcement discretion for Laboratory Developed Tests or 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 or our collaborators or customers will be required to obtain regulatory clearance(s) or approval(s), and we 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;
- 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;
- We depend on technology that is licensed to us by third parties. Any loss of our rights to these technologies could prevent us from selling our products;
- If we are unable to maintain our listing on the Nasdaq Capital Market or if we are unable to transfer our listing to another stock market our ability to publicly or privately sell equity securities and the liquidity of our common stock could be adversely affected;
- 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;
- We may not be successful in identifying and implementing any potential strategic alternatives in a timely manner, or at all, and any strategic transactions that we may consummate in the future could have negative consequences; and
- If a strategic transaction is not consummated, our Board may decide to pursue a dissolution and liquidation. In such an event, the amount of cash available for distribution to our stockholders will depend significantly on the timing of such liquidation as well as the amount of cash that may need to be reserved for commitments and contingent liabilities.

RISK FACTORS

Investing in our common stock involves a high degree of risk. You should consider and read carefully all of the risks and uncertainties described below, as well as other information included in this Quarterly Report, including our unaudited financial statements and related notes 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.

Risks related to our financial condition and need for additional capital

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

Since our inception, we have incurred recurring net losses and we expect that our losses will continue for the foreseeable future. We incurred net losses of \$91.9 million and \$188.6 million, and used cash in operations of \$62.4 million and \$95.4 million for the nine months ended September 30, 2024 and 2023, respectively. As of September 30, 2024, we had an accumulated deficit of \$673.1 million. We cannot predict if we will be profitable in the near future or at all. Our past acquisitions have increased our expenses and we expect that any future acquisitions of businesses, assets, products or technologies would 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. 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 recurring losses, negative cash flows and significant accumulated deficit have raised substantial doubt regarding our ability to continue as a going concern. We will need to raise additional capital, which may not be available on acceptable terms, if at all, to fund our existing operations. If we are unable to raise sufficient additional capital in the very near term, we will be required to further curtail our operations, liquidate or otherwise dispose of assets, wind-down or cease operations entirely. In these circumstances, investors may not receive full value, or any value, for their investment.

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. We believe that with receipt of the net proceeds in July 2024 from the July 2024 Offering, in October 2024 from the October 2024 Offering, and in May 2024 from the transaction pursuant to that certain securities purchase agreement dated May 24, 2024, between us and certain accredited investors and JGB Collateral LLC, as collateral agent for the investors (the “JGB Purchase Agreement”) and restructuring of redemption terms for our debt instruments, together with the Company’s existing cash and, cash equivalents and short-term investments, and after taking into account inaccessible “restricted cash” under the terms of the transaction under the JGB Purchase Agreement, based on the Company’s current business plans we will be able to fund our operating expenses and capital expenditure requirements into the fourth quarter of 2024. See Note 5 and 6 (Debt and Stockholders’ Equity and Stock-Based Compensation) to our unaudited condensed consolidated financial statements included elsewhere in this Quarterly Report for a further discussion of our recent debt and equity financings. Our existing cash and cash equivalents and short-term investments, will not be sufficient for us to achieve cash-flow break even and we expect to need to seek additional capital based on favorable market conditions or strategic considerations alternatives in the 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. We will continue to seek to raise additional capital, but without sufficient additional financing in the very near term we will not be able to continue as a going concern, we may have to reorganize or liquidate our business and may receive less than the value at which those assets are carried on our consolidated financial statements, further curtail planned operations or cease operations entirely and wind down our business. Any of these could materially and adversely affect our liquidity, financial condition and business prospects and, as a result, our investors may lose all or a part of their investment. In light of our existing cash and cash equivalents and our current obligations, such a liquidation or disposition process may occur subject to bankruptcy protections, which may further reduce the value that we may receive for our assets. 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. The Board has established a strategy committee to

work with the Company and outside advisors in evaluating our options and considering alternatives that we believe will maximize stakeholder value, including any of the following or a combination thereof: debt financing, equity investments, combinations with other companies, or the sale of all or part of the company. There can be no assurances that any transactions will be available to us or completed and if we are not able to raise sufficient additional capital in the very near term to fund our operations, we may seek relief available under applicable insolvency laws. We do not intend to make further announcements regarding this process unless and until the Board approves a specific transaction or otherwise determines that further disclosure is appropriate.

Our corporate cost saving initiatives and the associated headcount reductions we announced in May 2023, October 2023, March 2024, and September 2024 could disrupt our business, and may not achieve our intended objectives.

In May 2023, October 2023, March 2024, and September 2024, we undertook cost saving initiatives intended to decrease expenses and maintain a streamlined organization to support key programs and customers, and that are expected to conserve cash. These initiatives primarily related to the Company's efforts on the current installed base of OGM systems with less emphasis on new placements of OGM systems and more emphasis on ensuring customers are able to maximize their utilization of the OGM systems and included a reduction in force. These initiatives may be disruptive to our operations and there is no guarantee that they will achieve the intended benefits. 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, any employee litigation related to the headcount reductions could be costly and prevent management from fully concentrating on the business. In addition, Bionano Laboratories' phase out of the offering of certain testing services related to neurodevelopmental disorders ("NDDs"), including autism spectrum disorders ("ASDs"), and other disorders of childhood development could have a negative impact on our cash flow, financial conditions or results of operations. In 2023, these products generated approximately \$7.0 million of our overall \$36.1 million in revenues. Further, our reduction in personnel through these headcount reductions and voluntary attrition could limit our ability to segregate responsibility for certain accounting and related treasury functions within our organization.

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 cost saving initiatives including those we discussed under "Part I. Item 2. Management's Discussion and Analysis of Operations – Liquidity and Capital Resources", or if we experience significant adverse consequences of such initiatives, our business, financial condition, and results of operations may be materially adversely affected.

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. For example, in recent years we significantly grew our headcount through acquisitions of other businesses and, the expansion of our sales, marketing and research and development teams, and, more recently, have undertaken several rounds of reductions to our work force and the discontinuation of certain product offerings, all of which have resulted in significant fluctuations in our operating costs in a manner not historically reflected in our consolidated financial statements. Because our business model has evolved over time and may continue to evolve, this has impacted the composition and concentration of our revenues, and which may continue to change in the future. These changes in revenue and expenses, 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 and decreasing the size of our organization, integrating acquired businesses and implementing cost saving initiatives. 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.

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 OGM systems, Ionic Purification system or successor systems;
- our successful creation of an end-to-end solution for OGM;
- execution on our commercial and reimbursement strategy involving Bionano Laboratories;
- customer demand for our software solutions, including VIA software, and future software solutions developed through this platform;
- the position of our DNA isolation business in genome analysis space 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, conflicts in the Middle East, potential future disruptions in access to bank deposits or lending commitments due to bank failures, global pandemics, 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;
- any cost saving and restructuring initiatives and our ability to successfully maintain our business operations and customer support at historic levels;
- 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 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. Further our financial condition may result in certain additional restructuring or advisory expenses which may result in our corporate expenditures increasing, potentially materially, and we may observe fluctuations in the cash used in operating activities on a quarterly basis to sustain our current commercial offerings. 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. In particular as part of our cost saving plans we have also made a change in its business strategy and refocused our efforts on the current installed base of OGM systems with less emphasis on new placements of OGM systems and more emphasis on ensuring customers are able to maximize their utilization of the OGM systems. Investors should not rely on our operating results for any prior periods as an indication of our future operating performance. To effectively manage any 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 acquired businesses. Failure to effectively manage any future 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.

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

Our future capital needs are uncertain and we will require additional funding in the future to advance the commercialization of our OGM systems, Ionic Purification system, VIA software, and our other products, technologies and services, as well as continue our research and development efforts. If we fail to obtain sufficient additional funding, we will be forced to delay, reduce or eliminate significant portions of our commercialization and development efforts which could negatively impact our revenue opportunities.

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, and execute potential strategic transactions. In connection with the preparation of our financial statements for the three and nine months ended September 30, 2024, we had performed an analysis of our ability to continue as a going concern and based on our current business plan, we believed that our existing cash and cash equivalents and short-term investments would not be sufficient for the next twelve months from the issuance of the unaudited condensed consolidated financial statements included in this Quarterly Report and, accordingly, there continued to be substantial doubt about our ability to continue as a going concern within 12 months of the issuance of such financial statements. 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 need to raise substantial additional capital if we intend to:

- maintain and expand our sales and marketing efforts to further commercialize our products, technologies and services and address competitive developments;
- maintain and 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 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 to grow our 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 complementary 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.

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

- the cost of integrating our 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 ;
- high 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, the Israel-Hamas war, related sanctions, recent and, potential future disruptions in access to bank deposits or lending commitments due to bank failures and global pandemics; and
- the effect of competing technological and market developments.

As of September 30, 2024, we had \$8.8 million in cash and cash equivalents, \$3.2 million in short-term investments, and \$11.4 million in restricted cash and investments.

We received net proceeds of approximately \$9.3 million after deducting placement agent fees and offering expenses, from the issuance and sale of our securities in the July 2024 Offering and net proceeds of approximately \$2.7 million after deducting placement agent fees and offering expenses, from the issuance and sale of our securities in the October 2024 Offering. Based on our current business plans, we believe the net proceeds from such financings together with our existing cash and cash equivalents and short-term investments, and after taking into account inaccessible “restricted cash” under the terms of the JGB Purchase Agreement, will be sufficient to fund our operating expenses and capital expenditure requirements into at least the fourth quarter of 2024. Nevertheless, our existing cash and cash equivalents and short-term investments, will not be sufficient for us to achieve cash-flow break even and we expect to need to seek additional capital in the near future.

We have based this estimate on assumptions that may prove to be wrong, and we could use our capital resources sooner than we currently expect, requiring us to seek additional funds sooner than planned, through public or private equity or debt financings or other sources, such as strategic collaborations. 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. 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 and cash equivalents and short-term investments or “restricted cash” in the account control agreement due to market conditions such as recent and potential future disruptions in access to bank deposits or lending commitments due to bank failures. Based on our current business plans, we will continue to require additional capital in the very near term to fund our operating expenses and capital expenditure requirements, or we may need to further curtail or cease operations and seek protection by filing a voluntary petition for relief under the United States Bankruptcy Code. If this were to occur, the value available to our various stakeholders, including our creditors and stockholders, is uncertain and trading prices for our securities may bear little or no relationship to the actual recovery, if any, by holders of our securities in bankruptcy proceedings, if any.

Global economic conditions have been challenging, 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 will have to delay, reduce or eliminate significant portions of our development and commercialization efforts related to our technologies and products, any of which could, among other things, negatively impact our revenue opportunities. For example, in September 2024, we decided to focus our efforts on the current installed base of OGM systems with less emphasis on new placements of OGM systems and more emphasis on ensuring customers are able to maximize their utilization of the OGM systems. As a result, we anticipate a reduction in our future product revenue. Bionano Laboratories’

phase out of the offering of certain testing services related to NDDs, including ASDs, and other disorders of childhood development could also have a negative impact on our cash flow, financial conditions or results of operations. We also may have to further reduce marketing, customer support or other resources devoted to our products or technologies or cease operations entirely. 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. Any additional fundraising efforts may divert our management from their day-to-day activities, which may adversely affect our ability to conduct our strategic operations.

You may experience future dilution as a result of future equity offerings.

In order to raise additional capital, we may in the future offer additional shares of our common stock, or other securities convertible into or exchangeable for our common stock and, as a result, our stockholders may experience dilution. For example, as a result of our July 2024 Offering and October 2024 Offering, our investors experienced dilution of their ownership interests. We may sell additional shares of our common stock or other securities convertible or exchangeable into common stock in future equity offerings at a price per share that is less than the price per share paid by investors in previous equity offerings, and investors purchasing shares or other securities in the future could have rights superior to existing stockholders.

Servicing the Debentures requires a significant amount of cash, and we may not have sufficient cash flow from our business to pay our obligations under the Debentures or our other permitted indebtedness.

Our ability to make scheduled payments of principal or default interest, if any, or to refinance the Debentures or our other permitted indebtedness, depends on our future performance, which is subject to economic, financial, competitive and other factors, some of which are beyond our control. As of September 30, 2024, we had aggregate principal amount outstanding under the Debentures of \$20.0 million. Our business may not continue to generate cash flow from operations in the future sufficient to satisfy our obligations under the Debentures or our other permitted indebtedness. If we are unable to generate such cash flow, we may be required to adopt one or more alternatives, such as reducing or delaying investments or capital expenditures, selling assets, refinancing or obtaining additional equity capital on terms that may be onerous or highly dilutive. We may only prepay the Debentures in full without the consent of the holders under certain circumstances, and our ability to refinance the Debentures or our other permitted indebtedness will also depend on the capital markets and our financial condition at such time. We may not be able to engage in any of these activities or engage in these activities on desirable terms, which could result in a default on the Debentures or our other indebtedness. As of September 30, 2024, there is substantial doubt about our ability to continue as a going concern and servicing the Debentures continues to impact our cash flow and liquidity.

The terms of the Debentures and the Debenture Purchase Agreement restrict our current and future operations. Upon an event of default under the Debentures, we may not be able to make any accelerated payments under the Notes or our other permitted indebtedness.

The Debentures and the Debenture Purchase Agreement contain a number of restrictive covenants that impose significant operating and financial restrictions on us and may limit our ability to engage in acts that may be in our long-term best interest. In particular, the Debentures contain customary affirmative and negative covenants (including covenants that limit our ability to incur debt, make investments, transfer assets, engage in certain transactions with affiliates and merge with other companies, in each case, other than those permitted by the Debentures, and events of default, and the Debentures and the Debenture Purchase Agreement contains customary covenants (including covenants that limit our ability to issue additional securities during specified periods and enter into variable rate transactions). Furthermore, we will be required to maintain cash or investments subject to account control agreements in favor of the purchaser in a minimum amount equal to the lesser of (i) \$11.0 million and (ii) the then outstanding balance of the Debenture. Our ability to meet the financial tests under the Debentures can be affected by events beyond our control, and we may be unable to meet them.

A breach of the covenants or restrictions under the Debentures and the Debenture Purchase Agreement or under the agreements governing any of our other permitted indebtedness could result in an event of default under the applicable indebtedness. Such a default may allow holders of the Debentures, if any, or the holders or lenders of our other permitted indebtedness, as applicable, to accelerate the related indebtedness, which may result in the acceleration of other indebtedness to which a cross-acceleration or cross-default provision applies. In addition, such lenders or holders could terminate commitments to lend money, if any. Furthermore, if we were unable to repay the Debentures or other permitted indebtedness then due and payable, secured lenders could proceed against the assets, if any, securing such indebtedness. In the event such lenders or holders accelerate the repayment of the Debentures, or our other permitted borrowings, we may not have sufficient assets to repay that indebtedness. A default would also likely significantly diminish the market price of our common stock. Furthermore, as a result of these restrictions, we may be limited in how we conduct and grow our business, be unable to compete effectively or be unable to take advantage of new business opportunities. These restrictions may affect our ability to grow in accordance with our strategy.

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, potential future disruptions in access to bank deposits or lending commitments due to bank failures, slowing growth, rising interest rates and recession and the conflicts between Ukraine and Russia and in the Middle East. A severe or prolonged global economic downturn could result in a variety of risks to our business. For example, although inflation rates have been recently declining, particularly in the United States, they remain at levels not seen in years. Continuing high inflation rates may result in decreased demand for our products and services, increases in our operating costs (including our labor costs), prolonged unemployment, reduced liquidity and has limited and may continue to limit our ability to access credit or otherwise raise capital on acceptable terms, if at all. Risks of a prolonged 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.

Additionally, following the invasion of Ukraine by Russia, financial markets around the world experienced volatility. In response to the invasion, the United States, UK and EU, 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.

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 including the Tax Cuts and Jobs Act of 2017; the Coronavirus Aid, Relief, and Economic Security Act; and the IRA, 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 of 2017 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, 2023, we had federal and state tax net operating loss carryforwards of \$394.0 million and \$159.4 million, respectively. The federal tax loss carryforwards include \$370.2 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 \$23.8 million begin to expire in 2027 unless previously utilized. Our state tax loss carryforwards began to expire in 2024 and will continue to expire unless previously utilized. As of December 31, 2023, we also had federal and California research credit carryforwards of \$5.1 million and \$9.4 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 is 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 (the “Code”), and corresponding provisions of state law. We 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.

The Company performed an ownership change analysis pursuant to Section 382 of the Code and identified that ownership changes occurred on various dates that will limit the Company’s ability to utilize its net operating loss and R&D credit carryforwards. Based on the analysis, the Company’s deferred tax assets related to the tax attributes that will expire unused as a result of the ownership change limitations have been adjusted as of December 31, 2023 with related valuation allowance disclosed above. As a result of limitations arising from the prior ownership changes, \$33.0 million of federal and \$5.4 million of California net operating loss carry-forwards were removed from the inventory of deferred tax assets. In addition, \$6.4 million of federal R&D tax credits were removed from the deferred tax assets as of December 31, 2023. Further, the Company’s deferred tax assets associated with such tax attributes could be significantly reduced upon a future ownership change within the meaning of Section 382 of the Code. In addition, at the state level, there may be periods during which the use of net operating losses and certain tax credits are suspended or otherwise limited, which could accelerate or permanently increase state taxes owed. For example, on June 27, 2024, California Senate Bill 167 was enacted, which imposes limits for certain taxpayers on the usability of California state net operating losses and certain California state tax credits in tax years beginning on or after January 1, 2024, and before January 1, 2027.

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 judgments relating to our critical accounting policies change or if actual circumstances differ from our assumptions, estimates or judgments, our operating results may be adversely affected and could fall below our publicly announced guidance or the expectations of securities analysts and investors, resulting in a decline in the market price of our securities.

Risks related to our business operations

Acquisitions, joint ventures and other strategic transactions could disrupt or otherwise harm our business and may cause dilution to our stockholders.

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

- disruption in our relationships with 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 0.6 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 0.3 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 0.5 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.

In March 2021, we entered into a Sales Agreement with Cowen which provides for the sale, in our sole discretion, of shares of our common stock having a maximum 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 decrease the maximum aggregate offering price to \$200.0 million going forward. For the nine months ended September 30, 2024, we sold approximately 14.2 million shares of common stock under the Cowen ATM for gross proceeds of approximately \$17.7 million before deducting offering costs.

Further, the exercise of the Registered Warrants issued in the October 2023 Offering (as amended in February 2024) will dilute the ownership interests of existing stockholders to the extent we deliver shares upon exercise of the Registered Warrants. In addition, the existence of the Debentures and Registered Warrants may encourage short selling by market participants because the conversion of the Debentures and exercise of the Registered Warrants could be used to satisfy short positions, or anticipated conversion of the Debentures or exercise of the Registered Warrants into shares of our common stock could depress the price of our common stock. In addition, we issued shares of our common stock in connection with our acquisitions of Lineagen and BioDiscovery. We also issued shares of our common stock in connection with the April 2024 Registered Direct Offering pursuant to which we agreed to issue and sell to certain institutional investors (i) an aggregate of 6.5 million shares of common stock, (ii) pre-funded warrants to purchase up to an aggregate of 2.2 million shares of common stock and (iii) warrants to purchase up to 8.7 million shares of common stock. Additionally, we issued shares of our common stock in connection with the July 2024 Registered Direct Offering pursuant to which we agreed to issue and sell to certain institutional investors (i) an aggregate of 11.7 million shares of common stock, (ii) pre-funded warrants to purchase up to an aggregate of 5.8 million shares of common stock and (iii) warrants to purchase up to 35.0 million shares of common stock. In connection with the October

2024 Offering, we agreed to issue and sell to certain institutional investors (i) an aggregate of 9.9 million shares of common stock and (ii) warrants to purchase up to 19.8 million shares of common stock.

As a result of these issuances, our investors experienced dilution of their ownership interests. 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.

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. As of September 30, 2024, we had outstanding equity awards underlying those plans accounting for 3.8 million underlying shares. The total number of shares of our common stock available for the grant of awards under these plans is 2.7 million, 0.01 million and 0.3 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. 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. 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 future studies published or studies published in peer-reviewed journals, or the publication of other studies in peer-reviewed journals that contradict our previously published studies, could limit the adoption of our current products, assays and services and our planned future products, assays and services. For example, on March 1, 2024, we decided to phase out the offering by Bionano Laboratories of certain testing services related to NDDs, including ASDs, and other disorders of childhood development. In 2023, these products generated approximately \$7.0 million of our overall \$36.1 million in revenues.

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 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 OGM systems, Ionic Purification system, VIA 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 OGM systems, Ionic Purification system, VIA 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 and related sanctions, the conflicts in the Middle East, potential future disruptions in access to bank deposits or lending commitments due to bank failures and global pandemics.
- 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. Our recent decision to focus our efforts on the current installed base of OGM systems with less emphasis on new placements of OGM systems and more emphasis on ensuring customers are able to maximize their utilization of the OGM could also have a negative impact on our cash flow, financial conditions or results of operations.

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, 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;
- 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 Purigen acquisition in November 2022 and have devoted and will need to continue to devote time and resources in order to further develop and integrate 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 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”, 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, premarket approval application (“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 ("IVD"), 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 OGM systems 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 maintain and manage 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 OGM 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 and, our Ionic Purification instruments. 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 OGM services at a single laboratory facility in San Diego, California. All of our molecular diagnostics services are reported through a single facility in San Diego, California.

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 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 may 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 nine months ended September 30, 2024 and 2023, approximately 62% and 56%, 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 continue to come from international sources as we maintain our existing overseas operations and aim to 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. FCPA, 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 sell our products and services in local currency. If our international operations grow, our results of operations and cash flows will be subject to increasing fluctuations due to changes in foreign currency exchange rates, which could harm our business. 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.

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 senior management team, as well as our research and development, manufacturing and sales and marketing personnel. Competition for

qualified personnel is intense. Our growth depends, in particular, on attracting and retaining highly-trained sales personnel with the necessary scientific background and ability to understand our systems at a technical level to effectively identify and sell to potential new customers. 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 with whom we work, 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 with whom we work 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 with whom we work 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 with whom we work. 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, and the military conflict between Israel and Gaza, we and the third parties with whom we work 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 with whom we work are subject to a variety of evolving threats, including but not limited to social-engineering attacks (such as through deep fakes, which may be increasingly more difficult to identify as fake, and phishing attacks), malicious code (such as viruses and worms), malware (including as a result of advanced persistent threat intrusions), denial-of-service attacks (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, attacks enhanced or facilitated by AI, 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, ability to provide our products and services, 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.

It may be difficult and/or costly to detect, investigate, mitigate, contain, and remediate a security incident. Our efforts to do so may not be successful. Actions taken by us or the third parties with whom we work to detect, investigate, mitigate, contain, and remediate a security incident could result in outages, data losses, and disruptions of our business. Threat actors may also gain access to other networks and systems after a compromise of our networks and systems.

In addition, our reliance on third parties 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 parties 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 with whom we work 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 the third parties with whom we work 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 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.

While we have implemented security measures designed to protect against security incidents, there can be no assurance that these measures will be effective. We take steps designed to detect, mitigate, and remediate vulnerabilities in our information systems (such as our hardware and/or software, including that of third parties with whom we work). We may not, however, detect and remediate all such vulnerabilities including on a timely basis. Further, we may experience delays in deploying remedial measures and patches designed to address identified vulnerabilities. Vulnerabilities could be exploited and result in a security incident.

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 with whom we work. A security incident or other interruption could disrupt our ability (and that of third parties with whom we work) to provide our products, software and services. We may expend significant resources or modify our business activities (including our clinical trial 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.

Applicable data privacy and security obligations may require us, or we may voluntarily choose, to notify relevant stakeholders, including affected individuals, customers, regulators, and investors, of security incidents, or to take other actions, such as providing credit monitoring and identity theft protection services. Such disclosures and related actions can be costly, and the disclosures or the failure to comply with such applicable requirements could lead to adverse consequences. If we (or a third party with whom we work) 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; divergent of management attention; 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 Data 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, and rules, contractual obligations, industry standards, policies and other obligations related to data privacy and security. Our actual or perceived failure to comply with such obligations could lead to regulatory investigations or actions; litigation (including class claims) and mass arbitration demands; fines and penalties; 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 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, HIPAA, as amended by 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.

In the past few years, numerous U.S. states – including California, Virginia, Colorado, Connecticut, and Utah—have enacted comprehensive privacy laws that impose certain obligations on covered businesses, including providing specific disclosures in privacy notices and affording residents with certain rights concerning their personal data. As applicable, such rights may include the right to access, correct, or delete certain personal data, and to opt-out of certain data processing activities, such as targeted advertising, profiling, and automated decision-making. The exercise of these rights may impact our business and ability to provide our products and services. Certain states also impose stricter requirements for processing certain personal data, including sensitive information, such as conducting data privacy impact assessments. These state laws allow for statutory fines for noncompliance. For example, the California Consumer Privacy Act of 2018, as amended by the California Privacy Rights Act of 2020 (collectively, the “CCPA”) applies to personal information of consumers, business representatives, and employees who are California residents and requires businesses to provide specific disclosures in privacy notices and honor requests of California residents to exercise certain privacy rights. The CCPA allows for fines for noncompliance (up to \$7,500 per intentional violation and allows private litigants affected by certain data breaches to recover significant statutory damages). While these laws exempt some data processed in the context of clinical trials, these developments further complicate compliance efforts and increase legal risk and compliance costs for us and the third parties with whom we work. Similar laws are being considered in several other states, as well as at the federal and local levels, and we expect more states to pass similar laws in the future.

Outside the United States, an increasing number of laws, regulations, and industry standards apply to data privacy and security. For example, the EU GDPR and the UK GDPR impose strict requirements for processing the personal data of individuals. For example, under the GDPR, companies may face temporary or definitive bans on data processing and other corrective actions; fines of up to 20 million euros under the EU GDPR, 17.5 million pounds sterling under the UK GDPR, or, in each case 4% of annual global revenue, whichever is greater; or private litigation related to 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 UK have significantly restricted the transfer of personal data to the United States and other countries whose privacy laws it generally 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’s standard contractual clauses the UK’s International Data Transfer Agreement / Addendum, and the EU-U.S. Data Privacy Framework (which allows for transfers to relevant U.S.-based organizations who self-certify compliance and participate in the Framework), 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 ("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 are also subject to contractual obligations related to data privacy and security and our efforts to comply with such obligations may not be successful. We publish privacy policies, marketing materials, and other statements regarding data privacy and security. We may be subject 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 with whom we work. If we or the third parties with whom we work 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) and mass arbitration demands; additional reporting requirements and/or oversight; bans or restrictions on processing personal data; orders to destroy or not use personal data; and imprisonment of company officials. In particular, plaintiffs have become increasingly more active in bringing privacy-related claims against companies, including class claims and mass arbitration demands. Some of these claims allow for the recovery of statutory damages on a per violation basis, and, if viable, carry the potential for monumental statutory damages, depending on the volume of data and the number of violations. Any of these events could have a material adverse effect on our reputation, business, or financial condition, including but not limited to, loss of customers; interruptions or stoppages in our business operations; 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 ends enforcement discretion for Laboratory Developed Tests or 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 or our collaborators or customers will be required to obtain regulatory clearance(s) or approval(s), and we 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 materially adversely affect our business. On May 6, 2024 FDA issued final regulations under which it intends to phase out its enforcement discretion approach to LDTs over a period of four years. We and our collaborators or customers will be required to obtain PMA approval or 510(k) clearance for certain tests by October 1, 2027. We will also become subject to device registration and listing requirements, medical device reporting requirements and the requirements of the FDA's Quality System Regulation. We may be required to conduct clinical trials to support any PMA approval. This may increase the cost of conducting, or otherwise harm, our business.

The cost and time required to commercialize tests presently marked as LDTs 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 OGM technology are subject to unfavorable pricing regulations or third-party payor coverage and reimbursement policies, our business could be harmed.

Currently, our OGM systems are for RUO, but clinical laboratories may acquire our instrumentation through a capital purchase or capital lease and use the OGM system 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 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, 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 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, 2025 and March 31, 2025, 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 2025 to 2027 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 (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 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;
- 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;
- 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 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 in certain circumstances, including state health information privacy and data breach notification laws which govern the collection, use, disclosure, and protection of health-related 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 (“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.

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. FCPA, 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.

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 150 issued patents across approximately 39 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 more than 50 pending patent applications in and 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 \$2.10 on December 27, 2023 and a low price of \$0.28 on November 1, 2024 and November 4, 2024 (as adjusted for the reverse stock split effectuated on August 3, 2023). During this time, the price per share of common stock has ranged from an intra-day low of \$0.26 per share to an intra-day high of \$2.27 per share (as adjusted for the reverse stock split effectuated on August 3, 2023).

The trading price of our common stock 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. We cannot predict the actions of market participants and, therefore, can offer no assurances that the market for our common stock will be stable or appreciate over time. The market price of our common stock may be influenced by many factors, including but not limited to:

- 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 OGM systems, Ionic Purification systems or our VIA 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, conflicts in the Middle East, civil unrest, epidemics or pandemics, outbreaks, resurgences or major catastrophic events;
- general political and economic conditions, including potential future disruptions in access to bank deposits or lending commitments due to bank failures;
- our cost saving initiatives announced in May 2023, October 2023, March 2024, and September 2024; and
- other events or factors, many of which are beyond our control.

As a result, you may not be able to sell your shares of our common stock at or above the price at which you purchased them. 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.

The reverse stock split we implemented may not achieve the intended results and the market price of our common stock may be materially and negatively impacted.

At our 2023 Annual Meeting of Stockholders, our stockholders approved a proposal for 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. On August 2, 2023, our board of directors approved a reverse stock split at a ratio of 1-for-10, and on August 4, 2023, we filed a certificate of amendment to effect the reverse split ratio chosen by our board of directors. We cannot assure you that we will achieve any of the 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 could result in further dilution to our existing stockholders and have anti-takeover implications.

The total number of authorized shares of our common stock was not proportionately reduced in connection with our reverse stock split. As a result, the reverse stock split increased 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 are 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 reverse stock split was prompted by business and financial considerations, you should be aware the reverse stock split 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 (“Nasdaq”) or if we are unable to transfer our listing to another stock market. In order to maintain this listing, we must satisfy minimum financial and other continued listing requirements and standards, including a requirement to maintain a minimum bid price of our common stock of \$1.00 per share pursuant to Nasdaq Listing Rule 5550(a)(2) (the “Minimum Bid Price Requirement”).

On multiple occasions in the past, we have failed to comply with the per share minimum required for continued listing on Nasdaq. For example, on May 30, 2023, we received a letter (the “First Notice”) from Nasdaq advising us that for 30 consecutive trading days preceding the date of the First Notice, the bid price of our common stock had closed below the Minimum Bid Price Requirement.

While we implemented a reverse stock split, effective August 4, 2023 that temporarily enabled us to satisfy the Minimum Bid Price Requirement, on July 11, 2024, we received another letter (the “Second Notice”) from Nasdaq advising us that for 30 consecutive trading days preceding the date of the Second Notice, the bid price of our common stock had closed below the Minimum Bid Price Requirement. The Second Notice has no effect on the listing of our common stock at this time, and our common stock continues to trade on Nasdaq under the symbol “BNGO.”

Under Nasdaq Listing Rule 5810(c)(3)(A), we have 180 calendar days following the date of the Notice to regain compliance with the Minimum Bid Price Requirement. If at any time during this 180-day period the closing bid price of our common stock was at least \$1.00 for a minimum of 10 consecutive business days, we would regain compliance with the Minimum Bid Price Requirement and the matter will be closed.

If we do not regain compliance with the Minimum Bid Price Requirement within the applicable compliance period, our common stock will be subject to delisting. In addition, if we fail to satisfy another Nasdaq requirement for continued listing, Nasdaq staff could provide notice that our common stock may become subject to delisting.

Even if we undertake efforts to implement another reverse stock split to attempt to regain compliance with the Minimum Bid Price Requirement we cannot assure you that such a reverse stock split will allow us to successfully regain compliance with the Minimum Bid Price Requirement, or that such an event leading to notice from Nasdaq staff will not happen again 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. Moreover, any such delisting could trigger a default or event of default under certain agreements that we have in place with third parties. Delisting could also cause a loss of confidence of our customers, collaborators, vendors, suppliers and employees, which could harm our business and future prospects.

If 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 of 2002 (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, as a “non-accelerated filer” we are not 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.

We currently qualify as a smaller reporting company and a non-accelerated filer, 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. 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 for any fiscal year exceeds \$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, we have filed registration statements on Form S-8 under the Securities Act registering the issuance of an aggregate of 7.6 million 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, including because the number of shares that may be issued under certain employee equity benefit plans automatically increase as a result of the operation of certain “evergreen” provisions in our equity plans. Shares registered under these registration statements on Form S-8 are available for sale in the public market subject to vesting arrangements and exercise of options, and the restrictions of Rule 144 in the case of our affiliates. Further in connection with the Private Placement completed in October 2023, we filed a Form S-3 to enable the purchasers to resell the shares underlying the Private Placement Notes and the Private Placement Warrants (as defined in Note 5 (Debt) to our unaudited condensed consolidated financial statements). Following the redemptions in February and May 2024, the High Trail Private Placement Notes and the High Trail Registered Notes have been canceled. However, the purchaser retains the Private Placement Warrants to purchase up to \$6.8 million shares of our common stock. Further, in connection with the April 2024 Registered Direct Offering, we issued and sold, among other things, warrants to purchase approximately 8.7 million shares of our common stock; in connection with the July 2024 Registered Direct Offering, we issued

and sold, among other things, warrants to purchase approximately 35.0 million shares of our common stock following stockholder approval; and in connection with the October 2024 Registered Direct Offering, we issued and sold, among other things, warrants to purchase approximately 19.8 million shares of our common stock following stockholder approval.

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 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.

Although our common stock is listed on The Nasdaq Capital Market, there is a risk that an active trading market for our shares may 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. Any inactive trading market for our common stock may also impair our ability to raise capital to continue to fund our operations by selling shares and may impair our ability to acquire other companies or technologies by using our shares as consideration.

Risks Related to Our Review of Strategic Alternatives

We may not be successful in identifying and implementing any potential strategic alternatives in a timely manner, or at all, and any strategic transactions that we may consummate in the future could have negative consequences.

The Board has established a strategy committee to work with the Company and outside advisors in evaluating our options and considering alternatives that we believe will maximize stockholder value. We expect to devote substantial time and resources to exploring strategic alternatives that our Board believes will maximize stockholder value. Despite management devoting significant efforts to identify and evaluate potential strategic alternatives, there can be no assurance that this strategic review process will result in us pursuing any transaction or that we will be able to successfully consummate any particular strategic transaction on attractive terms, on a timely basis, or at all. For example, certain types of strategic transactions may require third-party consents, such as stockholder approval, which could be difficult or costly to obtain. We have not set a timetable for completion of this strategic review process, and our Board has not approved a definitive course of action. Additionally, there can be no assurance that any particular course of action, business arrangement or transaction, or series of transactions, will be pursued, successfully consummated or lead to increased stockholder value or that we will make any cash distributions to our stockholders.

The process of continuing to evaluate our strategic alternatives may be costly, time-consuming and complex, and we may incur significant legal, accounting and advisory fees and other expenses, some of which may be incurred regardless of whether we successfully enter into a transaction. We may also incur additional unanticipated expenses in connection with this process. Any such expenses will decrease the remaining cash available for use in our business. Our ability to pursue or consummate strategic transactions also depends upon our ability to retain certain of our employees, the loss of whose services may adversely impact the ability to identify, negotiate and consummate such transaction. If we are unable to successfully retain certain of our key remaining personnel, we are at risk of a disruption to our exploration and consummation of one or more strategic transactions.

In addition, potential counterparties in a strategic transaction involving us may place minimal or no value on our assets and our public listing and any strategic transactions that we may pursue could have a variety of negative consequences, and we may enter into a transaction that yields unexpected results that adversely affect our business and decreases the remaining cash available for use in our business. Any potential transaction would be dependent on a number of factors that may be beyond our control, including, among other things, market conditions, industry trends, the interest of third parties in a potential transaction with us, obtaining stockholder approval and the availability of financing to third parties in a potential transaction with us on reasonable terms. There can be no assurance that any particular course of action, business arrangement or transaction, or series of transactions, will be pursued, successfully consummated, lead to increased stockholder value, or achieve the anticipated results.

If we are not successful in setting forth a new strategic path for us, or if our plans are not executed in a timely fashion, this may cause reputational harm with our stockholders and the value of our securities may be adversely impacted. In addition, speculation regarding any developments related to the review of strategic alternatives and perceived uncertainties related to our future could cause our stock price to fluctuate significantly.

Even if we successfully consummate any strategic transaction, or series of transactions, from our strategic assessment, we may fail to realize all or any of the anticipated benefits of any such transaction, such benefits may take longer to realize than expected, we may encounter integration difficulties or we may be exposed to other operational and financial risks.

Our ability to realize the anticipated benefits of any potential strategic transaction will depend on a number of factors, including our ability to integrate with any future business partner, our ability to obtain value for portions of our business, if divested, and our ability to generate future stockholder value. The process may be disruptive to our business, and the expected benefits may not be achieved within the anticipated timeframe, or at all. The failure to overcome the challenges involved and to realize the anticipated benefits of any potential transaction could adversely affect our business and financial condition. The negotiation and consummation of any potential strategic transaction will require significant time on the part of our management, and the diversion of management's attention may disrupt our business.

The negotiation and consummation of any such transaction may also require more time or greater cash resources than we anticipate and expose us to other operational and financial risks, including, but not limited to, increased near-term and long-term expenditures, exposure to unknown liabilities, higher than expected acquisition or integration costs, incurrence of substantial debt or dilutive issuances of equity securities to fund future operations, including financings in connection with a strategic transaction, write-downs of assets or goodwill or incurrence of non-recurring, impairment or other charges, increased amortization expenses, difficulty and cost in combining the operations and personnel of any acquired or acquiring business with our operations and personnel, impairment of relationships with key suppliers or customers of any acquired or acquiring business due to changes in management and ownership, inability to retain our key employees or any acquired or acquiring business and possibility of future litigation. Any of the foregoing risks could have a material adverse effect on our business, financial condition and prospects.

If a strategic transaction is not consummated, our Board may decide to pursue a dissolution and liquidation. In such an event, the amount of cash available for distribution to our stockholders will depend significantly on the timing of such liquidation as well as the amount of cash that may need to be reserved for commitments and contingent liabilities.

If we do not successfully consummate a strategic transaction, our Board may decide to pursue a dissolution and liquidation. In such an event, the amount of cash available for distribution to our stockholders will depend heavily on the timing of such decision and, with the passage of time, the amount of cash available for distribution will be reduced as we continue to fund our operations. In addition, if our Board were to approve and recommend, and our stockholders were to approve, a dissolution and liquidation, we would be required under Delaware corporate law to pay our outstanding obligations, as well as to make reasonable provision for contingent and unknown obligations, prior to making any distributions in liquidation to our stockholders. As a result of this requirement, a portion of our assets may need to be reserved pending the resolution of such obligations and the timing of any such resolution is uncertain. In addition, we may be subject to litigation or other claims related to a dissolution and liquidation. If a dissolution and liquidation were pursued, our Board, in consultation with our advisors, would need to evaluate these matters and make a determination about a reasonable amount to reserve. Accordingly, holders of our common stock could lose all or a significant portion of their investment in the event of a liquidation, dissolution or winding up.

The value to stockholders in the event of a strategic transaction or dissolution may depend on the extent to which we will be able to successfully satisfy our existing contractual obligations to third parties on favorable terms, which may include the outcome of our negotiations to reduce or terminate such commitments.

We are currently subject to certain contractual obligations and commitments. In connection with our comprehensive exploration of strategic alternatives, we may seek to negotiate with third parties to reduce or eliminate such obligations and commitments. Our ability to successfully negotiate such obligations or commitments on favorable terms, or at all, or our ability to satisfy any such obligations may impact our ability to pursue a strategic transaction on terms favorable to us, the resulting value to stockholders in a strategic transaction or the cash available for distribution to our stockholders in the event of our dissolution. We may also incur substantial costs in connection with or as a result of such negotiations or termination of any of our commitments. There can be no assurance that we will be successful in negotiating to reduce or eliminate any of our existing contractual obligations and commitments, or that we will be able to satisfy any such obligations on a timetable that will allow us to maximize potential value to our stockholders.

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. 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.

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

All unregistered sales of equity securities during the quarter ended September 30, 2024 have been previously reported.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

ITEM 4. MINE SAFETY DISCLOSURES

None.

ITEM 5. OTHER INFORMATION

During the three months ended September 30, 2024, no director or officer of the Company adopted, terminated or modified a “Rule 10b5-1 trading arrangement” or “non-Rule 10b5-1 trading arrangement,” as defined in Item 408(a) of Regulation S-K of the Exchange Act.

ITEM 6. EXHIBITS

Exhibit Number	Description
3.1	Amended and Restated Certificate of Incorporation, as amended (incorporated by reference to Exhibit 3.1 to Registrant's Quarterly Report on Form 10-Q, filed with the SEC on November 8, 2023).
3.2	Amended and Restated Bylaws (incorporated by reference to Exhibit 3.2 to the Registrant's Current Report on Form 8-K, filed with the SEC on August 24, 2018).
3.3	Amendment to Amended and Restated Bylaws (incorporated by reference to Exhibit 3.2 to the Registrant's Current Report on Form 8-K, filed with the SEC on April 14, 2023).
4.1	Form of Common Stock Certificate (incorporated by reference to Exhibit 4.1 to the Registrant's Registration Statement on Form S-1 (File No. 333-225970), as amended, originally filed with the SEC on June 28, 2018).
4.2	Form of Warrant to Purchase Series D-1 Preferred Stock issued to Midcap Financial Trust (incorporated by reference to Exhibit 4.8 to the Registrant's Registration Statement on Form S-1 (File No. 333-225970), as amended, originally filed with the SEC on June 28, 2018).
4.3	Form of Warrant to Purchase Common Stock for Service Providers (incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K, filed with the SEC on November 21, 2018).
4.4	Form of Warrant to Purchase Common Stock issued to Investors in October 2019 Public Offering (incorporated by reference to Exhibit 4.13 to the Registrant's Registration Statement on Form S-1 (File No. 333-233828), as amended, originally filed with the SEC on September 18, 2019).
4.5	Form of Warrant to Purchase Common Stock issued to Investors in April 2020 Public Offering (incorporated by reference to Exhibit 4.16 to the Registrant's Registration Statement on Form S-1 (File No. 333-237074), as amended, originally filed with the SEC on March 11, 2020).
4.6	Form of Warrant to Purchase Common Stock issued to Purchaser in October 2023 Offering (incorporated by reference to Exhibit 4.2 to the Registrant's Current Report on Form 8-K, filed with the SEC on October 11, 2023).
4.7	Form of Warrant to Purchase Common Stock issued to Investors in April 2024 Registered Direct Offering (incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K, filed with the SEC on April 5, 2024).
4.8	Form of Warrant to Purchase Common Stock issued to Investors in April 2024 Registered Direct Offering (incorporated by reference to Exhibit 4.2 to the Registrant's Current Report on Form 8-K, filed with the SEC on April 5, 2024).
4.9 ⁺	Form of Senior Secured Convertible Debenture Due May 24, 2026 (incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K, filed with the SEC on May 28, 2024).
4.10	Form of Pre-Funded Warrant to Purchase Common Stock issued to Investors in July 2024 Registered Direct Offering (incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K, filed with the SEC on July 8, 2024).
4.11	Form of Warrant to Purchase Series A Common Stock issued to Investors in July 2024 Registered Direct Offering (incorporated by reference to Exhibit 4.2 to the Registrant's Current Report on Form 8-K, filed with the SEC on July 8, 2024).
4.12	Form of Warrant to Purchase Series B Common Stock issued to Investors in July 2024 Registered Direct Offering (incorporated by reference to Exhibit 4.3 to the Registrant's Current Report on Form 8-K, filed with the SEC on July 8, 2024).
4.13	Form of Warrant to Purchase Series C Common Stock issued to Investors in October 2024 Registered Direct Offering (incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K, filed with the SEC on October 31, 2024).
4.14	Form of Warrant to Purchase Series D Common Stock issued to Investors in October 2024 Registered Direct Offering (incorporated by reference to Exhibit 4.2 to the Registrant's Current Report on Form 8-K, filed with the SEC on October 31, 2024).
10.1 ⁺	Form of Securities Purchase Agreement, dated July 4, 2024, by and among the Company and the Purchasers named therein (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K, filed with the SEC on July 8, 2024).
10.2 ⁺	Form of Securities Purchase Agreement, dated April 4, 2024, by and among the Company and the Purchasers named therein (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K, filed with the SEC on April 5, 2024).

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)

* 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.

^ Certain schedules to this agreement have been omitted pursuant to Item 601(a)(5) of Regulation S-K. The Company agrees to furnish a copy of all omitted schedules to the SEC upon its request.

+ Pursuant to Item 601(b)(10)(iv) of Regulation S-K, certain portions of this exhibit have been redacted because they are both not material and is the type that the Registrant treats as private or confidential. The Registrant hereby agrees to furnish supplementally to the SEC, upon its request, an unredacted copy of this exhibit.

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.

Dated: November 14, 2024

BIONANO GENOMICS, INC.

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

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

Dated: November 14, 2024

By: /s/ Mark Adamchak

Mark Adamchak
Principal Accounting Officer
(Principal Accounting Officer)

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: November 14, 2024

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

R. Erik Holmlin, Ph.D.

President and Chief Executive Officer

(Principal Executive and Financial Officer)

CERTIFICATION

I, Mark Adamchak, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Bionano Genomics, Inc., a Delaware corporation (the “registrant”);
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant’s other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - i. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - ii. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - iii. Evaluated the effectiveness of the registrant’s disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - iv. Disclosed in this report any change in the registrant’s internal control over financial reporting that occurred during the registrant’s most recent fiscal quarter (the registrant’s fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant’s internal control over financial reporting; and
5. The registrant’s other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant’s auditors and the audit committee of the registrant’s board of directors (or persons performing the equivalent functions):
 - i. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant’s ability to record, process, summarize and report financial information; and
 - ii. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant’s internal control over financial reporting.

Dated: November 14, 2024

/s/ Mark Adamchak

Mark Adamchak

Principal Accounting Officer

(Principal Accounting Officer)

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 Mark Adamchak, Principal Accounting Officer of the Company, each hereby certifies that, to the best of their knowledge:

1. The Company’s Quarterly Report on Form 10-Q for the period ended September 30, 2024, as filed with the Securities and Exchange Commission on the date hereof (the “Periodic Report”), and to which this Certification is attached as Exhibit 32.1, fully complies with the requirements of Section 13(a) or Section 15(d) of the Exchange Act; and
2. The information contained in the Periodic Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: November 14, 2024

Dated: November 14, 2024

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

/s/ Mark Adamchak

R. Erik Holmlin, Ph.D.

Mark Adamchak

President and Chief Executive Officer

Principal Accounting Officer

(Principal Executive and Financial Officer)

(Principal 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.