U.S. SECURITIES AND EXCHANGE COMMISSION

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SEC

Table of Contents

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

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2023

OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934 FOR THE TRANSITION PERIOD FROM**

Commission File Number 001-38613

Bionano Genomics, Inc.

(Exact name of Registrant as specified in its Charter)

Delaware	**26-1756290**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
9540 Towne Centre Drive, Suite 100, San Diego, CA	**92121**
(Address of principal executive offices)	(Zip Code)

Registrant's telephone number, including area code: (858) 888-7600

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	BNGO	The Nasdaq Stock Market, LLC

Securities registered pursuant to Section 12(g) of the Act: None

Indicate by check mark if the Registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ¨ No x

Indicate by check mark if the Registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act. Yes ¨ No x

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

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☒
Emerging growth company	☐		

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report ☐

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to § 240.10D-1(b). ☐

Indicate by check mark whether the Registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). YES ☐ NO x

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant as of June 30, 2023 (the last business day of the registrant's most recently completed second fiscal quarter) was approximately $201,348,000 based on the closing price of the registrant's common stock on June 30, 2023 of $6.10 per share, as reported by the Nasdaq Capital Market.

As of February 29, 2024, the Registrant had 54,694,000 shares of common stock, $0.0001 par value per share, outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the definitive proxy statement, or the Proxy Statement, for the Registrant's 2024 Annual Meeting of Stockholders are incorporated by reference into Part III of this Annual Report on Form 10-K. The Proxy Statement will be filed with the Securities and Exchange Commission within 120 days of the Registrant's fiscal year ended December 31, 2023.

Table of Contents

		Page
PART I		
Item 1.	Business	8
Item 1A.	Risk Factors	29
Item 1B.	Unresolved Staff Comments	69
Item 1C.	Cybersecurity	70
Item 2.	Properties	72
Item 3.	Legal Proceedings	72
Item 4.	Mine Safety Disclosures	72
PART II		
Item 5.	Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities	72
Item 6.	[Reserved]	72
Item 7.	Management's Discussion and Analysis of Financial Condition and Results of Operations	72
Item 7A.	Quantitative and Qualitative Disclosures About Market Risk	83
Item 8.	Financial Statements and Supplementary Data	84
Item 9.	Changes in and Disagreements With Accountants on Accounting and Financial Disclosure	125
Item 9A.	Controls and Procedures	125
Item 9B.	Other Information	125
Item 9C.	Disclosure Regarding Foreign Jurisdictions that Prevent Inspections	125
PART III		
Item 10.	Directors, Executive Officers and Corporate Governance	126
Item 11.	Executive Compensation	126
Item 12.	Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters	126
Item 13.	Certain Relationships and Related Transactions, and Director Independence	126
Item 14.	Principal Accountant Fees and Services	126
PART IV		
Item 15.	Exhibit and Financial Statement Schedules	126
Item 16.	Form 10-K Summary	131
Signatures		131

As used in this Form 10-K, "Bionano," the "Company," "we," "our," and "us" refer to Bionano Genomics, Inc. and its subsidiaries or, as the context may require, Bionano Genomics, Inc. only. "Lineagen" (doing business as "Bionano Laboratories"), "BioDiscovery" and "Purigen" refer to our wholly owned subsidiaries, Lineagen, Inc., BioDiscovery, LLC and Purigen Biosystems, Inc., respectively.

Note Regarding Forward-Looking Statements

This Annual Report on Form 10-K (this "Annual Report") contains forward-looking statements and information within the meaning of the safe harbor provisions for the U.S. Private Securities Litigation Reform Act of 1955. All statements other than statements of historical facts contained in this Annual Report, including statements regarding our future results of operations or financial condition, business strategy and plans, and objectives of management for future operations, are forward-looking statements. In some cases, you can identify forward-looking statements because they contain words such as "anticipate," "believe," "contemplate," "continue," "could," "estimate," "expect," "intend," "may," "plan," "potential," "predict," "project," "should," "target," "will" or "would" or the negative of these words or other similar terms or expressions.

We have based these forward-looking statements largely on our current expectations and projections about future events and financial trends that we believe may affect our financial condition, results of operations, business strategy and financial needs. These forward-looking statements are subject to known and unknown risks, uncertainties and assumptions, including risks described in the section entitled "Risk Factors" and elsewhere in this Annual Report, regarding, among other things:

- the size and growth potential of the markets for our products, and our ability to serve those markets;
- the rate and degree of market acceptance of our products;
- our ability to manage the growth of our business and integrate acquired businesses;
- our ability to expand our commercial organization to address effectively existing and new markets that we intend to target;
- the impact from future regulatory, judicial, and legislative changes or developments in the U.S. and foreign countries;
- our ability to successfully execute our strategy and meet anticipated goals and milestones;
- our ability to compete effectively in a competitive industry;
- the introduction of competitive technologies or improvements in existing technologies and the success of any such technologies;
- the performance of our third-party contract sales organizations, suppliers and manufacturers;
- our ability to attract and retain key scientific or management personnel;
- the accuracy of our estimates regarding expenses, future revenues, reimbursement rates, capital requirements and needs for additional financing;
- the impact of geopolitical and macroeconomic developments, such as the ongoing conflict between Ukraine and Russia and related sanctions, the Israel-Hamas war, 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; on our business and operations, as well as the business or operations of our suppliers, customers, manufacturers, research partners and other third parties with whom we conduct business and our expectations with respect to the duration of such impacts and the resulting effects on our business;
- our ability to realize the anticipated benefits and synergies of our recent and any future acquisitions or other strategic transactions;
- our ability to continue as a going concern within 12 months of this Annual Report and our ability to obtain funding for our operations; and
- our ability to attract collaborators and strategic partnerships.

You should not rely on forward-looking statements as predictions of future events. The outcome of the events described in these forward-looking statements is subject to risks, uncertainties and other factors described in Part I, Item 1A Risk Factors and elsewhere in this Annual Report. Moreover, we operate in a very competitive and rapidly changing environment. New risks and uncertainties may emerge from time to time, and it is not possible for us to predict all risks and uncertainties that could have an impact on the forward-looking statements contained in this Annual Report.

The results, events and circumstances reflected in the forward-looking statements may not be achieved or occur, and actual results, events or circumstances could differ materially from those described in the forward-looking statements.

In addition, statements that “we believe” and similar statements reflect our beliefs and opinions on the relevant subject. These statements are based on information available to us as of the date of this Annual Report. And while we believe that information provides a reasonable basis for these statements, that information may be limited or incomplete. Our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all relevant information. These statements are inherently uncertain, and investors are cautioned not to unduly rely on these statements.

The forward-looking statements made in this Annual Report relate only to events as of the date on which the statements are made. We undertake no obligation to update any forward-looking statements made in this Annual Report to reflect events or circumstances after the date of this Annual Report or to reflect new information or the occurrence of unanticipated events, except as required by law. We may not actually achieve the plans, intentions, or expectations disclosed in our forward-looking statements, and you should not place undue reliance on our forward-looking statements. Our forward-looking statements do not reflect the potential impact of any future acquisitions, mergers, dispositions, joint ventures or investments.

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 Annual 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 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 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 (as defined below) 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 and there is substantial doubt about our ability to continue as a going concern;
- The terms of the Notes (as defined in the Notes to Consolidated Financial Statements) and the Purchase Agreement (as defined in the Notes to Consolidated Financial Statements) restrict our current and future operations. Upon an event of default under the Notes, we may not be able to make any accelerated payments under the Notes 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 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 Princeton University. Any loss of our rights to this technology could prevent us from selling our products; and
- The price of our securities has been and may in the future be volatile or may decline regardless of our operating performance, and you could lose all or part of your investment.

PART I

ITEM 1. BUSINESS

Overview

We are a global genomics company focused on elevating the health and wellness of all people. We are pioneers of optical genome mapping ("OGM") for genome analysis and provide a suite of genome analysis solutions designed to 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 our OGM solutions, our nucleic acid isolation and purification solutions, our genomic analysis and interpretation software, and our clinical testing and laboratory services, we believe that we have a suite of products that will drive new discoveries, elevate health and wellness, and increase our understanding of the genome in transformative ways.

We market and sell OGM systems, including the Saphyr® system and the Stratys™ system, which deliver OGM data to enable ultra-sensitive and ultra-specific detection of all classes of structural variation ("SV"). These systems are used to identify structural changes in chromosomes, the study of which is known as cytogenetics, and to accelerate the search for answers in genetic disease and cancer applications as well as in applications for cell and gene therapy. The systems are comprised of an instrument, chip consumables, reagents and software containing a suite of data analysis and visualization tools. OGM has been shown to outperform the current gold standard cytogenetic methods including karyotyping, fluorescence in-situ hybridization ("FISH"), Southern blot and chromosomal microarray ("CMA"), for the detection of SVs. OGM has also been shown to identify structural changes in chromosomes that cannot be identified using current commercially available gene sequencing solutions.

We market and sell the Ionic® Purification system, which is able to deliver high quality DNA in a more natural, native form and with fewer contaminants when compared to other isolation and purifications solutions. The Ionic Purification system is used to extract, purify, and concentrate DNA or RNA from a variety of sample types, and is comprised of an instrument, consumables, and reagents.

We market and sell the VIA™ software which delivers genomic data interpretation solutions tailored for research use in cytogenomics and molecular pathology labs in genetic disease and cancer research markets, with an emphasis on SV. This industry leading, platform agnostic software solution is designed to provide analysis, visualization, interpretation and reporting of SVs, single-nucleotide variants and absence of heterozygosity across the genome in one consolidated view. Our software currently enables analysis of OGM, next-generation sequencing (NGS) and microarray data. We believe the integration of OGM with data types common in the industry, such as Variant Call Format (VCF), and Binary Alignment Map (BAM), into the VIA software should accelerate and broaden our position in digital cytogenetics and comprehensive genome analysis by enabling us to simplify the assessment of clinically relevant variants in cytogenomics applications, potentially reducing interpretation time per sample and expanding our reach into the discovery and translational research markets through the combination of OGM and NGS.

Our Bionano Laboratories business provides proprietary genetic clinical testing services for individuals demonstrating clinical presentations consistent with neurodevelopmental disorders ("NDDs"), including autism spectrum disorders ("ASDs") and other disorders of childhood development. Their comprehensive genetic testing services include reporting for known NDD-causing genome variations, including testing for proprietary variations, and combines testing with our Proprietary Variant Index (PRISM) which uses a proprietary database of over 35,000 individuals with NDDs tested with over 60,000 tests that provides additional evidence for candidate genes associated with NDDs. This testing is a CLIA-certified diagnostic testing service, and we have expertise in selling cytogenetic assays to physicians, providing genetic counseling services to individuals undergoing testing and their families, and contracting with third-party payors for reimbursement. Additionally, Bionano Laboratories has developed OGM-based laboratory developed tests ("LDTs") for facioscapulohumeral muscular dystrophy type 1 (FSHD1), which is a progressive disorder that primarily affects the muscles of the face, shoulder blades (scapula), upper arms, and lower legs, and for detecting SVs in individuals with hematologic malignancies. As of March 1, 2024, we decided to phase out over time the offering by Bionano Laboratories of certain testing services related to NDDs, including ASDs, and other disorders of childhood development.

Bionano Laboratories also provides laboratory services to clinicians, scientists, pharmaceutical companies, and others who are seeking to incorporate OGM into their genomics research without the need to bring one of our OGM systems in house. Laboratory services for OGM are performed in our laboratory facilities in San Diego, California and at partner laboratories in the United States and Europe, and serve as solutions for researchers and clinicians who would like to use OGM for various applications in genomics but have yet to acquire an OGM system.

Over the past year, we believe we have transformed our business from an instrument company to a provider of a full suite of genomic solutions. We expanded into molecular genetic clinical testing services through our August 2020 acquisition of Lineagen. We furthered our transformation through the expansion into software solutions, made possible by our October 2021 acquisition of BioDiscovery and continued with our November 2022 acquisition of Purigen bringing their leading nucleic acid

isolation and purification technology to Bionano. We believe that these acquisitions, along with internal investments in research and development and the build out of our commercial teams, have positioned us well to provide solutions to our customers that we believe will make OGM the standard cytogenetic technique for structural variant analysis.

Recent Highlights

Achievement of 2023 ELEVATE! Milestones

Bionano executed on its 2023 ELEVATE! milestones and achieved or exceeded all publicly stated milestones outlined at the beginning of 2023.

- **Reimbursement:** We submitted a dossier to Medicare seeking a local coverage determination ("LCD") for OGM coverage.
- **Clinical Studies:** We received institutional review board (IRB) approval for our hematological and solid tumor studies. Site selection was completed, and sample enrollment commenced for our prenatal, postnatal, and hematological malignancy clinical trial studies. Data collection for our prenatal study was completed. We completed our postnatal study. We had an interim publication for our prenatal and hematological malignancy studies. We had a peer-reviewed interim publication from postnatal study.
- **Expand Awareness:** We achieved an installed base of 326 OGM systems. We conducted a pre-submission discussion with FDA in connection with the planned clearance of the Stratys™ system.
- **Product Developments:**
  - Full commercial release of our high throughput OGM instrument, called the Stratys™ system was announced in early 2024. The Stratys system is expected to enable a four-fold increase in raw data generation rate compared to the Saphyr® system and is designed for maximum lab flexibility by enabling up to 12 single access chips, accessible as they complete runs, without the need to batch multiple samples on a consumable.
  - We released VIA software, which replaces NxClinical™ software with a simple and integrated workflow for visualization, interpretation, and reporting for OGM, microarray and next-generation sequencing (NGS) data types for enhanced contextualization across multiple variant types and accelerated time to results at a reduced cost.
  - We released a pre-commercial version of the Ionic Purification System for isolation of DNA for OGM analysis running in the field with the full commercial launch planned for the second half of 2024.
  - We launched an OGM laboratory developed test (LDT) for constitutional genetic disease applications through Bionano Laboratories.

Commercial Adoption of Offerings for OGM

Bionano executed on its commercialization strategy, expanded the utilization of its OGM systems and increased the amount of Bionano data generated across the globe, driving commercial momentum.

- Grew our installed base of OGM systems to 326 as of December 31, 2023, an increase of approximately 36% from a total installed base of 240 as of December 31, 2022. Installed base represents the global number of OGM instruments installed at end-customer locations to perform optical genome mapping.
- For the year ended December 31, 2023, total flowcells sold reached 26,444, an increase of approximately 72% over the 15,375 flowcells sold during the year ended December 31, 2022. The OGM chip is the consumable that packages nanochannel arrays for DNA linearization. In its current form, each OGM chip has three flowcells. Flowcells sold refers to the units of genome mapping consumables used for analyzing one genome, purchased by customers to process optical genome mapping.

Continued to Validate the Utility of OGM for Applications in Clinical Research with Benchmarking, Scientific Publication and Adoption

Rigorous and extensive benchmarking of our OGM systems against traditional cytogenetic methods and long read sequencing has continued and these results were published and validated in several key publications, presentations and announcements including:

- In a study published in Nature Communications, OGM was used for the evaluation of CRISPR-Cas9 edited human induced pluripotent stem cell lines in order to uncover possible pathogenic structural alterations that may limit their usefulness for stem cell therapy. The study authors found that approximately 15% of CRISPR-Cas9 edited genomes had potentially pathogenic large chromosomal deletions at two unexpected off-target sites. In addition to those two off-target deletions, the authors reported that OGM identified a large, unexpected deletion at the target site.

- Researchers from Augusta University published a study comparing a combined approach of OGM and a 523-gene next-generation sequencing (NGS) panel to the common approach of karyotyping and FISH with a 54-gene NGS panel for the evaluation of myeloid cancers. OGM and the 523-gene NGS panel had an analytical concordance of 100% with karyotyping, FISH, and the 54-gene panel, and the OGM workflow also led to changes in risk assessment in 22% of myelodysplastic syndrome cases (2/9) and identified compound heterozygous events of potential clinical relevance in 20% of cases (6/30).
- A peer-reviewed publication covered an interim readout from the clinical trial designed to support establishing OGM as part of the standard of care (SOC) in diagnosis of genetic disease for postnatal patients. The clinical trial is designed to compare OGM to the SOC, including concordance, reproducibility, technical success rate and the rate of detecting reportable findings in cases. The study, which included 404 samples, showed OGM's high technical performance and reproducibility across sites versus SOC analysis, with 99.5% concordance, and an overall success rate of 98.8%.

Macroeconomic and Geopolitical Developments

We are subject to additional risks and uncertainties as a result of adverse geopolitical and macroeconomic developments, such as the ongoing conflict between Ukraine and Russia and related sanctions, the Israel-Hamas war, 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 a more detailed discussion of the impacts of macroeconomic and geopolitical developments on our business, see "Management's Discussion and Analysis of Financial Condition and Results of Operations - Macroeconomic and Geopolitical Developments."

Industry Background

Genome analysis is the process of extracting and interpreting biological information from DNA and RNA. DNA is the code that is found in all living cells and determines the characteristics and health of all living organisms. Although each organism's DNA order is unique, all DNA is composed of the same four nucleotides that come in pairs, which are referred to as base pairs. The human genome is composed of six billion of these base pairs (three billion of which are the maternal copy and three billion of which are the paternal copy of the genome), distributed across 23 pairs of chromosomes ranging in size from approximately 50 million to approximately 250 million base pairs. Genome variation is defined as at least one base pair differing in a comparison of sequence against a reference standard and can be as large as tens of millions of base pairs.

Genome structure refers to the way in which the various functional elements of the genome such as genes, reading frames, promoters and others are ordered, oriented and organized across the 23 pairs of chromosomes. SVs represent differences in the amount or location of genomic DNA from one individual compared to a reference genome. SV is one of the most biologically important aspects of the human genome and is a major factor for the cause of genetic disorders and cancer. Each SV involves the rearrangement or repetition of as few as several hundred base pairs to as many as tens of millions of base pairs. SVs may be inherited or arise spontaneously. SVs are well-known to cause diseases such as constitutional genetic disorders and cancer. Many researchers and clinicians now agree that despite major advances in the speed and cost-effectiveness of DNA sequencing, it fails to reliably detect SVs. OGM enables the detection of all known classes of SVs, and we believe no methodology exists that can detect SVs more comprehensively or cost efficiently than our OGM systems.

We believe the traditional cytogenomic methods of detecting SVs for research and clinical applications, such as karyotyping, CMA, and FISH are antiquated and cumbersome and can only detect a small proportion of the SVs across an entire genome. OGM is designed to offer cytogeneticists the ability to fully digitize and replace these traditional methods with one simplified, cost effective and scalable workflow using one of our OGM systems.

We believe that DNA isolation is the critical first step in the analysis of DNA. Short and long read sequencing applications typically require nucleotide lengths of 150 and, generally, 10,000 to 20,000 base pairs, respectively. OGM, conversely, optimally requires DNA lengths of greater than 100,000 base pairs. Due to market needs, the vast majority of DNA isolation and preparation technologies have been directed to meeting the requirements for short and long read sequencing applications. We believe that DNA isolation and purification processes that allow long segments of DNA (ultra-high molecular weight (UHMW) DNA) to remain intact are important for the success of OGM. Our Ionic Purification system has the capability to isolate and purify UHMW DNA that is ideal for OGM applications. We believe that the system's ease of use, reproducibility, and cost per sample profile has the potential to accelerate the adoption of OGM across a broad spectrum of applications.

We believe that software is necessary for genome analysis and should be the primary interface for how cytogeneticists interact with the data and report their findings. We believe the software's ease of use, core analysis functionality and the time necessary to obtain a reportable result are the most important factors to customers when considering a platform adoption decision and that data interpretation is typically a critical bottleneck in methods of genome analysis and therefore software is a key component in the entire workflow. The majority of software solutions on the market today have been developed with NGS as the primary application with the focus on the interpretation and reporting of single nucleotide variants (SNVs) instead of SVs. The

predecessor of our VIA software (NxClinical) was developed with copy number variants (CNV) as the core focus and became established as an industry leading solution for interpretation and reporting of CNVs for CMA and NGS. With the integration of OGM into our VIA software, we believe that our software is the first software solution delivering a fully integrated interpretation capability for SVs from OGM as well as seamless analysis with NGS, and that this integration will enable complementary OGM and NGS workflows through one software solution.

Our Solutions

We believe that an end-to-end OGM solution begins with the sample and ends with data analysis. The OGM workflow includes several steps: DNA isolation, DNA labeling, DNA mapping, data processing and data analysis. At each step we have either organically developed a solution or partnered with a third party to enable and provide a solution. We highly value our relationships with third parties that enable us to provide these solutions and will continue to work with others to ensure our customers' needs are being met. We are constantly on the look-out for opportunities to better meet the needs of our customers whether that is through partnerships, organic development, or strategic acquisitions that accelerate and up-shift our capabilities. To that end, we have recently engaged in two transactions, which we believe will substantially benefit our customers and their adoption of OGM as a solution of choice for SV and CNV analysis. In 2021 we acquired BioDiscovery and its leading NxClinical software for data analysis, and in 2022 we acquired Purigen, and its proprietary isolation and purification technology. We believe that each of these acquisitions, together with our organic development, will significantly enhance the customer experience with OGM.

OGM Systems

Our systems use a proprietary approach to measure genome structure and SV through OGM. The OGM workflow is novel, comprehensive, scalable, cost effective and highly differentiated. OGM data is currently generated using our OGM systems, which directly measure sequence specific patterns ("SSPs") along UHMW DNA molecules in an unbiased approach without any amplification. Using the SSPs, software constructs a detailed physical map of the genome that accurately assigns the chromosomal location, order, orientation and quantity of sequence and in-turn, all the genome's functional elements. We believe OGM is capable of comprehensive, cost-effective and efficient detection of all classes of SVs and CNVs. Today, these SVs cannot be reliably detected by genome sequencing, from existing high throughput sequencers, which is focused on identifying genomic differences involving a few base pairs or SNVs, which our OGM systems do not identify. We believe that our OGM systems are ideally suited to be adopted alongside the installed base of high throughput sequencers as a complement that is designed to give users the ability to see a much wider scope of genome variation, from single bases of DNA to full chromosomes.

OGM was built upon four key elements:

- **Extremely long molecules for analysis (or UHMW DNA).** Our OGM systems are capable of analyzing single molecules that are on average approximately 250,000 base pairs in length and can be as long as millions of base pairs. These lengths are over 1,000 times longer than the average short read length with Illumina sequencing systems and approximately 10-20 times longer than the average long read lengths with Pacific Biosciences of California (PacBio), and Oxford Nanopore systems. We believe these long read lengths overcome the inherent challenges of genome complexity and are the key to our OGM systems' unprecedented sensitivity and specificity.
- **Proprietary nanotechnology for massively parallel linearization and analysis of long molecules with single molecule imaging.** Analyzing UHMW DNA required invention. We invented, patented, developed and commercialized nanochannel arrays to capture long single molecules of DNA from a solution and unwind and linearize them for SV analysis. Each molecule is imaged separately, making it possible to deconvolute complex mixtures including haplotypes and heterogeneous tumors.

- **DNA labeling chemistry specifically for physical mapping.** The detailed analysis of SSPs we use is also highly unique and novel. Instead of identifying the sequence of every base pair in these long fragments, we label and detect SSPs or motifs that occur universally across every genome with an average frequency of approximately one site for every few thousand base pairs. The key to our method entails introducing fluorescent tags at the sequence-specific site using highly specific and robust enzymatic chemistry along the extremely long fragments. These fragments, stretched out in nanochannels, are then directly imaged allowing us to measure the distance between labels with high accuracy. The pattern of labels detected on all these fragments can then be related to the pattern of sequence motif sites in a reference genome for comparison. Changes in the pattern indicate SV.
- **Bioinformatic tools for SV analysis.** Finally, our approach includes a novel bioinformatics platform that we developed from the ground-up to take advantage of the unique benefits of our solution. It comprises proprietary algorithms for the construction of a structurally accurate physical map of the genome to assign structure. Physical maps of a test subject are then compared to a reference or other subjects in cross-mapping analysis that allows our system to detect genome wide SV, including the most complex balanced events.

Our OGM systems provide solutions for comprehensive SV analysis at a higher resolution than traditional techniques allowing for more answers that matter to be obtained in genetic disease and cancer applications. We believe that our OGM systems are the only products capable of detecting SVs at high sensitivity and specificity with a workflow that is cost-effective and time efficient.

Our customers include researchers and clinicians who seek to identify and understand the biological implications of genome variation. We believe that our OGM systems can replace more traditional cytogenetic tools which are expensive, slow and labor-intense, with an advanced solution designed to simplify workflow, reduce cost, and increase assay success rates. We believe our OGM systems have the potential to significantly increase success rates and provide more answers across a wide range of applications in genomics.

Nucleic Acid Isolation and Purification Systems

Our nucleic acid isolation and purification system uses a novel and proprietary application of isotachophoresis (“ITP”) to isolate nucleic acid molecules in a gentle and efficient process. The process involves the gentle lysis of biological samples followed by the addition of the sample and buffer to an Ionic® fluid chip. An electric field is applied to the chip and the nucleic acid is isolated in its natural, native form. Traditional methods of isolating nucleic acid, including column-based isolation and bead-based isolation, can be laborious, and result in molecules that are denatured, dehydrated and fragmented, and solutions that are contaminated and have low purity. An additional limitation of many of the traditional isolation processes is the number of cells that are required to be processed in order to obtain sufficient nucleic acid molecules for OGM analysis. Current methodologies require upwards of 1.5 million cells in order to isolate sufficient DNA for use on an OGM system. Our Ionic Purification system, employing ITP technology, addresses many of these deficiencies and yields high purity nucleic acid that is not denatured, dehydrated or fragmented. Additionally, the Ionic Purification system is capable of isolating sufficient quantities of DNA for use in OGM applications from far fewer cells in contrast to traditional methods. We believe the addition of the Ionic Purification system to the OGM workflow will provide a more efficient yield of DNA at higher quality than can be achieved with current processes.

Although OGM is our primary focus, the Ionic Purification system has a current customer base of non-OGM users that use the system to isolate and purify nucleic acid molecules from sample types including formalin-fixed, paraffin-embedded (FFPE) sample, tissue, cells, and viral. We anticipate continuing to support and expanding this customer base.

Software Solutions

We offer industry leading genome analysis software that enables genomics labs to analyze and interpret data across a wide range of platforms to generate highly informative data visualizations for streamlined and simple reporting of causal variants. Today, VIA software is among the most comprehensive solutions for analysis and interpretation OGM data and any microarray or NGS generated data integrating CNVs, absence of heterozygosity (AOH) and loss of heterozygosity (LOH), as well as SNVs from sequencing data into a single well integrated interface that is used across the globe by renowned academic and commercial clinical laboratories.

Our acquisition of BioDiscovery has expanded our portfolio into providing data analysis and interpretation solutions across NGS, CMA and OGM. These software solutions are expected to allow us to leverage and expand our network of Bionano customers in ways that we believe will help accelerate the adoption of OGM. We believe that the integration of OGM data into the VIA software can substantially improve the analysis and reporting capabilities of our current OGM systems, making OGM easier to adopt and use by our customers. Additionally, through our VIA software, we serve the NGS and array markets directly though with an industry leading data interpretation solution for revealing more answers with delivery of copy number variants across the genome. Our software monetization strategy for the NGS and array markets is based on a pay-per-sample model where customers running NGS and/or array today can adopt, which sets the stage for potential future OGM adoptions by these

customers. Software is a way for us to participate directly in the NGS market while also enabling OGM data to be seamlessly integrated with NGS in one view for a comprehensive analysis, which is unique to Bionano.

Testing and Laboratory Services

Our Bionano Laboratories business offers tests that use CMA for evaluation of patients suspected of having certain genetic diseases, which is recommended by the American College of Medical Genetics and Genomics, the American Academy of Pediatrics, and the American Academy of Neurology, among other renowned societies. We are actively performing research to determine whether OGM with an OGM system can replace CMA as the front-line test for children with developmental disorders. As the scientific, peer-reviewed literature supports this claim, the coding entities such as the Centers for Medicare & Medicaid Services ("CMS") and the American Medical Association ("AMA") would need to adopt the proper procedural codes to allow for insurance reimbursement of new testing methodologies before they become mainstream clinical diagnostic instruments. Importantly, OGM is expected to be able to detect full mutations consistent with fragile X syndrome, which is another front-line test for children, especially males, with autism spectrum disorder and intellectual disability. Studies are ongoing to determine the sensitivity and specificity for OGM as it relates to fragile X syndrome. Bionano Laboratories also employs Whole Exome Sequencing, which aims to detect genome SNVs that are different from genome SVs and are not detectable by OGM.

We believe that Bionano Laboratories is uniquely positioned to develop LDT's that can improve upon the existing SOC for diagnostic testing for NDDs. Bionano Laboratories is working with payers to secure reimbursement alternatives for OGM-based testing. If reimbursements can be established, Bionano Laboratories intends to share its strategies with other labs which may drive demand for the OGM systems. Bionano Laboratories plans to expand its testing menu with inclusion of OGM to demonstrate workflow implementation in a clinical setting in order to drive adoption as well as serve as a conduit for enabling access for those customers unable to make a capital equipment expenditure. Bionano Laboratories is working to enable access, demonstrate excellence of the OGM workflow as a model within a CLIA setting for educational purposes, and drive advancements in product development for clinical grade testing of OGM at scale.

Our Commercial Offerings

Our OGM Systems and Consumables

We develop and market the Saphyr system and the Stratys system. Each system is a complete sample-to-result solution for SV analysis by OGM that empowers comprehensive genome analysis and facilitates a deeper understanding of genetic variation and function. We believe these systems are capable of addressing the needs for SV analysis because they are:

- **Highly sensitive.** We believe these systems are the most sensitive detector of SV larger than 500 base pairs currently on the market.
- **Cost effective.** The consumables cost per genome, at an average of approximately $500, can be less than the combination of standard techniques and well below both short-read and long-read WGS at a depth of 160x coverage.
- **Scalable and fast.** Relative to traditional techniques, these systems have demonstrated up to a 75% reduction in turnaround time for analysis of acute lymphoblastic leukemia (ALL) subjects when used instead of karyotyping, FISH and MLPA. Additionally, the Stratys system is a higher throughput system designed to meet the needs of medium and high-volume labs and offers approximately 4 times the throughput of a Saphyr system.

The OGM Instruments

The OGM instruments are each single-molecule imagers that include high performance optics, automated sample loading based on machine learning algorithms and computational hardware and control software. The instrument's high-performance optics simultaneously image DNA linearized in hundreds of thousands of nanochannels. The instrument's control interface is the user's primary control center to design and monitor experiments as they occur in real time. The computational hardware is responsible for the secondary processing of the image data being produced on the instruments. The Saphyr instrument is currently capable of analyzing up to 4,000 human genomes per year at 100x coverage. At the end of 2022 we announced the placement of a pre-commercial unit that we expect to significantly increase the throughput. The Stratys instrument is currently capable of analyzing up to 13,500 human genomes per year at 100x coverage.

OGM Chips

The Saphyr Chip® is the consumable that packages the nanochannel arrays for DNA linearization for use in the Saphyr instrument. In its current form, each Saphyr chip has three flow cells containing approximately 120,000 nanochannels that are roughly 30 nanometers wide, and each flowcell can hold one unique sample. The Stratys Chip™ is the consumable that packages the nanochannel arrays for DNA linearization for use on the Stratys instrument. In its current form, each Stratys Chip has one flow cell containing approximately 120,0000 nanochannels that are roughly 30 nanometers wide, and each flowcell can hold one unique sample. To manufacture the arrays, we use photolithography in a semiconductor fabrication facility to print hundreds of thousands of tiny grooves on silicon wafers and then dice the wafers into individual chips. Our chips are inexpensive to manufacture and highly scalable. The fluidic environment in each channel allows individual molecules to move swiftly utilizing only the charge of DNA. Hundreds of thousands of molecules can move through hundreds of thousands of parallel nanochannels simultaneously, enabling extremely high-throughput processing on a single-molecule basis.

Saphyr Sample Prep and Labeling Kits

Our Bionano Prep™ kits and DNA labeling kits provide the reagents and protocols needed to extract and label UHMW DNA for use with OGM systems. These kits are optimized for performing our genome mapping applications on a variety of sample types.

Our workflow begins with the isolation of UHMW DNA. Our Bionano Prep kits are optimized for isolating and purifying UHMW DNA in a process that is gentler than existing DNA extraction methods. The resulting purified DNA is up to millions of base pairs long and optimal for use with our systems. Our kits and protocols enable the extraction of UHMW DNA from a variety of sample types including human or animal tissue and tumors, plant tissue, cell lines, bone marrow aspirates and human blood.

Our labeling reagents are optimized for applications on our genome mapping systems. Starting with UHMW DNA purified using the appropriate Bionano Prep kit, fluorescent labels are attached to specific sequence motifs. The result is uniquely identifiable genome-specific label patterns that enable de novo map assembly, anchoring sequencing contigs and discovery of SVs as small as 500 base pairs to up to chromosome arm lengths.

Our kit for DNA labeling, the Direct Label and Stain (DLS) kit, is a proprietary, nondestructive chemistry for sequence motif labeling of genomic DNA that improves every aspect of our genome mapping. DLS uses a single direct-labeling enzymatic reaction to attach a fluorophore to the DNA at a specific 6-base pair sequence motif, yielding approximately 16 labels per 100,000 base pairs in the human genome. After labeling, the molecules are linearized in the nanochannel chips on the OGM instruments and imaged. Through the isolation, labeling and linearization steps, the molecules maintain an average length of around 250,000 base pairs. The label patterns on each molecule allow them to be uniquely identified and aligned in a pair-wise comparison against all other molecules imaged from the same sample.

The Ionic Purification System

We acquired the Ionic Purification system through our November 2022 acquisition of Purigen. The Ionic Purification system uses a proprietary ITP method to isolate and purify nucleic acid molecules. The technology was initially developed at Stanford University and intellectual property from that development was exclusively licensed to Purigen. The technology was further developed and commercialized by Purigen. The system includes an instrument, consumable and reagents necessary to process samples. The system works by applying an electric field to specially formulated reagents in a consumable. The electric field electrophoretically focuses nucleic acid into a narrow band and purifies the molecules away from other potential inhibitors. This results in a higher yield of pure nucleic acid than traditional bind-and-strip approaches that is also less fragmented and free from bead or wash buffer contamination.

We offer reagents to isolate DNA and RNA from FFPE, tissue, and cells. We are optimizing the system with the intent it be used in an OGM workflow. We believe that the isolation and purification of DNA using the Ionic system in an OGM workflow will create a number of opportunities, including, enabling additional sample types not currently available to OGM, increasing sample throughput, decreasing sample preparation complexity.

Software Solutions

Our data solutions offering includes a complete suite of hardware and software for end-to-end experiment management, algorithms for assembling genome maps and algorithms and databases for bioinformatics processing, all of which is driven through convenient web-based management and monitoring tools.

We have a suite of proprietary algorithms and databases that fully enable our proprietary bioinformatic and SV analysis pipelines. Using pairwise alignment of the single molecule images, consensus genome maps are constructed, refined, extended and merged. Molecules are then clustered into two alleles, and a diploid assembly is created to allow for heterozygous SV detection. Genome maps typically span entire chromosome arms in single, contiguous maps. Comparative analysis of maps reveals SV. Our customers use our variant annotation workflow to specifically uncover rare and sample-specific mutations.

Our hardware solution includes the Saphyr and Stratys Compute Servers, which provides cluster-like performance in an affordable, compact solution and the Bionano Compute Server, which expands the analytical capacity of the suite of tools. With these solutions, our customers are capable of performing multiple simultaneous analyses and sustaining continuous throughput, which allows them to spend less time waiting for data, so they can focus on investigating results. We also offer a cloud-based solution for data analysis.

Our VIA software is among the most comprehensive and up-to-date solutions for cytogenetics and molecular genetics, providing one solution for analysis and interpretation of all genomic variants from microarray and NGS data. VIA evolved from our NxClinical software to incorporate OGM data and is now our primary software solution for interpretation and reporting of genomic features from OGM data.

Testing and Laboratory Services

Our Bionano Laboratories business offers OGM based RUO testing to researchers, biotech and pharmaceutical companies, and others seeking OGM data. Bionano Laboratories also offers four OGM-based LDTs.

- OGM-Dx™ HemeOne is a test that detects SVs defined by professional & medical guidelines as cytogenomic targets that aid in the diagnosis, prognosis, and therapeutic management of individuals with hematologic malignancies;
- OGM-Dx™ FSHD is a test intended for individuals suspected of having FSHD type 1;
- OGM-Dx™ Postnatal Whole Genome SV is an assay that detects SVs across the genome and provides comprehensive testing; and
- OGM-Dx™ Prenatal Whole Genome SV is an assay that detects SVs across the genome and provides comprehensive testing for most common and rare chromosomal abnormalities for prenatal indications.

Additionally, Bionano Laboratories previously offered molecular genetic clinical testing services for individuals demonstrating clinical presentations consistent with NDDs, including ASDs and other disorders of childhood development, but as of March 1, 2024 has determined to phase out over time the offering of these products, including:

- FirstStepDx PLUS is a CMA designed to identify an underlying genetic cause in individuals with autism spectrum disorder, developmental delay, and intellectual disability;
- Fragile X syndrome (FXS) testing is designed to detect individuals (both males and females) with FXS, as well as carriers of the condition; and
- NextStepDx PLUS is a whole exome sequencing test designed to identify genetic variants that are associated with disorders of childhood development.

Market Opportunity

According to MarketsandMarkets, the worldwide market for genomics products and services is expected to reach approximately $54.4 billion by 2025, up from approximately $22.7 billion in 2020, representing a compound annual growth rate of 19%.

We expect to see OGM adoption in cytogenomics, in discovery research and in cell and gene therapy applications. Within cytogenetics and molecular pathology, we estimate that there are approximately 10,000 cytogenetic labs on a worldwide basis (excluding India and developing countries). We estimate that these labs analyze approximately 10.0 million samples per year. Additionally, we estimate that approximately 1,400 pharmaceutical and biotech companies are engaged in research and development of various cell therapies that rely on methods, including cytogenetics. Based on these estimates, we believe the economic potential for OGM in these markets is approximately $10.0 billion annually, $3.0 billion of which we attribute to cell and gene therapy applications. We believe there are additional potential future market opportunities for OGM including newborn screening, population genomics, and neurological and cardiological risk assessment which are not included in our estimates above.

We believe the three areas of the genomics market that are driving demand for the OGM systems today:

- ***Consolidation of traditional cytogenetics techniques in two applications - constitutional genetic disease and cancer.*** To provide a robust clinical analysis, cytogenetic assays detect SVs that are linked to specific diseases or therapeutic responses. The technologies used for detecting SVs are expensive and involve cumbersome workflows with relatively limited ability to scale to higher volumes or more complex testing panels. Sequencers tend not to be used for cytogenetics due to their inability to reliably detect SVs. Cytogenetics laboratories are beginning to adopt OGM systems as a more effective, scalable and efficient approach to finding the SVs causative to constitutional genetic diseases and cancer. For this segment, an OGM system can be used as the sole tool for providing comprehensive and accurate detection of all classes of SVs and enable clinically relevant calls without the need for any sequencing or legacy cytogenetic technology. We estimate that labs analyze approximately 1.7 million constitutional genetic disease samples per year and approximately 8.3 million cancer samples per year.
- ***Cell and gene therapy applications.*** An important part of cell and gene therapy applications is to ensure that genomic modifications did not introduce any SVs into the cell population. Our OGM systems have been used by researchers to evaluate the ability of OGM to detect SVs that may impact cellular stability. Several studies have been published showing the OGM can be used to evaluate cellular stability. We believe that cell and gene therapy is an emerging market opportunity and could be up to $3.0 billion annually with the potential for approximately 2.4 million samples per year analyzed.

We believe that if our OGM-based solutions can successfully penetrate these addressable market opportunities, and should spur additional basic and translational research creating new areas where the OGM instruments and OGM data can be used to improve the standard of care and patient management. These may include preconception, products of conception and prenatal

genetic applications, uses to advance gene editing techniques and precision medicine. In the long term, we anticipate potential opportunities in newborn screening, population genomics, and neurological and cardiological risk assessment.

Our Strategy

We are primarily focused on driving adoption of OGM through our OGM systems. Our goal is to streamline SV identification and enable new research in genomics to allow greater insight into their role in human health in ways that have not been possible with any other current research and diagnostic technologies.

Our strategy to achieve this goal includes:

- ***Demonstrate that our OGM systems are a superior alternative to traditional techniques in constitutional genetic disorders and hematologic malignancy applications.*** Optical genome mapping has demonstrated superior detection sensitivity for all classes of SVs relative to karyotyping, FISH and CMA in numerous peer-reviewed publications over the past several years and offers benefits of improved assay success rates, faster time to result and a lower total cost. The value proposition and competitive differentiation for OGM in cytogenetics market is exceptionally strong with an immediate opportunity to digitize legacy microscope techniques (karyotyping) with a superior approach using an OGM system.
- ***Accelerate broad reimbursement for OGM and establish it as the SOC in guidelines by professional medical societies.*** We are investing in four multi-center clinical studies for postnatal, prenatal, hematologic malignancies and solid tumor analyses relative to SOC. Each study is designed with an expectation for recruitment of 1,000 subjects and will assess sensitivity, specificity, reproducibility, concordance and incremental clinically relevant findings relative to SOC. We are investing in these programs to build the necessary evidence to establish reimbursement and to pave the way for inclusion in professional society guidelines to advance SOC.
- ***Support the publication of findings with OGM by our customers beyond the more than 1000 papers published to date.*** The annual number of publications featuring data generated by Bionano OGM systems has steadily increased since 2010 when the first publication appeared. Of these 1000 peer-reviewed and pre-print papers, more than 67% were published since 2021. We intend to continue to support and foster our customer base to help grow the number of publications featuring our systems' data. We believe that these publications are impactful as they cover SVs in areas of high unmet medical need, such as rare and undiagnosed pediatric diseases, neurological and muscular diseases, developmental delays and disorders, multiple leukemia, lymphoma and myelomas as well as cell and gene therapy applications.
- ***Continue to innovate our products and technologies.*** We designed our OGM systems to accommodate performance enhancements without the need for replacement of the entire instrument. For example, hardware upgrades and new consumables may be made available to purchase by customers. We intend for these performance enhancements to be delivered on a regular basis. In addition, we periodically make available software upgrades to customers through download. We expect to continue developing and refining our technologies to improve the ease of use of our OGM systems and enable our existing installed systems to meaningfully increase sample throughput and sensitivity and specificity of SV detection. The Saphyr system images DNA at a rate of approximately 205 gigabase pairs (Gbp) per hour, and the Stratys system images nearly 820 Gbp per hour.
- ***Partner with industry-leading companies and laboratories to expand adoption in clinical markets.*** Establish additional collaborations with customers to help drive validating studies. Expand partnership efforts with clinical diagnostic companies to commercialize LDTs in the U.S. as well as LDTs and approved tests outside the U.S.
- ***Complement NGS with OGM in translational, applied and discovery research markets.*** In addition to the three areas of the genomics market that are driving demand for the OGM systems today, we believe the combination of NGS and OGM can provide the most comprehensive and cost-effective analysis of genome variants from SNVs to whole chromosomes. NGS is capable of measuring genome variants below 500 bp while OGM bridges the gap by enabling detection of all SVs above 500 bp to reveal more answers and resolve previously unresolved cases from using NGS alone. There are over 15,000 NGS instruments installed globally and our vision is for each of these sequencers to be complemented with an OGM system to provide a more comprehensive picture of the genome for more discoveries, publications and translation into molecular genetics.

Sales and Marketing

As of December 31, 2023, our commercial team consisted of 146 individuals in sales, sales support and marketing. Our sales support personnel include individuals in customer solutions, field service engineers and field application specialists. This commercial staff is primarily located in North America, Europe, and China. Most of our sales support team is located at our headquarters in San Diego, California and some work remotely throughout North America, Europe, and China.

We sell our products through a direct sales force based in North America and Europe. Our sales strategy involves the use of a combination of sales managers and sales representatives. We intend to increase our sales, support, and marketing efforts in the future by continuing to expand our direct footprint in North America and Europe as well as developing a more comprehensive support network in China and India, where we believe significant market opportunities exist, as we expand our business.

We sell our products through a network of distributors in the Asia-Pacific region and select other markets outside of North America and Europe. For example, we distribute our instruments and reagents via third-party distributors in markets such as China, Japan, South Korea, Singapore, Australia, India and South Africa.

The role of our sales managers and sales representatives is to educate customers on the advantages of OGM and the applications that our systems make possible. The role of our field application specialists is to provide on-site training and scientific technical support to prospective and existing customers. Our field application specialists are technical experts with advanced degrees, including nine with PhDs., and generally have extensive experience in academic research and core sequencing lab experience.

In addition, we maintain an applications lab team in San Diego, California composed of scientific experts who can transfer knowledge from the research and development team to the field application specialists. The applications lab team also runs foundational scientific collaborations and proof of principle studies, which help demonstrate the value of our product offering to prospective customers. This team also provides commercial services by running samples on an OGM system for researchers who do not have an OGM system of their own.

Our systems are relatively new to the life science marketplace and require a capital investment by our customers. The sales process typically involves numerous interactions and demonstrations with multiple people within an organization. Some potential customers conduct in-depth evaluations of the system including having us run experiments on in-house OGM systems. In addition, in most countries, sales to academic or governmental institutions require participation in a tender process involving preparation of extensive documentation and a lengthy review process. Because of these factors and the budget cycles of our customers, our sales cycle, the time from initial contact with a customer to our receipt of a purchase order, can often be nine to 12 months.

Bionano Laboratories primarily sells a suite of LDTs to pediatric physicians through a physician-directed “in-person” sales model. This commercial staff is located in North America, and the sales personnel primarily work remotely in U.S. states where Bionano Laboratories has obtained insurance reimbursement. The sales and marketing efforts are targeted primarily at specialty pediatricians, including pediatric neurologists, medical geneticists, and developmental and behavioral pediatricians. Bionano Laboratories also targets general pediatricians with large numbers of patients. Their managed care efforts are directed to establishing contracts and/or credentialing with private and governmental insurance carriers that provide coverage for patients with ASD and other forms of NDDs. As of March 1, 2024, we have determined to phase out over time the offering of these LDTs.

Instruments

Our first Stratys instruments are being manufactured in-house; however, we will eventually be moving manufacturing of the Stratys instrument to the same third-party medical device manufacturer that manufactures our Saphyr instrument. Complete or nearly complete instruments are shipped by the manufacturer to us for final assembly and quality control testing. Upon completion, we ship directly to our customers’ locations globally, or distributors’ locations in the case of certain systems sold in the Asia-Pacific region. Installation of, and training on, our products is provided by our employees in the markets where we conduct direct sales, and by distributors in those markets where we operate with distributors.

We believe this manufacturing strategy is efficient and conserves capital. However, in the event it becomes necessary to utilize a different contract manufacturer, we would experience additional costs, delays and difficulties in doing so, and our business could be harmed. This manufacturer actively manages obsolescence of all components in our system. This is done through their supply management process where we get notified of any parts that will become obsolete with enough lead time to identify alternatives.

Consumables

All of our chip consumables for both OGM and ITP applications are produced by third-party manufacturers at their facilities; however, we have established procedures for replacement manufacturers if required. We complete final assembly and quality control assessments of our chips at our headquarters in San Diego, California.

Our OGM reagents are sourced from a limited number of suppliers, including certain single source suppliers. Our ITP reagents are sourced from a limited number of suppliers, including certain single source suppliers and also prepared in-house at our facility in San Diego, California. The OGM reagents include all components required to run a sample on OGM, such as capture and detector reagents, enzyme reagents and enzyme substrate. The ITP reagents include all the components required to run a sample for isolation and purification of nucleic acid. Although we believe that alternatives would be available for both our OGM reagents and ITP reagents, it would take time to identify and validate replacement reagents for our assay kits, which could negatively affect our ability to supply assay kits on a timely basis. Some reagents are supplied through a single source

supplier. This supplier requires a sufficient notification period to allow for supply continuity and the identification and technology transfer to a new supplier in the event either party wishes to terminate the relationship.

We actively manage component obsolescence by subscribing to our vendors' end-of-life notifications. If a vendor is unable to provide sufficient notification, we keep safety stock of the component to minimize disruption to operations.

Manufacturing and Supply

Our manufacturing strategy is to outsource instrument and chip manufacturing and internally develop and assemble reagent kits in our own facility.

Software

Our fundamental long-term software strategy is based on our goal of making OGM ubiquitous. We believe that simplified data interpretation and a seamless integration with NGS and array data to provide the most compressive genome analysis will increase utilization. In addition, we can participate directly in the NGS and array markets for genetic disease and cancer applications independent of OGM using a monetization model with a pay-per-sample VIA software offering. In this manner we can expand our network of Bionano customers into our software ecosystem with among the most comprehensive platform-agnostic genome interpretation solution where our proprietary original content in OGM can be adopted when needed to obtain a more comprehensive view of the genome by revealing all classes of SVs.

Testing and Laboratory Services

Bionano Laboratories' OGM testing is performed at our lab in San Diego, California, or at our partner labs in the United States and Europe. Bionano Laboratories intends to increase its testing capacity. Bionano Laboratories has CLIA certification for its San Diego lab.

For diagnostic testing, Bionano Laboratories maintains contracts with a network of laboratories to perform the wet work on various non-OGM LDT tests in order to conserve capital and maintain flexibility of adjusting contract labs to seek the best-in-class/most updated technology and customer service. As of March 1, 2024, we have determined that Bionano Laboratories will phase out over time the offering of the non-OGM LDT tests. As of December 31, 2023, Bionano Laboratories has established contracts with four primary laboratories to perform wet lab services. All third-party laboratories have met stringent criteria and are CLIA-certified. Bionano Laboratories obtains raw data from contracted laboratories for select tests and then performs its own interpretation and reporting. In addition, Bionano Laboratories' plans to continue to offer OGM-based LDTs to be performed at its San Diego facility, four of which have been announced.

Key Agreements

License Agreement with Princeton University

In January 2004, we entered into a license agreement (the Princeton License Agreement) with Princeton University (Princeton). Pursuant to the Princeton License Agreement, we received a worldwide, exclusive right and license to, among other things, manufacture and market products or services utilizing patents and inventions related to our sample preparation, DNA imaging and genomic data analysis platform and other key technology.

We are obligated to pay Princeton an annual license maintenance fee in the mid-four digits, which can be reduced by royalties paid to Princeton during the preceding 12 month period. We are also obligated to make royalty payments to Princeton equal to (i) a percentage in the mid-single digits of our and any of our sub-licensees' net sales of products covered by the Princeton License Agreement and (ii) a percentage in the low-single digits of our and any of our sub-licensees' revenue from services covered by the Princeton License Agreement. Our royalty obligations continue on a licensed product-by-licensed product and licensed service-by-licensed service basis, in every country of the world, until the later of the last sale of a licensed product or service or the expiration of all the Princeton patent rights covering such products or services.

The term of the Princeton License Agreement will continue until all of our royalty payment obligations have expired, unless terminated earlier. Princeton may terminate the Princeton License Agreement upon written notice in the event of our material breach of the Princeton License Agreement if such breach remains uncured for 60 days. We may terminate the Princeton License Agreement without cause upon 60 days' advance written notice to Princeton.

License Agreement with Stanford University

In connection with our November 2022 acquisition of Purigen, we acquired an amended and restated license agreement (the Stanford License Agreement) between Purigen and the Board of Trustees of the Leland Stanford Junior University (Stanford). Pursuant to the Stanford License Agreement, we received a worldwide, exclusive right and license to, among other things, make, have made, use, import, offer to sell and sell certain products utilizing patents and inventions related to our ITP-based sample preparation platform.

We are obligated to pay Stanford an annual license maintenance fee in the low-five digits, which can be reduced by royalties paid to Stanford during the preceding 12 month period. We are also obligated to make royalty payments to Stanford equal to a percentage in the low-single digits of our and any of our sub-licensees' annual net sales of products covered by the Stanford License Agreement. Our royalty obligations continue on a licensed product-by-licensed product basis, in every country of the world, until the later of the last sale of a licensed product or the expiration of all the Stanford patent rights covering such products.

The term of the Stanford License Agreement will continue until all of our royalty payment obligations have expired, unless terminated earlier. Stanford may terminate the Stanford License Agreement upon written notice in the event of our material breach of the Stanford License Agreement if such breach remains uncured for 60 days. We may terminate the Stanford License Agreement without cause upon 30 days' advance written notice to Stanford.

Agreement for the Manufacture of Our Instruments

We have engaged a single third-party manufacturer to produce and test our instruments on an as-ordered basis. The manufacturer of our instruments has no obligation to manufacture our instruments without a purchase order. In addition, this manufacturer has no obligation to maintain inventory in excess of any open purchase orders or materials in excess of the amount it reasonably determines will be consumed within 90 days. We are obligated to purchase any material deemed in excess pursuant to the agreement. The price we pay is determined according to a mutually agreed-upon pricing formula. We may terminate a purchase order by giving the manufacturer at least 30 days' written notice.

Agreement for the Manufacture of Our Chip Consumables

We have engaged a single third-party manufacturer to manufacture our chip consumables used in our Saphyr system and provide engineering services to us. This third-party has no obligation to manufacture our chip consumables without a purchase order. The prices and fees we pay are established in our agreement with this manufacturer or determined by the manufacturer pursuant if supported by appropriate information. Our agreement with this manufacturer automatically renews for successive one year terms unless a party notifies the other party in writing at least 30 days prior to the expiration of the then-current term. We may terminate an order of the agreement at any time upon 30 days' written notice.

Intellectual Property

Genome Analysis

Our core technology for nucleic acid research is related to methods and devices for non-sequencing based analysis of macromolecules such as nucleic acids. Using this technology, long (UHMC) nucleic acids can be suitably labeled and elongated in order to ascertain structural information such as scaffold organization, copy number, and genomic repeats that is not readily obtained with current sequencing-based approaches. We recently added a portfolio of patents and patent applications related to ITP through the Purigen acquisition, which we plan to continue to pursue and develop. We have secured and continue to pursue intellectual property rights globally, including rights related to isolation, purification and analysis of nucleic acid molecules, as well as innovations in the molecular biology and bioinformatics spaces. Additionally, our portfolio includes patents and patent applications directed to related parts of our business, including certain diagnostic tests and methods of diagnosis and analysis of microarray and image data.

We have developed a global patent portfolio that includes more than 151 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.

In addition to pursuing patents, we have taken steps to protect our intellectual property and proprietary technology by entering into confidentiality agreements and intellectual property assignment agreements with our employees, consultants, corporate partners and, as applicable, advisors.

In addition to a robust and active patent portfolio, we believe that our software and algorithms for analysis, visualization and interpretation of genomic data represent a valuable asset that we continue to develop and exploit through current and planned software offerings.

Government Regulation

Our business is subject to and impacted by extensive and frequently changing laws and regulations in the United States (at both the federal and state levels) and internationally. These include laws and regulations particular to our business and laws and regulations relating to conducting business generally (e.g., export controls laws, U.S. Foreign Corrupt Practices Act and similar laws of other jurisdictions). We also are subject to inspections and audits by governmental agencies. Set forth below are highlights of certain key regulatory schemes applicable to our business. Below are discussions concerning government regulation of our Optical Genome Mapping, or OGM, products and services and, separately, the Diagnostic Services performed by Bionano Laboratories.

Optical Genome Mapping

Our OGM products are currently intended for RUO applications, although our customers may use our products to develop their own products that are subject to regulation by the FDA. Although most products intended for RUO are not currently subject to clearance or approval by the FDA, RUO products fall under the FDA's jurisdiction if they are used for clinical rather than research purposes. Consequently, our products are labeled "For Research Use Only."

The FDA's 2013 Guidance for Industry and Food and Drug Administration Staff on "Distribution of In Vitro Diagnostic Products Labeled for Research Use Only or Investigational Use Only," or, the RUO/IUO Guidance, provides the FDA's thinking on when IVD products are properly labeled for RUO or for IUO. The RUO/IUO Guidance explains that the FDA will review the totality of the circumstances when evaluating whether equipment and testing components are properly labeled as RUO. Merely including a labeling statement that a product is intended for research use only will not necessarily exempt the device from the FDA's 510(k) clearance, premarket approval, or other requirements, if the circumstances surrounding the distribution of the product indicate that the manufacturer intends its product to be used 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.

When marketed for clinical diagnostic use, our products will be regulated by the FDA as medical devices. The FDA defines a medical device in part as an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article which is intended for the diagnosis of disease or other conditions or in the cure, mitigation, treatment, or prevention of disease in man. FDA regulates the development, testing, manufacturing, marketing, post-market surveillance, distribution, advertising and labeling of medical devices. The FDA also requires the device to be registered by the medical device manufacturer and listed as a marketed product.

The FDA classifies medical devices into one of three classes on the basis of the intended use of the device, the risk associated with the use of the device for that indication, as determined by the FDA, and on the controls deemed by the FDA to be necessary to reasonably ensure their safety and effectiveness. Class I devices, which have the lowest level of risk associated with them, are subject to general controls. Class II devices are subject to general controls and special controls, including performance standards. Class III devices, which have the highest level of risk associated with them, are subject to general controls and premarket approval. Most Class I devices and some Class II devices are exempt from a requirement that the manufacturer submit a premarket notification, or 510(k), and receive clearance from the FDA which is otherwise a premarketing requirement for a Class II device. Class III devices may not be commercialized until a premarket approval application, or PMA, is submitted to and approved by the FDA.

510(k) Clearance Pathway

To obtain 510(k) clearance, a sponsor must submit to the FDA a premarket notification demonstrating that the device is substantially equivalent, or SE, to a device legally marketed in the U.S. for which a PMA was not required. The FDA is supposed to make a SE determination within 90 days of FDA's receipt of the 510(k), but it often takes longer if the FDA requests additional information. Most 510(k)s do not require supporting data from clinical trials, but the FDA may request such data.

Premarket Approval Pathway

A PMA must be submitted if a new device cannot be cleared through the 510(k) process. The PMA process is generally more complex, costly and time consuming than the 510(k) process. A PMA must be supported by extensive data including, but not limited to, technical, preclinical, clinical trials, manufacturing and labeling to demonstrate to the FDA's satisfaction the safety and effectiveness of the device for its intended use. After a PMA is sufficiently complete, the FDA will accept the application for filing and begin an in-depth review of the submitted information. By statute, the FDA has 180 days to review the accepted application, although, review of the application generally can take between one and three years. During this review period, the FDA may request additional information or clarification of information already provided. Also during the review period, an advisory panel of experts from outside the FDA may be convened to review and evaluate the application and provide recommendations to the FDA as to the approvability of the device. In addition, the FDA will conduct a preapproval inspection of the manufacturing facility to ensure compliance with its quality system regulations, or QSRs. New premarket approval applications or premarket approval application supplements are also required for product modifications that affect the safety and efficacy of the device.

Clinical Trials

Clinical trials are usually required to support a PMA and are sometimes required for a 510(k). In the U.S., if the device is determined to present a "significant risk," the manufacturer may not begin a clinical trial until it submits an investigational device exemption application, or IDE, and obtains approval of the IDE from the FDA. These clinical trials are also subject to the review, approval and oversight of an IRB at each clinical trial site. The clinical trials must be conducted in accordance with the FDA's IDE regulations and good clinical practices. A clinical trial may be suspended by the FDA, the sponsor or an IRB at its institution at any time for various reasons, including a belief that the risks to the study participants outweigh the benefits of participation in the trial. Even if a clinical trial is completed, the results may not demonstrate the safety and efficacy of a device to the satisfaction of the FDA, or may be equivocal or otherwise not be sufficient to obtain approval of a device.

After a medical device is placed on the market, numerous regulatory requirements apply. These include among other things:

- Compliance with QSRs, which require manufacturers to follow stringent design, testing, control, documentation, record maintenance, including maintenance of complaint and related investigation files, and other quality assurance controls during the manufacturing process;
- Reporting of device malfunctions, serious injuries or deaths;
- Registration of the establishments where the devices are produced and listing of the devices with the FDA;
- Labeling regulations, which prohibit the promotion of products for uncleared or unapproved uses; and
- Medical device reporting obligations, which require that manufacturers investigate and report to the FDA adverse events, including deaths, or serious injuries that may have been or were caused by a medical device and malfunctions in the device that would likely cause or contribute to a death or serious injury if it were to recur.

Failure to comply with applicable regulatory requirements can result in enforcement action by the FDA, which may include sanctions, including but not limited to, warning letters; fines, injunctions, and civil penalties; recall or seizure of the device; operating restrictions, partial suspension or total shutdown of production; refusal to grant 510(k) clearance or PMA approvals of new devices; withdrawal of 510(k) clearance or PMA approvals; and civil or criminal prosecution. To ensure compliance with regulatory requirements, medical device manufacturers are subject to market surveillance and periodic, pre-scheduled and unannounced inspections by the FDA.

Laboratory Developed Tests (LDTs)

Federal agencies involved in the regulation of LDTs include CMS and the FDA. CMS regulates the quality of clinical laboratories and the clinical testing process pursuant to the Clinical Laboratory Improvement Amendments of 1988 (CLIA) and the FDA regulates the safety and effectiveness of the diagnostic test pursuant to authorities in the Federal, Food, Drug, and Cosmetic Act (FDCA). Although the FDA has statutory authority to regulate medical devices, the FDA has historically exercised its enforcement discretion and not enforced applicable provisions of the FDCA and FDA regulations with respect to LDTs, which are a subset of in vitro diagnostic tests that are intended for clinical use and designed, manufactured and used entirely within a single laboratory. The FDA does not consider devices to be LDTs if they are designed or manufactured completely, or partly, outside of the laboratory that offers and uses them. We sell our OGM systems on an RUO basis to CLIA certified cytogenetic laboratories, which may use the system to develop LDTs.

On October 3, 2023 FDA issued proposed regulations under which it would phase out its enforcement discretion approach to LDTs over a period of four years. Although the proposed regulation is subject to a period of notice and comment, if finalized as proposed, we and our collaborators or customers would be required to obtain PMA approval or 510(k) clearance for certain tests by October 1, 2027. We would also be 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 prior to continuing to sell our existing LDTs.

Europe/Rest of World Government Regulation

Whether or not we obtain FDA approval for a product, we must obtain the requisite approvals from regulatory authorities in non-U.S. countries prior to the commencement of clinical trials or marketing of our product for clinical diagnostic use in those countries. The regulations in other jurisdictions vary from those in the U.S. and may be easier or more difficult to satisfy and are subject to change. For example, the European Union ("EU") recently published new regulations that will result in greater regulation of medical devices and IVDs. The IVD Regulation is significantly different from the IVD Directive that it replaces in that it will ensure that the new requirements apply uniformly and on the same schedule across the member states, including a risk-based classification system and increasing the requirements for conformity assessment. The conformity assessment process results in the receipt of a CE designation which has been sufficient to begin marketing many types of IVDs. That process will become more difficult and costly to complete.

Other Governmental Regulation

We are subject to laws and regulations related to the protection of the environment, the health and safety of employees and the handling, transportation and disposal of medical specimens, infectious and hazardous waste and radioactive materials. For example, the U.S. Occupational Safety and Health Administration has established extensive requirements relating specifically to workplace safety for healthcare employers in the U.S. This includes requirements to develop and implement multi-faceted programs to protect workers from exposure to blood-borne pathogens, including preventing or minimizing any exposure through needle stick injuries. For purposes of transportation, some biological materials and laboratory supplies are classified as hazardous materials and are subject to regulation by one or more of the following agencies: the U.S. Department of Transportation, the U.S. Public Health Service, the U.S. Postal Service and the International Air Transport Association. We generally use third-party vendors to dispose of regulated medical waste, hazardous waste and radioactive materials that we may use during our research.

Laboratories that purchase certain of our OGM products and perform clinical diagnostic testing are also subject to extensive regulation under the Clinical Laboratory Improvement Amendments of 1988 ("CLIA"), requiring clinical laboratories to meet specified standards in areas such as personnel qualifications, administration, participation in proficiency testing, patient test management, quality control, quality assurance and inspections. Adverse interpretations of current CLIA regulations or future changes in CLIA regulations could have an adverse effect on sales of any affected products. Moreover, if we decide to operate our own clinical testing laboratory with respect to our OGM products, such clinical testing would require compliance with CLIA. If, in the future, we operate our own clinical laboratory to perform clinical diagnostic testing with respect to our OGM products, such activities would become subject to the Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), and its corresponding regulations, as well as additional federal and state laws that impose a variety of fraud and abuse prohibitions on healthcare providers, including clinical laboratories.

Coverage and Reimbursement

Currently, our OGM products are for research use only, but clinical laboratories may acquire our instrumentation through a capital purchase or capital lease and use of an OGM system and direct label and stain chemistry to create their own diagnostic tests and potentially seek reimbursement for such tests. Our customers may generate revenue for these testing services by seeking the necessary approval of their product from the FDA or CMS, along with coverage and reimbursement from third-party payors, including government health programs and private health plans. The ability of our customers to commercialize diagnostic tests based on our technology will depend in part on the extent to which coverage and reimbursement for these tests will be available from such third-party payors.

In the U.S., molecular pathology tests have multiple options for reimbursement coding. Current Procedural Terminology ("CPT") codes developed by the American Medical Association ("AMA"), can be assigned to new products through applying for either a Proprietary Laboratory Analysis ("PLA") code or through applying for a category 1 CPT code. IT is also an option to use an unlisted molecular pathology code such as 81479. There are several PLA codes on the Medicare Clinical Lab Fee Schedule ("CLFS") for OGM-based tests as of January 01, 2024. Additionally, CMS, through its Medicare contractors, can write coverage determinations for molecular testing through their LCD process. 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 or services 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 ("UK") 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 and services is uncertain, and whether laboratories that use our instruments to develop their own products or services will attain coverage and adequate reimbursement is unknown. In the U.S., there is no uniform policy for determining coverage and reimbursement. Coverage can differ from payor to payor, and the process for determining whether a payor will provide coverage may be separate from the process for setting the reimbursement rate. In addition, the U.S. government, state legislatures and foreign governments have shown significant interest in implementing cost containment programs to limit the growth of government-paid healthcare costs, including price controls and restrictions on reimbursement.

Diagnostic Services

Clinical Laboratory Improvement Amendments of 1988 and State Regulation

As a clinical laboratory, Bionano Laboratories is required to hold certain federal and state licenses, certifications and permits to conduct is business. As to federal certifications, in 1988, Congress passed the CLIA, establishing more rigorous quality standards for all commercial laboratories that perform testing on human specimens for the purpose of providing information for the diagnosis, prevention, or treatment of disease or the assessment of the health or impairment of human beings. CLIA requires such laboratories to be certified by the federal government and mandates compliance with various operational, personnel, facilities administration, quality and proficiency testing requirements intended to ensure the accuracy, reliability and timeliness of patient test results. CLIA certification is also a prerequisite to be eligible to bill state and federal healthcare programs, as well as many commercial third-party payers, for laboratory testing services. Both of Bionano Laboratories' facilities, one located in Salt Lake City, Utah and the other in San Diego, California are CLIA certified. These laboratories must comply with all applicable CLIA requirements. If a clinical laboratory is found to be out of compliance with CLIA standards, CMS may impose sanctions, limit or revoke the laboratory's CLIA certificate (and prohibit the owner, operator or laboratory director from owning, operating, or directing a laboratory for two years following license revocation), a directed plan of correction, on-site monitoring, civil monetary penalties, civil actions for injunctive relief, criminal penalties, or suspension or exclusion from the Medicare and Medicaid programs.

CLIA provides that a state may adopt laboratory licensure requirements and regulations that are more stringent than those under federal law and requires compliance with such laws and regulations. The State of Utah follows all CLIA regulations for laboratory facility and personnel requirements. Utah does not have any additional licensure and regulations. The State of California follows CLIA regulations for in-state laboratory facilities, but requires additional licensing requirements for laboratory personnel established by the California Department of Public Health (CDPH). As of December 31, 2023, we received CAP accreditation for the San Diego facility.

Additionally, certain states require clinical laboratories to obtain out-of-state licenses to test specimens from patients, or to receive orders from physicians, within those states. Our Salt Lake City and San Diego facilities currently hold such out-of-state laboratory licenses in Pennsylvania and Maryland.

HIPAA and other Privacy Laws

HIPAA established comprehensive federal standards for the privacy and security of health information. The HIPAA standards apply to three types of organizations: health plans, healthcare clearing houses, and healthcare providers that conduct certain healthcare transactions electronically ("Covered Entities"). Title II of HIPAA, the Administrative Simplification Act, contains provisions that address the privacy of health data, the security of health data, the standardization of identifying numbers used in the healthcare system and the standardization of certain healthcare transactions. The privacy regulations protect medical records and other protected health information by, among other things, limiting their use and release, giving patients the right to access their medical records and limiting most disclosures of health information to the minimum amount necessary to accomplish an intended purpose. The HIPAA security standards require the adoption of administrative, physical, and technical safeguards and the adoption of written security policies and procedures.

On February 17, 2009, Congress enacted Subtitle D of the Health Information Technology for Economic and Clinical Health Act ("HITECH"), provisions of the American Recovery and Reinvestment Act of 2009. HITECH expanded and strengthened HIPAA, created new targets for enforcement, imposed new penalties for noncompliance and established new breach notification requirements for Covered Entities. Regulations implementing major provisions of HITECH were finalized on January 25, 2013 through publication of the HIPAA Omnibus Rule.

Under HITECH's breach notification requirements, Covered Entities must report breaches of protected health information that has not been encrypted or otherwise secured in accordance with guidance from the Secretary of the U.S. Department of Health and Human Services (the "Secretary"). Required breach notices must be made as soon as is reasonably practicable, but no later than 60 days following discovery of the breach. Reports must be made to affected individuals and to the Secretary and, in some

cases depending on the size of the breach, they must be reported through local and national media. Breach reports can lead to investigation, enforcement and civil litigation, including class action lawsuits.

As a result of the clinical diagnostic services offered by Bionano Laboratories, Bionano Laboratories, is currently subject to HIPAA and maintains an active compliance program that is designed to identify security incidents and other issues in a timely fashion and enable us to remediate, mitigate harm or report if required by law. Bionano Laboratories is subject to prosecution and/or administrative enforcement and increased civil and criminal penalties for non-compliance, including a new, four-tiered system of monetary penalties adopted under HITECH. Bionano Laboratories is also subject to enforcement by state attorneys general who were given authority to enforce HIPAA under HITECH. To mitigate penalties under the HITECH breach notification provisions, Bionano Laboratories must ensure that breaches of protected health information are promptly detected and reported within the company, so that Bionano Laboratories can make all required notifications on a timely basis. However, even if Bionano Laboratories makes required reports on a timely basis, Bionano Laboratories may still be subject to penalties for the underlying breach.

In addition to the federal privacy and security regulations, there are a number of state laws regarding the privacy and security of health information and personal data that are applicable to our clinical laboratories. Many states have also implemented genetic testing and privacy laws imposing specific patient consent requirements and protecting test results by strictly limiting the disclosure of those results. State requirements are particularly stringent regarding predictive genetic tests, due to the risk of genetic discrimination against healthy patients identified through testing as being at a high risk for disease. We believe that we have taken the steps required of us to comply with health information privacy and security statutes and regulations, including genetic testing and genetic information privacy laws in all jurisdictions, both state and federal. However, these laws constantly change, and we may not be able to maintain compliance in all jurisdictions where we do business. Failure to maintain compliance, or changes in state or federal laws regarding privacy or security could result in civil and/or criminal penalties, significant reputational damage and could have a material adverse effect on our business.

The General Data Protection Regulation (“GDPR”), which applies to all EU member states from May 25, 2018, also applies to some of our operations. The GDPR is discussed in more detail elsewhere in this report. The GDPR applies not only to organizations within the EU, but also applies to organizations outside of the EU that offer goods or services to EU data subjects or that process or hold personal data of EU data subjects. Additionally, from January 1, 2021, companies have had to comply with the GDPR and also the UK GDPR (“UK GDPR”), which, together with the amended United Kingdom Data Protection Act 2018, retains the GDPR in the UK national law. Both the GDPR and the UK GDPR regulations specify potential liabilities for certain data protection violations, and we anticipate that it will result in a greater compliance burden for us as we conduct our business in the EU. Fines for non-compliance can range from the greater of 2% of annual global revenues or €10 million, up to the greater of 4% of annual global revenues or €20 million. The GDPR is discussed in more detail under the heading “International Regulations” below.

Reimbursement and Billing

Reimbursement and billing for diagnostic services is highly complex. Laboratories must bill various payors, such as private third-party payors, including managed care organizations, and state and federal health care programs, such as Medicare and Medicaid, and each may have different billing requirements. Additionally, the audit requirements Bionano Laboratories must meet to ensure compliance with applicable laws and regulations, as well as our internal compliance policies and procedures, add further complexity to the billing process. Other factors that complicate billing include:

- variability in coverage and information requirements among various payors;
- patient financial assistance programs;
- missing, incomplete or inaccurate billing information provided by ordering physicians;
- billings to payors with whom we do not have contracts;
- disputes with payors as to which party is responsible for payment; and
- disputes with payors as to the appropriate level of reimbursement.

Depending on the reimbursement arrangement and applicable law, the party that reimburses us for our services may be:

- a third-party who provides coverage to the patient, such as an insurance company or managed care organization;
- a state or federal healthcare program; or
- the patient.

Presently, approximately 90% of the diagnostic service revenue for Bionano Laboratories is paid by private third-party payors.

Federal and State Fraud and Abuse Laws

A variety of state and federal laws prohibit fraud and abuse involving state and federal health care programs, such as Medicare and Medicaid. These laws are interpreted broadly and enforced aggressively by various state and federal agencies, including CMS, the Department of Justice, the Office of Inspector General for the Department of Health and Human Services ("OIG"), and various state agencies. In addition, the Medicare and Medicaid programs increasingly use a variety of contractors to review claims data and to identify improper payments as well as fraud and abuse. Any overpayments must be repaid within 60 days of identification unless a favorable decision is obtained on appeal. In some cases, these overpayments can be used as the basis for an extrapolation, by which the error rate is applied to a larger set of claims, and which can result in even higher repayments.

Anti-Kickback Laws

The Anti-Kickback Statute prohibits, among other things, knowingly and willfully offering, paying, soliciting, receiving or providing remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual, or the furnishing, arranging for or recommending of an item or service that is reimbursable, in whole or in part, by a federal health care program. "Remuneration" is broadly defined to include anything of monetary value, such as, for example, cash payments, gifts or gift certificates, discounts, or the furnishing of services, supplies or equipment. The Anti-Kickback Statute can be interpreted broadly to prohibit many arrangements and practices that are lawful in businesses outside of the health care industry.

Recognizing the potential breadth of interpretation of the Anti-Kickback Statute and the fact that it may technically prohibit many otherwise innocuous or beneficial arrangements within the health care industry, the OIG has issued a series of regulations, or safe harbors intended to protect such arrangements. Compliance with all requirements of a safe harbor immunizes the parties to the business arrangement from prosecution under the Anti-Kickback Statute. The failure of a business arrangement to fit within a safe harbor does not necessarily mean that the arrangement is illegal or that the OIG will pursue prosecution but would be evaluated on a case-by-case basis. Still, in the absence of an applicable safe harbor, a violation of the Anti-Kickback Statute may occur even if only one purpose of an arrangement is to induce referrals. The penalties for violating the Anti-Kickback Statute can be severe. These sanctions include criminal, civil and administrative penalties, imprisonment and possible exclusion from the federal health care programs. Many states have adopted laws similar to the Anti-Kickback Statute, and some apply to items and services reimbursable by any payor, including private third-party payors.

Further, the Eliminating Kickbacks in Recovery Act of 2018 ("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.

Physician Self-Referral Bans

The federal ban on physician self-referrals, commonly known as the "Stark Law", prohibits, subject to certain exceptions, physician referrals of Medicare patients to an entity providing certain designated health services, which include laboratory services, if the physician or an immediate family member of the physician has any financial relationship with the entity. Several Stark Law exceptions are relevant to arrangements involving clinical laboratories, including but not limited to: (1) fair market value compensation for the provision of items or services; (2) payments by physicians to a laboratory for clinical laboratory services; (3) certain space and equipment rental arrangements that satisfy certain requirements; and (4) personal services arrangements. Penalties for violating the Stark Law include the return of funds received for all prohibited referrals, fines, civil monetary penalties and possible exclusion from federal health care programs. In addition to the Stark Law, many states have their own self-referral bans, which may extend to all self-referrals, regardless of the payor.

State and Federal Prohibitions on False Claims

The federal False Claims Act ("FCA") imposes liability on any person or entity that, among other things, knowingly presents, or causes to be presented, a false or fraudulent claim for payment to the federal government. Under the FCA, a person acts knowingly if he or she has actual knowledge of the information or acts in deliberate ignorance or in reckless disregard of the truth or falsity of the information. Specific intent to defraud is not required. The qui tam provisions of the FCA allow a private individual to bring an action on behalf of the federal government and to share in any amounts paid by the defendant to the government in connection with the action. Penalties include payment of up to three times the actual damages sustained by the government, plus significant civil penalties, as well as possible exclusion from federal health care programs. In addition, various states have enacted similar laws modeled after the FCA that apply to items and services reimbursed under Medicaid and other state health care programs, and, in several states, such laws apply to claims submitted to any payor.

Civil Monetary Penalties Law

The federal Civil Monetary Penalties Law (the “CMP Law”), prohibits, among other things, (1) the offering or transfer of remuneration to a Medicare or state health care program beneficiary if the person knows or should know it is likely to influence the beneficiary’s selection of a particular provider, practitioner, or supplier of services reimbursable by Medicare or a state health care program, unless an exception applies; (2) employing or contracting with an individual or entity that the provider knows or should know is excluded from participation in a federal health care program; (3) billing for services requested by an unlicensed physician or an excluded provider; and (4) billing for medically unnecessary services. The penalties for violating the CMP Law include exclusion, substantial fines, and payment of up to three times the amount billed, depending on the nature of the offense.

Penalties

Failure to comply with the aforementioned fraud and abuse laws could result in significant penalties, including 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. 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.

International Regulations

We market some of our tests outside of the United States and are subject to foreign regulatory requirements governing laboratory licensure, human clinical testing, use of tissue, privacy and data security, and marketing approval for our tests. These requirements vary by jurisdiction, differ from those in the United States and may require us to implement additional compliance measures or perform additional pre-clinical or clinical testing. For example, the In Vitro Diagnostic Medical Devices (2017/746/EU) (“IVDR”) will replace the existing In Vitro Diagnostic Medical Devices Directive (98/79/EC) (“IVDD”) in the EU. The IVDR was published in May 2017, marking the start of a five-year period of transition from the IVDD. During the transitional period the IVDR will come into force gradually, starting with the provisions related to the designation of Notified Bodies and the ability of manufacturers to apply for new certificates under the IVDR. The transitional period will end on 26 May 2022, the “Date of Application” of the IVDR. From that point the IVDR will apply fully. The EU has also implemented the GDPR, which requires us to meet new and more stringent requirements regarding the handling of personal data about EU residents. In many countries outside of the United States, coverage, pricing and reimbursement approvals are also required. We are also required to maintain accurate information on and control over sales and distributors’ activities that may fall within the purview of the U.S. Foreign Corrupt Practices Act, as amended (“FCPA”) its books and records provisions and its anti-bribery provisions.

Other Regulatory Requirements

Our laboratories, and the laboratories of Bionano Laboratories, are subject to federal, state and local regulations relating to the handling and disposal of regulated medical waste, hazardous waste and biohazardous waste, including chemical, biological agents and compounds, blood and bone marrow samples and other human tissue. Typically, we use outside vendors who are contractually obligated to comply with applicable laws and regulations to dispose of such waste. These vendors are licensed or otherwise qualified to handle and dispose of such waste.

We are subject to laws and regulations related to the protection of the environment, the health and safety of employees and the handling, transportation and disposal of medical specimens, infectious and hazardous waste and radioactive materials. For example, the U.S. Occupational Safety and Health Administration (“OSHA”) has established extensive requirements relating specifically to workplace safety for healthcare employers in the U.S. This includes requirements to develop and implement multi-faceted programs to protect workers from exposure to blood-borne pathogens, including preventing or minimizing any exposure through needle stick injuries. For purposes of transportation, some biological materials and laboratory supplies are classified as hazardous materials and are subject to regulation by one or more of the following agencies: the U.S. Department of Transportation, the U.S. Public Health Service, the United States Postal Service, the Office of Foreign Assets Control, and the International Air Transport Association. We generally use third-party vendors to dispose of regulated medical waste, hazardous waste and radioactive materials and contractually require them to comply with applicable laws and regulations.

Healthcare Reform

In the U.S. and abroad, there have been and continue to be a number of legislative initiatives to contain healthcare costs and change the way healthcare is financed. By way of example, in March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, (collectively, 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.

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 is unconstitutional in its entirety because the "individual mandate" was repealed by Congress. It is possible that the ACA will be subject to judicial or Congressional challenges in the future. It is unclear how such challenges and the healthcare reform measures of the Biden administration will impact the ACA and our business.

Further, other legislative changes have been proposed and adopted since the ACA was enacted. For example, on August 16, 2022, President Biden signed the Inflation Reduction Act into law, which among other things, extends enhanced subsidies for individuals purchasing health insurance coverage in ACA marketplaces through plan year 2025. The Inflation Reduction Act of 2022 ("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 CLFS. PAMA requires certain laboratories performing clinical diagnostic laboratory tests to report to CMS the amounts paid by private payors for laboratory tests. 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 additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services. In addition, sales of our tests outside of the U.S. will subject us to foreign regulatory requirements, which may also change over time.

Acquisitions

We acquired Purigen in November 2022. For a further discussion of this acquisition, please refer to Note 14 (Acquisitions), to our consolidated financial statements included in this Annual Report.

Human Capital Management

As of December 31, 2023, we had 344 employees, of which 146 work in sales, sales support and marketing, 127 work in research and development, and 71 work in general and administrative. This is slightly higher than our expected number of employees as announced in October 2023. Based on a continuing assessment of needs we determined that 17 employees would be needed longer than anticipated and we extended the employment of 11 employees to January 2, 2024, of four employees to varying dates in February 2024, of one employee to March 2024, and of one employee to April 2024. Additionally, we determined that six employees would not be included in the originally planned reduction. As of December 31, 2023, of our 344 employees, 273 were located in the U.S. and 71 were employed outside the U.S. None of our employees are represented by a labor union or are subject to a collective bargaining agreement.

Our human capital resources objectives include, as applicable, identifying, recruiting, retaining, incentivizing and integrating our existing and new employees, advisors and consultants. The principal purposes of our equity incentive plans are to attract, retain and reward personnel through the granting of stock-based compensation awards, in order to increase stockholder value and the success of our company by motivating such individuals to perform to the best of their abilities and achieve our objectives.

We value diversity, equity, and inclusion across our workforce, in our communities, and in the work that we do. We will continue to focus on diversity, equity, and inclusion initiatives that support a culture that is centered on belonging while aligning with our shared corporate mission and values.

Corporate Information

We were formed in January 2003 as BioNanomatrix LLC, a Delaware limited liability company. In August 2007, we became BioNanomatrix Inc., a Delaware corporation. In October 2011, we changed our name to BioNano Genomics, Inc., and in July 2018, we changed our name to Bionano Genomics, Inc.

Our principal executive offices are located at 9540 Towne Centre Drive, Suite 100, San Diego, California 92121, and our telephone number is (858) 888-7600. Our website address is www.bionano.com. Information contained in, or that can be accessed through, our website is not incorporated by reference into this Annual Report, and you should not consider information on our website to be part of this Annual Report. Our design logo, "Bionano," and our other registered and common law trade names, trademarks and service marks are the property of Bionano Genomics, Inc.

Available Information

Access to our Annual Report, quarterly reports on Form 10-Q, current reports on Form 8-K, and amendments to these reports filed with or furnished to the SEC, may be obtained through the investor section of our website at http://www.bionano.com. We do not charge for access to and viewing of these reports. Information in the investor section and on our website is not part of this Annual Report or any of our other securities filings. Our filings with the SEC may be accessed through the SEC's website at www.sec.gov. All statements made in any of our securities filings, including all forward-looking statements or information,

are made as of the date of the document in which the statement is included unless otherwise specified, and we do not assume or undertake any obligation to update any of those statements or documents unless we are required to do so by law.

ITEM 1A. RISK FACTORS

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 Annual Report, including our financial statements and related notes appearing below. The risks described below are not the only ones facing us. The occurrence of any of the following risks or additional risks and uncertainties not presently known to us or that we currently believe to be immaterial could materially and adversely affect our business, financial condition or results of operations. In such case, the trading price of our securities could decline. This Annual Report also contains forward-looking statements and estimates that involve risks and uncertainties. Our actual results could differ materially from those anticipated in the forward-looking statements as a result of specific factors, including the risks and uncertainties described below.

Risks related to our financial condition and need for additional capital

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

Since our inception, we have incurred recurring net losses. We incurred net losses of $232.5 million and $132.6 million, and used cash in operations of $24.2 million and $82.8 million for the twelve months ended December 31, 2023 and 2022, respectively. As of December 31, 2023, we had an accumulated deficit of $581.2 million. We cannot predict if we will be profitable in the near future or at all. We expect that our losses will continue for the foreseeable future as we plan to invest significant additional funds toward the expansion of our commercial organization, research and development efforts and capital expenditures, among other things. Our recent acquisitions have increased our expenses and we expect that any future acquisitions of businesses, assets, products or technologies will further increase our expenses, which may result in additional losses. We also expect significant increases in our stock-based compensation expense in future periods, reflecting higher stock option valuations as a public company and the issuance of additional equity awards. 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.

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 received net proceeds of approximately $75.2 million, after deducting placement agent fees and offering expenses from the issuance and sale of our securities pursuant to the Purchase Agreement in October 2023, as amended pursuant to that certain letter agreement (the “Letter Agreement”) and Amendment to the Registered Note (the “Amendment”) entered into by us with the Purchaser of the Notes in February 2024. Based on our current business plans, we believe such net proceeds together with our existing cash and cash equivalents and short-term investments, will be sufficient to fund our operating expenses and capital expenditure requirements into at least the third quarter of 2024. This estimate assumes the inclusion of the amount equal to the sum of (i) the outstanding principal amount of the Registered Notes plus (ii) approximately $0.7 million that we are required to hold as restricted cash in an account control agreement under the terms of the Registered Notes. See Note 9 (High Trail Agreement) to our consolidated financial statements for a further discussion of our recent debt financing. 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. If we are unable to obtain sufficient funding, our business, prospects, financial condition and results of operations will be materially and adversely affected and we may be unable to continue as a going concern. If we are unable to continue as a going concern, we may have to liquidate our assets and may receive less than the value at which those assets are carried on our consolidated financial statements, and it is likely that investors will lose all or a part of their investment. Future reports from our independent registered public accounting firm may also contain statements expressing doubt about our ability to continue as a going concern. If we seek additional

financing to fund our business activities in the future and there remains doubt about our ability to continue as a going concern, investors or other financing sources may be unwilling to provide additional funding on commercially reasonable terms or at all.

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

We are an early commercial-stage company and have a limited commercial history. Our limited commercial history may make it difficult to evaluate our current business and, especially when combined with the other risk factors listed in this section, makes predictions about our future success or viability subject to significant uncertainty. In particular, we had significantly increased our headcount through recent acquisitions of other businesses and the expansion of our sales, marketing and research and development teams, which has increased our operating costs in a manner not historically reflected in our consolidated financial statements. Because our business model has evolved over time, and combined with our recent acquisitions, this has impacted the composition and concentration of our revenues, which we expect to continue to change with any future acquisitions and further expansion of our operations. These changes 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 the size of our organization, integrating acquired businesses and implementing cost savings 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 current BioDiscovery software solutions, including VIA software, and future software solutions developed through BioDiscovery’s platform;
- the position of our Purigen business in the DNA isolation space of genome analysis and customer demand for our Ionic Purification system;
- the timing of customer orders and payments and our ability to recognize revenue;
- the rate of utilization of consumables by our customers;
- reductions in or other difficulties relating to staffing, capacity, shutdowns or slowdowns of laboratories and other institutions in our customer base, such as reduced or delayed investment in new technologies or spending on products, technologies or consumables;
- differences in purchasing patterns across our customer base, including potential differences in consumables spending between earlier adopters of our technologies and more recent customers and variances in rates of increase of consumables spending following new technology purchases;
- geopolitical and macroeconomic developments, such as the conflict between Ukraine and Russia and related sanctions, 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;
- the timing of the introduction of new systems, products, technologies, system and product enhancements and services;
- changes in governmental funding of life sciences research and development or other changes that impact budgets, budget cycles or seasonal or other spending patterns of our customers;
- future accounting pronouncements or changes in our accounting policies; and
- the outcome of any current or future litigation or governmental investigations involving us or other third parties with whom we do business.

In addition, a significant portion of our operating expenses are relatively fixed in nature, including our existing and recently acquired leases, and planned expenditures are based in part on expectations regarding future revenue. Accordingly, unexpected revenue shortfalls could decrease our gross margins and cause significant changes in our operating results from quarter to quarter. If this occurs, the trading price of our securities could fall substantially. This variability and unpredictability caused by factors such as those described above and elsewhere in this section could also result in our failing to meet the expectations of industry or financial analysts or investors for any period. If our revenue or operating results fall below the expectations of analysts or investors or below any guidance we may provide, or if the guidance we provide is below the expectations of analysts or investors, the price of our securities could decline substantially. Such a stock price decline could occur even when we have met or exceeded any previously publicly stated guidance or expectations.

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

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

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

Our future capital needs are uncertain and we may require additional funding in the future to advance the commercialization of our 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.

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 fiscal year ended December 31, 2023, we performed an analysis of our ability to continue as a going concern. We believe, based on our current business plan, that our existing cash and cash equivalents and short-term investments will not be sufficient for the next twelve months from the issuance of our report for the fiscal year ended December 31, 2023. Our ability to execute our operating plan depends on our ability to generate sales and obtain additional funding through equity offerings, debt financings or potential licensing and collaboration arrangements. For example, we will likely need to raise substantial additional capital to:

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

- expand our research and development efforts to improve our existing products, technologies and services and develop and launch new products, technologies and services, particularly if any of our products, technologies and services are deemed by the U.S. Food and Drug Administration, or FDA, to be medical devices or otherwise subject to additional regulation by the FDA;
- pursue a regulatory path with the FDA, or a regulatory body outside the United States, to market our existing RUO products or new products utilized for diagnostic purposes;
- lease additional facilities or build-out existing facilities as we continue to grow our 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 and, if applicable, in the future, loss of our status as a smaller reporting company or changes in our status from a non-accelerated filer to an accelerated filer or large accelerated filer.

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

- the cost of integrating our newly acquired businesses or of acquiring future businesses;
- market acceptance of our products, technologies and services, and the variability in costs to achieve such acceptance;
- the cost and timing of establishing additional sales, marketing and distribution capabilities;
- the cost of our research and development activities;
- our ability to satisfy any outstanding or future debt obligations including our obligations under the Notes and the Purchase Agreement;
- increasing interest rates;
- supply chain disruptions;
- the success of our existing distribution and marketing arrangements and our ability to enter into additional arrangements in the future;
- the effects of geopolitical or macroeconomic developments, such as the ongoing military conflict between Russia and Ukraine 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; and
- the effect of competing technological and market developments.

As of December 31, 2023, we had $17.9 million in cash and cash equivalents, $48.8 million in short-term investments, and $35.5 million in restricted cash and cash equivalents and restricted short-term investments,. We received net proceeds of approximately$75.2 million from the issuance and sale of our securities pursuant to the Purchase Agreement in October 2023, a portion of which was used to redeem the $17.0 million aggregate principal amount outstanding of Private Placement Notes in February 2024. Based on our current business plans, we believe such net proceeds together with our existing cash and cash equivalents and short-term investments, will be sufficient to fund our operating expenses and capital expenditure requirements into at least the third quarter of 2024. This estimate assumes the inclusion of the amount equal to the sum of (i) the outstanding principal amount of the Registered Notes plus (ii) approximately $0.7 million that we are required to hold as restricted cash in an account control agreement under the terms of the Registered Notes. 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. We cannot assure you that we will be able to obtain additional funds on acceptable terms, or at all. If we raise additional funds by issuing equity or equity-linked securities, our stockholders may experience dilution. Any equity or debt securities we issue could provide for rights, preferences, or privileges senior to those of holders of our common stock. Future debt financing, if available, may involve covenants restricting our operations or our ability to incur additional debt. Any debt or equity financing may contain terms that are not favorable to us or our stockholders. If we

raise additional funds through collaboration and licensing arrangements with third parties, it may be necessary to relinquish some rights to our technologies or our products, or grant licenses on terms that are not favorable to us. In addition, we may not be able to access a portion of our existing cash and cash equivalents and short-term investments or “restricted cash or restricted investments” in the account control agreement due to market conditions such as potential future disruptions in access to bank deposits or lending commitments due to bank failures.

Global economic conditions have been worsening, with disruptions to, and volatility in, the credit and financial markets in the U.S. and worldwide resulting from the effects of ongoing geopolitical or macroeconomic developments. If these conditions persist or worsen, we could experience an inability to access additional capital. If we do not have, or are not able to obtain, sufficient funds, we may have to delay development or commercialization of our technologies and products. We also may have to reduce marketing, customer support or other resources devoted to our products or technologies or cease operations. Any of these factors could have a material adverse effect on our financial condition, operating results and business. Any of the foregoing could significantly harm our business, prospects, financial condition and results of operation and could cause the price of our securities to decline. 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. Any failure or delay in securing financing could impact our ability to continue as a going concern.

Servicing the Notes requires a significant amount of cash, and we may not have sufficient cash flow from our business to pay our obligations under the Notes or our other permitted indebtedness.
Our ability to make scheduled payments of principal or default interest, if any, or to refinance the Notes 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 December 31, 2023, we had aggregate principal amount outstanding under the Notes of $61.0 million and following the redemptions in February 2024 as described in Note 9 (High Trail Agreement) to our consolidated financial statements we had approximately $24.3 million outstanding under the Notes. Our business may not continue to generate cash flow from operations in the future sufficient to satisfy our obligations under the Notes 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 Notes in full without the consent of the holders under certain circumstances, and our ability to refinance the Notes 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 Notes or our other indebtedness. As of December 31, 2023, there is substantial doubt about our ability to continue as a going concern and servicing the Notes continues to impact our cash flow and liquidity.

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

The Notes and the 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 Notes 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 Notes, and that require us to maintain a share reserve in respect of the Notes and Registered Warrants (as defined in the Notes to Consolidated Financial Statements)) and events of default, and the Notes and the 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: (A) cash and cash equivalents subject to account control agreements in favor of the Purchaser in a minimum amount equal to the sum of (i) the outstanding principal amount of the Registered Notes plus (ii) approximately $0.7 million; (B) an “at the market” program, equity line of credit, or similar program approved by the Purchaser with aggregate available, accessible and unused capacity to generate gross proceeds to us of at least $50 million; and (C) beginning with the fiscal quarter ending March 31, 2024, our and our wholly owned subsidiaries’ Available Cash (as defined under the Notes) on the last calendar day of each quarter shall be greater than or equal to (x) our and our wholly owned subsidiaries’ cash and cash equivalents on the last day of the immediately preceding fiscal quarter, less (y) $30.0 million. Our ability to meet the financial tests under the Notes 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 Notes and the 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 Notes, 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 Notes 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 Notes, 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 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.

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

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

Our corporate cash saving 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.

In May 2023, October 2023 and March 2024, we undertook a cash savings initiative that included a reduction in force. These initiatives may be disruptive to our operations. For example, our headcount reductions could yield unanticipated consequences and costs, such as increased difficulties in implementing our business strategy due to the loss of institutional knowledge and expertise, reduced strength of our sales force and marketing efforts, attrition beyond the intended number of employees, decreased morale among our remaining employees, and the risk that we may not achieve the anticipated benefits of the reduction in force. In addition, while certain positions have been eliminated, certain functions necessary to our operations remain, and we may be unsuccessful in distributing the duties and obligations of departed employees among our remaining employees. The reduction in workforce could also make it difficult for us to pursue, or prevent us from pursuing, new opportunities and initiatives, including restricting the strength of our sales force and marketing efforts, due to insufficient personnel, or require us to incur additional and unanticipated costs to hire new personnel to pursue such opportunities or initiatives. Moreover, employee litigation related to the headcount reductions could be costly and prevent management from fully concentrating on the business. In addition, Bionano Laboratories’ planned phase out of the offering of certain testing

services related to NDDs, including 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.

Our future financial performance and our ability to develop our product candidates or additional assets will depend, in part, on our ability to effectively manage future growth or restructuring, as the case may be. In addition, if we are unable to realize the anticipated benefits from our cash savings initiatives including those we discussed under “Part II. Item 7. Management’s Discussion and Analysis of Operations – Liquidity and Capital Resources”, or if we experience significant adverse consequences of such initiative, our business, financial condition, and results of operations may be materially adversely affected.

Risks related to our business operations

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

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

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

Foreign acquisitions involve unique risks in addition to those mentioned above, including those related to integration of operations across different cultures and languages, currency risks and the particular economic, political and regulatory risks associated with specific countries.

In addition, in connection with any such transactions, we may also issue equity securities in a dilutive manner, incur additional debt, assume contractual obligations or liabilities or expend significant cash. Such transactions could harm our operating results and cash position, negatively affect the price of our stock and cause dilution to our current stockholders. For example, in connection with our acquisition of Lineagen, a U.S.-based provider of proprietary molecular diagnostics services for individuals presenting with certain neurodevelopmental disorders, we issued 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 and Company, LLC (“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 (the “Cowen ATM”). In the fiscal year ended December 31, 2022, we sold 0.7 million shares of common stock under the Cowen ATM for gross proceeds of approximately $23.1 million before deducting offering costs. In the year ended December 31, 2023, we sold approximately 12.5 million shares of common stock under the Cowen ATM for gross proceeds of approximately $57.8 million before deducting offering costs.

Further the conversion of the Notes, and exercise of the Registered Warrants issued in the Offering and Private Placement in October 2023 (as amended in February 2024) will dilute the ownership interests of existing stockholders to the extent we

deliver shares upon conversion of the Notes or exercise of the Registered Warrants. In addition, if the Purchaser exercises its option to purchase the Subsequently Purchased Notes (as defined in Note 9 (High Trail Agreement) to our consolidated financial statements) and warrants, this will dilute the ownership interests of existing stockholders further to the extent we deliver shares upon conversion of such Subsequently Purchased Notes and exercise of the warrants. Any sales in the public market of the common stock issuable upon such conversion could adversely affect prevailing market prices of our common stock. In addition, the existence of the Notes and Registered Warrants may encourage short selling by market participants because the conversion of the Notes and exercise of the Registered Warrants could be used to satisfy short positions, or anticipated conversion of the Notes 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. Any future significant sales of our capital stock or strategic transactions in which we use equity as consideration would result in further dilution to our current stockholders. As a result of these issuances, our investors experienced dilution of their ownership interests.

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

In order to provide persons who have a responsibility for our management and/or growth with additional incentive, to increase their proprietary interest in our success, and to support and increase our ability to attract and retain individuals of exceptional talent, we maintain multiple equity incentive plans. As of December 31, 2023, we had outstanding equity awards underlying those plans accounting for 3.3 million underlying shares. The total number of shares of our common stock available for the grant of awards under these plans is 1.3 million, 1.3 million and 0.1 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. For example on February 15, 2023, our board of directors granted our executive officers options to purchase an aggregate of 0.3 million shares of our common stock, and 0.1 million restricted stock units (“RSUs”), which represented approximately 0.7% of our outstanding shares of common stock based on the 54.7 million shares of common stock outstanding as of February 29, 2024. 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.

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

The sales process for our systems generally involves numerous interactions with multiple individuals within an organization, and often includes in-depth analysis by potential customers of our technology and products and a lengthy review process. Our customers' evaluation processes often involve a number of factors, many of which are beyond our control. As a result of these factors, the capital investment required to purchase our systems and the budget cycles of our customers, the time from initial contact with a customer to our receipt of a purchase order can vary significantly. Given the length and uncertainty of our sales cycle, we have in the past experienced, and expect to in the future experience, fluctuations in our sales on a period-to-period basis. In addition, any failure to meet customer expectations could result in customers choosing to retain their existing systems, use existing assays not requiring capital equipment or purchase systems other than ours.

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

Our business is dependent on the continued improvement of our existing products and technologies and our development of new products and technologies utilizing our current or other potential future technology. As we introduce new products or technologies or refine, improve or upgrade versions of existing products or technologies, we cannot predict the level of market acceptance or the amount of market share these products or technologies will achieve, if any.

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

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

- correctly identify customer needs and preferences and predict future needs and preferences;
- allocate our research and development funding to products and technologies with higher growth prospects;
- anticipate and respond to our competitors' development of new products and technological innovations;
- innovate and develop new technologies and applications, including software applications through our BioDiscovery subsidiary, and acquire or obtain rights to third-party technologies that may have valuable applications in the markets we serve;
- our ability to successfully market our Ionic Purification system through our Purigen business;
- 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 will need 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 Annual 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 manage and expand our sales force, and increase the scope of our marketing efforts. We may also enter into additional distribution arrangements in the future. Because we have limited experience in marketing and selling our products and technologies, our ability to forecast demand, the infrastructure required to support such demand and the sales cycle to customers is unproven. If we do not build an efficient and effective sales force, our business and operating results will be adversely affected.

We rely on a single contract manufacturer for our 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, including our Ionic Purification instruments. See the section titled "Business — Key Agreements" in this Annual Report. 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 Salt Lake City, Utah.

Our facilities and equipment could be harmed or rendered inoperable by natural or man-made disasters, including war, fire, earthquake, power loss, communications failure, terrorism, burglary, public health crises (including restrictions that may result from various geopolitical and macroeconomic developments, such as the ongoing conflict between Ukraine and Russia) or

other events, which may make it difficult or impossible for us to perform our testing services for some period of time or to receive and store samples. The inability to perform tests or to reduce the backlog of sample analysis that could develop if one or both of our facilities become inoperable, for even a short period of time, may result in the loss of revenue, loss of customers or harm to our reputation, and we may be unable to regain that revenue, those customers or repair our reputation in the future. Furthermore, integral parties in our supply chain are operating from single sites, increasing their vulnerability to natural disasters and man-made disasters or other sudden, unforeseen and severe adverse events.

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

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

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

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

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

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

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

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

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

If our customers develop or use our products or assays for diagnostic purposes, someone could file a product liability claim alleging that one of our products contained a design or manufacturing defect that resulted in the failure to adequately perform, leading to death or injury. In addition, the marketing, sale and use of our current or future products and assays could lead to the

filing of product liability claims against us if someone alleges that our products failed to perform as designed. We may also be subject to liability for errors in the results we provide or for a misunderstanding of, or inappropriate reliance upon, the information we provide.

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

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

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

We intend to continue to grow our business internationally, and to do so we must attract additional distributors and retain existing distributors to maximize the commercial opportunity for our products. There is no guarantee that we will be successful in attracting or retaining desirable sales and distribution partners or that we will be able to enter into such arrangements on favorable terms. Distributors may not commit the necessary resources to market and sell our products to the level of our expectations or may choose to favor marketing the products of our competitors. If current or future distributors do not perform adequately, or we are unable to enter into effective arrangements with distributors in particular geographic areas, we may not realize long-term international revenue growth. In addition, if our distributors fail to comply with applicable laws and ethical standards, including anti-bribery laws, this could damage our reputation and could have a significant adverse effect on our business and our revenues.

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

During the twelve months ended December 31, 2023 and 2022, approximately 56% and 58%, respectively, of our revenue was generated from customers located outside of the United States. We believe that a substantial percentage of our future revenue will come from international sources as we expand our overseas operations and develop opportunities in additional areas. We have limited experience operating internationally and engaging in international business involves a number of difficulties and risks, including:

- required compliance with existing and changing foreign regulatory requirements and laws;
- difficulties and costs of staffing and managing foreign operations;
- difficulties protecting or procuring intellectual property rights;
- required compliance with anti-bribery laws, such as the U.S. 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. As 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 recently expanded senior management team, as well as our research and development, manufacturing and sales and marketing personnel. Competition for qualified personnel is intense. Our growth depends, in particular, on attracting and retaining highly-trained sales personnel with the necessary scientific background and ability to understand our systems at a technical level to effectively identify and sell to potential new customers. Additionally, our growth depends on attracting and retaining highly-skilled personnel with the necessary technical and scientific background needed to develop new products and technologies. Because of the complex and technical nature of our products and technologies and the dynamic market in which we compete, any failure to attract, train, retain, motivate and integrate qualified personnel could materially harm our operating results and growth prospects. In response to competition, rising inflation rates and labor shortages, we may need to adjust employee cash compensation, which would affect our operating costs and our margins, or equity compensation, which would affect our outstanding share count, causing dilution to existing shareholders and possibly souring investor sentiment, which could in turn make it difficult to achieve our goals.

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

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

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

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

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

Some actors now engage and are expected to continue to engage in cyber-attacks, including without limitation nation-state actors for geopolitical reasons and in conjunction with military conflicts and defense activities. During times of war and other major conflicts, including as a result of the ongoing military conflict between Russia and Ukraine and the related sanctions imposed against Russia, and the military conflict between Israel and Gaza, we and the third parties upon which we rely may be vulnerable to a heightened risk of these attacks, including retaliatory cyber-attacks that could materially disrupt our systems and operations, supply chain, and ability to produce, sell and distribute our goods and services.

We and the third parties upon which we rely are subject to a variety of evolving threats, including but not limited to social-engineering attacks (such as through 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.

In addition, our reliance on third-party service providers and technologies to operate critical business systems to process Sensitive Data could introduce new cybersecurity risks and vulnerabilities and other threats to our business operations. We rely

on third-party service providers in a variety of contexts, including, without limitation, third-party providers of cloud-based infrastructure, encryption and authentication technology, employee email, content delivery to customers, and other functions and, as a result, we and the third parties upon which we rely face a variety of evolving threats, including but not limited to ransomware attacks, which could cause security incidents. Our ability to monitor these third parties' cybersecurity practices is limited, and these third parties may not have adequate information security measures in place. While we may be entitled to damages if our third-party service providers fail to satisfy their privacy or security-related obligations to us, any award may be insufficient to cover our damages, or we may be unable to recover such award. We 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 upon which we rely). 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 upon whom we rely. A security incident or other interruption could disrupt our ability (and that of third parties upon whom we rely) to provide our products, software and services. We may expend significant resources or modify our business activities (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 to notify relevant stakeholders, including affected individuals, customers, regulators, and investors, of security incidents. Such disclosures are costly, and the disclosures or the failure to comply with such requirements could lead to adverse consequences. If we (or a third party upon whom we rely) experience a security incident or are perceived to have experienced a security incident, we may experience adverse consequences, such as government enforcement actions (for example, investigations, fines, penalties, audits, and inspections); additional reporting requirements and/or oversight; restrictions on processing data (including personal data); litigation (including class claims); indemnification obligations; negative publicity; reputational harm; monetary fund diversions; 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 upon whom we rely. 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 on which we rely. If we or the third parties on which we rely fail, or are perceived to have failed, to address or comply with data privacy and security obligations, we could face significant consequences. These consequences may include, but are not limited to, government enforcement actions (e.g., investigations, fines, penalties, audits, inspections, and similar); litigation (including class action claims) and mass arbitration demands; additional reporting requirements and/or oversight; bans 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 affect our business. On October 3, 2023 FDA issued proposed regulations under which it would phase out its enforcement discretion approach to LDTs over a period of four years. Although the proposed regulation is subject to a period of notice and comment, if finalized as proposed, we and our collaborators or customers would be required to obtain PMA approval or 510(k) clearance for certain tests by October 1, 2027. We would also be 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 prior to continuing to sell our existing LDTs. This may increase the cost of conducting, or otherwise harm, our business.

If the FDA requires laboratories to undergo premarket review and comply with other applicable FDA requirements in the future, the cost and time required to commercialize an LDT will increase substantially, and may reduce the financial incentive for us to continue to offer our Bionano Laboratories genetic diagnostic services or for our customer laboratories to develop LDTs, which could reduce demand for our RUO instruments and our other products. In addition, if the FDA were to change the way that it regulates LDTs to require that we undergo pre-market review or comply with other applicable FDA requirements before we can sell our RUO instruments or our other products to clinical cytogenetics laboratories, our ability to sell our RUO instruments and other products to this addressable market would be delayed, thereby impeding our ability to penetrate this market and generate revenue from sales of our instruments and our other products.

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

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

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

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

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

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

Several factors make the billing process complex, including:

- differences between the billing rates and reimbursement rates for our products;
- compliance with complex federal and state regulations related to billing government healthcare programs, including Medicare, Medicaid and TRICARE;
- risk of government audits related to billing;
- disputes among payors as to which party is responsible for payment;
- differences in coverage and information and billing requirements among payors, including the need for prior authorization and/or advanced notification;
- the effect of patient co-payments or co-insurance and our ability to collect such payments from patients;
- changes to billing codes used for our products;
- changes to requirements related to our current or future clinical studies, including our registry studies, which can affect eligibility for payment;
- ongoing monitoring provisions of LCDs for our products, which can affect the circumstances under which a claim would be considered medically necessary;
- incorrect or missing billing information; and
- the resources required to manage the billing and claims appeals process.

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

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

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

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

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

Our Bionano Laboratories-related revenue depends on achieving and maintaining broad coverage and adequate reimbursement for our Bionano Laboratories products and diagnostic assays from third-party payors, including both government and commercial third-party payors. If third-party payors do not provide coverage of, or do not provide adequate reimbursement for,

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

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

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

Our claims for reimbursement from third-party payors may be denied upon submission, and we may need to take additional steps to receive payment, such as appealing the denials. Such appeals and other processes are time-consuming and expensive, and may not result in payment. Third-party payors may perform audits of historically paid claims and attempt to recoup funds years after the funds were initially distributed if the third-party payors believe the funds were paid in error or determine that our Bionano Laboratories products and diagnostic assays were medically unnecessary. If a third-party payor audits our claims and issues a negative audit finding, and we are not able to overturn the audit findings through appeal, the recoupment may result in a material adverse effect on our revenue. Additionally, in some cases commercial third-party payors for whom we are not a participating provider may elect at any time to review claims previously paid and determine the amount they paid was too much. In these situations, the third-party payor will typically notify us of their decision and then offset whatever amount they determine they overpaid against amounts they owe us on current claims. We cannot predict when, or how often, a third-party payor might engage in these reviews and we may not be able to dispute these retroactive adjustments.

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

If diagnostic procedures that are enabled by our 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 151 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 approximately 105 pending patent applications and granted patents in particular jurisdictions outside the United States. If we fail to protect and/or maintain our intellectual property, third parties may be able to compete more effectively against us, we may lose our technological or competitive advantage, and/or we may incur substantial litigation costs in our attempts to recover or restrict use of our intellectual property.

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

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

viable products or product features, may not provide us with any competitive advantages, or may be challenged and invalidated by third parties, patent offices, and/or the courts;

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Competitors may infringe our patents or the patents we license in. In the event of infringement or unauthorized use, we may file one or more infringement lawsuits, which can be expensive and time-consuming. An adverse result in any such litigation proceedings could put one or more of our patents at risk of being invalidated, being found to be unenforceable, and/or being interpreted narrowly and could put our patent applications at risk of not issuing and/or could impact the validity or enforceability positions of our other patents or those we license. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation.

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

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

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

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

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

As is common in the life sciences industry, we engage the services of consultants and independent contractors to assist us in the development of our products, technologies and services. Many of these consultants and independent contractors were previously employed at, or may have previously or may be currently providing consulting or other services to, universities or other technology, biotechnology or pharmaceutical companies, including our competitors or potential competitors. We may become subject to claims that our company, a consultant or an independent contractor inadvertently or otherwise used or disclosed trade secrets or other information proprietary to their former employers or their former or current clients. We may similarly be subject to claims stemming from similar actions of an employee, such as one who was previously employed by another company, including a competitor or potential competitor. We may become subject to claims that one or more current or

former employees, consultants, advisors, or independent contractors of ours owns rights in our intellectual property and/or has assigned or is under an obligation to assign rights in our intellectual property to another party. This may include a competitor of ours. If a competitor has rights in our patents, the competitor or a licensee or related entity of the competitor may be able to make, use, sell, import, and/or export the patented technology without liability to us under our patents or the patents we license. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to our management team. If we were not successful, we could lose valuable intellectual property rights.

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

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

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

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

Filing, prosecuting, maintaining, and defending patents on current and future products, technologies and services in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States can be less extensive than those in the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. Consequently, regardless of whether we are able to prevent third parties from practicing our inventions in the United States, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not pursued and obtained patent protection to develop their own products, technologies or services, and further, may export otherwise infringing products or technologies to territories where we have patent protection, but enforcement is not as strong as it is in the United States. These products, technologies or services may compete with our products, technologies or services and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing. Even if we pursue and obtain issued patents in particular jurisdictions, our patent claims or other intellectual property rights may not be effective or sufficient to prevent third parties from so competing. Patent protection must ultimately be sought on a country-by-country basis, which is an expensive and time-consuming process with uncertain outcomes. Accordingly, we may choose not to seek patent protection in certain countries, and we will not have the benefit of patent protection in such countries.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents and other intellectual property protection, particularly those relating to biotechnology, which could make it difficult for us to stop the infringement of our patents or marketing of competing products, technologies or services in violation of our proprietary rights generally. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing, and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful.

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

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

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

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

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

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

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

Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other provisions during the patent process. There are situations in which noncompliance can result in abandonment or lapse of a patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, competitors might be able to enter the market earlier than would otherwise have been the case. In some cases, our licensors may be responsible for these payments, thereby decreasing our control over compliance with these requirements.

If our trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our markets of interest and our business may be adversely affected.

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

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

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

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

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

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

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

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

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

- others may be able to develop and/or use technologies that are similar to our technologies or aspects of our technologies but that does not cover the claims of any our patents or patents that may issue from our patent applications or those we license;
- we or the licensor of our licensed-in patents might not have been the first to make the inventions disclosed and/or claimed in a pending patent application that we own or license;
- we or the licensor of our licensed-in patents might not have been the first to file patent applications disclosing and/or claiming an invention;
- others may independently develop similar or alternative technologies without infringing our or our licensors' intellectual property rights;
- pending patent applications that we own or license may not lead to issued patents or may not result in the claims that we want (for example, as to the scope of issued claims, if any);
- patents, if issued, that we own or license may not provide us with any competitive advantages, or may be held invalid or unenforceable, as a result of legal challenges by our competitors or other third parties;
- third parties may compete with us in jurisdictions where we do not pursue and obtain patent protection;

- we may not be able to obtain and/or maintain necessary or useful licenses on reasonable terms or at all;
- third parties may assert an ownership interest in our intellectual property and, if successful, such disputes may preclude us from exercising exclusive rights over that intellectual property;
- we may not be able to maintain the confidentiality of our trade secrets or other proprietary information;
- we may not develop or in-license additional proprietary technologies that are patentable; and
- the patents or other intellectual property of others may have an adverse effect on our business.

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

Risks related to ownership of our securities

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

Our stock price has been and may continue to be volatile. The daily closing market price for our common stock has varied significantly in the last 12 months, ranging between a high price of $19.70 on February 2, 2023 and a low price of $1.09 on February 5, 2024. During this time, the price per share of common stock has ranged from an intra-day low of $1.04 per share to an intra-day high of $20.20 per share.

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

- our commercial progress in marketing and selling our genome analysis systems, including sales and revenue trends;
- changes in laws or regulations applicable to our systems;
- adverse developments related to our laboratory facilities;
- increased competition in the diagnostics services industry;
- 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 savings initiatives announced in May 2023, October 2023 and March 2024;
- the reverse stock split of the Company's common stock effected on August 4, 2023; and
- other events or factors, many of which are beyond our control.

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

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 antitakeover 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 or if we are unable to transfer our listing to another stock market. In order to maintain this listing, we must satisfy minimum financial and other continued listing requirements and standards, including a requirement to maintain a minimum bid price of the Company’s common stock of $1.00 per share.

In the past, we have failed to comply with the per share minimum required for continued listing on The Nasdaq Capital Market (“Nasdaq”) pursuant to Nasdaq Listing Rule 5550(a)(2) (the “Minimum Bid Price Requirement”). On May 30, 2023, we received a letter (the “Notice”) from Nasdaq advising us that for 30 consecutive trading days preceding the date of the Notice, the bid price of our common stock had closed below the Minimum Bid Price Requirement.

Under Nasdaq Listing Rule 5810(c)(3)(A), we had 180 calendar days following the date of the Notice to regain compliance with the Minimum Bid Price Requirement. 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. On August 21, 2023, we announced that we had received a letter from the staff of Nasdaq notifying us that we had regained compliance with the Minimum Bid Price Requirement and the matter is now closed.

While we regained compliance with the Minimum Bid Requirement there can be no guarantee that we will be able to maintain our Nasdaq listing in the future. If in the future we fail to comply with the Minimum Bid Price Requirement or 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. 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; for example, a delisting for a period of at least five trading days constitutes an event of default under the Notes, which entitles the holder thereof to declare the Notes immediately due and payable. 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 Annual Report, we have filed registration statements on Form S-8 under the Securities Act registering the issuance of an aggregate of 5.3 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 Purchaser to resell the shares underlying the Private Placement Notes and the Private Placement Warrants (as defined in the Notes to Consolidated Financial Statements). Following the redemptions in February 2024, the Private Placement Notes have been canceled. However, if the Purchaser exercises its option to purchase the Subsequently Purchased Notes, such Subsequently Purchased Notes are initially convertible into 8.7 million shares of our common stock and the Private Placement Warrants are to purchase up to 6.8 million shares of our common stock.

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.

Our shares of common stock began trading on The Nasdaq Capital Market on September 21, 2018. Given the limited trading history of our common stock, there is a risk that an active trading market for our shares will not be sustained, which could put

downward pressure on the market price of our common stock and thereby affect the ability of our stockholders to sell their shares.

General Risk Factors

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

The trading market for our securities will depend in part on the research and reports that securities or industry analysts publish about us or our business. 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 1B. UNRESOLVED STAFF COMMENTS

None.

ITEM 1C. CYBERSECURITY

Risk management and strategy

We have implemented and maintain various information security processes designed to identify, assess and manage material risks from cybersecurity threats to our critical computer networks, third party hosted services, communications systems, hardware and software, and our critical data, including intellectual property, confidential information that is proprietary, strategic or competitive in nature, and customer data that use to provide services for our customers ("Information Systems and Data").

Our Chief Information Security Officer ("CISO") with help from our legal department and our security and compliance team from our IT infrastructure department help identify, assess and manage the Company's cybersecurity threats and risks. The Company identifies and assesses risks from cybersecurity threats by monitoring and evaluating our threat environment using various methods including, for example using manual and automated tools, conducting scans of the threat environment, conducting internal and external threat and vulnerability assessments, conducting internal and external audits, subscribing to reports and services that identify cybersecurity threats, analyzing reports of threats and actors, conducting third party assessments and evaluating threats reported to us.

Depending on the environment, we implement and maintain various technical, physical, and organizational measures, processes, standards and policies designed to manage and mitigate material risks from cybersecurity threats to our Information Systems and Data, including, for example: an incident response plan, incident detection and response, disaster recovery plan, encryption of certain data, network security controls, access controls, asset management, tracking and disposal, employee training, penetration testing, systems monitoring and cybersecurity insurance.

Our assessment and management of material risks from cybersecurity threats are integrated into the Company's overall risk management processes. For example, the security and compliance team works with management to prioritize our risk management processes and mitigate cybersecurity threats that are more likely to lead to a material impact to our business, and evaluates material risks from cybersecurity threats and reports to the audit committee of the board of directors ("Audit Committee"), which evaluates our overall enterprise risk.

We use third-party service providers to assist us from time to time to identify, assess, and manage material risks from cybersecurity threats, including for example professional services firms including outside legal counsel, cybersecurity consultants, penetration testing firms, cybersecurity software providers, managed cybersecurity service providers and threat intelligence service providers.

We use third-party service providers to perform a variety of functions throughout our business, such as application providers and hosting companies. We have a vendor management program to manage cybersecurity risks associated with our use of these providers. The program includes vulnerability scans related to vendors and a review of vendors' security certification reports. Depending on the nature of the services provided, the sensitivity of the Information Systems and Data at issue, and the identity of the provider, the Company may involve different levels of assessment designed to help identify cybersecurity risks associated with a provider and impose contractual obligations related to cybersecurity on the provider.

We have not experienced a cybersecurity incident that would materially affect the company's business strategy, results of operations or financial position.

For a description of the risks from cybersecurity threats that may materially affect the Company and how they may do so, see our risk factors under Part 1. Item 1A. Risk Factors in this Annual Report, including "*If our information technology systems or data or those of third parties upon which we rely, are or were compromised, we could experience adverse consequences resulting from such compromise, including but not limited to regulatory investigations or actions; litigation; fines and penalties; disruptions of our business operations; reputational harm; loss of revenue or profits; loss of customers or sales; and other adverse consequences.*"

Governance

Our board of directors addresses the Company's cybersecurity risk management as part of its general oversight function. The Audit Committee is responsible for overseeing the Company's cybersecurity risk management processes, including oversight of mitigation of risks from cybersecurity threats.

Our cybersecurity risk assessment and management processes are implemented and maintained by certain Company management, including our CFO who serves as our CISO. Our CISO relies on both internal and external cybersecurity resources to manage overall cybersecurity risks.

The Company's CFO is responsible for hiring appropriate personnel, helping to integrate cybersecurity risk considerations into the Company's overall risk management strategy, and communicating key priorities to relevant personnel. The Company's CFO is responsible for approving budgets, helping prepare for cybersecurity incidents, approving cybersecurity processes, and reviewing security assessments and other security-related reports.

Our cybersecurity incident response plan is designed to escalate certain cybersecurity incidents to members of management depending on the circumstances, including IT security leadership, the CFO, CEO, General Counsel ("GC") and third-party consultants as needed. IT security leadership, the CFO, CEO and GC work with the Company's incident response team to help the Company mitigate and

remediate cybersecurity incidents of which they are notified. In addition, the Company's incident response plan includes reporting to the Audit Committee for certain cybersecurity incidents.

The Audit Committee receives periodic reports concerning the Company's significant cybersecurity threats and risk and the processes the Company has implemented to address them. The Audit Committee also receives various reports, summaries or presentations related to cybersecurity threats, risk and mitigation.

ITEM 2. PROPERTIES

We lease an aggregate of approximately 41,101 square feet of office, laboratory, and manufacturing space in two buildings at our headquarters in San Diego, California, with the lease for all rented space expiring December 31, 2025. In December 2021, we executed a new lease for approximately 11,978 additional square feet of office and laboratory space in San Diego, California that expires in January 2026. In January 2022, we executed an amendment to our headquarters lease for a new unit adding an additional 5,278 square feet of office and laboratory space in San Diego, California that expires in January 2026.

In August 2020, through the acquisition of Lineagen we obtained a lease for approximately 9,710 square feet of office space in Salt Lake City, Utah under a non-cancelable operating lease that expires in December 2026. We conduct part of our Bionano Laboratories business at this property. 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. The Company will continue to lease the property through June 2024.

In October 2021, through the acquisition of BioDiscovery, we obtained a finance lease for approximately 4,786 square feet of office space in El Segundo, California that expires in February 2041. We conduct part of our BioDiscovery business at this property.

In November 2022, through the acquisition of Purigen, we obtained an operating lease for approximately 16,165 square feet of office and laboratory space in Pleasanton, California that expires in July 2027. We conduct part of our Purigen business at this property.

We believe our properties are sufficient to satisfy our current needs.

ITEM 3. LEGAL PROCEEDINGS

We are not currently a party to any material legal proceedings and we are not aware of any pending or threatened legal proceedings against us that could reasonably be expected to have a material adverse effect on our business, financial condition or results of operations.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

PART II

ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

Market Information

Our common stock trades on The Nasdaq Capital Market under the symbol "BNGO."

Common Stock Holders

As of February 29, 2024, there were approximately 62 holders of record of our common stock. Certain shares of our common stock are held in "street" name and thus the actual number of beneficial owners of such shares is not known or included in the foregoing number.

Dividend Policy

We have never declared or paid cash dividends on our capital stock. We currently intend to retain any future earnings for use in the operation of our business and do not intend to declare or pay any cash dividends in the foreseeable future. Any future determination to pay dividends on our capital stock would be at the discretion of our board of directors, subject to applicable laws, and would depend on our financial condition, results of operations, capital requirements, general business conditions and other factors that our board of directors considers relevant.

Purchases of Equity Securities by the Issuer and Affiliated Purchasers

None.

Recent Sales of Unregistered Securities

Not applicable.

ITEM 6. [RESERVED]

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

You should read the following discussion and analysis of our financial condition and results of operations together in conjunction with our financial statements and the related notes included elsewhere in this Annual Report. Some of the information contained in this discussion and analysis or set forth elsewhere in this Annual Report, including information with respect to our plans and strategy for our business and expected financial results, includes forward-looking statements that involve risks and uncertainties. You should review the risks described in Part I, Item 1A Risk Factors and elsewhere in this Annual Report.

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 OGM solutions, diagnostic services and software. We offer OGM solutions for applications across basic, translational and clinical research, and for other applications including bioprocessing. Through our Bionano Laboratories business, we also provide diagnostic testing for patients with clinical presentations consistent with autism spectrum disorder and other neurodevelopmental disabilities. Through our BioDiscovery business, we offer an industry-leading, platform-agnostic software solution, which integrates next-generation sequencing and microarray data designed to provide analysis, visualization, interpretation and reporting of copy number variants, single-nucleotide variants and absence of heterozygosity across the genome in one consolidated view. Through our Purigen business, we offer nucleic acid extraction and purification solutions using proprietary ITP technology.

We expect to see OGM adoption in cytogenomics, discovery research and cell bioprocessing quality control (QC). Within cytogenetics and molecular pathology, we estimate the number of cytogenetic labs on a worldwide basis (excluding India and developing countries) to be approximately 10,000. We estimate that these labs analyze approximately 10.0 million samples per year. Additionally, we estimate the number of pharmaceutical and biotech companies that are engaged in research and development of various cell therapies that rely on methods, including cytogenetics, for QC of the cell modification and manufacturing process to be approximately 1,400. Based on these estimates, we believe the economic potential for OGM in these markets is approximately $10.0 billion annually, $3.0 billion of which we attribute to cell bioprocessing QC. We believe there are additional potential future market opportunities for OGM including newborn screening, population genomics, and neurological and cardiological risk assessment which are not included in our estimates above.

We have incurred losses in each year since our inception. Our net losses were $232.5 million and $132.6 million for the years ended December 31, 2023, and 2022, respectively. As of December 31, 2023, we had an accumulated deficit of $581.2 million.

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

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

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

Macroeconomic and Geopolitical Developments

We are subject to additional risks and uncertainties as a result of adverse geopolitical and macroeconomic developments, such as the ongoing conflict between Ukraine and Russia and related sanctions, the Israel-Hamas war, 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.

Following the invasion of Ukraine by Russia, the U.S. and global financial markets experienced volatility, which has led to disruptions to trade, commerce, pricing stability, credit availability, supply chain continuity and reduced access to liquidity globally. In response to the invasion, the United States, United Kingdom 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 and 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 on acceptable terms, in both Europe and globally, and has introduced significant uncertainty into global markets. 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 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 twelve months ended December 31, 2023, 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, 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

On March 5, 2024, we announced a cost savings plan that aims to reduce annual savings of operating expenses of approximately $35.0 to $40.0 million starting in the second half of 2024. As part of the plan, we expect to reduce our overall headcount by approximately 110 to 125 employees, which represents approximately 34% to 39% of our full-time employees as of the date of this Annual Report. In addition, Bionano Laboratories will phase out over time the offering of certain testing services related to neurodevelopmental disorders, including autism spectrum disorders and other disorders of childhood development. These cost-saving measures are incremental to the cost saving initiatives previously announced in May 2023 and October 2023. At this time, we are unable to make a good faith determination of the cost estimates, or ranges of cost estimates, associated with implementation of the plan, including the reduction in force.

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 genomics data, are made on a subscription basis. We generate service revenue from the sale of diagnostic testing services for those with autism spectrum disorder and other neurodevelopmental disabilities through Bionano Laboratories, as well as services performed related to customer sample evaluations using an OGM system. Other revenue consists of warranty and other service-based revenue, including support, repair and maintenance services.

The following table presents our revenue for the periods indicated:

	Years Ended December 31,	
	2023	2022
Product revenue	$ 26,727,000	$ 20,425,000
Service and other revenue	9,389,000	7,377,000
Total	$ 36,116,000	$ 27,802,000

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, Middle East and Africa. Asia Pacific includes China, Japan, South Korea, Singapore, Australia and India.

	Years Ended December 31,			
	2023		2022	
	$	%	$	%
Americas	$ 18,020,000	50 %	$ 13,862,000	50 %
EMEA	12,963,000	36 %	8,960,000	32 %
Asia Pacific	5,133,000	14 %	4,980,000	18 %
Total	$ 36,116,000	100 %	$ 27,802,000	100 %

Cost of Revenue

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

Research and Development Expenses

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

Selling, General and Administrative Expenses

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

Results of Operations

The following table sets forth our results of operations for the years ended December 31, 2023 and 2022:

	Years Ended December 31,		Period-to-Period Change	
	2023	2022	$	%
Revenues:				
Product revenue	$ 26,727,000	$ 20,425,000	$ 6,302,000	31%
Service and other revenue	9,389,000	7,377,000	2,012,000	27%
Total revenue	36,116,000	27,802,000	8,314,000	30%
Cost of revenue:				
Cost of product revenue	20,415,000	15,966,000	4,449,000	28%
Cost of service and other revenue	6,135,000	5,891,000	244,000	4%
Total cost of revenue	26,550,000	21,857,000	4,693,000	21%
Research and development	54,032,000	49,047,000	4,985,000	10%
Selling, general and administrative	93,499,000	88,596,000	4,903,000	6%
Goodwill Impairment	77,280,000	—	77,280,000	100 %
Total operating expenses	224,811,000	137,643,000	87,168,000	63%
Loss from operations	(215,245,000)	(131,698,000)	(83,547,000)	63%
Other income (expenses):				
Interest income	3,311,000	1,507,000	1,804,000	120%
Interest expense	(5,119,000)	(298,000)	(4,821,000)	1,618%
Other income (expenses)	3,449,000	(223,000)	3,672,000	(1,647)%
Loss on High Trail Agreement	(18,827,000)	—	(18,827,000)	100%
Total other income (expenses)	(17,186,000)	986,000	(18,172,000)	(1,843)%
Loss before income taxes	(232,431,000)	(130,712,000)	(101,719,000)	78%
Benefit (provision) for income taxes	(62,000)	(1,884,000)	1,822,000	(97)%
Net loss	$ (232,493,000)	$ (132,596,000)	$ (99,897,000)	75%

Revenue

	Years Ended December 31,		Period-to-Period Change	
	2023	2022	$	%
Instruments	$ 9,999,000	$ 8,567,000	$ 1,432,000	17%
Consumables	11,157,000	6,731,000	4,426,000	66%
Software	5,571,000	5,127,000	444,000	9%
Total product revenue	26,727,000	20,425,000	6,302,000	31%
Services and other	9,389,000	7,377,000	2,012,000	27%
Total revenue	$ 36,116,000	$ 27,802,000	$ 8,314,000	30%

Revenue increased by $8.3 million, or 30% to $36.1 million for the year ended December 31, 2023, as compared to $27.8 million for the same period in 2022, driven primarily from an increase in instrument, consumable, and service and other revenue as discussed below.

Instrument revenue increased $1.4 million, or 17%, to $10.0 million for the year ended December 31, 2023, as compared to $8.6 million for the year ended December 31, 2022, due to an increase in OGM and Ionic instruments sold. For the year ended December 31, 2023, our installed base grew to 326 OGM systems compared to the 240 OGM systems for the year ended December 31, 2022. We expect the number of our OGM system placements to continue to grow during 2024, driven by increased market awareness, the full commercial release of our Stratys system in the first quarter of 2024, additional published data demonstrating the utility of OGM solutions, along with continued efficiencies gained in the OGM workflow through research and development, and the acquisitions of BioDiscovery and Purigen.

Consumables revenue increased $4.4 million, or 66%, to $11.2 million for the year ended December 31, 2023, as compared to $6.7 million for the year ended December 31, 2022. The increase in consumable revenue was attributable to higher OGM

consumable sales given the growth of the instrument installed base and an increase in the consumable purchase quantities under our reagent rental program. For the year ended December 31, 2023, total flowcells sold reached 26,444, an increase of approximately 72% from the 15,375 flowcells sold during the year ended December 31, 2022.

Software revenue increased $0.4 million, or 9%, to $5.6 million for the year ended December 31, 2023, as compared to $5.1 million for the year ended December 31, 2022. The increase is attributed to an increase in sales of our VIA software.

Service and other revenue increased $2.0 million, or 27%, to $9.4 million for the year ended December 31, 2023 as compared to $7.4 million for the year ended December 31, 2022. The increase was primarily due to a $1.9 million increase in diagnostic and service project revenue contributed from Bionano Laboratories. As of March 1, 2024, we have determined that Bionano Laboratories will phase out over time the products related to testing services for individuals demonstrating clinical presentations consistent with NDDs, including ASDs and other disorders of childhood development.

Cost of Revenue, Gross Profit, and Gross Margin

	Years Ended December 31,		Period-to-Period Change	
	2023	2022	$	%
Gross profit (loss):				
Product	$ 6,312,000	$ 4,459,000	$ 1,853,000	42%
Service and other	3,254,000	1,486,000	1,768,000	119%
Total gross profit	$ 9,566,000	$ 5,945,000	$ 3,621,000	61%
Gross margin:				
Product	24 %	22 %		
Service and other	35 %	20 %		
Total gross margin	26 %	21 %		

Cost of product revenue increased by $4.4 million, or 28%, to $20.4 million for the year ended December 31, 2023, compared to $16.0 million for the year ended December 31, 2022. The increase in cost of product revenue was primarily due to higher sales of instruments and consumables.

Cost of service and other revenue increased $0.2 million, or 4%, to $6.1 million for the year ended December 31, 2023, compared to $5.9 million for the year ended December 31, 2022. The increase in cost of service and other revenue was primarily due to increased service costs on our growing installed base as well as increased costs to support the service offerings from Bionano Laboratories.

Product gross profit increased $1.9 million, or 42%, to $6.3 million for the year ended December 31, 2023, compared to $4.5 million for the year ended December 31, 2022. The increase in gross profit was primarily due to higher sales of instruments and consumables.

Service and other gross profit increased by $1.8 million, or 119%, to $3.3 million for the year ended December 31, 2023, compared to $1.5 million for the year ended December 31, 2022. The increase in gross profit was primarily due to increased sales of our Bionano Laboratories service offerings.

Research and Development Expenses

Research and development expenses increased by $5.0 million, or 10%, to $54.0 million for the year ended December 31, 2023 as compared to $49.0 million for the same period in 2022. The increase was primarily due to a $6.8 million increase in headcount-related expenses. On a full year basis, we averaged 28 more employees allocated to research and development departments in 2023 than we did in 2022. This was mostly attributed to the fourth quarter 2022 acquisition of Purigen and partially offset by the cost-savings initiatives announced in early 2023. In addition, we recognized a $2.0 million increase in materials and supplies costs, a $1.4 million increase in information technology (“IT”) and software related costs, a $1.3 million increase in facilities costs, and a $1.2 million increase in depreciation expense. These increases were incurred in support of our efforts to develop more scalable and efficient manufacturing workflows, clinical trial research, expand the utility of OGM, and develop the next versions of OGM products – including integration of OGM data into our VIA software and full commercial launch of the Stratys system. The increases were primarily offset by a decrease in stock-based compensation of $8.3 million due to the vesting of stock issued as consideration in the BioDiscovery acquisition, which primarily rolled up into research and development expense and vested in full in 2022, as further described in Note 10 (Stockholders’ Equity and Stock-Based

Compensation). We anticipate that our research and development expenses will decrease in 2024 as a result of our cost savings initiatives announced in May 2023 and October 2023.

Selling, General and Administrative Expenses

Selling, general and administrative expenses increased $4.9 million, or 6%, to $93.5 million for the year ended December 31, 2023 as compared to $88.6 million for the same period in 2022. The increase was primarily due to a $4.6 million increase in headcount-related expenses. On a full year basis, we averaged 16 more employees allocated to selling, general and administrative departments in 2023 than we did in 2022. This was mostly attributed to the fourth quarter 2022 acquisition of Purigen and partially offset by the cost-savings initiatives announced in early 2023. In addition, we recognized a $2.2 million increase in marketing expenses, a $1.5 million increase in consulting and professional fees, and a $1.4 million increase in amortization of acquisition-related intangibles — including an additional 11 months of amortization expense from the Purigen acquisition. The increases are being offset by decreases of $1.9 million in materials and supplies, $1.5 million in facilities costs, and $0.9 million in legal expenses. We anticipate that our SG&A expenses will decrease in 2024 in part due to the cost savings initiatives announced in May 2023 and October 2023.

Goodwill impairment

Goodwill impairment increased for the twelve months ended December 31, 2023 compared to the twelve months ended December 31, 2022. The carrying value of the net assets of the Company’s reporting unit exceeded its enterprise wide fair value and the Company recognized a goodwill impairment charge of $77.3 million on the consolidated statements of operations and comprehensive loss for the year ended December 31, 2023.

Interest Expense

Interest expense increased by $4.8 million, or 1,618%, to $5.1 million for the year ended December 31, 2023, as compared to $0.3 million for the same period in 2022. The increase was primarily driven by the debt issuance costs incurred in connection with the convertible notes. See Note 9 (High Trail Agreement) to our consolidated financial statements for further discussion.

Interest Income

Interest income increased by $1.8 million, or 120%, to $3.3 million for the year ended December 31, 2023, as compared to $1.5 million for the same period in 2022 resulting from positive returns on investments. Our total short-term investments balance was $48.8 million as of December 31, 2023.

Loss on High Trail Agreement

A loss on the High Trail Agreement of $18.8 million was recognized during the year ended December 31, 2023 for the difference between the combined fair value of the Notes and option to purchase additional Notes and the proceeds from the transaction, which is recorded as Loss on High Trail Agreement on the consolidated statement of operations.

Income tax benefit (expense)

Income tax expense decreased by $1.8 million, or 97%, to a $0.1 million expense for the year ended December 31, 2023, as compared to a $1.9 million expense for the same period in 2022, driven by the acquisition of BioDiscovery. We adjusted the business combination accounting for the tax impact of the BioDiscovery acquisition within the one year measurement period for the acquisition. The effect of the adjustment was to decrease the net deferred tax liability, decrease goodwill, and increase the valuation allowance associated with our deferred taxes by $1.8 million, which we recorded to deferred tax expense for the year ended December 31, 2022.

Liquidity and Capital Resources

Since our inception, we have incurred net losses and negative cash flows from operations. We incurred net losses of $232.5 million and $132.6 million, and used $125.2 million and $124.8 million of cash from our operating activities for the years ended December 31, 2023 and 2022, respectively. As of December 31, 2023, we had an accumulated deficit of $581.2 million, cash and cash equivalents of $17.9 million, $48.8 million in short-term investments and $35.5 million in restricted cash and cash equivalents and restricted short-term investments.

Sources of Liquidity and Capital Resources

In the years ended December 31, 2023 and 2022, we have generated cash flows from sales of common stock, other equity instruments and the issuance of convertible notes payable. 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 Notes 9 (High Trail Agreement) and 10 (Stockholder’s Equity and Stock-Based Compensation) to our consolidated financial statements for a discussion of our recent debt and equity activity.

As of December 31, 2023, we received net proceeds of approximately $75.2 million, after deducting placement agent fees and offering expenses from the issuance and sale of our securities pursuant to the Purchase Agreement in October 2023. Based on

our current business plans, we believe such net proceeds together with our existing cash and cash equivalents and short-term investments, will be sufficient to fund our operating expenses and capital expenditure requirements into at least the third quarter of 2024. This estimate assumes the inclusion of the amount equal to the sum of (i) the outstanding principal amount of the Registered Notes plus (ii) approximately $0.7 million that we are required to hold as restricted cash in an account control agreement under the terms of the Registered Notes. 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 strategic consideration alternatives in the future.

As of December 31, 2023, we had $69.8 million of Notes at fair value, which is classified as current. At the holder's option, as of December 31, 2023, we would have been required to redeem $62.1 million of Notes at the Repayment Price (as defined in Note 9 (High Trail Agreement) to our consolidated financial statements) in 2024. Because the Notes have a history of both redemptions ($20.7 million) and conversions ($10.0 million) since issuance in October 2023 through February 1, 2024, and twelve months of redemptions at the Repayment Price represents most of the outstanding balance of the Notes, we have classified the entire amount of Notes as current as of December 31, 2023. Additionally, we would have been required to pay a retirement fee to the holder based on amounts redeemed when the outstanding balance is paid in full, which as of December 31, 2023, was estimated at $4.4 million assuming full redemption and no further conversions. On January 1, 2024, and February 1, 2024, the holders redeemed an aggregate of $9.0 million of principal, at the Repayment Price of $10.4 million. In February 2024, in connection with the Letter Agreement and Amendment we redeemed an aggregate of $27.7 million of Notes for a total redemption payment of approximately $31.9 million, together with a retirement fee of approximately $3.2 million. Following the redemptions we have $24.3 million of principal of the Notes outstanding. See Note 9 (High Trail Agreement) to our consolidated financial statements.

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 increasing 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, research and development expenses associated with expanding our offerings, and expenses associated with being a public company. Our short-term capital expenditure needs relate primarily to our facilities, service lab and service-related capabilities, research and development expenses related to current and future product offerings, and enhancements to information technology. We expect such expenditures to continue throughout 2024.

We had $17.9 million in cash and cash equivalents, $48.8 million short-term investments, and $35.5 million in restricted cash and cash equivalents and restricted short-term investments as of December 31, 2023. 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 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 Annual 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 and cash equivalents and available for sale securities, 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 Operations) to our consolidated financial statements included elsewhere in this Annual Report for more information.

Cash Flows

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

	Years Ended December 31,	
	2023	**2022**
Net cash provided by (used in):		
Operating activities	$ (125,181,000)	$ (124,816,000)
Investing activities	24,158,000	82,767,000
Financing activities	113,815,000	23,007,000

Operating Activities

2023 Compared to 2022

We derive cash flows from operations primarily from the sale of our products and services. Our cash flows from operating activities are also significantly influenced by our use of cash for operating expenses to support the growth of our business. We have historically experienced negative cash flows from operating activities as we have developed our technology, expanded our business and built our infrastructure, and this may continue in the future. As discussed above, we anticipate our available cash balance will not be sufficient for the next twelve months from the issuance of this report. We plan to raise additional capital to fulfill our operating and capital requirements for at least 12 months through equity or debt financings, however, we may not be able to secure such financing in a timely manner or on favorable terms, if it all. We anticipate that our cash used in operating activities will decrease over the next 12 to 24 months; however, we may observe fluctuations in the cash used in operating activities on an annual basis to sustain the expansion of our commercial offerings.

Net cash used in operating activities was $125.2 million during the year ended December 31, 2023 as compared to $124.8 million during the year ended December 31, 2022. The increase in cash used in operating activities of $0.4 million is primarily attributed to an increase in our net loss in the current year offset by a decrease in our working capital usage due to higher inventory purchases in the prior year.

Investing Activities

2023 Compared to 2022

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. Net cash provided by investing activities was $24.2 million during the year ended December 31, 2023, compared to $82.8 million provided by investing activities during the year ended December 31, 2022. This decrease in cash provided by investment activities of $58.6 million is attributed to an increase in purchases of available-for-sale securities of $111.3 million as of December 31, 2023, compared to purchases of available-for-sale securities of $84.2 million as of December 31, 2022, in addition to the acquisition of Purigen, net of cash acquired of $31.3 million that occurred during the year ended December 31, 2022 only. The decrease in cash is offset by the sales and maturity of available-for-sale securities of $137.0 million as of December 31, 2023, compared to the sales and maturity of available-for-sale securities of $200.9 million as of December 31, 2022.

Financing Activities

2023 Compared to 2022

Net cash provided by financing activities was $113.8 million during the year ended December 31, 2023 as compared to $23.0 million during the year ended December 31, 2022, an increase of $90.8 million. This increase in cash provided by financing activities is mainly attributed to the proceeds from the issuance of convertible notes payable and warrants of $80.0 million as further discussed in Note 9 (High Trail Agreement). During the year ended December 31, 2023, we raised approximately $57.8 million in gross proceeds from sales under the Cowen ATM as compared to $23.1 million during the year ended December 31, 2022.

Financial Information about Affiliates Whose Securities Collateralize a Registrant's Securities and Consolidated Subsidiaries

The Notes are secured by a first-priority lien, subject only to certain permitted liens, on substantially all of our and our subsidiaries' (other than certain foreign subsidiaries) tangible and intangible assets, whether now owned or hereafter acquired (other than certain excluded property). For a list of subsidiaries whose securities collateralize the Notes, see Exhibit 22 to this Annual Report.

The Notes are our senior secured obligations, rank pari passu with the up to $25.0 million of additional notes that may be issued pursuant to the securities purchase agreement, senior in right of payment to all of our indebtedness that is expressly subordinated to the Notes in right of payment, effectively senior to all of our unsecured indebtedness to the extent of the collateral securing the Notes, effectively junior to all of our indebtedness secured by permitted liens, to the extent of the value of the assets subject to such permitted liens and to the extent such permitted liens have lien priority by contract or law and structurally junior to all indebtedness and other liabilities (including trade payables) of our subsidiaries that are not party to the security documents. We do not believe there is any trading market for any of our subsidiaries whose securities are pledged as collateral for the Notes.

See Note 9 (High Trail Agreement) to our consolidated financial statements for further details about the terms, conditions and other factors that may affect payments to holders and the collateral arrangements of the Notes.

Rule 13-02 of Regulation S-X requires the presentation of summarized financial information of the combined affiliates whose securities are pledged as collateral for the Notes unless such information is not material. Because the combined assets, liabilities and results of operations of the Company and the affiliates whose securities are pledged as collateral for the Notes are not materially different than the corresponding amounts presented in our consolidated financial statements, summarized financial information of affiliates whose securities are pledged as collateral for the Notes is not required to be presented under Rule 13-02.

Contingent Consideration

As part of the merger agreement related to the acquisition of BioDiscovery, we agreed to pay a milestone payment of $10.0 million in cash contingent on the achievement of a commercial milestone within eighteen months of the acquisition date. We determined the fair value of the milestone consideration using a scenario-based technique, as the trigger for payment is event driven. The outcome of the milestone consideration is binary, meaning the milestone is either achieved or not achieved, and the only other variable factor is the timing of when the milestone is achieved. On October 2, 2023, the $10.0 million milestone consideration was paid in full.

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

The fair value of the Purigen milestones are reassessed on a quarterly basis using a probability weighted model and a Monte Carlo Simulation. We determined the fair value of this milestone consideration using a scenario-based technique, as the trigger for payment is event driven. We determined the likelihood of each independent milestone and used probability factors which were applied to the individual payments over the five year milestone term. A Monte Carlo Simulation was performed to determine the likelihood that the milestone will be achieved and was applied to the milestone consideration payment.

Based on these valuation assumptions, the fair value of the contingent consideration liabilities was determined to be $10.9 million as of December 31, 2023, $0.0 of which is current as of December 31, 2023.

Contractual Obligations

The following table summarizes our future cash outflows for contractual obligations as of December 31, 2023.

	Payments Due by Period				
	Total	Less than 1 Year	1-3 Years	3-5 Years	More than 5 years
Operating lease obligations, including interest	$ 6,456,000	$ 2,684,000	$ 3,517,000	$ 255,000	$ —
Finance lease obligations, including interest, related party	6,963,000	330,000	685,000	721,000	5,227,000
Convertible notes payable*	70,150,000	62,100,000	8,050,000	—	—
Total contractual obligations	$ 83,569,000	$ 65,114,000	$ 12,252,000	$ 976,000	$ 5,227,000

*Also refer to Note 9 (High Trail Agreement) in our consolidated financial statements.

Operating lease obligations relate to our office, laboratory and manufacturing space for our corporate headquarters in San Diego, California, Bionano Laboratories operations in Salt Lake City, Utah, and Purigen office and laboratory space in

Pleasanton, California. Finance lease obligations relate to our BioDiscovery office in El Segundo, California. See Note 11, Commitments and Contingencies to our consolidated financial statements included in this Annual Report.

Purchase obligations primarily represent commitments for purchases of inventory from our supplier as disclosed in Note 11, Commitments and Contingencies to our consolidated financial statements included in this 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 consolidated financial statements, which have been prepared in accordance with generally accepted accounting principles in the United States. These accounting principles require us to make certain estimates, judgments and assumptions that affect the reported amounts of assets and liabilities as of the date of the financial statements, as well as the reported amounts of revenues and expenses during the periods presented. We 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. While our significant accounting policies are more fully described in Note 2, (Summary of Significant Accounting Policies) to our consolidated financial statements in this Annual Report, the significant accounting estimates that we believe are important to aid in fully understanding and evaluating our reported financial results include the following:

Stock-Based Compensation Expense

We recognize compensation expense for employees based on an estimated grant date fair value using the Black-Scholes option-pricing method. We have elected to account for forfeitures as they occur.

The inputs for the Black-Scholes valuation model require management's significant assumptions. The common share price was determined by using the quoted price on the grant date. The risk-free interest rates were based on the rate for U.S. Treasury securities at the date of grant with maturity dates approximately equal to the expected life at the grant date. The expected life was based on the simplified method in accordance with the SEC Staff Accounting Bulletin Nos. 107 and 110. The expected volatility was estimated based on historical volatility information of the Company and peer companies that are publicly available. Our expected dividend yield assumption is zero as we have never paid dividends and have no present intention to do so in the future.

Valuation of Goodwill

Goodwill is tested annually for impairment, in the fourth quarter, and in interim periods if events or changes in circumstances indicate that the assets may be impaired. We first assess qualitative factors to determine whether it is necessary to perform a quantitative goodwill impairment test. The qualitative factors include economic environment, business climate, market capitalization, operating performance, competition, and other factors. If, after completing such assessment, we determine it is more likely than not that the fair value of a reporting unit is greater than its carrying amount, then there is no need to perform any further testing. If we conclude otherwise, or if we proceed directly to perform a quantitative assessment, then we calculate the estimated fair value of the reporting unit and compare the fair value with the carrying value of the reporting unit. If the carrying amount of the reporting unit exceeds the fair value, we record an impairment loss based on the difference.

If a quantitative assessment is performed, the evaluation includes management estimates of cash flow projections based on internal future projections and/or use of a market approach by looking at market values of comparable companies. Key assumptions include, but are not limited to, future revenue growth, operating margins, capital expenditures, terminal growth rates and discount rates. We also consider our market capitalization as a part of our analysis.

As described further in Note 2, (Summary of Significant Accounting Policies) to our consolidated financial statements in this Annual Report, we performed qualitative goodwill impairment tests as of September 30, 2023 and concluded that it is more likely than not that the fair value of the reporting unit is less than its carrying value. Therefore, we performed a quantitative impairment test and recognized a goodwill impairment charge, impairing goodwill of $77.3 million in full on the consolidated statements of operations and comprehensive loss for the quarter ended September 30, 2023. During the years ended December 31, 2023, the Company recognized no additional impairment losses on goodwill and during the year ended December 31, 2022, no impairment losses were recorded on goodwill.

Business Combinations

We apply the provisions of Accounting Standards Codification (“ASC”) 805, Business Combinations, in accounting for acquisitions. It requires us to recognize separately from goodwill the identifiable assets acquired and the liabilities assumed at the acquisition date fair values. Goodwill as of the acquisition date is measured as the excess of consideration transferred over the net of the acquisition date fair values of the identifiable assets acquired and the liabilities assumed. While we use our best estimates and assumptions to accurately value assets acquired and liabilities assumed at the acquisition date as well as any contingent consideration, where applicable, our estimates are inherently uncertain and subject to refinement. As a result, during the measurement period, which may be up to one year from the acquisition date, we may record adjustments to the assets acquired and liabilities assumed with the corresponding offset to goodwill. Upon the conclusion of the measurement period or final determination of the values of assets acquired or liabilities assumed, whichever comes first, any subsequent adjustments are required to be recorded to our consolidated statements of operations.

Accounting for business combinations requires management to make significant estimates and assumptions, especially at the acquisition date, including estimates for intangible assets, contractual obligations assumed, pre-acquisition contingencies and any contingent consideration, where applicable. Although we believe that the assumptions and estimates we have made in the past have been reasonable and appropriate, they are based in part on historical experience and information obtained from management of the acquired company and are inherently uncertain.

We generally use the income approach to derive the fair value of the above identified intangible assets when accounting for business combinations. This approach calculates fair value by estimating future cash flows attributable to the assets and then discounting these cash flows to a present value using a risk-adjusted discount rate. We selected this method because we believe the income approach most appropriately measures the value of our income producing assets. This approach requires significant management judgment with respect to future volume, revenue and expense growth rates, changes in working capital use, appropriate discount rates, terminal values and other assumptions and estimates. The estimates and assumptions used are consistent with our business plans. The use of alternative estimates and assumptions could increase or decrease the estimated fair value of the asset. Actual results may differ from management’s estimates.

We record contingent consideration resulting from a business combination at its fair value on the acquisition date. On a quarterly basis, we revalue this obligation and record any increase or decrease in fair value as an adjustment to the consolidated statement of operations. Changes to the fair value of the contingent consideration obligation may result from changes to the discount rate, the passage of time, or changes in our estimate of the likelihood or timing of achieving the criteria for payment of the contingent consideration. Significant judgment is employed in determining the appropriateness of these assumptions as of the acquisition date and for each subsequent reporting period. Accordingly, changes in the assumptions described above could have a material impact on the amount of income or expense we record for contingent consideration in any given period.

Convertible Notes Payable

As described further in Note 2, (Summary of Significant Accounting Policies) to our consolidated financial statements in this Annual Report, the Company elected to account for the convertible notes payable issued using the fair value option under ASC 825-10. Such instruments are recognized at estimated fair value on the date of issuance, with changes in fair value after issuance recorded in other (income) expense, net on the consolidated statements of operations as a gain or loss, unless the change is a result of a change in credit risk, in which case such change in estimated fair value is recorded within other comprehensive income.

Increases or decreases in the fair value of the convertible notes payable can result from updates to assumptions such as the expected timing or probability of a qualified financing event, expected volatility or changes in discount rates. Judgment is used in determining these assumptions as of the initial valuation date and at each subsequent reporting period. Updates to assumptions could have a significant impact on the Company’s results of operations in any given period.

Recent Accounting Pronouncements

Refer to Note 2 - Summary of Significant Accounting Policies, in the accompanying notes to our consolidated financial statements included in this Annual Report for a discussion of recent accounting pronouncements.

ITEM 7A. 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 $17.9 million in cash and cash equivalents,$48.8 million in short-term investments, and $35.5 million in restricted cash and cash equivalents and restricted short-term investments as of December 31, 2023. Our short-term investments include highly liquid, investment grade debt securities. Such interest-bearing instruments are exposed to a certain degree of interest rate risk. The primary objective of our investment activities is to preserve principal while at the same time maximizing

yields without significantly increasing risk. We do not enter into investments for trading or speculative purposes and have not used any derivative financial instruments to manage our interest rate risk exposure. To achieve this objective, we invest in highly liquid and high-quality government and other debt securities. To minimize our exposure due to adverse shifts in interest rates, we invest primarily in short-term securities.

Although we are seeing, and expect to continue to see, increased interest rates, due to our investment in highly liquid and high quality government and other debt securities as well as short-term securities, as of the date of this Annual Report, we do not expect anticipated changes in interest rates to have a material effect on our interest rate risk in future reporting periods. Due to the short holding period of our investments and the nature of our investments, a hypothetical change of 100 basis points would have approximately a $0.1 million impact on our investments income or expense.

Our liabilities for acquisition-related contingent consideration, convertible notes payable and purchase option liability are adjusted to fair value each reporting period, are also impacted by changes in interest rates. The risk-free interest rate used to estimate our weighted average cost of capital is a component of the discount rate used to calculate the present value of future cash flows due upon the achievement of certain milestones for the contingent consideration or upon maturity of the convertible notes payable and purchase option liability As a result, any changes in the underlying risk-free interest rate could result in material changes to the fair value of such liabilities and could materially impact the amount of non-cash expense (or income) recorded each reporting period. As a consequence of the U.S. Federal Reserve raising interest rates, the underlying risk-free interest rate we use for purposes of calculating fair value of our liabilities for acquisition-related contingent consideration, convertible notes payable and purchase option liability has increased from our prior reporting periods, but such increase did not have a material impact on our financial statements, and we currently do not expect anticipated future changes to have a material effect in future reporting periods.

Foreign Currency Exchange Rate Risk

We conduct a portion of our business in currencies other than our U.S. dollar functional currency. Transactional exposure arises where transactions occur in currencies other than the functional currency. Transactions in foreign currencies are recorded at the exchange rate prevailing at the date of the transaction. The resulting monetary assets and liabilities are translated into the appropriate functional currency at exchange rates prevailing at the balance sheet date and the resulting gains and losses are reported in foreign currency translation adjustments in the 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 income (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 December 31, 2023 and December 31, 2022, we had minimal assets and liabilities denominated in foreign currencies and expect similar levels of foreign currency denomination in the next 12 months. We believe a hypothetical 10% change in foreign exchange rates as of December 31, 2023 would not have a material impact on our business, financial condition, or results of operations.

Inflation

Geopolitical and macroeconomic events, including the ongoing conflict between Ukraine and Russia and related sanctions, the Israel-Hamas war, and the recent and potential future disruptions in access to bank deposits or lending commitments due to bank failures have contributed to supply chain challenges, which the Company believes have resulted in inflation headwinds, particularly increased logistical costs and raw material prices. In prior periods, the Company experienced increased costs to secure certain component parts in our products and to produce our products at our contract manufacturers. However the Company does 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 as of December 31, 2023 was not significantly impacted by the cost increases we experienced. While the effects of the above-described geopolitical and macroeconomic events, as well as other inflationary pressures, are highly uncertain, as of the date of this Annual Report, 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 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

Index to Consolidated Financial Statements

	Pages
Reports of Independent Registered Public Accounting Firm (BDO USA, P.C.; San Diego, California; PCAOB ID#243)	86
Consolidated Balance Sheets	88
Consolidated Statements of Operations	89
Consolidated Statements of Comprehensive Loss	90
Consolidated Statements of Stockholders' Equity	91
Consolidated Statements of Cash Flows	92
Notes to Consolidated Financial Statements	94

Report of Independent Registered Public Accounting Firm

Stockholders and Board of Directors

Bionano Genomics, Inc.

San Diego, California

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheets of Bionano Genomics, Inc. (the "Company") as of December 31, 2023 and 2022, the related consolidated statements of operations, comprehensive loss, stockholders' equity, and cash flows for each of the years then ended, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2023 and 2022, and the results of its operations and its cash flows for each of the years then ended, in conformity with accounting principles generally accepted in the United States of America.

Going Concern Uncertainty

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As described in Note 1 to the financial statements, the Company has suffered recurring losses from operations that raise substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 1. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's consolidated financial statements based on our audit. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) ("PCAOB") and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

Critical Audit Matters

The critical audit matters communicated below are matters arising from the current period audit of the consolidated financial statements that were communicated or required to be communicated to the audit committee and that: (i) relate to accounts or disclosures that are material to the consolidated financial statements and (ii) involved our especially challenging, subjective, or complex judgments. The communication of the critical audit matters does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matters below, providing separate opinions on the critical audit matters or on the accounts or disclosures to which they relate.

Contingent Consideration – Purigen Biosystems, Inc.

As described in Note 4 to the Company's consolidated financial statements, the Company's contingent consideration is related to potential future payments to be made upon achievement of milestones related to the acquisition of Purigen Biosystems, Inc. (Purigen) in the prior year. The fair value of the Purigen contingent consideration as of December 31, 2023 was approximately $10.9 million, which was calculated by using a probability weighted model and a Monte Carlo simulation.

We identified management's estimates used in determining the probabilities of achieving milestones when the Company estimated the fair value of the Purigen contingent consideration as a critical audit matter. The principal considerations for our

determination were the subjectivity and significant judgement required by management in assessing the probabilities. Auditing these elements involved especially challenging auditor judgment due to the nature and extent of audit effort required to address this matter.

The primary procedures we performed to address this critical audit matter included:

- Evaluating the reasonableness of forecasted sales, including forecasted sales from the launch of a new product, by comparing them to historical sales and assessing them in relation to internal and external analyses.
- Corroborating management's estimated probabilities of achievement by reviewing the Company's internal product development plans.
- Considering disconfirming evidence by performing a market analysis of similar product types to corroborate the feasibility of the milestones.

High Trail Agreement

As described in Notes 4 and 9 to the Company's consolidated financial statements, the Company entered into a securities purchase agreement (the "Purchase Agreement") with High Trail Special Situations LLC in October 2023, pursuant to which the Company issued $80.0 million aggregate principal amount of convertible notes payable, warrants and an option to purchase additional convertible notes ("purchase option liability"). The Company received $75.2 million net proceeds after deducting the expenses and placement agent fees. The convertible notes payable and the purchase option liability were recorded at fair value, which were $89.1 million at issuance and $69.8 million as of December 31, 2023, and $9.8 million at issuance and $8.5 million as of December 31, 2023, respectively. The warrants qualified for classification as equity instruments and were recorded at $0, which represented the residual amount after allocation of proceeds to the convertible notes payable and the purchase option liability at fair value on the issuance date.

We identified (i) the accounting evaluation of all financial instruments within the Purchase Agreement, (ii) the allocation of the proceeds among the elements of the Purchase Agreement, and (iii) the valuation of the convertible notes payable and the purchase option liability at issuance and as of December 31, 2023 as a critical audit matter. Our principal considerations included (i) the existence of accounting complexities related to such evaluation and significant judgments involved in the interpretation of the terms of the agreements and in the application of appropriate accounting guidance, and (ii) the valuation models used in determining the fair value of the convertible notes payable and the purchase option liability were complex and consisted of certain assumptions that were subjective, such as the expected volatility and the debt discount rates utilized in the valuation models. Auditing these elements required especially challenging and complex auditor judgment due to the nature and extent of audit effort required, including the extent of specialized skills or knowledge needed.

The primary procedures we performed to address this critical audit matter included:

- Analyzing: (i) the terms of the Purchase Agreement, and (ii) the Company's application of the relevant accounting literature including the allocation of the proceeds received.
- Utilizing personnel with specialized skills and knowledge in accounting to assist in: (i) evaluating relevant terms of the Purchase Agreement in relation to the appropriate accounting literature, and (ii) assessing the appropriateness of the conclusions reached by the Company.
- Utilizing personnel with specialized skills and knowledge in valuation to assist in: (i) assessing the appropriateness of the valuation models used in estimating the fair value of the convertible notes payable and the purchase option liability; (ii) developing independent estimates of the expected volatility and the debt discount rates.

/s/ BDO USA, P.C.

We have served as the Company's auditor since 2020.

San Diego, CA

March 5, 2024

BIONANO GENOMICS, INC.
Consolidated Balance Sheets

	December 31, 2023	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	$ 17,948,000	$ 5,091,000
Investments	48,823,000	108,095,000
Accounts receivable, net	9,319,000	7,022,000
Inventory	22,892,000	29,761,000
Prepaid expenses and other current assets	6,019,000	7,329,000
Restricted investments	35,117,000	—
Total current assets	140,118,000	157,298,000
Restricted cash	400,000	400,000
Property and equipment, net	23,345,000	18,029,000
Operating lease right-of-use assets	5,633,000	7,222,000
Finance lease right-of-use assets	3,503,000	3,707,000
Intangible assets, net	33,974,000	41,143,000
Goodwill	—	77,289,000
Other long-term assets	7,431,000	2,414,000
Total assets	$ 214,404,000	$ 307,502,000
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 10,384,000	$ 12,534,000
Accrued expenses	8,089,000	10,552,000
Contract liabilities	783,000	871,000
Operating lease liability	2,163,000	2,260,000
Finance lease liability	272,000	285,000
Contingent consideration	—	9,382,000
Purchase option liability (at fair value)	8,534,000	—
Convertible notes payable (at fair value)	69,803,000	—
Total current liabilities	100,028,000	35,884,000
Operating lease liability, net of current portion	3,590,000	5,504,000
Finance lease liability, net of current portion	3,585,000	3,619,000
Contingent consideration, net of current portion	10,890,000	12,970,000
Long-term contract liabilities	154,000	127,000
Total liabilities	$ 118,247,000	$ 58,104,000
Commitments and contingencies (Note 11)		
Stockholders' equity:		
Preferred stock, $0.0001 par value; 10,000,000 shares authorized and no shares issued or outstanding as of December 31, 2023 and 2022	—	—
Common stock, $0.0001 par value, 400,000,000 shares authorized at December 31, 2023 and 2022; 45,752,000 and 29,718,000 shares issued and outstanding at December 31, 2023 and 2022, respectively	5,000	3,000
Additional paid-in capital	677,337,000	599,234,000
Accumulated deficit	(581,208,000)	(348,715,000)
Accumulated other comprehensive income (loss)	23,000	(1,124,000)
Total stockholders' equity	96,157,000	249,398,000
Total liabilities and stockholders' equity	$ 214,404,000	$ 307,502,000

See accompanying notes to the consolidated financial statements.

BIONANO GENOMICS, INC.
Consolidated Statements of Operations

	Years Ended December 31,	
	2023	2022
Revenue:		
Product revenue	$ 26,727,000	$ 20,425,000
Service and other revenue	9,389,000	7,377,000
Total revenue	36,116,000	27,802,000
Cost of revenue:		
Cost of product revenue	20,415,000	15,966,000
Cost of service and other revenue	6,135,000	5,891,000
Total cost of revenue	26,550,000	21,857,000
Operating expenses:		
Research and development	54,032,000	49,047,000
Selling, general and administrative	93,499,000	88,596,000
Goodwill impairment	77,280,000	—
Total operating expenses	224,811,000	137,643,000
Loss from operations	(215,245,000)	(131,698,000)
Other expenses		
Interest income	3,311,000	1,507,000
Interest expense	(5,119,000)	(298,000)
Other income (expenses)	3,449,000	(223,000)
Loss on High Trail Agreement	(18,827,000)	—
Total other income (expense)	(17,186,000)	986,000
Loss before income taxes	(232,431,000)	(130,712,000)
Benefit (provision) for income taxes	(62,000)	(1,884,000)
Net loss	$ (232,493,000)	$ (132,596,000)
Net loss per share, basic and diluted	$ (6.81)	$ (4.58)
Weighted-average common shares outstanding, basic and diluted	34,150,000	28,921,000

See accompanying notes to the consolidated financial statements.

BIONANO GENOMICS, INC.
Consolidated Statements of Comprehensive Loss

	Years Ended December 31,	
	2023	2022
Net Loss:	$ (232,493,000)	$ (132,596,000)
Other comprehensive income (loss):		
Unrealized gain (loss) on investment securities	1,082,000	(548,000)
Foreign currency translation adjustments	65,000	(37,000)
Other comprehensive income (loss)	$ 1,147,000	$ (585,000)
Total comprehensive loss	$ (231,346,000)	$ (133,181,000)

See accompanying notes to the consolidated financial statements.

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

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Income (Loss)	Total Stockholders' Equity
	Shares	Amount				
Balance at January 1, 2022	28,960,000	$ 3,000	$ 553,773,000	$ (216,119,000)	$ (539,000)	$ 337,118,000
Stock option exercises	47,000	—	343,000	—	—	343,000
Stock-based compensation expense	—	—	22,417,000	—	—	22,417,000
Issue common stock, net of issuance costs	664,000	—	22,551,000	—	—	22,551,000
Issue stock for employee stock purchase plan	30,000	—	150,000	—	—	150,000
Issuance of common stock due to the vesting of restricted stock units, net of shares withheld to cover taxes	17,000	—	—	—	—	—
Issue stock for acquisition	—	—	—			—
Net loss	—	—	—	(132,596,000)	—	(132,596,000)
Other comprehensive loss	—	—	—	—	(585,000)	(585,000)
Balance at December 31, 2022	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	—	—	15,178,000	—	—	15,178,000
Issue common stock, net of issuance costs	12,507,000	1,000	56,313,000	—	—	56,314,000
Issue stock for employee stock purchase plan	30,000	—	108,000	—	—	108,000
Issuance of common stock due to the vesting of restricted stock units, net of shares withheld to cover taxes	1,000	—	(61,000)	—	—	(61,000)
Issuance of common stock for convertible notes payable	3,492,000	1,000	6,542,000	—	—	6,543,000
Net loss	—	—	—	(232,493,000)	—	(232,493,000)
Other comprehensive income	—	—	—	—	1,147,000	1,147,000
Balance at December 31, 2023	45,752,000	$ 5,000	$ 677,337,000	$ (581,208,000)	$ 23,000	$ 96,157,000

See accompanying notes to the consolidated financial statements.

BIONANO GENOMICS, INC
Consolidated Statements of Cash Flows

	Years Ended December 31,	
	2023	2022
Operating activities:		
Net loss	$ (232,493,000)	$ (132,596,000)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization expense	13,708,000	9,621,000
Goodwill impairment	77,280,000	—
Amortization of financing lease right-of-use asset	204,000	219,000
Amortization (accretion) of interest on securities	(539,000)	638,000
Net realized loss (gain) on investments	23,000	66,000
Non-cash lease expense	56,000	478,000
(Benefit) expense from deferred income taxes	—	1,760,000
Stock-based compensation	15,178,000	22,417,000
Cost of leased equipment sold to customer	382,000	204,000
Change in fair value of contingent consideration	(1,462,000)	316,000
Change in fair value of convertible notes payable and option liability	(575,000)	—
Loss on High Trail Agreement	18,826,000	—
Contingent consideration cash payment in excess of acquisition-date fair value	(1,000,000)	—
Changes in operating assets and liabilities (net of assets acquired and liabilities assumed in acquisition)		
Accounts receivable	(2,296,000)	(2,251,000)
Inventory	(4,150,000)	(23,676,000)
Prepaid expenses and other current assets	1,213,000	(3,197,000)
Other assets	(5,020,000)	(1,130,000)
Accounts payable	(1,995,000)	1,949,000
Accrued expenses and contract liabilities	(2,521,000)	366,000
Net cash used in operating activities	(125,181,000)	(124,816,000)
Investing activities:		
BioDiscovery acquisition, return of purchase consideration from escrow	—	694,000
Purigen acquisition, return of purchase consideration from escrow	96,000	—
Purigen acquisition, net of cash acquired	—	(31,344,000)
Purchases of property and equipment	(1,691,000)	(2,408,000)
Sale of property and equipment	—	26,000
Construction in process	—	(792,000)
Purchases of intangible assets	—	(102,000)
Purchase of available for sale securities	(111,264,000)	(84,195,000)
Sale and maturities of available for sale securities	137,017,000	200,888,000
Net cash provided by investing activities	24,158,000	82,767,000
Financing activities:		
Principal payments of financing lease liability	(47,000)	(36,000)
Proceeds from sale of common stock	57,697,000	23,128,000
Offering expenses on sale of common stock	(1,444,000)	(578,000)
Proceeds from sale of common stock under employee stock purchase plan	107,000	150,000
Proceeds from warrant and option exercises	23,000	343,000
Proceeds from High Trail Agreement	80,000,000	—
Payments on convertible notes payable	(9,000,000)	—
Debt issuance costs related to High Trail Agreement	(4,521,000)	—
Contingent consideration milestone payment	(9,000,000)	—
Net cash provided by financing activities	113,815,000	23,007,000
Effect of exchange rates on cash and cash equivalents and restricted cash	65,000	(38,000)
Net increase (decrease) in cash and cash equivalents and restricted cash	12,857,000	(19,080,000)

	Years Ended December 31,	
	2023	2022
Cash and cash equivalents and restricted cash at beginning of period	5,491,000	24,571,000
Cash and cash equivalents and restricted cash at end of period	$ 18,348,000	$ 5,491,000
Reconciliation of cash and cash equivalents and restricted cash reported within the consolidated balance sheets to the total amounts reported on the consolidated statements of cash flows		
Cash and cash equivalents	17,948,000	5,091,000
Restricted cash	400,000	400,000
Total cash and cash equivalents and restricted cash at end of period	$ 18,348,000	$ 5,491,000
Supplemental disclosure of cash flow information		
Cash paid for interest	$ 1,648,000	$ 298,000
Cash paid for operating lease liabilities	$ 2,586,000	$ 1,622,000
Supplemental disclosure of non-cash financing and investing activity		
Contingent consideration related to Purigen acquisition	$ —	$ 12,970,000
Operating lease liabilities resulting from obtaining and modifying right-of-use assets	$ —	$ 517,000
Transfer of instruments and servers from inventory into property and equipment, net	$ 10,979,000	$ 7,244,000
Property and equipment included in accounts payable	$ 6,000	$ 90,000
Debt issuance costs included in accounts payable	$ 150,000	$ —
Conversion of convertible notes payable into common stock at fair value	$ 6,542,000	$ —

See accompanying notes to the consolidated financial statements.

BIONANO GENOMICS, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

1. Organization and Operations

Description of Business

Bionano Genomics, Inc. (collectively, with its consolidated subsidiaries, the "Company") is a provider of genome analysis solutions that can enable researchers and clinicians to reveal answers to challenging questions in biology and medicine. The Company offers optical genome mapping ("OGM") solutions for applications across basic, translational and clinical research, and for other applications including bioprocessing. Through its Lineagen, Inc. (doing business as Bionano Laboratories, "Bionano Laboratories") business, the Company also provides diagnostic testing for patients with clinical presentations consistent with autism spectrum disorder and other neurodevelopmental disabilities. Through its BioDiscovery, LLC ("BioDiscovery") business, the Company also offers platform-agnostic software solution, which integrates next-generation sequencing and microarray data designed to provide analysis, visualization, interpretation and reporting of copy number variants, single-nucleotide variants and absence of heterozygosity across the genome in one consolidated view. Through its Purigen Biosystems Inc. ("Purigen") business, the Company offers nucleic acid extraction and purification solutions using proprietary isotachophoresis ("ITP") technology.

Liquidity and Going Concern

The Company has experienced recurring net losses from operations, negative cash flows from operating activities, and significant accumulated deficit since its inception and expects to continue to incur net losses into the foreseeable future. As of December 31, 2023, the Company had approximately $17.9 million in cash and cash equivalents, $48.8 million in short-term investments, $35.5 million in restricted cash and cash equivalents and restricted short-term investments, and working capital of $40.1 million.

The Company has an accumulated deficit of $581.2 million as of December 31, 2023. In 2023, the Company used $125.2 million cash in operations.

As of December 31, 2023, the Company reported $69.8 million of Notes at fair value, which are classified as current. At the holder's option, as of December 31, 2023, the Company may have been required to redeem $62.1 million of Notes at the Repayment Price (as defined in Note 9 (High Trail Agreement)) in 2024. Additionally, the Company will be required to pay a retirement fee to the holder based on amounts redeemed when the outstanding balance is paid in full, which as of December 31, 2023, was estimated at $4.4 million assuming full redemption and no further conversions. On January 1, 2024, and February 1, 2024, the holders redeemed an aggregate of $9.0 million of Notes, at the Repayment Price of $10.4 million. In February 2024, in connection with the Letter Agreement and Amendment (each as defined in Note 9 (High Trail Agreement)) the Company redeemed an aggregate of $27.7 million of Notes for a total redemption payment of approximately $31.9 million, together with a retirement fee of approximately $3.2 million. Following the redemptions we have $24.3 million of principal on the Notes outstanding. See Note 9 (High Trail Agreement) for additional information.

Management expects operating losses and negative cash flows to continue for at least the next year as the Company continues to incur costs related to research and commercialization efforts. Management has prepared cash flows forecasts which indicate that based on the Company's expected operating losses and negative cash flows, there is substantial doubt about the Company's ability to continue as a going concern within twelve months after the date that the financial statements for the year ended December 31, 2023, are issued. Management's ability to continue as a going concern is dependent upon its ability to raise additional funding. Management's plans to raise additional capital to fulfill its operating and capital requirements for at least 12 months include public or private equity or debt financings. However, the Company may not be able to secure such financing in a timely manner or on favorable terms, if at all.

The 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.

2. Summary of Significant Accounting Policies

Use of Estimates

The preparation of financial statements in conformity with U.S. generally accepted accounting principles ("U.S. GAAP") requires management to make significant estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting periods. Significant estimates and assumptions used by management include but are not limited to revenue recognition, the fair value of financial instruments measured at fair value, fair value of contingent consideration, the recoverability of long-lived assets, fair value of reporting units, equity based compensation expense, and net deferred tax assets (and related valuation allowance). Although the Company regularly assesses these estimates, actual results could differ

materially from these estimates. Changes in estimates are recorded in the period in which they become known. The Company bases its estimates on historical experience and various other assumptions that it believes to be reasonable under the circumstances.

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 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 consolidated financial statements are prepared in accordance with U.S. GAAP and include the accounts of the Company's 100%-owned subsidiaries. All intercompany transactions and balances have been eliminated in consolidation.

Restructuring Expenses

The Company's restructuring expense consists primarily of actions taken in May and October 2023 in order to reduce costs and improve operations and manufacturing efficiency. This was 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 reduction in force the Company initiated in May and October 2023, such plans are intended to decrease expenses and maintain a streamlined organization to support its business.

Business Combinations

The Company accounted for its acquisition of Purigen using the acquisition method of accounting pursuant to Accounting Standards Codification Topic 805, Business Combinations ("ASC 805"). See Note 14, (Acquisitions), for a more fulsome discussion of our acquisition of Purigen. Under ASC 805, the tangible and identifiable intangible assets acquired and liabilities assumed in a business combination are recorded based on their estimated fair values as of the acquisition date. Any excess purchase price over the estimated fair value assigned to the tangible and identifiable intangible assets acquired and liabilities assumed is recorded to goodwill.

The Company estimated the fair value of identifiable intangible assets acquired with the assistance of independent valuations that use information and assumptions provided by the Company's management.

Under ASC 805, acquisition-related transaction costs (such as advisory, legal, valuation, other professional fees) are expensed in the statements of operations in the periods incurred.

Cash and Cash Equivalents

Cash equivalents primarily represent funds invested in readily available money market accounts. The Company has not experienced any losses in such accounts. The Company believes that it is not exposed to any significant credit risk on cash and cash equivalents.

Restricted Cash and Investments

Restricted cash consists of cash restricted from withdrawal and usage and represents funds that are restricted related to the lease assumed in the acquisition of Purigen, which is further discussed in Note 14. As of December 31, 2023, restricted investments consisted of the proceeds received from the Private Placement Notes as described further in Note 9 (High Trail Agreement) that was deposited into a restricted account subject to an account control agreement that only permits funds to be released once per calendar month upon the satisfaction of certain funding conditions specified in the Notes.

Fair Value Measurements

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

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

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

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

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

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

Investment Securities

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

Concentrations

Credit Risks

Financial instruments, which potentially subject the Company to significant concentration of credit risk, consist primarily of cash and cash equivalents and accounts receivable. The Company maintains deposits in federally insured major financial institutions in excess of federally insured limits. The Company has not experienced any losses in such accounts and management believes that the Company is not exposed to significant credit risk due to the financial position of the depository institution in which those deposits are held.

The Company’s customers are located throughout the world. The Company generally does not require collateral from its customers. More information on accounts receivable is contained in the paragraph titled “Accounts Receivable” below.

Sources of Materials and Products

The materials and components for the Company’s product offerings are currently obtained from single or limited sources. The Company competes with other companies for production capacity, therefore, the Company is exposed to a risk of inventory being unavailable at acceptable prices, or at all, if suppliers are unable (or decide) to provide sufficient levels of materials and components and the Company is unable to identify alternative suppliers.

Accounts Receivable and Allowance for Credit Losses

	December 31, 2023	December 31, 2022	December 31, 2021
Accounts receivable, net:			
Accounts receivable, trade	$ 9,802,000	$ 7,315,000	$ 5,624,000
Less allowance for credit losses	(483,000)	(293,000)	(690,000)
	$ 9,319,000	$ 7,022,000	$ 4,934,000

Changes to the allowance for credit losses from December 31, 2021 to December 31, 2023 were as follows:

	Allowance for Credit Losses
Balance as of January 1, 2022	$ (690,000)
Provision for expected credit loss	(144,000)
Write-offs	541,000
Balance as of January 1, 2023	(293,000)
Provision for expected credit loss	(227,000)
Write-offs	37,000
Balance as of December 31, 2023	$ (483,000)

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

For OGM products and services, credit is extended based upon an evaluation of each customer's credit history, financial condition, and other factors. Estimates of allowances for credit losses are determined by evaluating individual customer circumstances, historical payment patterns, length of time past due, forecasts about the future, and economic and other factors. Provision for expected credit losses is recorded as necessary to maintain an appropriate level of allowance for credit losses in selling, general and administrative expense. Amounts are charged to the allowance for credit losses when collection efforts have been exhausted and are deemed uncollectible.

Accounts receivable is subject to concentration risk whenever a customer has a balance that meets or exceeds 10% of the Company's total accounts receivable balance. As of December 31, 2023 and 2022, no customers met or exceeded 10% of the Company's total accounts receivable balance.

Inventory

Inventory is stated at the lower of cost or net realizable value, on a first-in, first-out basis. Inventory is valued at standard cost. Inventory includes raw materials, work in process, and finished goods that may be used in the research and development process and such items are expensed as consumed or expired. Provisions for slow-moving, excess, and obsolete inventories are estimated based on product life cycles, historical experience, and usage forecasts.

The components of inventories, net of reserve, are as follows:

	December 31,	
	2023	2022
Inventory:		
Raw materials	$ 7,567,000	$ 5,319,000
Work in process	9,790,000	7,055,000
Finished goods	10,245,000	17,387,000
	$ 27,602,000	$ 29,761,000
Inventories current	$ 22,892,000	$ 29,761,000
Inventories non-current (included in other long-term assets)	$ 4,710,000	$ —

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 December 31, 2023, $4.7 million of inventories were included in Other long term assets.

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

Long-lived assets consist of property and equipment and acquired finite-lived intangible assets. Property and equipment generally consist of laboratory equipment, computer and office equipment, furniture and fixtures, and leasehold improvements. Property and equipment are recorded at cost and depreciated or amortized using the straight-line method over the estimated useful lives of the assets (generally three to five years, or the remaining term of the lease for leasehold improvements, whichever is shorter). Repairs and maintenance costs are charged to expense as incurred.

Intangible assets acquired in a business combination are recognized separately from goodwill and are initially recognized at their fair value at the acquisition date. Finite-lived intangible assets are amortized over the estimated useful life of the asset on a basis that approximates the pattern of economic benefit.

As a result of the Lineagen, BioDiscovery, and Purigen acquisitions, the Company recorded intangible assets, which consist of trade name intangibles, customer relationship intangibles, and a developed technology intangible, which are amortized on a straight-line basis over their estimated useful lives of five years, with the exception of the developed technology intangible acquired through the acquisition of Purigen, which is amortized over fifteen years. Straight-line amortization was determined to be materially consistent with the pattern of expected use of the 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 year ended December 31, 2023, the Company experienced a triggering event that required evaluation of our asset groups for impairment. The Company performed a recoverability test and there was sufficient cushion related to the cash flows of each of our asset groups. There was no indications of impairment of intangible assets during the year ended December 31, 2022.

During the years ended December 31, 2023 and 2022, the Company recognized no impairment losses on long-lived assets. Substantially all of the Company's long-lived assets are located in the U.S.

Contingent Consideration

The Company recorded contingent consideration resulting from a business combination at its fair value on the acquisition date. On a quarterly basis, the Company revalues this obligation and records any increase or decrease in fair value as an adjustment to the consolidated statement of operations. Changes to the fair value of the contingent consideration obligation may result from changes to the discount rate, the passage of time, or changes in the estimate of the likelihood or timing of achieving the criteria for payment of the contingent consideration.

Goodwill

Changes to goodwill from December 31, 2021 to December 31, 2023 were as follows:

	Goodwill
Balance as of December 31, 2021	$ 56,160,000
Acquisitions	22,651,000
Measurement period adjustments	(1,522,000)
Balance as of December 31, 2022	77,289,000
Measurement period adjustments	(9,000)
Goodwill impairment	(77,280,000)
Balance as of December 31, 2023	$ —

Goodwill arises when the purchase price of an acquired business exceeds the fair value of the identifiable net assets acquired, with such excess recorded as goodwill on the balance sheet. Goodwill is not subsequently amortized. Goodwill is reviewed for impairment annually (during the fourth quarter) or more frequently if indications of impairment exist. Goodwill is assigned to specific reporting units for purposes of impairment assessment. The Company has determined that it has a single operating segment and a single reporting unit.

In testing goodwill for impairment, the Company will first assess qualitative factors to determine whether it is more likely than not that the fair value of the reporting unit is less than its carrying amount. If the qualitative assessment indicates that it is more likely than not that the fair value of the reporting unit is less than its carrying value, then the Company will perform a quantitative impairment analysis by comparing the fair value of the reporting unit to the carrying value of the reporting unit, including goodwill. An impairment charge for goodwill is recognized for the amount by which the carrying value of the reporting unit exceeds its fair value, not to exceed the total goodwill allocated to the reporting unit.

During the quarter ended September 30, 2023, the Company performed a qualitative assessment of goodwill impairment which included an evaluation of changes in industry, market and macroeconomic conditions as well as consideration of our financial performance and any significant trends, including a sustained decline in our stock price. Our qualitative assessment indicated that it is more likely than not that the fair value of the reporting unit was less than its carrying value as of September 30, 2023; therefore, we performed a quantitative impairment analysis. The Company determined the fair value of its reporting unit using a

combination of the income and market approaches. The Company placed a 50% weighting on the market and income approach methods. The determination of fair value using a market approach requires management to make significant assumptions related to the determination of an appropriate group of peer companies, and market revenue multiples from within the selected group of peer companies. Under the income approach, the Company uses a discounted cash flow method, or DCF, to estimate the fair value of a reporting unit. Estimates and assumptions used in the income approach included projected cash flows and a discount rate. Discount rates were determined using a weighted average cost of capital for risk factors specific to the Company and other market and industry data. Annual estimated cash flows and a terminal value are then discounted to their present value at an appropriate discount rate to obtain an indication of fair value. The discount rate utilized reflects estimates of required rates of return for investments that are seen as similar to an investment in the reporting unit. Because DCF analyses are based on management's long-term financial projections and require significant estimates and judgments, the market approach is conducted in addition to the income approach in estimating the fair value of a reporting unit. Under the market approach, the Company uses both a Guideline Public Company Method and Guideline Transactions Method to estimate the fair value of equity and the business enterprise value of a reporting unit. The Guideline Public Company approach uses financial metrics from similar public traded companies to estimate fair value. The Guideline Transaction Method calculates fair value by analyzing the actual prices paid for recent mergers and acquisitions in the industry. The Company believes that the current methodology used in determining the fair value at its reporting unit represent its best estimates. In addition, the Company compares the aggregate fair value of the reporting unit to its overall market capitalization, including an estimated control premium based upon control premiums observed in comparable market transactions and other factors. During the quarter ended September 30, 2023, the carrying value of equity of the Company's reporting unit exceeded its enterprise wide fair value of equity and the Company recognized a goodwill impairment charge, impairing goodwill of $77.3 million in full on the consolidated statements of operations. During the year ended December 31, 2023, the Company recognized no additional impairment losses on goodwill and during the year ended December 31, 2022, no impairment losses were recorded on goodwill.

Leases

Right-of-use ("ROU") assets represent our right to use an underlying asset during the lease term, and lease liabilities represent our obligation to make lease payments arising from the lease. Operating leases are included in operating lease right-of-use assets and operating lease liabilities in the consolidated balance sheets, while finance leases are included in finance lease right-of-use assets and finance lease liabilities.

Lease assets and liabilities are recognized at commencement based on the present value of lease payments over the lease term. The Company generally uses its incremental borrowing rate based on the estimated rate of interest for collateralized borrowing over a similar term of the lease payments. The ROU assets also include any prepaid or accrued lease payments and is adjusted for lease incentives and initial direct costs.

Lease terms may include options to extend or terminate the lease which are recognized when it is reasonably certain that the Company will exercise that option. The Company has not included any options to extend in their lease term. Leases with terms of 12 months or less are not recorded on the balance sheet. Lease expense is recognized on a straight-line basis over the lease terms, or in some cases, the useful life of the underlying asset. Variable lease payments are excluded from the measurement of ROU assets and lease liabilities and are recognized in the period in which the obligation for those payments is incurred. The Company accounts for the lease and non-lease components as a single lease component for all classes of underlying assets.

Convertible Notes Payable

The Company elected to account for convertible notes issued in October 2023 using the fair value option under ASC 825-10, Recognition and Measurement of Financial Assets and Financial Liabilities (or "ASC 825-10"). Such instruments are recognized at estimated fair value on the date of issuance, with changes in fair value after issuance recorded in other (income) expense, net on the consolidated statements of operations as a gain or loss, unless the change is a result of a change in credit risk, in which case such change in estimated fair value is recorded within other comprehensive income. Direct issuance costs are expensed as incurred and are included in interest expense in the consolidated statements of operations.

Increases or decreases in the fair value of the convertible notes payable can result from updates to assumptions such as the expected volatility or changes in discount rates. Judgment is used in determining these assumptions as of the initial valuation date and at each subsequent reporting period.

Financial Instruments with Characteristics of Both Liabilities and Equity

The Company accounts for issued warrants either as a liability or equity in accordance with ASC 480-10, Distinguishing Liabilities From Equity (or "ASC 480-10"), and ASC 815-40, Derivatives and Hedging: Contracts in Entity's Own Equity (or "ASC 815-40"). Under ASC 480-10, warrants are considered a liability if mandatorily redeemable and require settlement in cash, other assets, or a variable number of shares. If warrants do not meet liability classification under ASC 480-10, the Company considers the requirements of ASC 815-40 to determine whether the warrants should be classified as a liability or as equity. Under ASC 815-40, contracts that may require settlement for cash that are not under the control of the Company are liabilities, regardless of the probability of the occurrence of the triggering event. Liability-classified warrants are measured at

fair value on the date of issuance and on a recurring basis at the end of each reporting period with any change in fair value after issuance recorded in other (income) expense, net on the consolidated statements of operations as a gain or loss. If warrants do not require liability classification under ASC 815-40, in order to conclude warrants should be classified as equity, the Company assesses whether the warrants are indexed to its common stock and whether the warrants are classified as equity under ASC 815-40 or under another applicable GAAP standard. Equity-classified warrants are accounted for at fair value on the issuance date, or in a bundled transaction on a residual basis based on an allocation of proceeds first to the instruments measured at fair value on a recurring basis, and are not subsequently remeasured. The Company's outstanding warrants do not meet the requirements for liability classification under ASC-480-10 or ASC-815-40. Therefore, the Company's outstanding warrants are classified as equity as of and for the years ended December 31, 2023 and 2022.

Revenue Recognition

The Company generates revenue primarily from the sale of products and services. The Company considers revenue to be earned when all of the following criteria are met: the Company has a contract with a customer that creates enforceable rights and obligations; promised products or services are identified; the transaction price, or the amount the Company expects to receive, including an estimate of uncertain amounts subject to a constraint to ensure revenue is not recognized in an amount that would result in a significant reversal upon resolution of the uncertainty, is determinable; and the Company has transferred control of the promised items to the customer. A performance obligation is a promise in a contract to transfer a distinct good or service to the customer, and is the unit of account in the contract. The transaction price for the contract is measured as the amount of consideration the Company expects to receive in exchange for the goods and services expected to be transferred. A contract's transaction price is allocated to each distinct performance obligation and recognized as revenue when, or as, control of the distinct good or service is transferred.

The Company provides assurance type warranties on many of its products. As customers cannot purchase such warranties independently of the products under the contract and they are not priced separately, assurance type warranties are not separate performance obligations.

The Company recognizes a receivable when we have an unconditional right to payment, which is generally at the time of delivery of software, consumables and instruments, including any extended warranties, or at the time services are rendered. Payment terms are typically 30 days for sales to customers in the United States but may be longer in international markets. The Company treats shipping and handling costs performed after a customer obtains control of the good as a fulfillment cost and records these costs within selling, general and administrative expenses, less any amounts reimbursed by the customer, when the corresponding revenue is recognized.

Revenue is recorded net of discounts and sales tax. The Company's contracts typically do not provide for product returns or refunds. In general, estimates of variable consideration and constraints are not material to the Company's financial statements. Employee sales commissions are recorded as selling, general and administrative expenses when incurred as the amortization period for such costs, if capitalized, would have been one year or less.

Product revenue recognition

Product revenue consists of sales of our OGM systems and related consumables, as well as sales of software. These products are sold primarily through a direct sales force, and within international markets, there is more reliance on distributors. In addition, the Company provides the OGM systems to certain customers under its reagent rental program, under which the Company provides OGM systems to customers at no cost and the customers agree to purchase minimum quantities of consumables.

Transfer of control for the Company's products is generally at shipment or delivery, depending on contractual terms, but occurs when title and risk of loss transfers to the customer which represents the point in time when the customer obtains control of the product. Transfer of control of software is recognized at the point-in-time when the software license is transferred to the customer. As such the Company's performance obligation related to product sales is satisfied at a point in time.

For transfers of instruments and consumables to customers under the Company's rental reagent program, the Company allocates the total contract consideration between the instrument and the consumables based on estimates of stand-alone selling prices, and recognizes the instrument revenue evenly over the rental period, and the consumables revenue when the consumables are delivered. Rental revenue related to the reagent rental program recognized over-time totaled $ 1.1 million and $0.4 million during the years ended December 31, 2023 and 2022, respectively.

Revenue related to software license maintenance agreements is recognized over-time based on the contract term. Revenue recognized over-time related to software sales totaled $ 0.4 million and $0.4 million during the years ended December 31, 2023 and 2022, respectively.

Service and other revenue recognition

Service and other revenue primarily consist of revenue from diagnostic testing services, license maintenance agreements, software hosting arrangements, and support, repair and maintenance services and extended warranties on OGM systems.

Revenue from the completion of diagnostic testing services is initially recorded at the estimated consideration the Company expects to receive from contractual and non-contractual payors, and is subject to adjustment based on the amount actually collected. The Company performs its obligation under a contract with a customer by processing diagnostic tests and communicating the test results, which the Company has determined is the point at which control is transferred to the customer for revenue recognition purposes.

Revenue for hosting arrangements is recognized over-time on a usage basis as the customer processes the number of genetic samples purchased with the software. Hosting arrangements revenue recognized over-time totaled $ 0.7 million and $0.5 million during the years ended December 31, 2023 and 2022, respectively.

Revenue from support and maintenance contracts and extended warranties is recognized over time based on the contract term, which represents a faithful depiction of the transfer of goods and services given the stand-ready nature of the performance obligations. Service revenue related to repairs and customer sample evaluations is recognized as the services are performed based on the specific nature of the service. Warranty and maintenance revenue recognized over-time totaled $ 0.9 million and $0.7 million during the years ended December 31, 2023 and 2022, respectively.

Remaining Performance Obligations

As of December 31, 2023, the estimated revenue expected to be recognized in the future related to performance obligations that are unsatisfied was $0.9 million. These remaining performance obligations primarily relate to extended warranty and support and maintenance obligations, as well as obligations related to software under hosting arrangements. The Company expects to recognize approximately 81.7% in 2024, 12.6% in 2025 and 2.5% in 2026 and 3.3% in 2027 and thereafter.

We periodically review the warranty reserve for adequacy and adjust the warranty accrual, if necessary, based on actual experience and estimated costs to be incurred. Warranty expense is recorded as a component of cost of product revenue. The Company’s liability for product warranties provided under its agreements with customers was $0.4 million and $0.5 million as of December 31, 2023 and 2022, respectively. Warranty expense recorded in cost of goods sold totaled $ 0.6 million and $1.0 million during the years ended December 31, 2023 and 2022, respectively.

Contract Assets and Liabilities

Contract assets primarily relate to the Company’s conditional right to consideration for work completed but not billed at the reporting date. Contract assets at the beginning and end of the period, as well as the changes in the balance, were immaterial.

Contract liabilities primarily relate to payments received from customers in advance of performance under the contract. The Company records a contract liability, or deferred revenue, when it has an obligation to provide service, and to a much lesser extent product, to the customer and payment is received or due in advance of performance. Contract liabilities primarily relate to support and maintenance contracts and extended warranty obligations. Contract liabilities are classified as other current liabilities and other long-term liabilities on the consolidated balance sheets. The Company recognized revenue of $1.4 million and $0.7 million during the years ended December 31, 2023 and 2022, respectively, which was included in the contract liability balance at the end of the previous year.

Distributor Transactions

In certain markets, the Company sells products and provides services to customers through distributors that specialize in life sciences products. In cases where the product is delivered to a distributor, revenue recognition generally occurs when the distributors obtains control of the product. The terms of sales transactions through distributors are generally consistent with the terms of direct sales to customers and do not contain return rights. Distributor sales transactions typically differ from direct customer sales as they do not require the Company’s services to install the instrument at the end customer or perform the services for the customer that are beyond the standard warranty in the first year following the sale. These transactions are accounted for in accordance with the Company’s revenue recognition policy described herein.

Cost of Revenue

Cost of revenue for products consists of the Company’s raw material parts costs and associated freight, shipping and handling costs, contract manufacturing costs, royalties due to third parties, 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 salaries and other personnel costs, and facility costs associated with costs related to warranties and other costs of servicing equipment at customer sites, and performance of diagnostics services.

Research and Development Costs

Costs incurred for research and product development, including acquired technology and costs incurred for technology in the development stage, are expensed as incurred.

Patent Costs

Costs related to filing and pursuing patent applications are recorded as selling, general and administrative expense and expensed as incurred since recoverability of such expenditures is uncertain.

Stock-based Compensation

The Company issues stock-based awards as compensation to employees and directors. Stock-based awards may include stock options, restricted stock units, and performance stock units. These awards are accounted for as equity awards. To-date, the Company recognizes stock-based compensation expense net of actual forfeitures on a straight-line basis over the underlying award's requisite service period, which is generally the vesting period, as measured using the award's grant date fair value. The Company determines grant date fair value of stock option awards using the Black-Scholes option-pricing model. The fair value of restricted stock units and performance stock units are determined using the closing price of the Company's common stock on the grant date. For service based vesting grants, expense is recognized over the requisite service period based on the number of options or shares expected to ultimately vest. For performance stock units, expense is recognized over the implicit service period, assuming vesting is probable. No expense is recognized for the performance stock units if it is not probable the vesting criteria will be satisfied.

Income Taxes

The Company accounts for income taxes under the asset and liability method, which requires the recognition of deferred tax assets and liabilities for the expected future tax consequences of events that have been included in the financial statements. Under this method, deferred tax assets and liabilities are determined on the basis of the differences between the financial statements and tax basis of assets and liabilities using enacted tax rates in effect for the year in which the differences are expected to reverse. The effect of a change in tax rates on deferred tax assets and liabilities is recognized in income in the period that includes the enactment date.

The Company recognizes deferred tax assets to the extent that the Company believes these assets are more likely than not to be realized. In making such a determination, management considers all available positive and negative evidence, including future reversals of existing taxable temporary differences, projected future taxable income, tax-planning strategies, and results of recent operations. If management determines that the Company would be able to realize its deferred tax assets in the future in excess of their recorded amount, management would make an adjustment to the deferred tax asset valuation allowance, which would reduce the provision for income taxes. Changes in the valuation allowance when they are recognized in the provision for income taxes may result in a change in the estimated annual effective tax rate.

The Company recognizes the impact of uncertain tax positions at the largest amount that is "more likely than not" to be sustained upon audit by the relevant taxing authority. An uncertain tax position will not be recognized if it does not have a greater than 50% likelihood of being sustained. The Company recognizes interest and penalties related to unrecognized tax benefits within income tax expense. Any accrued interest and penalties are included within the related tax liability.

Segment Reporting

Operating segments are identified as components of an enterprise about which separate discrete financial information is available for evaluation by the chief operating decision-maker in making decisions regarding resource allocation and assessing performance. The Company's chief operating decision-maker, the Chief Executive Officer, views the Company's operations and manages its business as one operating segment.

Net Loss Per Share

Basic net loss per share is calculated by dividing the net loss by the weighted-average number of common shares outstanding for the period. Diluted net loss per share is computed by dividing the net loss by the weighted average number of common shares and common share equivalents outstanding for the period. Common share equivalents are only included when their effect is dilutive. The Company's potentially dilutive securities which include convertible notes payable into common stock and outstanding warrants to purchase stock under the High Trail Agreement, 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 due to the Company's net loss position.

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

	Years Ended December 31,	
	2023	2022
Common stock options	3,268,000	2,402,000
Common warrants	21,696,000	436,000
Convertible notes payable into common stock	21,301,000	—
RSUs	239,000	10,000
PSUs	29,000	29,000
Total	46,533,000	2,877,000

Recently Adopted Accounting Pronouncements

In February 2016, the Financial Accounting Standards Board (“FASB”) issued Accounting Standards Update (“ASU”) No. 2016-13, Financial Instruments - Credit Losses: Measurement of Credit Losses on Financial Instruments (ASU 2016-13), which amends the impairment model by requiring entities to use a forward-looking approach based on expected losses to estimate credit losses on certain types of financial instruments, including trade receivables and available for sale debt securities. For trade receivables and other instruments, entities will be required to use a new forward-looking expected loss model that generally will result in the earlier recognition of allowances for losses. For available-for-sale debt securities with unrealized losses, the losses will be recognized as allowances rather than as reductions in the amortized cost of the securities. The Company adopted ASU 2016-13 as of January 1, 2023.

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

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

3. Revenue from Contracts with Customers

Revenue by Source

	Years Ended December 31,	
	2023	2022
Instruments	$ 9,999,000	$ 8,567,000
Consumables	11,157,000	6,731,000
Software	5,571,000	5,127,000
Total product revenue	26,727,000	20,425,000
Services and other	9,389,000	7,377,000
Total revenue	$ 36,116,000	$ 27,802,000

Revenue by Geographic Location

	Years Ended December 31,			
	2023		2022	
	$	%	$	%
Americas	$ 18,020,000	50 %	$ 13,862,000	50 %
EMEA	12,963,000	36 %	8,960,000	32 %
Asia Pacific	5,133,000	14 %	4,980,000	18 %
Total	$ 36,116,000	100 %	$ 27,802,000	100 %

The tables above provide revenue from contracts with customers by source and geographic location 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, Australia and India. For the years ended December 31, 2023 and 2022, sales in the United States represented 44% and 42% of revenues, respectively. During the years ended December 31, 2023 and 2022, sales in China accounted for 10% and 14% of revenues, respectively. No other countries represented greater than 10% of revenue during the years ended December 31, 2023 and 2022.

4. 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 in the Consolidated Balance Sheets:

	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	$ 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

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

Money market funds are classified as cash equivalents on the consolidated balance sheets.

Contingent Consideration

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

The fair value of the BioDiscovery contingent consideration liability is reassessed on a quarterly basis using a probability weighted model. Assumptions used to estimate the fair value of the contingent consideration related to the acquisition of BioDiscovery include the probability of achieving, or changes in timing of certain milestones, and a discount rate of 3%. The Company determined the fair value of the BioDiscovery milestone consideration using a scenario-based technique, as the trigger for payment is event driven. The fair value of the contingent consideration as of December 31, 2022 was $9.4 million. On October 2, 2023, the $10.0 million milestone consideration was paid in full. Any change in fair value of the contingent consideration during the years ended December 31, 2023 and December 31, 2022 was due to the passage of time.

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

The fair value of the Purigen milestones are reassessed on a quarterly basis using a probability weighted model and a Monte Carlo Simulation. Assumptions used to estimate the 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% and 15.3% as of December 31, 2023 and 2022, respectively. The Company determined the fair value of this milestone consideration using a scenario-based technique, as the trigger for payment is event driven. The Company determined the likelihood of each independent milestone and used probability factors ranging from 9% to 49% which were applied to the individual payments over the five year milestone term. The probability factors as of December 31, 2022 ranged from 20% to 80%. For one 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 rate of 7.0% and 6.5% and a discount rate of 13.2% and 15.3% as of December 31, 2023 and 2022, respectively. The fair value of the Purigen contingent consideration as of December 31, 2023 and 2022 were $ 10.9 million and $13.0 million, respectively.

Convertible notes payable and purchase option liability

The estimated fair value of the convertible notes payable (or “Notes”, refer to Note 9 - High Trail Agreement) was based on a lattice model. Assumptions used to estimate the fair value of the Notes are as follows:

	December 31, 2023	October 13, 2023
Expected volatility	80.20 %	74.30 %
Risk-free interest rate	4.92 %	5.17 %
Term to maturity (years)	0.80	1.47
Debt discount rate	17.11 %	18.00 %
Equity discount rate	4.92 %	5.17 %

The table above uses a weighted average of assumptions based on the fair value of the Notes.

The volatility is based on an analysis of the Company, 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 connection with the Notes, the Purchaser was granted an option which expires on the maturity date of the Notes to purchase up to an additional $25.0 million aggregate principal amount of private placement notes and warrants (refer to Note 9 - High Trail Agreement). The estimated fair value of the 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 $9.8 million at inception of the agreement and $8.5 million at December 31, 2023.

The terms used to estimate the fair value of the Subsequently Purchased Notes and Subsequently Purchased Warrant underlying the Purchase Option Liability are as follows:

	Subsequently Purchased Notes		Subsequently Purchased Warrants	
	December 31, 2023	October 13, 2023	December 31, 2023	October 13, 2023
Expected volatility	80.20 %	74.30 %	66.20 %	59.60 %
Risk-free interest rate	4.46 %	5.17 %	3.80 %	4.60 %
Term to maturity (years)	1.50	1.47	5.00	5.00
Dividend yield	— %	— %	— %	— %
Exercise price	—	—	$3.19	$3.19
Debt discount rate	16.60 %	18.00 %	— %	— %
Equity discount rate	4.46 %	5.17 %	— %	— %

Changes in estimated fair value of contingent consideration liability, convertible notes payable and option liability in the year ended December 31, 2023 are as follows:

	Contingent Consideration Liability (Level 3 Measurement)	Convertible Notes Payable (Level 3 Measurement)	Option Liability (Level 3 Measurement)
Balance as of December 31, 2022	$ 22,352,000	$ —	$ —
Issuance of convertible notes payable and option	—	89,063,000	9,763,000
Change in estimated fair value, recorded in selling, general and administrative expenses	(1,462,000)	—	—
Changes in estimated fair value, recorded in other income (expense), net	—	(3,718,000)	(1,229,000)
Conversions to common stock	—	(6,542,000)	—
Cash payments or redemptions	(10,000,000)	(9,000,000)	—
Balance as of December 31, 2023	$ 10,890,000	$ 69,803,000	$ 8,534,000

Changes in estimated fair value of contingent consideration liability in the year ended December 31, 2022 is as follows:

	Contingent Consideration Liability (Level 3 Measurement)
Balance as of December 31, 2021	$ 9,066,000
Liability recorded as a result of current period acquisition	12,970,000
Change in estimated fair value, recorded in selling, general and administrative expenses	316,000
Cash payments	—
Balance as of December 31, 2022	$ 22,352,000

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 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 listed as 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 December 31, 2022, there were no available for sale securities listed as restricted investments.

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

	Remaining Contractual Maturity (in years)	Amortized Cost	Unrealized Gains	Unrealized Losses	Aggregate Estimated Fair Value
Commercial paper	Less than 1	$ 20,093,000	$ —	$ (73,000)	$ 20,020,000
Corporate notes/bonds	Less than 1	72,823,000	—	(910,000)	71,913,000
U.S. treasuries	Less than 1	1,998,000	—	(16,000)	1,982,000
Total maturity less than 1 year		$ 94,914,000	$ —	$ (999,000)	$ 93,915,000
Corporate notes/bonds	1 to 5	14,268,000	—	(88,000)	14,180,000
Total		$ 109,182,000	$ —	$ (1,087,000)	$ 108,095,000

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)

As of December 31, 2022, 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
Commercial paper	$ 20,020,000	$ (73,000)	$ —	$ —	$ 20,020,000	$ (73,000)
Corporate notes/bonds	9,661,000	(27,000)	74,452,000	(971,000)	84,113,000	(998,000)
U.S. treasuries	1,981,000	(16,000)	—	—	1,981,000	(16,000)
Total	$ 31,662,000	$ (116,000)	$ 74,452,000	$ (971,000)	$ 106,114,000	$ (1,087,000)

As of December 31, 2023, the Company held 15 securities which have been in an unrealized loss position for a period of less than 12 months. As of December 31, 2023, the Company held 2 securities which have been in an unrealized loss position for a period of greater than 12 months. As of December 31, 2022, the Company held 16 securities which had been in an unrealized loss position for a period of less than 12 months. As of December 31, 2022, the company held 24 securities which had been in an unrealized loss position for a period greater than 12 months.

As of December 31, 2023 and December 31, 2022, the Company did not intend to sell these investments and it is not more likely than not that the Company will be required to sell the investments before recovery of their amortized cost basis. The Company does not believe the unrealized losses incurred during the period are due to credit-related factors. The credit ratings of the securities held remain of high quality, and 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. As such, the Company has not recognized any credit losses in its financial statements related to its available for sale investment securities.

During the year ended December 31, 2023, there were no sales of the Company's available for sale securities. During the year ended December 31, 2022, the Company received proceeds of $22.8 million relating to sales of its available for sale securities, and recognized a loss of $0.1 million 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.

Included in interest income for the year ended December 31, 2023 was interest income related to the Company's available for sale securities of $3.3 million. Included in interest income for the year ended December 31, 2022 was interest income related to the Company's available for sale securities of $1.5 million. All available-for-sale securities are classified as current assets, even if the maturity when acquired by the Company is greater than one year due to the ability to liquidate within the next 12 months.

5. Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets consist of the following:

	December 31, 2023	December 31, 2022
Prepayment to supplier	$ 1,000	$ 245,000
Prepaid insurance	907,000	948,000
Interest receivable	342,000	474,000
Prepaid employee related expenses	94,000	680,000
Internal use cloud computing arrangement software development costs	1,430,000	530,000
Prepaid software subscriptions	2,075,000	1,601,000
Prepaid marketing expenses	194,000	439,000
Other current assets	976,000	2,412,000
Total	$ 6,019,000	$ 7,329,000

6. Property and Equipment, Net

Property and equipment, net consist of the following:

	December 31, 2023	December 31, 2022
Computer and office equipment	$ 2,984,000	$ 1,622,000
Lab equipment	18,438,000	15,080,000
Service equipment placed at customer sites	17,254,000	10,403,000
Leasehold improvements	3,746,000	4,001,000
Total property and equipment, gross	42,422,000	31,106,000
Less accumulated depreciation and amortization	(19,077,000)	(13,077,000)
Total property and equipment, net	$ 23,345,000	$ 18,029,000

For the years ended December 31, 2023 and 2022, the Company recorded depreciation expense of $6.5 million and $3.8 million, respectively, which includes an allocation to cost of revenue of $3.5 million and $1.5 million respectively.

7. Intangible Assets, Net

Intangible assets that are subject to amortization consisted of the following at December 31, 2023 and 2022:

	2023			2022		
	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount
Trade name	$ 2,630,000	$ (1,078,000)	$ 1,552,000	$ 2,630,000	$ (552,000)	$ 2,078,000
Customer relationships	4,150,000	(2,002,000)	2,148,000	4,150,000	(1,172,000)	2,978,000
Developed technology	41,600,000	(11,428,000)	30,172,000	41,600,000	(5,615,000)	35,985,000
Intangibles, net	$ 48,380,000	$ (14,508,000)	$ 33,872,000	$ 48,380,000	$ (7,339,000)	$ 41,041,000

The Company recorded amortization expense for intangible assets of $7.2 million and $5.8 million for the years ended December 31, 2023 and 2022 respectively, in selling, general and administrative expenses. Intangible assets are amortized on a straight-line basis over their estimated useful lives of five years, with the exception of the developed technology intangible acquired through the acquisition of Purigen, which is amortized over fifteen years. As of December 31, 2023, trade name intangibles, customer relationships, and developed technology have weighted average remaining amortization periods of three years, three years, and nine years, respectively.

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

Future amortization expense of intangible assets is as follows:

2024	$ 7,169,000
2025	7,064,000
2026	5,737,000
2027	1,473,000
2028	1,253,000
Thereafter	11,176,000
Total	$ 33,872,000

8. Accrued Expenses

Accrued expenses consist of the following:

	December 31, 2023	December 31, 2022
Compensation expenses	$ 5,030,000	$ 7,002,000
Taxes payable	1,099,000	825,000
Insurance	512,000	613,000
Professional fees and royalties	387,000	210,000
Warranty liabilities	391,000	489,000
Accrued clinical study fees	138,000	250,000
Customer deposits	17,000	17,000
Other	515,000	1,146,000
Total	$ 8,089,000	$ 10,552,000

9. High Trail Agreement

The Company entered into a securities purchase agreement (the "Purchase Agreement") with High Trail Special Situations LLC (the "Purchaser") on October 11, 2023, pursuant to which the Company agreed to issue and sell, for an aggregate $80.0 million in gross proceeds:

(i) in a registered offering by the Company directly to the Purchaser (the "Offering")

(a) $45.0 million aggregate principal amount of senior secured convertible notes payable due 2025 (the "Registered Notes")

initially convertible by the Purchaser at a price of $2.86 into 15.7 million shares of the Company's common stock and

(b) warrants to purchase up to 21.7 million shares of the Company's common stock at a price of $3.19 per share (the "Registered Warrants"), and

(ii) in a concurrent private placement to the Purchaser (the "Private Placement"), $35.0 million aggregate principal amount of senior secured convertible notes payable due 2025 initially convertible at a price of $2.86 into 12.2 million shares of the Company's common stock (the "Private Placement Notes" and together with the Registered Notes, the "Notes").

The Company also granted the Purchaser an Option to purchase up to an additional $25.0 million aggregate principal amount of Private Placement Notes, in their sole discretion, initially convertible into shares of the Company's common stock (the "Subsequently Purchased Notes") at a conversion price equal to $1,000 divided by a fraction (1) whose numerator is $1,000; and (2) whose denominator is the sum of (a) $0.09375 and (b) the greater of (x) the Nasdaq Minimum Price (as defined in Nasdaq Rule 5635(d)) on the date of the Purchase Agreement and (y) the Nasdaq Minimum Price (as defined in Nasdaq Rule 5635(d)) on the date of the issuance of the Subsequently Purchased Notes) Notice per the terms of the Notes and warrants (the "Private Placement Warrants" and together with the Registered Warrants, the "Warrants") to purchase up to 6.8 million shares of the Company's common stock at an exercise price calculated as the greater of (x) 115% of the Nasdaq Minimum Price on the date of the applicable Subsequently Purchased Securities Notice is delivered and (y) the Nasdaq Minimum Price on the date of signing the Purchase Agreement, per the terms, in a subsequent private placement on the same terms as the Notes and the Registered Warrants (any such subsequent private placement, a "Subsequent Private Placement").

The $35.0 million proceeds of the Private Placement Notes was deposited into a restricted account subject to an account control agreement that only permitted funds to be released once per calendar month upon the satisfaction of certain funding conditions specified in the Notes.

The Offering and Private Placement closed on October 13, 2023. The Company's net proceeds from the sale of the Notes and the Registered Warrants were approximately $ 75.2 million, after deducting the Offering and Private Placement expenses and placement agent fees.

As of December 31, 2023, the Company had aggregate principal outstanding under the Notes of $61.0 million, reported at fair value of $69.8 million (refer to Note 4 - Investments and Fair Value Measurements, for fair value measurements and additional discussion) and broken out as follows:

	Notes
Principal balance, October 13, 2023	$ 80,000,000
Less:	
Conversions	10,000,000
Partial redemption payments of principal	9,000,000
Notes principal balance, December 31, 2023	$ 61,000,000

There were no amounts outstanding under the Notes as of December 31, 2022.

The Notes are secured by a first-priority lien, subject only to certain permitted liens, on substantially all of the Company's and subsidiaries' (other than certain foreign subsidiaries) tangible and intangible assets, whether now owned or hereafter acquired (other than certain excluded property) and includes a pledge of the stock of the Company's subsidiaries and a portion of the stock of foreign subsidiaries.

All payments due under the Notes rank (i) pari passu with all Other Notes, (ii) effectively senior to all unsecured obligations of the Company to the extent of the value of the collateral securing the Notes for so long as the collateral secures the Notes in accordance with the terms and (iii) senior to any subordinated indebtedness.

The Company recorded the Notes at their fair value at issuance of $89.1 million, per the fair value option under ASC 825 (refer to Note 4 - Investments and Fair Value Measurements) and will be measured on a recurring basis and adjusted through other income and expense. The Option was recorded as a liability at fair value at issuance of $9.8 million (refer to Note 4 - Investments and Fair Value Measurements). The Warrants qualified for classification as equity instruments and were recorded at $ 0 in additional paid in capital, which represents the residual amount after allocation of proceeds to the Notes and option to purchase additional Notes ("Option") at fair value. The Company recognized an initial loss on the issuance of the Notes and Option of $18.8 million for the difference between the combined fair value of the Notes and Option and proceeds from the transaction, which is recorded in Loss on High Trail Agreement on the consolidated statement of operations. The Company incurred debt issuance costs of $ 4.8 million related to the Offering, which was charged to interest expense.

Terms of Repayment

The Notes were sold at 100% of their principal amount and will be repaid at 115% of the principal amount (the “Repayment Price”). The Notes do not bear regular interest and mature on September 1, 2025 (the “Maturity Date”), unless earlier repurchased, redeemed or converted.

On the earlier to occur of (i) the date that no principal amount remains outstanding or (ii) the Maturity Date, the Company will be required to pay a retirement fee (the “Retirement Fee”) to the holders of the Notes equal to (x) with respect to the Registered Notes, the product of (a) $2.8 million multiplied by (b) a fraction, whose numerator is an amount equal to $45.0 million less the aggregate principal amount of such Registered Notes converted into shares of the Company’s common stock, and whose denominator is $45.0 million; and (y) with respect to any Subsequently Purchased Notes, an amount equal to the product of (a) 6.25% of the initial principal amount of such Subsequently Purchased Notes multiplied by (b) a fraction, whose numerator is an amount equal to the initial principal amount of such Subsequently Purchased Notes less the aggregate principal amount of such Subsequently Purchased Notes converted into shares of the Company’s common stock, and whose denominator is an amount equal to the initial principal amount of such Subsequently Purchased Notes. In connection with the redemption of the Private Placement Notes in February 2024, the Company paid a Retirement Fee of $3.2 million.

Conversion

The holder may convert the principal amount of the Notes in whole at any time prior to maturity, or in part in denominations of $1,000, per the terms. The holder’s ability to convert the Notes is limited if after such conversion the holder and its affiliates and attribution parties beneficially own an aggregate of 4.99% of the Company’s common stock, which percentage may be changed at the holders’ election to a higher or lower percentage not in excess of 9.99% upon 61 days’ notice subject to the terms of the Notes.

The Company may require conversion of all, but not less than all, of the Notes upon occurrence of a forced conversion trigger and if certain equity conditions are satisfied on date of notice, pursuant to the terms of the Notes. A forced conversion trigger occurs if the last reported sale price of the Company’s common stock exceeds 175% of the conversion price on at least 20 volume-weighted average price (“VWAP”) trading days in any 30 consecutive trading day period.

The Notes contain standard antidilution provisions which adjust the conversion rate upon stock dividends, splits and combinations, certain events which include the distribution of rights, options and warrants, spin-offs and other distributed property, cash dividends or distributions, and tender or exchange offers. The Company may increase the conversion rate on any portion of the Notes for any period of time (which decreases the conversion price) if the Board of Directors determines in good faith that such an increase is in the best interest of the Company.

As of December 31, 2023, the holder had converted $10.0 million principal into 3.5 million shares of the Company’s common stock, at the conversion price of $2.86 per share.

Redemption

The holders have the option to partially redeem a portion of the Notes on the first day of each month beginning on November 1, 2023, (except for March 1, 2024, and subject to a delay of the April 2024 partial redemption date to April 20, 2024), at the Repayment Price, for an amount not to exceed $5.2 million, which amount may be increased upon agreement of both parties.

The Company has the right to redeem all of the then outstanding principal amount of the Notes under certain circumstances beginning on the 30th day following the date that the Resale Registration Statement became effective, and the holders of the Notes may require the Company to redeem the Notes upon a fundamental change, which includes a change in control, liquidation provisions or if the Company’s common stock ceases to be listed on any eligible exchange (as defined in the Notes), in each case for a redemption price set forth in the Notes.

If an event of default occurs (other than certain bankruptcy provisions which require automatic acceleration) and has not been waived by the holder, the holder may declare the Notes due and payable for cash in an amount equal to the event of default acceleration amount as set forth in the Notes. Events of default include, among other things, non-timely Form 10-Q and 10-K Exchange filings, “Big R” restatement for any previously filed 10-Q or 10-K and ceasing to satisfy the eligibility requirement under Section I.A. of General Instruction to Form S-3. If an event of default occurs, default interest of 15% will automatically accrue on the principal amount outstanding until cured and interest is paid, as specified in the Notes.

As of December 31, 2023, the holders have redeemed $9.0 million of principal amount of the Notes at the Repayment Price of $10.4 million. As of December 31, 2023, at the holder’s option, the Company may be required to make future aggregate redemptions of at the Repayment Price as follows (unless earlier converted per the terms):

2024	$	62,100,000
2025		8,050,000
Thereafter		—
Total	$	70,150,000

As of December 31, 2023, and assuming no future conversions, the Company would be required to pay a retirement Fee of $4.4 million, based on full redemption of principal.

On January 1, 2024, and February 1, 2024, the holders redeemed an aggregate of $9.0 million of principal, at the Repayment Price of $10.4 million. In February 2024, in connection with the Letter Agreement and Amendment, the Company redeemed an aggregate of $27.7 million of Notes for a total redemption payment of approximately $31.9 million, together with a retirement fee of approximately $3.2 million. Following the redemptions the Company has $24.3 million of Notes outstanding, see “Debt Financing Amendment” below.

Covenants and Restrictions

The Notes subject the Company to various affirmative and negative covenants, and events of default that, among other things, restrict, subject to certain exceptions, the ability of the Company and its subsidiaries to incur or amend indebtedness, grant liens on their assets, make investments, make distributions or pay certain dividends, transfer assets, and place limitations or requirements on business combination events. The Company must comply with certain financial maintenance covenants and shall have at all times a minimum liquidity amount which is tested monthly and must maintain a minimum cash spend availability tested quarterly. As long as the Notes remain outstanding, the Company is required to maintain a share reserve and a required funding program, the Company and each subsidiary is prohibited from directly or indirectly entering into any variable rate transactions subject to certain exclusions, the Company is subject to certain restricted periods during which it will not issue equity or equity linked securities subject to certain exclusions, and as long as any Notes or Warrants remain outstanding the Company may not issue any Notes or Warrants or other securities which would cause a breach or default, without the consent of the required holders.

The Notes contain provisions for liquidated damages, and require the Company to reimburse the holder for out-of-pocket costs incurred in connection their reliance on receipt of shares as applicable, if the Company fails to timely deliver shares upon conversion of the Notes or exercise of the Warrants or fails to deliver certificates with removal of restrictive legend when required, and in the event the Company fails to reserve the required number of authorized but unissued shares.

As of December 31, 2023, the Company was in compliance with its covenants.

Warrants

In connection with the Notes, the Company issued Warrants to purchase up to 21.7 million shares of the Company’s common stock at an exercise price of $3.19 per share and a term of 5 years from the date of issuance. The Warrants qualified for classification as equity instruments, and as discussed above, were recorded in additional paid in capital at $0, which represents the residual amount after allocation of proceeds to the Notes and Option at fair value (refer to Note 10 - Stockholders’ Equity and Stock-Based Compensation).

Debt Financing Amendment

On February 27, 2024, the Company entered into a letter agreement (the “Letter Agreement”) and an Amendment to the Registered Note (the “Amendment”), with the Purchaser of the Notes 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 Registered Notes plus (ii) approximately $0.7 million, which will be further reduced as the remaining principal on the 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 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 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 Private Placement Notes to $3.2 million payable concurrently with redemptions of the Initial Private Placement Note.

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

10. Stockholders’ Equity and Stock-Based Compensation

Common Stock

The Company is currently authorized to issue up to 400 million shares of $0.0001 par value common stock. All issued shares of common stock are entitled to vote on a 1 share/1 vote basis.

Preferred Stock

The Company is currently authorized to issue up to 10 million shares of $0.0001 par value preferred stock. No preferred stock issued or outstanding as of December 31, 2023 and December 31, 2022.

Series A Preferred Stock

On April 13, 2023, the Company entered into an agreement with David Barker, the Chair of the Company's board of directors, pursuant to which the Company agreed to issue and sell one share of the Company's Series A Preferred Stock, par value $0.0001 per share for a purchase price of $100.00. The closing of the sale and purchase of the share of Series A Preferred was completed on April 13, 2023.The share of Series A Preferred was entitled 3.0 billion votes, but had the right to vote only on a proposal submitted to the stockholders of the Company to adopt an amendment, or a series of alternate amendments, to the Company's Amended and Restated Certificate of Incorporation, as amended, to combine the outstanding shares of common stock into a smaller number of shares of common stock at a ratio specified in or determined in accordance with the terms of such amendment or series of alternate amendments ("Reverse Stock Split Proposal"), and had no voting rights (i) except with respect to a Reverse Stock Split Proposal and the votes of the share of Series A Preferred were required to be cast for and against such Reverse Stock Split Proposal in the same proportion as shares of common stock were voted for and against such Reverse Stock Split Proposal (with any shares of common stock that were not voted, whether due to abstentions, broker non-votes or otherwise not counted as votes for or against a Reverse Stock Split Proposal) and (ii) unless the holders of one-third (1/3rd) of the outstanding shares of common stock were present and voted, in person or by proxy, at the meeting of stockholders at which the Reverse Stock Split Proposal was submitted for stockholder approval (or any adjournment thereof). The share of Series A Preferred voted together with the common stock as a single class on the Reverse Stock Split Proposal at the Company's 2023 Annual Meeting of Stockholders held on June 14, 2023. The Series A Preferred had no other voting rights, except as may have been required by the General Corporation Law of the State of Delaware. The outstanding share of Series A Preferred was redeemed in whole, for a redemption price of $100.00, paid out of funds lawfully available therefor automatically immediately following the approval by the stockholders of the Reverse Stock Split Proposal on June 14, 2023.

Sale of Common Stock

Cowen At-the-Market Facility

On March 23, 2021, the Company entered into a Sales Agreement with Cowen and Company, LLC ("Cowen") which provides for the sale, in the Company's sole discretion, of shares of common stock having an aggregate offering price of up to $350.0 million through or to Cowen, acting as sales agent or principal, which was amended on March 9, 2023 to decrease the maximum aggregate offering price to $200.0 million for sales made on and after the date of the amendment (the "Cowen ATM"). The Company agreed to pay Cowen a commission of up to 3.0% of the aggregate gross proceeds from each sale of shares, reimburse legal fees and disbursements and provide Cowen with customary indemnification and contribution rights. In August 2022, the Company sold approximately 0.7 million shares of common stock under the Cowen ATM at an average share price of $34.59 per share, and received gross proceeds of approximately $23.1 million before deducting offering costs of $0.6 million. During the twelve months ended December 31, 2023, the Company sold approximately 12.5 million shares of common stock under the Cowen ATM at an average share price of $4.62 per share, and received gross proceeds of approximately $57.8 million before deducting offering costs of $1.4 million.

In January and February 2024, the Company sold approximately 9.1 million shares of common stock under the Cowen ATM at an average share price of $1.38 per share, and received gross proceeds of approximately $12.5 million before deducting offering costs of $0.3 million.

Stock Warrants

A summary of the Company's warrant activity for the year ended December 31, 2023 was as follows:

	Shares of Stock under Warrants	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term	Aggregate Intrinsic Value
Outstanding at January 1, 2022	436,000	$ 59.60	0.76	$ 273,000
Granted	—	—		—
Exercised	—	—		—
Canceled	—	—		—
Outstanding at December 31, 2022	436,000	$ 59.60	0.76	$ 273,000
Granted	21,661,000	3.19		—
Exercised	—	—		—
Canceled	(401,000)	—		—
Outstanding at December 31, 2023	21,696,000	$ 4.38	4.78	$ —

In connection with the issuance of the Notes on October 13, 2023, the Company issued warrants to purchase 21.7 million shares of the Company's common stock (refer to Note 9 - High Trail Agreement).

2018 Equity Incentive Plan

In August 2018, the Company's board of directors (the "Board") and its stockholders adopted the 2018 Equity Incentive Plan (the "2018 Plan"), as a successor to and continuation of the Company's 2006 Equity Incentive Plan (the "2006 Plan"). Under the 2018 Plan, the Company may grant stock options, stock appreciation rights, restricted stock, restricted stock units and other awards to individuals who are then its employees, directors and consultants, including employees and consultants of its affiliates. The Company has initially reserved 1.5 million shares of common stock for issuance under the 2018 Plan, which is the sum of (1) 1.0 million new shares, plus (2) the number of shares that remained available for issuance under the 2006 Plan at the time the 2018 Plan became effective, and (3) any shares subject to outstanding stock options or other stock awards that were granted under the 2006 Plan that would have otherwise returned to the 2006 Plan. In addition, the number of shares of common stock reserved for issuance under the 2018 Plan will automatically increase on January 1 of each calendar year, starting on January 1, 2019 through January 1, 2028, in an amount equal to 5% of the total number of shares of the Company's capital stock outstanding on the last day of the calendar month before the date of each automatic increase, or a lesser number of shares determined by the Board. As of December 31, 2023, 1.3 million shares of common stock were authorized for future grants under the 2018 Plan.

2020 Inducement Plan

In August 2020, the Company's Board adopted the 2020 Inducement Plan, which was further amended by the Board on October 6, 2021, and November 21, 2022. Under the 2020 Plan, the Company may grant stock options, stock appreciation rights, restricted stock, restricted stock units and other awards to individuals who are then its employees, directors and consultants, including employees and consultants of its affiliates. The Company initially reserved 2.1 million shares of common stock for issuance under the 2020 Plan. An additional 1.0 million of shares of common stock were reserved for issuance under the Inducement Plan on each of October 6, 2021 and November 21, 2022 for a total of 4.1 million shares pursuant to amendments approved by the Board. As of December 31, 2023, there were approximately 0.1 million shares of common stock authorized for future grants under the 2020 Plan.

Stock Options

A summary of the Company's stock option activity is as follows:

	Shares of Stock under Stock Options	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term	Aggregate Intrinsic Value
Outstanding at January 1, 2023	2,402,000	$ 32.80	8.5	$ 2,068,000
Granted	1,446,000	12.09		
Exercised	(4,000)	5.49		25,000
Canceled	(576,000)	26.58		
Outstanding and expected to vest at December 31, 2023	3,268,000	24.79	7.8	3,000
Vested and exercisable at December 31, 2023	1,529,000	$ 30.40	6.8	$ —

The weighted-average grant date fair value of stock option grants during the years ended December 31, 2023 and 2022 was $8.15 and $13.50, respectively. The total intrinsic value of the stock options exercised during the years ended December 31, 2023 and 2022 were $0.03 million and $0.6 million, respectively. The contractual term of stock options granted to employees was 10 years, which is also the maximum contractual term permitted for stock options (and stock appreciation rights) issued under the 2018 Plan. Stock options generally vest or become exercisable monthly over a four-year period.

Restricted Stock

Restricted Stock

A restricted stock award in the amount of 0.5 million shares with a grant date fair value of $52.00 a share was granted as part of the acquisition of BioDiscovery. One-third of the Restricted Shares was scheduled to vest on October 18, 2022 and one-twelfth of the Restricted Shares was scheduled to vest every three months following October 18, 2022, subject to continuous service of the key employee. The fair value of the restricted stock award was based on the market value of common stock as of the date of grant and was amortized to stock-based compensation expense over the service period.

On October 4, 2022, the restricted stock award was modified due to the change in employment status of the key employee from full time to emeritus. As a result of the modification, the restricted stock award vested in full on October 4, 2022. The award was revalued on the modification date, resulting in a modified grant date fair value of $20.40 a share ($15.8 million less than the initial grant date fair value of the award). The fair value of the modified restricted stock award was based on the market value of common stock as of the modification date.

Executive Option Grants and RSUs

On February 15, 2023, the compensation committee of the Company’s board of directors granted various executive officers stock options to purchase an aggregate of 0.3 million shares of common stock at an exercise price of $16.30 per share, and RSUs amounting to 0.1 million shares of common stock at a grant date fair value of $16.30 per share, in each case with an effective grant date and vesting commencement date of February 15, 2023 (the “Grant Date”). These stock option grants and RSUs were issued from the 2018 Plan. The shares subject to the option shall vest monthly over 48 months beginning on the one-month anniversary of the Grant Date, such that the option shall be fully vested and exercisable on the four-year anniversary of the Grant Date. The RSUs shall vest monthly over 48 months beginning one year after the Grant Date, and the balance of the shares vest in a series of three successive equal annual installments measured from the first anniversary of the Grant Date, such that the option shall be fully vested and exercisable on the four-year anniversary of the Grant Date.

Restricted Stock Units and Performance Stock Units

The Company issues restricted stock units (RSU) and performance stock units (PSU). The Company grants restricted stock pursuant to the 2018 Plan and satisfy such grants through the issuance of new shares. RSUs are share awards that, upon vesting, will deliver to the holder shares of our common stock. RSUs generally vest over a two-year period with equal vesting annually prior to 2023, and over a four-year period with equal vesting monthly beginning one year after the grant date beginning in 2023. The Company issues PSUs for which the number of shares issuable at the end of a four-year performance period is based on our performance relative to specified revenue targets and continued employment through the vesting period.

Restricted stock activity was as follows:

	Stock Units	Weighted- Average Grant Date Fair Value per Share
Outstanding at January 1, 2023	10,000	$ 47.40
Granted	290,000	14.29
Released	(10,000)	47.40
Forfeited	(51,000)	—
Outstanding at December 31, 2023	239,000	$ 16.30

The total fair value of the RSUs that vested during the years ended December 31, 2023 and 2022 were $0.5 million and $1.3 million, respectively, determined as of the date of vesting. The weighted average remaining contractual term for the RSUs is 2.9 years as of December 31, 2023.

Performance stock activity was as follows:

	Stock Units	Weighted- Average Grant Date Fair Value per Share
Outstanding at January 1, 2023	29,000	$ 47.40
Granted	—	—
Released	—	—
Forfeited	—	—
Outstanding at December 31, 2023	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 as of December 31, 2023.

Stock-Based Compensation Expense

The Company recognized stock-based compensation expense for the years ended December 31, 2023 and 2022 was as follows:

	Years Ended December 31,	
	2023	2022
Cost of product revenue	$ 520,000	$ —
Cost of service and other revenue	183,000	—
Research and development	5,092,000	13,402,000
General and administrative	9,383,000	9,015,000
Total stock-based compensation expense	$ 15,178,000	$ 22,417,000

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

	Years Ended December 31,	
	2023	2022
Risk-free interest rate	4.0%	2.4%
Expected volatility	75.3%	68.0%
Expected term (in years)	5.9	5.8
Expected dividend yield	0.0%	0.0%

Risk-free interest rate. The risk-free rate assumption is based on the U.S. Treasury instruments, the terms of which were consistent with the expected term of the Company's stock options.

Expected volatility. Prior to 2023, due to the Company's limited operating history and lack of company-specific historical or implied volatility as a private company, the expected volatility assumption was determined by examining the historical volatilities of a group of industry peers whose share prices are publicly available. Beginning in 2023, we incorporated the Company's own volatility assumption into the expected volatility calculation for Black-Scholes by using an equal weighting of the Company's historical stock volatility and the historical volatilities of a group of industry peers whose share prices are publicly available.

Expected term. The expected term of stock options represents the weighted-average period the stock options are expected to be outstanding. The Company does not have sufficient historical exercise data to provide a reasonable basis upon which to estimate expected term due to the limited period of time its equity shares have been publicly traded. As a result, the Company uses the simplified method for estimating the expected term as provided by the SEC. The simplified method calculates the expected term as the average of the time-to-vesting and the contractual life of the options.

Expected dividend yield. The expected dividend assumption is based on the Company's history and expectation of dividend payouts. The Company has not paid and does not intend to pay dividends.

Forfeitures. The Company reduces stock-based compensation expense for actual forfeitures during the period.

Unrecognized Stock-Based Compensation Expense

As of December 31, 2023, the unrecognized compensation expense for all non-vested share-based awards was $24.5 million and is expected to be recognized as expense over a weighted-average period of 2.3 years.

Employee Stock Purchase Plan

In August 2018, the Board and the Company's stockholders adopted the 2018 Employee Stock Purchase Plan (the "ESPP"). A total of 0.2 million shares of common stock were initially reserved for issuance under the ESPP. In addition, the number shares of common stock reserved for issuance under the ESPP will automatically increase on January 1 of each calendar year, beginning on January 1, 2019, through January 1, 2028, by the lesser of (1) 1% of the total number of shares of the Company's common stock outstanding on the last day of the calendar month before the date of the automatic increase, (2) 220,000 shares, or (3) a lesser number of shares as determined by the Board. As of December 31, 2023, 1.3 million shares of common stock were authorized for future grants under the ESPP.

11. Commitments and Contingencies

Leases

Operating leases

The Company leases approximately 41,101 square feet of office, laboratory, and manufacturing space in two buildings at our headquarters in San Diego, California, with the lease for all rented space expiring December 31, 2025. In December 2021, the Company executed a new lease for approximately 11,978 additional square feet square feet of office and laboratory space in San Diego, California that expires in January 2026. In January 2022, the Company executed a new lease for an additional 5,278 square feet of office and laboratory space in San Diego, California that expires in January 2026. In December 2022, the Company executed a new lease, subject to the consent of a third party that was obtained in February 2023, for an additional 18,005 square feet of office and laboratory space in San Diego, California that commences in April 2023 and expires in March 2024. Rent payments for the additional space are $0.05 million each month through the end of the lease term.

In August 2020, through the acquisition of Lineagen, the Company obtained a lease for approximately 9,710 square feet of office space in a Salt Lake City, Utah under a non-cancelable operating lease that expires in December 2026. As further described under the heading "Restructuring" below, 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. The Company will continue to lease the property through June 2024.

In November 2022, through the acquisition of Purigen, the Company obtained a lease for approximately 16,165 square feet of office and laboratory space in Pleasanton, California, under a non-cancelable operating lease agreement that expires in July 2027.

Finance lease

In October 2021, through the acquisition of BioDiscovery, the Company obtained a finance lease of 4,786 square feet of office space in El Segundo, California that expires in February 2041. The portion of the future payments designated as principal repayment and related interest was classified as a finance lease obligation on our consolidated balance sheets.

Supplemental information

For all leases, the Company has the ability to enter into renewal negotiations, prior to the lease end date, with no specific terms. At this time, it is not reasonably certain that we will extend the term of the lease and therefore the renewal period has been excluded from the aforementioned ROU asset and lease liability measurements. The leases are subject to variable charges for common area maintenance and other costs that are determined based on actual costs and includes certain lease incentives such as tenant improvement allowances. The base rent for the leases is subject to an annual increase each year. Rent expense is being recognized on a straight-line basis over the term of the lease. The Company's estimated incremental borrowing rate summarized in the table below was used in its present value calculations as the operating and finance leases do not have a stated rate and the implicit rate was not readily determinable. In determining the incremental borrowing rate, the Company considered the interest rate of the Term Loans as well as publicly available data for discount rates used by peer companies.

Supplemental information pertaining to the Company's leases in which the Company is the lessee is as follows:

	Year Ended December 31,	
	2023	2022
Cash payments included in the measurement of lease liabilities:		
Operating cash flows from operating leases	$ 2,586,000	$ 1,622,000
Operating cash flows from finance leases	$ 275,000	$ 278,000
Financing cash flows from finance leases	$ 47,000	$ 36,000
Weighted-average remaining lease term:		
Operating leases	2.47 years	3.41 years
Finance leases	17.17 years	18.17 years
Weighted-average discount rate:		
Operating leases	8.3 %	8.3 %
Finance leases	7.1 %	7.1 %
Noncash lease liabilities resulting from obtaining right-of-use assets		
Operating leases	$ —	$ 517,000

The following table provides the components of the Company's lease cost:

	Year Ended December 31,	
	2023	2022
Operating leases		
Operating lease costs	$ 2,663,000	$ 2,084,000
Variable lease costs	702,000	940,000
Total rent expense	3,365,000	3,024,000
Finance lease		
Amortization of right of use assets	204,000	219,000
Interest on lease liabilities	275,000	278,000
Variable lease costs	40,000	32,000
Total finance lease costs	519,000	529,000
Gross sublease income	(106,000)	(106,000)
Total lease costs	$ 3,778,000	$ 3,447,000

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

	Operating Leases	Finance Lease
2024	2,684,000	330,000
2025	2,788,000	338,000
2026	729,000	347,000
2027	255,000	356,000
2028	—	365,000
Thereafter	—	5,227,000
Total future lease payments	6,456,000	6,963,000
Less: imputed interest	(703,000)	(3,106,000)
Total lease liabilities	5,753,000	3,857,000
Less: lease liability, current portion	2,163,000	272,000
Lease liability, net of current portion	$ 3,590,000	$ 3,585,000

Purchase Commitments

The Company had a contractual commitment with a supplier to purchase $0.3 million of products every month for an initial term of two years which began in May 2021 and ended in May 2023. $1.4 million and $3.2 million of materials were purchased under this minimum purchase commitment during the years ended December 31, 2023 and 2022, respectively.

Restructuring

In October, 2023, the Company committed to a series of cost saving initiatives including a reduction in force (the "Workforce Reduction") and, as a result of reducing facility costs and discretionary spending unrelated to headcount and combined with the cost savings from the reduction in force the Company initiated in May 2023, such plan is intended to decrease expenses and maintain a streamlined organization to support its business. In connection with the Workforce Reduction, the Company incurred $ 0.7 million of severance costs for impacted employees, consisting primarily of cash, which the Company recognized during the fourth quarter of 2023. The Company substantially completed the Workforce Reduction as of December 31, 2023. The Company had accrued severance of $0.1 million and none as of December 31, 2023 and 2022, respectively. 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 Workforce Reduction. 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 will result in a one-time termination fee of approximately $ 0.2 million in the third quarter of 2024. The Company will continue to lease the property through June 2024.

On March 1, 2024, the Board of Directors approved a cost savings plan that it expects to reduce its annualized operating expenses which will include a reduction in force. This cost savings plan is incremental to the 2023 Workforce Reduction. As part of the plan, the Company will further reduce its overall headcount by approximately 110 to 125 employees. In addition, Bionano Laboratories will phase out over time the offering of certain testing services related to neurodevelopmental disorders, including autism spectrum disorders, and other disorders of childhood development. As of the issuance of these consolidated financial statements, the Company is not able to estimate the impact of these actions on the financial statements

Litigation

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

Contingent Consideration

Refer to Note 4 -Investments and Fair Value Measurements for discussion regarding contingent consideration.

12. Income Taxes

The domestic and foreign components of income (loss) from continuing operations are as follows:

	Year Ended December 31,	
	2023	2022
Domestic	$ (235,852,000)	$ (131,237,000)
Foreign	3,421,000	525,000
Loss before provision for income taxes	$ (232,431,000)	$ (130,712,000)

The provision for domestic and foreign income taxes is as follows:

	Year Ended December 31,	
	2023	2022
Current:		
Federal	$ —	$ —
Foreign	63,000	123,000
State and local	(1,000)	1,000
Total current income tax provision (benefit)	$ 62,000	$ 124,000
Deferred:		
Federal	$ —	$ (277,000)
Foreign	—	—
State and local	—	2,037,000
Total deferred income tax provision (benefit)	—	1,760,000
Income tax provision (benefit)	$ 62,000	$ 1,884,000

Reconciliations of the income tax computed at the federal statutory tax rate to the expense for income taxes are as follows:

	Year Ended December 31,	
	2023	2022
Income taxes at statutory rates	$ (48,811,000)	$ (27,447,000)
State income tax, net of federal benefit	(1,050,000)	(1,321,000)
Reduction of tax attributes under section 382	43,680,000	—
Goodwill impairment	16,229,000	—
Research credits	(5,416,000)	(1,733,000)
Convertible notes payable and warrants	4,211,000	—
Stock-based compensation	1,836,000	1,345,000
Other permanent differences	9,000	434,000
Limitation of compensation under section 162(m)	(1,145,000)	2,447,000
Other, net	1,822,000	817,000
Change in valuation allowance	(11,303,000)	27,342,000
Income tax expense (benefit)	$ 62,000	$ 1,884,000

Significant components of the Company’s deferred tax assets at December 31, 2023 and 2022 are as follows:

	December 31,	
	2023	2022
Deferred tax assets:		
Net operating loss carryforwards	$ 91,977,000	$ 109,612,000
Research and development credits	8,283,000	9,816,000
Stock-based compensation	1,991,000	1,639,000
ASC 842 - lease liability	2,113,000	2,599,000
UNICAP	826,000	1,049,000
Sec 174 Capitalization	13,483,000	6,831,000
Other	1,413,000	1,944,000
Total gross	120,086,000	133,490,000
Deferred tax liabilities:		
Amortization	(7,360,000)	(9,033,000)
ASC 842 - ROU asset	(2,013,000)	(2,441,000)
Less: valuation allowance	(110,713,000)	(122,016,000)
Deferred tax assets, net of valuation allowance	$ —	$ —

As of December 31, 2023, the Company has 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 is limited to 80% of the Company’s taxable income in any given tax year based on current federal tax laws. The remaining federal tax loss carryforwards of $23.8 million and state tax loss carryforwards begin to expire in 2027 and 2024, respectively, unless previously utilized. As of December 31, 2023, the Company also has 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.

Management assesses all available evidence to estimate if sufficient future taxable income will be generated to use the existing deferred tax assets. The Company has experienced net losses since inception, and the revenue and income potential of the Company’s business and market are unproven. Due to the Company’s continuing research and development (“R&D”) activities, the Company expects to continue to incur net losses into the foreseeable future. As such, the Company cannot conclude that it is more likely than not that its deferred tax assets will be realized. A valuation allowance of $110.7 million, and $122.0 million as of December 31, 2023, and 2022, respectively, has been established to offset the deferred tax assets.

The Company acquired BioDiscovery, LLC. an entity designated for income tax purposes as a corporation in a plan of reorganization within the meaning of Section 368(a)(1)(A) on October 18, 2021. Under ASC 805-740, the Company recorded deferred tax liabilities of $5.8 million related to customer lists, patents/trademarks, developed technology, and fixed assets as part of the business combination. As the deferred tax liability recorded in the business combination constitutes a source of

future taxable income, the Company recorded a decrease to its valuation allowance against its deferred tax assets of $5.8 million as a deferred income tax benefit for the year ended December 31, 2021.

As permitted under ASC 805, the Company is allowed a measurement period, which may not exceed one year, in which to complete its accounting for the acquisition. During the year ended December 31, 2022, the Company recorded a decrease to the deferred tax liabilities previously recorded by $1.8 million due to adjustments to pre-acquisition tax losses and the state rate change. The Company recorded a corresponding increase in the valuation allowance of $1.8 million as a deferred income tax expense for the year ended December 31, 2022. The purchase price for BioDiscovery was finalized during the year ended December 31, 2022.

In November 2022, the Company completed the stock acquisition of Purigen Biosystems, Inc. The Company recorded a net deferred tax asset of $11.5 million of which $4.4 million related to deferred tax liabilities for non-deductible intangibles and $15.4 million related to deferred tax assets for pre-acquisition tax loss and credit carryforwards. As management determined that the net deferred tax asset was not more likely than not to realize, a full valuation allowance was recorded. There was no impact on the Company's income tax provision as of December 31, 2022. There was no adjustment to the deferred taxes related to the Purigen acquisition during the measurement period which is now closed.

Utilization of the net operating losses and R&D credit carryforwards may be subject to annual limitations due to ownership changes that have occurred or that could occur in the future, as required by Sections 382 and 383 of the Internal Revenue Code of 1986, as amended (the "Code"), as well as similar state and foreign provisions. These ownership changes may limit the amount of net operating losses and R&D credit carryforwards that can be utilized annually to offset future taxable income and tax, respectively. In general, an "ownership change" as defined by Section 382 of the Code results from a transaction or series of transactions over a three-year period resulting in an ownership change of more than 50 percentage points of outstanding stock of a company by certain stockholders.

The Company has 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.

Reconciliations of the beginning and ending amount of unrecognized tax benefits, excluding interest and penalties, are as follows:

	December 31,	
	2023	2022
Balance at beginning of the year	$ 7,281,000	$ 5,119,000
Additions/(reductions) for tax positions - prior year	(3,643,000)	903,000
Increase related to current year positions	1,349,000	1,259,000
Balance at the end of the year	$ 4,987,000	$ 7,281,000

The Company recognizes the benefit of uncertain tax positions at the largest amount that is more likely than not to be sustained upon audit by the relevant taxing authority. An uncertain tax position will not be recognized if it has less than a 50% likelihood of being sustained. Due to the valuation allowance position, none of the unrecognized tax benefits, if recognized, will impact the Company's effective tax rate. The Company does not anticipate a significant change in the unrecognized tax benefits during the next twelve months.

The Company's practice is to recognize interest and penalties related to income tax matters in income tax expense. The Company had no accrual of interest and penalties on the Company's balance sheets and has not recognized any interest and penalties in the statements of operations for the years ended December 31, 2023 and 2022.

The Company is subject to taxation in the United States, the United Kingdom and China. The Company's tax years from 2007 (inception) are subject to examination by the United States and state authorities due to the carry forward of unutilized net operating losses and R&D credits.

13. Employee Benefits

The Company has a defined contribution 401(k) plan available to eligible employees. Under the terms of the plan, employees may make voluntary contributions as a percent of compensation, limited to the maximum amount allowable under federal tax

regulations. The Company, at its discretion, may make certain contributions to the 401(k) plan. The Company expensed matching contributions of $1.9 million and $1.5 million for the years ended December 31, 2023 and 2022, respectively.

14. Acquisitions

Purigen Acquisition

In November 2022, the Company, Mazdan Merger Sub, Inc., a wholly owned subsidiary of the Company ("Purigen Merger Sub"), Purigen and Shareholder Representative Services LLC, solely in its capacity as the securityholders' representative, entered into an Agreement and Plan of Merger (the "Purigen Merger Agreement") pursuant to which the Company agreed to acquire Purigen. Pursuant to the terms and conditions of the Purigen Merger Agreement, Purigen Merger Sub merged with and into Purigen, whereupon the separate corporate existence of Purigen Merger Sub ceased, with Purigen continuing as the surviving corporation of such merger and a wholly owned subsidiary of the Company. Purigen's isotachophoresis (ITP) technology is expected to expand and accelerate the adoption of OGM.

Pursuant to Purigen Merger Agreement, the Company paid upfront consideration consisting of a combination of approximately $32.0 million in cash. The upfront consideration is subject to adjustment for, among other things, cash, unpaid indebtedness, unpaid transaction expenses and working capital relative to a target. Under the Purigen Merger Agreement, the Company has also agreed to pay additional consideration, up to an aggregate of $32.0 million in cash based on the achievement of certain milestones. Cash of $1.2 million will be held in an escrow fund for purposes of satisfying any post-closing purchase price adjustments and indemnification claims under the Purigen Merger Agreement.

The Company accounted for its acquisition of Purigen using the acquisition method of accounting pursuant to ASC 805. The tangible and identifiable intangible assets acquired and liabilities assumed were recorded at their estimated fair values as of the acquisition date, and the excess of the purchase price over the estimated fair value assigned to the tangible and identifiable intangible assets acquired and liabilities assumed was recorded to goodwill. Goodwill relates to the expected synergies from combining the operations of the companies. The acquisition was structured as a stock sale and therefore goodwill is non-tax deductible.

The purchase price allocation for the acquisition of Purigen was finalized during the year ended December 31, 2023.

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

Cash	$	32,034,000
Estimated fair value of milestone consideration	$	12,970,000
Return of cash to buyer from escrow	$	(95,000)
Total estimated purchase price	$	44,909,000

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

Cash & cash equivalents	$	290,000
Accounts receivable		259,000
Inventory		944,000
Prepaid expenses and other current assets		184,000
Property and equipment, net		805,000
Restricted cash		400,000
Operating lease right-of-use assets		1,636,000
Other long-term assets		533,000
Intangible assets		20,000,000
Goodwill		22,646,000
Accounts payable and other accrued liabilities		(1,152,000)
Operating lease liability (short-term and long-term)		(1,636,000)
Net assets acquired	$	44,909,000

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

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

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

The customer relationships and trade name intangibles are being amortized on a straight-line basis over their estimated useful lives of 5 years. The developed technology intangible is being amortized on a straight-line basis over its estimated useful life of 15 years. Straight-line amortization was determined to be materially consistent with the pattern of expected use of the intangible assets.

As the Company began integrating Purigen's operations with its existing operations during the fourth quarter of 2022, it is not practical or meaningful to distinguish Purigen's expenses or net income or loss from that of the combined operations. Purigen revenues included in the Company's consolidated statement of operations from the date of acquisition through December 31, 2023 were not significant.

The Company recognized approximately $1.8 million of acquisition-related transaction costs for the acquisition of Purigen, including financial advisor fees, legal expenses and accounting fees for the years ended December 31, 2022. These costs are included in the consolidated statement of operations in selling, general and administrative expense.

Pro forma Financial Information

The unaudited pro forma financial information in the table below summarizes the combined results of operations for the Company, and Purigen as if the companies had been combined as of the beginning of the year prior to the acquisition. These amounts have been calculated after applying the Company's accounting policies and adjusting the results of Purigen to reflect the additional amortization that would have been charged assuming the fair value adjustments to intangible assets had been applied at the beginning of the year prior to the acquisition. The following unaudited pro forma financial information is for informational purposes only and is not necessarily indicative of the results of operations that would have been achieved as if the acquisitions had taken place as of January 1, 2021.

	Years Ended December 31, (Unaudited)	
		2022
Revenue	$	29,893,000
Net loss		(141,068,000)
Basic and diluted net loss per share	$	(4.88)

15. Related Party Transactions

Through the acquisition of BioDiscovery in October 2021, the Company inherited a building lease with a landlord owned by BioDiscovery's former Director and Chief Executive Officer, who served as the Company's Chief Informatics Officer from the date of the acquisition through October 2022. The Company recorded $0.5 million in finance lease costs related to this lease for the year ended December 31, 2022. Refer to Note 11 - Commitments and Contingencies for future commitments pertaining to this finance lease.

ITEM 9. CHANGES IN DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

None.

ITEM 9A. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

We maintain “disclosure controls and procedures,” as defined in Rules 13a-15(e) and Rule 15d-15(e) of the Exchange Act of 1934, as amended (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 December 31, 2023, our management, with the participation of our principal executive officer and principal financial officer, evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act). Our management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives, and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on this assessment, our management, including our principal executive officer and principal financial officer, has concluded that our disclosure controls and procedures were effective as of December 31, 2023.

Management’s Annual Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting as such term as defined in Exchange Act Rule 13a-15(f). Internal control over financial reporting is a process designed by, or under the supervision and with the participation of our management, including our principal executive and financial officers, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with accounting principles generally accepted in the United States of America.

As of December 31, 2023, under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting based on the framework in Internal Control-Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on this assessment, our management concluded that, as of December 31, 2023, our internal control over financial reporting was effective based on those criteria.

Changes in Internal Control over Financial Reporting

Except as described below, there were no changes to our internal control over financial reporting (as defined in Rules 13a-15(f) and 15-d-15(f) under the Exchange Act) that occurred during the quarter ended December 31, 2023 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

In November 2022, we acquired Purigen Biosystems Inc.. We have completed our integration of internal controls of the acquired business into our overall system of internal control over financial reporting as of December 31, 2023.

ITEM 9B. OTHER INFORMATION

During the three months ended December 31, 2023, 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 9C. DISCLOSURE REGARDING FOREIGN JURISDICTIONS THAT PREVENT INSPECTIONS

Not applicable.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS, AND CORPORATE GOVERNANCE

The information required by this item will be set forth under the captions “Proposal 1 – Election of Directors,” “Information Regarding the Board of Directors and Corporate Governance,” “Information Regarding Committees of the Board of Directors,” “Executive Officers,” and “Delinquent Section 16(a) Reports,” if any, in our definitive proxy statement to be filed with the SEC in connection with our 2024 Annual Meeting of Stockholders, or the Proxy Statement, which is expected to be filed not later than 120 days after the end of our fiscal year ended December 31, 2023, and is incorporated in this Annual Report by reference.

We have adopted a code of business conduct and ethics, or the Ethics Code, that applies to all our employees, officers and directors. This includes our principal executive officer, principal financial officer and principal accounting officer or controller, or persons performing similar functions. The full text of the Ethics Code is available on our website at www.bionanogenomics.com. If we ever were to amend or waive any provision of our Ethics Code that applies to the Company’s principal executive officer, principal financial officer, principal accounting officer or controller, or any person performing similar functions, we intend to satisfy our disclosure obligations, if any, with respect to any such waiver or amendment by posting such information on our website set forth above rather than by filing a Current Report on Form 8-K. Information contained in, or that can be accessed through, our website is not incorporated by reference herein, and you should not consider information on our website to be part of this Annual Report.

ITEM 11. EXECUTIVE COMPENSATION

The information required by this item will be set forth under the caption “Executive and Director Compensation” and “Item 402(v) Pay Versus Performance Disclosure” in the Proxy Statement and is incorporated in this Annual Report by reference.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

The information required by this item will be set forth under the captions “Security Ownership of Certain Beneficial Owners and Management” and “Equity Compensation Plan Information” in the Proxy Statement and is incorporated in this Annual Report by reference.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

The information required by this item will be set forth under the captions “Transactions With Related Persons and Indemnification” and “Information Regarding the Board of Directors and Corporate Governance” in the Proxy Statement and is incorporated in this Annual Report by reference.

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

The information required by this item will be set forth under the captions “Principal Accountant Fees and Services” and “Pre-Approval Policies and Procedures” in the Proxy Statement and is incorporated in this Annual Report by reference.

PART IV

ITEM 15. EXHIBIT AND FINANCIAL STATEMENT SCHEDULES

List the following documents filed as a part of the report:

(1) Financial statements

The response to this portion of Item 15 is set forth under Item 8 above.

The following consolidated financial statements of Bionano Genomics, Inc are included in Item 8 of this report:

- Reports of Independent Registered Public Accounting Firm
- Consolidated Balance Sheets — December 31, 2023 and 2022
- Consolidated Statements of Operations — Years ended December 31, 2023 and 2022
- Consolidated Statements of Comprehensive Loss — Years ended December 31, 2023 and 2022
- Consolidated Statements of Stockholders’ Equity (Deficit) – Years ended December 31, 2023 and 2022
- Consolidated Statements of Cash Flows — Years ended December 31, 2023 and 2022
- Notes to Consolidated Financial Statements

(2) Financial statement schedule.

All schedules have been omitted because they are not required or because the required information is given in the financial statements or notes thereto set forth under Item 8 above.

(3) Exhibits

A list of exhibits filed with this Annual Report or incorporated herein by reference can be found in the Exhibit Index below.

Exhibit Index

Exhibit Number	Description
2.1^€ [1]	Agreement and Plan of Merger, dated October 8, 2021, by and among the Company, Starship Merger Sub I, Inc., Starship Merger Sub II, LLC, BioDiscovery, Inc. and Soheil Shams.
2.2^€ [2]	Agreement and Plan of Merger, dated November 23, 2022, by and among the Company, Mazdan Merger Sub, Inc., Purigen Biosystems, Inc. and Shareholder Representative Services LLC.
2.3^€ [3]	First Amendment to Agreement and Plan of Merger, dated March 4, 2023, by and between the Company and Soheil Shams, as the Securityholders' Representative.
2.4^€ [4]	Second Amendment to Agreement and Plan of Merger, dated July 15, 2023, by and among the Company, Starship Merger Sub I, Inc., Starship Merger Sub II, LLC, BioDiscovery, Inc. and Soheil Shams
3.1^€ [5]	Certificate of Elimination of Series A Preferred Stock.
3.1[3]	Amended and Restated Certificate of Incorporation, as amended.
3.2[4]	Amended and Restated Bylaws.
3.4[17]	Amendment to Amended and Restated Bylaws.
4.1[5]	Form of Common Stock Certificate.
4.2[5]	Form of Warrant to Purchase Series D-1 Preferred Stock issued to Midcap Financial Trust.
4.3[8]	Form of Warrant to Purchase Common Stock issued to Investors in October 2019 Public Offering.
4.4[9]	Form of Warrant to Purchase Common Stock issued to Investors in April 2020 Public Offering.
4.5	Description of the Company's Securities.
4.6[18]	Form of Note, representing the Company's Senior Secured Convertible Notes due 2025.
4.7[19]	Form of Warrant to Purchase Common Stock issued to Purchaser in October 2023 Offering.
4.8[62]	Amendment to Initial Registered Note issued to Purchaser dated February 27, 2024
10.1+[10]	Bionano Genomics, Inc. 2018 Equity Incentive Plan, as amended (the "2018 Plan").
10.1A+	Forms of grant notice, stock option agreement and notice of exercise under the 2018 Plan.
10.1B+	Forms of director grant notice, stock option agreement and notice of exercise under the 2018 Plan.
10.1C+	Forms of double-trigger grant notice, stock option agreement and notice of exercise under the 2018 Plan.
10.1D+[5]	Forms of international grant notice, stock option agreement and notice of exercise under the 2018 Plan.
10.1E+[11]	Forms of restricted stock unit grant notice and restricted stock unit award agreement under the Bionano Genomics, Inc. 2018 Equity Incentive Plan.
10.2+[12]	Bionano Genomics, Inc. 2018 Employee Stock Purchase Plan.
10.3+[2]	Bionano Genomics, Inc. 2020 Inducement Plan, as amended.
10.3A+[13]	Form of Stock Option Grant Notice and Stock Option Agreement under the Bionano Genomics, Inc. 2020 Inducement Plan.
10.4+[14]	Bionano Genomics, Inc. Non-Employee Director Compensation Policy, as amended
10.5+[5]	Form of Indemnification Agreement by and between the Registrant and each director and executive officer.
10.6+[5]	Employment Agreement by and between the Registrant and R. Erik Holmlin, Ph.D., dated November 7, 2017, as amended.
10.7+[15]	Employment Agreement, effective as of September 1, 2020, by and between Christopher Stewart and the Company.
10.8+[15]	Employment Agreement, effective as of August 31, 2020, by and between Alka Chaubey and the Company.
10.90+[5]	Employment Agreement by and between the Registrant and Mark Oldakowski, dated November 7, 2017.
10.10[5]	Lease by and between the Registrant and The Irvine Company LLC, dated January 16, 2012.
10.10A[5]	First Amendment to the Lease by and between the Registrant and The Irvine Company LLC, dated September 10, 2013.
10.10B[5]	Second Amendment to the Lease by and between the Registrant and The Irvine Company LLC, dated July 1, 2015.
10.10C[3]	Third Amendment to the Lease by and between the Registrant and The Irvine Company LLC, dated December 19, 2019.
10.10D[3]	Fourth Amendment to the Lease by and between the Registrant and The Irvine Company LLC, dated February 15, 2021.
10.10E[14]	Fifth Amendment to the Lease by and between the Registrant and The Irvine Company, LLC, dated January 12, 2022.
10.11[14]	Standard Industrial/Commercial Single-Tenant Lease, made effective as of November 23, 2021, by and between the Company and 6777 Nancy Ridge LLC.

Exhibit Number	Description
10.12[14]	Commercial Single-Tenant Lease – Net, dated February 28, 2016, by and between Tesa Beach LLC and BioDiscovery, Inc.
10.13	Lease, dated August 22, 2016, by and between SFF BBC, LLC and Purigen Biosystems, Inc.
10.13A	First Amendment to the Lease by and between Purigen Biosystems Inc, and SFF BBC, LLC, dated August 22, 2016
10.14[16]	Sales Agreement, dated March 23, 2021, by and between the Company and Cowen and Company, LLC.
10.14A[3]	Amendment No. 1 to Sales Agreement, dated March 9, 2023, by and between the Company and Cowen and Company, LLC.
10.15#[5]	License Agreement by and between Princeton University and the Registrant, dated January 7, 2004.
10.15A#[5]	First Amendment to the License Agreement by and between Princeton University and the Registrant, dated December 17, 2004.
10.15B#[5]	Second Amendment to the License Agreement by and between Princeton University and the Registrant, dated February 25, 2010.
10.15C#[5]	Third Amendment to the License Agreement by and between Princeton University and the Registrant, dated October 17, 2011.
10.15D#[5]	Fourth Amendment License Agreement by and between Princeton University and the Registrant, dated February 9, 2012.
10.16#[5]	Master Services Agreement by and between the Registrant and Skorpios Technologies, Inc. (f/k/a Novati Technologies, Inc. and f/k/a SVTC Technologies, LLC), dated March 2, 2009, as amended.
10.17#[5]	License Agreement by and between the Registrant and New York University dated November 4, 2013.
10.18#[5]	License Agreement by and between the Registrant and Q Biotechnology CV dated May 1, 2014.
10.18A#[5]	Amendment to Non-Exclusive Patent License Agreement by and between the Registrant and Q Biotechnology CV dated May 1, 2014.
10.19#[5]	Manufacturing Services Agreement by and between the Registrant and Paramit Corporation, dated February 18, 2015.
10.20#[5]	Option and Sublicense Agreement by and between the Registrant and Pacific Biosciences of California, Inc. dated February 2, 2016.
10.21^€	Amended and Restated Exclusive License Agreement with Equity, dated July 16, 2021, by and between The Board of Trustees of the Leland Stanford Junior University and Purigen Biosystems, Inc.
10.21A^€	Amendment No. 1 to the Amended and Restated Exclusive License Agreement Effective the 16th Day of July 2021 Between Stanford University and Purigen Biosystems, Inc., dated November 14, 2022, by and between The Board of Trustees of the Leland Stanford Junior University and Purigen Biosystems, Inc.
10.22	Employment Agreement, effective as of September 11, 2023, by and between Gülsen Kama and the Company.
10.23	Transition, Separation and Consulting Agreement dated as of August 11, 2023, by and between Christopher Stewart and the Company.
10.24^[18]	Securities Purchase Agreement, dated October 11, 2023, by and among the Company and the Purchaser named therein.
10.25^[63]	Letter Agreement between the Company and the Purchaser named therein, dated February 27, 2024.
21.1	Subsidiaries of the Registrant.
22.1	Affiliates whose securities collateralize securities of the registrant
23.1	Consent of BDO USA, P.C., independent registered public accounting firm.
24.1	Power of Attorney (included on signature page).
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 pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2*	Certification of Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
97.1*	Bionano Genomics, Inc. Incentive Compensation Recoupment Policy
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.

Exhibit Number	Description
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document.
104	Cover Page Interactive Data File (formatted in Inline XBRL and contained in Exhibit 101)
(1)	Incorporated by reference to Exhibit 2.1 of the Registrant's Current Report on Form 8-K, filed with the SEC on October 19, 2021.
(2)	Incorporated by reference to Exhibit 2.1 of the Registrant's Current Report on Form 8-K, filed with the SEC on November 28, 2022.
(3)	Incorporated by reference to the Registrant's Quarterly Report on Form 10-Q, filed with the SEC on May 9, 2023.
(4)	Incorporated by reference to the Registrant's Quarterly Report on Form 10-Q, filed with the SEC on November 8, 2023
(5)	Incorporated by reference to the Registrant's Current Report on Form 8-K, filed with the SEC on August 4, 2023.
(6)	Incorporated by reference to Exhibit 3.1 of the Registrant's Annual Report on Form 10-K, filed with the SEC on March 23, 2021
(7)	Incorporated by reference to Exhibit 3.2 of the Registrant's Current Report on Form 8-K, filed with the SEC on August 24, 2018.
(8)	Incorporated by reference to Exhibit 3.2 of the Registrant's Current Report on Form 8-K, filed with the SEC on April 14, 2023.
(9)	Incorporated by reference to Exhibit 3.1 of the Registrant's Annual Report on Form 10-K, filed with the SEC on March 23, 2021
(10)	Incorporated by reference to Exhibit 3.2 of the Registrant's Current Report on Form 8-K, filed with the SEC on August 24, 2018.
(11)	Incorporated by reference to Exhibit 3.2 of the Registrant's Current Report on Form 8-K, filed with the SEC on April 14, 2023.
(12)	Incorporated by reference to Exhibit 4.13 of the Registrant's Registration Statement on Form S-1 (File No. 333-233828), as amended.
(13)	Incorporated by reference to Exhibit 4.16 of the Registrant's Registration Statement on Form S-1 (File No. 333-237074), as amended, filed with the SEC on March 24, 2020.
(14)	Incorporated by reference to Exhibit 4.10 of the Registrant's Annual Report on Form 10-K, filed with the SEC on March 9, 2023.
(15)	Incorporated by reference to Exhibit 4.1 of the Registrant's Current Report on Form 8-K, filed with the SEC on October 11, 2023.
(16)	Incorporated by reference to Exhibit 4.2 of the Registrant's Registration Statement on Form S-3 (File No. 333-275181).
(17)	Incorporated by reference to Exhibit 10.2 of the Registrant's Registration Statement on Form S-1 (File No. 333-225970), as amended, filed with the SEC on August 17, 2018.
(18)	Incorporated by reference to Exhibit 10.3 of the Registrant's Registration Statement on Form S-1 (File No. 333-225970), as amended, filed with the SEC on August 17, 2018.
(19)	Incorporated by reference to Exhibit 99.1 of the Registrant's Registration Statement on Form S-8 (File No. 333-245764), filed with the SEC on August 14, 2020.
(20)	Incorporated by reference to Exhibit 10.2A of the Registrant's Annual Report on Form 10-K, filed with the SEC on March 9, 2023.
(21)	Incorporated by reference to Exhibit 10.2B of the Registrant's Annual Report on Form 10-K, filed with the SEC on March 9, 2023.
(22)	Incorporated by reference to Exhibit 10.2C of the Registrant's Annual Report on Form 10-K, filed with the SEC on March 9, 2023.
(23)	Incorporated by reference to Exhibit 10.5 of the Registrant's Registration Statement on Form S-1 (File No. 333-225970), as amended, filed with the SEC on August 17, 2018.
(24)	Incorporated by reference to Exhibit 99.5 of the Registrant's Registration Statement on Form S-8 (File No. 333-227073), filed with the SEC on August 28, 2018.
(25)	Incorporated by reference to Exhibit 10.1 of the Registrant's Current Report on Form 8-K, filed with the SEC on November 28, 2022.
(26)	Incorporated by reference to Exhibit 10.2 of the Registrant's Current Report on Form 8-K, filed with the SEC on August 4, 2020.
(27)	Incorporated by reference to Exhibit 10.7 of the Registrant's Annual Report on Form 10-K, filed with the SEC on March 1, 2022.
(28)	Incorporated by reference to Exhibit 10.7 of the Registrant's Registration Statement on Form S-1 (File No. 333-225970), as amended, filed with the SEC on August 17, 2018.
(29)	Incorporated by reference to Exhibit 10.10 of the Registrant's Registration Statement on Form S-1 (File No. 333-225970), as amended, filed with the SEC on August 17, 2018.
(30)	Incorporated by reference to Exhibit 10.6 of the Registrant's Quarterly Report on Form 10-Q, filed with the SEC on November 13, 2020.

Exhibit Number	Description
(31)	Incorporated by reference to Exhibit 10.7 of the Registrant's Quarterly Report on Form 10-Q, filed with the SEC on November 13, 2020.
(32)	Incorporated by reference to Exhibit 10.14 of the Registrant's Registration Statement on Form S-1 (File No. 333-225970), as amended, filed with the SEC on August 17, 2018.
(33)	Incorporated by reference to Exhibit 10.20 of the Registrant's Registration Statement on Form S-1 (File No. 333-225970), as amended, filed with the SEC on August 17, 2018.
(34)	Incorporated by reference to Exhibit 10.21 of the Registrant's Registration Statement on Form S-1 (File No. 333-225970), as amended, filed with the SEC on August 17, 2018.
(35)	Incorporated by reference to Exhibit 10.22 of the Registrant's Registration Statement on Form S-1 (File No. 333-225970), as amended, filed with the SEC on August 17, 2018.
(36)	Incorporated by reference to Exhibit 10.22 of the Registrant's Annual Report on Form 10-K, filed with the SEC on March 23, 2021
(37)	Incorporated by reference to Exhibit 10.23 of the Registrant's Annual Report on Form 10-K, filed with the SEC on March 23, 2021
(38)	Incorporated by reference to Exhibit 10.39 of the Registrant's Annual Report on Form 10-K, filed with the SEC on March 1, 2022.
(39)	Incorporated by reference to Exhibit 10.33 of the Registrant's Annual Report on Form 10-K, filed with the SEC on March 1, 2022.
(40)	Incorporated by reference to Exhibit 10.38 of the Registrant's Annual Report on Form 10-K, filed with the SEC on March 1, 2022.
(41)	Incorporated by reference to Exhibit 10.14 of the Registrant's Annual Report on Form 10-K, filed with the SEC on March 9, 2023.
(42)	Incorporated by reference to Exhibit 10.14A of the Registrant's Annual Report on Form 10-K, filed with the SEC on March 9, 2023.
(43)	Incorporated by reference to Exhibit 1.1 of the Registrant's Current Report on Form 8-K, filed with the SEC on March 24, 2021.
(44)	Incorporated by reference to the Registrant's Quarterly Report on Form 10-Q, filed with the SEC on May 9, 2023
(45)	Incorporated by reference to Exhibit 10.25 of the Registrant's Registration Statement on Form S-1 (File No. 333-225970), as amended, filed with the SEC on August 17, 2018.
(46)	Incorporated by reference to Exhibit 10.26 of the Registrant's Registration Statement on Form S-1 (File No. 333-225970), as amended, filed with the SEC on August 17, 2018.
(47)	Incorporated by reference to Exhibit 10.27 of the Registrant's Registration Statement on Form S-1 (File No. 333-225970), as amended, filed with the SEC on August 17, 2018.
(48)	Incorporated by reference to Exhibit 10.28 of the Registrant's Registration Statement on Form S-1 (File No. 333-225970), as amended, filed with the SEC on August 17, 2018.
(49)	Incorporated by reference to Exhibit 10.29 to the Registrant's Registration Statement on Form S-1 (File No. 333-225970), as amended, filed with the SEC on August 17, 2018.
(50)	Incorporated by reference to Exhibit 10.23 of the Registrant's Registration Statement on Form S-1 (File No. 333-225970), as amended, filed with the SEC on August 17, 2018.
(51)	Incorporated by reference to Exhibit 10.34 of the Registrant's Registration Statement on Form S-1 (File No. 333-225970), as amended, filed with the SEC on August 17, 2018.
(52)	Incorporated by reference to Exhibit 10.32 of the Registrant's Registration Statement on Form S-1 (File No. 333-225970), as amended, filed with the SEC on August 17, 2018.
(53)	Incorporated by reference to Exhibit 10.33 of the Registrant's Registration Statement on Form S-1 (File No. 333-225970), as amended, filed with the SEC on August 17, 2018.
(54)	Incorporated by reference to Exhibit 10.24 of the Registrant's Registration Statement on Form S-1 (File No. 333-225970), as amended, filed with the SEC on August 17, 2018.
(55)	Incorporated by reference to Exhibit 10.35 of the Registrant's Registration Statement on Form S-1 (File No. 333-225970), as amended, filed with the SEC on August 17, 2018.
(56)	Incorporated by reference to Exhibit 10.22 of the Registrant's Annual Report on Form 10-K, filed with the SEC on March 9, 2023.
(57)	Incorporated by reference to Exhibit 10.22A of the Registrant's Annual Report on Form 10-K, filed with the SEC on March 9, 2023.
(58)	Incorporated by reference to Exhibit 10.1 of the Registrant's Quarterly Report on Form 10-Q, filed with the SEC on November 8, 2023.
(59)	Incorporated by reference to Exhibit 10.2 of the Registrant's Quarterly Report on Form 10-Q, filed with the SEC on November 8, 2023.
(60)	Incorporated by reference to Exhibit 10.1 of the Registrant's Current Report on Form 8-K, filed with the SEC on October 11, 2023.

Exhibit Number	Description
(61)	Incorporated by reference to Exhibit 21.1 of the Registrant's Annual Report on Form 10-K, filed with the SEC on March 9, 2023.
(62)	Incorporated by reference to Exhibit 10.2 of the Registrant's Current Report on Form 8-K, filed with the SEC on February 28, 2024
(63)	Incorporated by reference to Exhibit 10.1 of the Registrant's Current Report on Form 8-K, filed with the SEC on February 28, 2024
^	Certain exhibits and schedules have been omitted pursuant to Item 601(a)(5) of Regulation S-K. The Registrant hereby undertakes to furnish supplementally a copy of any omitted exhibit or schedule upon request by the SEC.
+	Indicates management contract or compensatory plan.
#	Confidential treatment has been granted with respect to certain portions of this exhibit. Omitted portions have been filed separately with the SEC.
€	Pursuant to Item 601(b)(10) of Regulation S-K, certain portions of this exhibit have been omitted (indicated by "[***]") because the Company has determined that the information is not material and is the type that the Company treats as private or confidential.
*	This certification is furnished herewith and 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 (whether made before or after the date of this Annual Report on Form 10-K), irrespective of any general incorporation language contained in such filing.

ITEM 16. FORM 10-K SUMMARY

None.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, as amended, the Registrant has duly caused this Annual Report to be signed on its behalf by the undersigned, thereunto duly authorized**.**

Bionano Genomics, Inc.

Date: March 5, 2024

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

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

POWER OF ATTORNEY

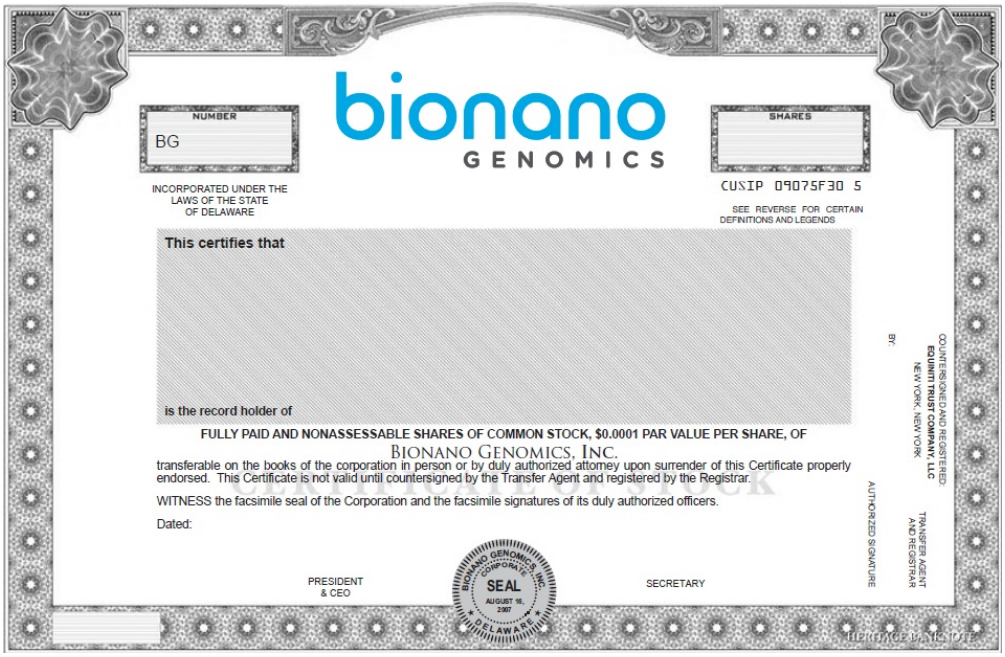
KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints each of R. Erik Holmlin, Ph.D. and Gülsen Kama as his or her true and lawful attorney-in-fact and agent, with full power of substitution and resubstitution, for him or her and in his or her name, place and stead, in any and all capacities, to sign this Annual Report on Form 10-K of Bionano Genomics, Inc., and any or all amendments thereto, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorney-in-fact and agent full power and authority to do and perform each and every act and thing requisite or necessary to be done in and about the premises hereby ratifying and confirming all that said attorney-in-fact and agent, or his or her substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, this Annual Report has been signed below by the following persons on behalf of the Registrant in the capacities and on the dates indicated.

Signature	Title	Date
/s/ R. Erik Holmlin, Ph.D. R. Erik Holmlin, Ph.D.	Chief Executive Officer and Director *(Principal Executive Officer)*	March 5, 2024
/s/ Gülsen Kama Gülsen Kama	Chief Financial Officer *(Principal Financial and Accounting Officer)*	March 5, 2024
/s/ David L. Barker, Ph.D. David L. Barker, Ph.D.	Director	March 5, 2024
/s/ Albert A. Luderer, Ph.D. Albert A. Luderer, Ph.D.	Director	March 5, 2024
/s/ Yvonne Linney, Ph.D. Yvonne Linney, Ph.D.	Director	March 5, 2024
/s/ Hannah Mamuszka Hannah Mamuszka	Director	March 5, 2024
/s/ Aleksandar Rajkovic, M.D., Ph.D Aleksandar Rajkovic, M.D., Ph.D.	Director	March 5, 2024
/s/ Christopher Twomey Christopher Twomey	Director	March 5, 2024
/s/ Kristiina Vuori, M.D., Ph.D. Kristiina Vuori, M.D., Ph.D.	Director	March 5, 2024
/s/ Vincent Wong, J.D., M.B.A. Vincent Wong, J.D., M.B.A.	Director	March 5, 2024

EX-4.1 2 bngo-ex41x20231231.htm EX-4.1

Exhibit 4.1



bionano GENOMICS

NUMBER

BG

SHARES

INCORPORATED UNDER THE LAWS OF THE STATE OF DELAWARE

CUSIP 09075F30 5

SEE REVERSE FOR CERTAIN DEFINITIONS AND LEGENDS

This certifies that

is the record holder of

FULLY PAID AND NONASSESSABLE SHARES OF COMMON STOCK, $0.0001 PAR VALUE PER SHARE, OF

BIONANO GENOMICS, INC.

transferable on the books of the corporation in person or by duly authorized attorney upon surrender of this Certificate properly endorsed. This Certificate is not valid until countersigned by the Transfer Agent and registered by the Registrar.

WITNESS the facsimile seal of the Corporation and the facsimile signatures of its duly authorized officers.

Dated:

PRESIDENT & CEO

SECRETARY

SEAL

AUGUST 16, 2007

DELAWARE

COUNTERSIGNED AND REGISTERED:
EQUINITI TRUST COMPANY, LLC
NEW YORK, NEW YORK

TRANSFER AGENT AND REGISTRAR

BY:

AUTHORIZED SIGNATURE

HERITAGE BANK OF

The Corporation shall furnish without charge to each stockholder who so requests a statement of the powers, designations, preferences and relative, participating, optional or other special rights of each class of stock of the Corporation or series thereof and the qualifications, limitations or restrictions of such preferences and/or rights. Such requests shall be made to the Corporation's Secretary at the principal office of the Corporation.

KEEP THIS CERTIFICATE IN A SAFE PLACE. IF IT IS LOST, STOLEN,OR DESTROYED THE CORPORATION WILL REQUIRE A BOND INDEMNITY AS A CONDITION TO THE ISSUANCE OF A REPLACEMENT CERTIFICATE.

The following abbreviations, when used in the inscription on the face of this certificate, shall be construed as though they were written out in full according to applicable laws or regulations:

TEN COM – as tenants in common
TEN ENT – as tenants by the entireties
JT TEN – as joint tenants with right of survivorship and not as tenants in common
COM PROP – as community property

UNIF GIFT MIN ACT – ..... Custodian .....
(Cust) (Minor)
under Uniform Gifts to Minors Act.....
(State)

UNIF TRF MIN ACT – ..... Custodian (until age .....)
(Cust)
..... under Uniform Transfers
(Minor)
to Minors Act.....
(State)

Additional abbreviations may also be used though not in the above list.

FOR VALUE RECEIVED, _____ hereby sell(s), assign(s) and transfer(s) unto

PLEASE INSERT SOCIAL SECURITY OR OTHER IDENTIFYING NUMBER OF ASSIGNEE

_____

_____
(PLEASE PRINT OR TYPEWRITE NAME AND ADDRESS, INCLUDING ZIP CODE, OF ASSIGNEE)

_____

_____

_____ shares of the capital stock represented by within Certificate, and do hereby irrevocably constitute and appoint

_____ attorney-in-fact to transfer the said stock on the books of the within named Corporation with full power of the substitution in the premises.

Dated _____

X _____

X _____

Signature(s) Guaranteed:

NOTICE: THE SIGNATURE TO THIS ASSIGNMENT MUST CORRESPOND WITH THE NAME AS WRITTEN UPON THE FACE OF THE CERTIFICATE IN EVERY PARTICULAR, WITHOUT ALTERATION OR ENLARGEMENT OR ANY CHANGE WHATSOEVER.

By _____

THE SIGNATURE(S) SHOULD BE GUARANTEED BY AN ELIGIBLE GUARANTOR INSTITUTION, (BANKS, STOCKBROKERS, SAVINGS AND LOAN ASSOCIATIONS AND CREDIT UNIONS WITH MEMBERSHIP IN AN APPROVED SIGNATURE GUARANTEE MEDALLION PROGRAM), PURSUANT TO S.E.C. RULE 17Ad-15. GUARANTEES BY A NOTARY PUBLIC ARE NOT ACCEPTABLE. SIGNATURE GUARANTEES MUST NOT BE DATED.

Exhibit 4.5

DESCRIPTION OF SECURITIES

General

The following summary describes Bionano Genomic, Inc.'s (or "we," "our" or "us") securities registered under Section 12 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), certain provisions of our amended and restated certificate of incorporation, as amended ("Restated Certificate"), amended and restated and bylaws, as amended ("Bylaws"), and certain provisions of Delaware law. Because it is only a summary, it does not contain all of the information that may be important to you. For a complete description of the matters set forth in this Description of Securities, you should refer to our Restated Certificate, Bylaws, form of warrant certificate and form of warrant agent agreement, each of which are filed as exhibits to our Annual Report on Form 10-K, as well as the applicable provisions of the General Corporation Law of the State of Delaware ("DGCL"). The Restated Certificate authorizes us to issue 400,000,000 shares of common stock, par value $0.0001 per share, and 10,000,000 shares of preferred stock, par value $0.0001 per share. Our board of directors has the authority, without stockholder approval, except as required by the listing standards of The Nasdaq Stock Market LLC, to issue additional shares of our capital stock. In addition, our board of directors has the authority, without further action by our stockholders, to designate the rights, preferences, privileges, qualifications and restrictions of our preferred stock in one or more series.

Common Stock

Voting Rights

Our common stock is entitled to one vote for each share held of record on all matters submitted to a vote of the stockholders, including the election of directors, and does not have cumulative voting rights. The Restated Certificate establishes a classified board of directors that is divided into three classes with staggered three-year terms. Only the directors in one class will be subject to election by a plurality of the votes cast at each annual meeting of our stockholders, with the directors in the other classes continuing for the remainder of their respective three-year terms.

Economic Rights

Except as otherwise expressly provided in the Restated Certificate or required by applicable law, all shares of common stock have the same rights and privileges and rank equally, share ratably, and are identical in all respects for all matters, including those described below.

Dividends. Subject to preferences that may be applicable to any then-outstanding preferred stock, the holders of common stock are entitled to receive dividends, if any, as may be declared from time to time by our board of directors out of legally available funds.

Liquidation Rights. In the event of our liquidation, dissolution or winding-up, holders of our common stock are entitled to share ratably in the net assets legally available for distribution to stockholders after the payment of all of our debts and other liabilities, subject to the satisfaction of any liquidation preference granted to the holders of any outstanding shares of preferred stock.

No Preemptive or Similar Rights

The holders of our shares of common stock are not entitled to preemptive rights, and are not subject to conversion, redemption or sinking fund provisions. The rights, preferences and privileges of the holders of our common stock are subject to, and may be adversely affected by, the rights of the holders of shares of any series of our preferred stock that we may designate and issue in the future.

Preferred Stock

Our board of directors may authorize the issuance of preferred stock with voting or conversion rights that could adversely affect the voting power or other rights of the holders of the common stock. The issuance of preferred stock, while providing flexibility in connection with possible acquisitions and other corporate purposes, could, among other things, have the effect of delaying, deferring or preventing a change in our control that may otherwise benefit holders of our common stock and may adversely affect the market price of the common stock and the voting and other rights of the holders of common stock. We have no current plans to issue any shares of preferred stock.

Anti-Takeover Provisions

The provisions of the DGCL, the Restated Certificate and the Bylaws, certain provisions of which are summarized below, may have the effect of delaying, deferring or discouraging another person from acquiring control of our company. They are also designed, in part, to encourage persons seeking to acquire control of us to negotiate first with our board of directors. We believe that the benefits of increased protection of our potential ability to negotiate with an unfriendly or unsolicited acquirer outweigh the disadvantages of discouraging a proposal to acquire us because negotiation of these proposals could result in an improvement of their terms.

Section 203 of the Delaware General Corporation Law

We are subject to Section 203 of the DGCL, which prohibits a Delaware corporation from engaging in any business combination with any interested stockholder for a period of three years after the date that such stockholder became an interested stockholder, with the following exceptions

- before such date, the board of directors of the corporation approved either the business combination or the transaction that resulted in the stockholder becoming an interested stockholder;
- upon completion of the transaction that resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction began, excluding for purposes of determining the voting stock outstanding, but not the outstanding voting stock owned by the interested stockholder, those shares owned (i) by persons who are directors and also officers and (ii) employee stock plans in which employee participants do not have the right to determine confidentially whether shares held subject to the plan will be tendered in a tender or exchange offer; or
- on or after such date, the business combination is approved by the board of directors and authorized at an annual or special meeting of the stockholders, and not by written consent, by the affirmative vote of at least 66 2/3% of the outstanding voting stock that is not owned by the interested stockholder.

In general, Section 203 defines a “business combination” to include the following:

- any merger or consolidation involving the corporation and the interested stockholder;
- any sale, transfer, pledge or other disposition of 10% or more of the assets of the corporation involving the interested stockholder;
- subject to certain exceptions, any transaction that results in the issuance or transfer by the corporation of any stock of the corporation to the interested stockholder;
- any transaction involving the corporation that has the effect of increasing the proportionate share of the stock or any class or series of the corporation beneficially owned by the interested stockholder; or
- the receipt by the interested stockholder of the benefit of any loans, advances, guarantees, pledges or other financial benefits by or through the corporation.

In general, Section 203 defines an “interested stockholder” as an entity or person who, together with the entity or person’s affiliates and associates, beneficially owns, or is an affiliate or associate of the corporation and within three years prior to the time of determination of interested stockholder status did own, 15% or more of the outstanding voting stock of the corporation.

A Delaware corporation may “opt out” of these provisions with an express provision in its certificate of incorporation. We have not opted out of these provisions, which may as a result, discourage or prevent mergers or other takeover or change of control attempts of us.

Certificate of Incorporation and Bylaws

Among other things, the Restated Certificate and the Bylaws:

- do not provide stockholders with cumulative voting rights such that stockholders holding a plurality of the voting power of our shares of common stock may be able to elect all of our directors;
- provide for stockholder actions to be taken at a duly called meeting of stockholders and not by written consent;
- provide that a special meeting of stockholders may only be called by a majority of our board of directors, the chair of our board of directors or our chief executive officer;
- establish an advance notice procedure for stockholder proposals to be brought before an annual meeting of our stockholders, including proposed nominations of persons for election to our board of directors;
- divide our board of directors into three classes with staggered three-year terms;
- provide that the authorized number of directors may be changed only by resolution adopted by a majority of the authorized number of directors constituting the board of directors;
- provide that the board of directors or any individual director may only be removed with cause and the affirmative vote of the holders of at least 66 2/3% of the voting power of all of our then outstanding shares of common stock; and

- provide that all vacancies, including newly created directorships, may, except as otherwise required by law or subject to the rights of holders of preferred stock as designated from time to time, be filled by the affirmative vote of a majority of directors then in office, even if less than a quorum.

The foregoing provisions make it difficult for another party to obtain control of us by replacing our board of directors. Since our board of directors has the power to retain and discharge our officers, these provisions could also make it more difficult for existing stockholders or another party to effect a change in management. In addition, the authorization of undesignated preferred stock makes it possible for our board of directors to issue preferred stock with voting or other rights or preferences that could impede or discourage an attempt to obtain control of us by means of a merger, tender offer, proxy contest or otherwise.

These provisions are designed to reduce our vulnerability to an unsolicited acquisition proposal and to discourage certain tactics that may be used in proxy fights. However, such provisions could have the effect of discouraging others from making tender offers for our shares and may have the effect of deterring hostile takeovers or delaying changes in our control or management. As a consequence, these provisions may also inhibit fluctuations in the market price of our stock that could result from actual or rumored takeover attempts.

Choice of Forum

The Restated Certificate provides that the Court of Chancery of the State of Delaware is the exclusive forum for: (i) any derivative action or proceeding brought on our behalf; (ii) any action asserting a claim of breach of fiduciary duty owed by any of our directors, officers or other employees to us or our stockholders; (iii) any action asserting a claim against us or any of our directors or officers or other employees arising under the Delaware General Corporation Law, the Restated Certificate or the Bylaws; or (iv) any action asserting a claim against us or any of our directors or officers or other employees that is governed by the internal affairs doctrine. The Restated Certificate further provides that U.S. federal district courts will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act of 1933, as amended. These choice of forum provisions of the Restated Certificate will not apply to suits brought to enforce a duty or liability created by the Exchange Act.

EX-22.1 4 bngo-ex221x20231231.htm EX-22.1

Exhibit 22.1

Bionano Genomics, Inc.
Subsidiary Guarantors

Bionano Genomics, Inc. (“Bionano”) issued (i) in a registered offering, $45 million aggregate principal amount of senior secured convertible notes due in 2025 and (ii) in a private placement, $35 million aggregate principal amount of senior secured convertible notes due in 2025 (collectively, the “Notes”). The following subsidiaries of Bionano are guarantors of the Notes:

Lineagen, Inc.

Purigen Biosystems, Inc.

Biodiscovery, LLC

EX-23.1 5 exhibit231-bdoauditorconse.htm EX-23.1

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in the Registration Statements on Form S-3 (File Nos. 333-237070, 333-239360, 333-245762, 333-251956 and 333-252216) and Form S-8 (Nos. 333-227073, 333-230589, 333-237069, 333-245764, 333-248468, 333-254654, 333-260762 and 333-263176) of Bionano Genomics, Inc. (the “Company”) of our report dated March 5, 2024, relating to the consolidated financial statements which appear in this Annual Report on Form 10-K. Our report contains an explanatory paragraph regarding the Company’s ability to continue as a going concern.

/s/ BDO USA, P.C.

San Diego, California
March 5, 2024

Exhibit 31.1

CERTIFICATION

I, R. Erik Holmlin, certify that:

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

Date: March 5, 2024

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

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

Exhibit 31.2

CERTIFICATION

I, Gülsen Kama, certify that:

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

Date: March 5, 2024

/s/ Gülsen Kama

Gülsen Kama
Chief Financial Officer
(Principal Financial and Accounting Officer)

Exhibit 32.1

CERTIFICATION

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

1. The Company’s Annual Report on Form 10-K for the fiscal year ended December 31, 2023, as filed with the Securities and Exchange Commission on the date hereof (the “Annual 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 Annual Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: March 5, 2024

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

President and Chief Executive Officer
(Principal Executive Officer)

This certification accompanies and is being “furnished” with this Annual 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 Securities Exchange Act of 1934, as amended, whether made before or after the date of this Annual Report, irrespective of any general incorporation language contained in such filing.

Exhibit 32.2

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, Gülsen Kama, Chief Financial Officer of Bionano Genomics, Inc., a Delaware corporation (the “Company”), hereby certifies that, to the best of her knowledge:

1. The Company’s Annual Report on Form 10-K for the fiscal year ended December 31, 2023, as filed with the Securities and Exchange Commission on the date hereof (the “Annual Report”), and to which this Certification is attached as Exhibit 32.2, fully complies with the requirements of Section 13(a) or Section 15(d) of the Exchange Act; and

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

Date: March 5, 2024

/s/ Gülsen Kama

Gülsen Kama
Chief Financial Officer
(Principal Financial and Accounting Officer)

This certification accompanies and is being “furnished” with this Annual 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 Securities Exchange Act of 1934, as amended, whether made before or after the date of this Annual Report, irrespective of any general incorporation language contained in such filing.

Exhibit 97.1

Bionano Genomics, Inc.
Incentive Compensation Recoupment Policy

1. Introduction

The Board of Directors (the "***Board***") of Bionano Genomics, Inc., a Delaware corporation (the "***Company***"), has determined that it is in the best interests of the Company and its stockholders to adopt this Incentive Compensation Recoupment Policy (this "***Policy***") providing for the Company's recoupment of Recoverable Incentive Compensation that is received by Covered Officers of the Company under certain circumstances. Certain capitalized terms used in this Policy have the meanings given to such terms in Section 3 below.

This Policy is designed to comply with, and shall be interpreted to be consistent with, Section 10D of the Exchange Act, Rule 10D-1 promulgated thereunder ("***Rule 10D-1***") and Nasdaq Listing Rule 5608 (the "***Listing Standards***").

2. Effective Date

This Policy shall apply to all Incentive Compensation that is received by a Covered Officer on or after October 2, 2023 (the "***Effective Date***"). Incentive Compensation is deemed "***received***" in the Company's fiscal period in which the Financial Reporting Measure specified in the Incentive Compensation award is attained, even if the payment or grant of such Incentive Compensation occurs after the end of that period.

3. Definitions

"***Accounting Restatement***" means an accounting restatement that the Company is required to prepare due to the material noncompliance of the Company with any financial reporting requirement under the securities laws, including any required accounting restatement to correct an error in previously issued financial statements that is material to the previously issued financial statements, or that would result in a material misstatement if the error were corrected in the current period or left uncorrected in the current period.

"***Accounting Restatement Date***" means the earlier to occur of (a) the date that the Board, a committee of the Board authorized to take such action, or the officer or officers of the Company authorized to take such action if Board action is not required, concludes, or reasonably should have concluded, that the Company is required to prepare an Accounting Restatement, or (b) the date that a court, regulator or other legally authorized body directs the Company to prepare an Accounting Restatement.

"***Administrator***" means the Compensation Committee or, in the absence of such committee, the Board.

"***Code***" means the U.S. Internal Revenue Code of 1986, as amended, and the regulations promulgated thereunder.

"***Compensation Committee***" means the Compensation Committee of the Board.

"***Covered Officer***" means each current and former Executive Officer.

"***Exchange***" means the Nasdaq Stock Market.

"***Exchange Act***" means the U.S. Securities Exchange Act of 1934, as amended.

"***Executive Officer***" means the Company's president, principal financial officer, principal accounting officer (or if there is no such accounting officer, the controller), any vice-president of the Company in charge of a principal business unit, division, or function (such as sales, administration, or finance), any other officer who performs a policy-making function, or any other person who performs

similar policy-making functions for the Company. Executive officers of the Company's parent(s) or subsidiaries are deemed executive officers of the Company if they perform such policy-making functions for the Company. Policy-making function is not intended to include policy-making functions that are not significant. Identification of an executive officer for purposes of this Policy would include at a minimum executive officers identified pursuant to Item 401(b) of Regulation S-K promulgated under the Exchange Act.

"***Financial Reporting Measures***" means measures that are determined and presented in accordance with the accounting principles used in preparing the Company's financial statements, and any measures derived wholly or in part from such measures, including Company stock price and total stockholder return ("***TSR***"). A measure need not be presented in the Company's financial statements or included in a filing with the SEC in order to be a Financial Reporting Measure.

"***Incentive Compensation***" means any compensation that is granted, earned or vested based wholly or in part upon the attainment of a Financial Reporting Measure.

"***Lookback Period***" means the three completed fiscal years immediately preceding the Accounting Restatement Date, as well as any transition period (resulting from a change in the Company's fiscal year) within or immediately following those three completed fiscal years (except that a transition period of at least nine months shall count as a completed fiscal year). Notwithstanding the foregoing, the Lookback Period shall not include fiscal years completed prior to the Effective Date.

"***Recoverable Incentive Compensation***" means Incentive Compensation received by a Covered Officer during the Lookback Period that exceeds the amount of Incentive Compensation that would have been received had such amount been determined based on the Accounting Restatement, computed without regard to any taxes paid (*i.e.*, on a gross basis without regard to tax withholdings and other deductions). For any compensation plans or programs that take into account Incentive Compensation, the amount of Recoverable Incentive Compensation for purposes of this Policy shall include, without limitation, the amount contributed to any notional account based on Recoverable Incentive Compensation and any earnings to date on that notional amount. For any Incentive Compensation that is based on stock price or TSR, where the Recoverable Incentive Compensation is not subject to mathematical recalculation directly from the information in an Accounting Restatement, the Administrator will determine the amount of Recoverable Incentive Compensation based on a reasonable estimate of the effect of the Accounting Restatement on the stock price or TSR upon which the Incentive Compensation was received. The Company shall maintain documentation of the determination of that reasonable estimate and provide such documentation to the Exchange in accordance with the Listing Standards.

"***SEC***" means the U.S. Securities and Exchange Commission.

4. Recoupment

(a) Applicability of Policy. This Policy applies to Incentive Compensation received by a Covered Officer (i) after beginning services as an Executive Officer, (ii) who served as an Executive Officer at any time during the performance period for such Incentive Compensation, (iii) while the Company had a class of securities listed on a national securities exchange or a national securities association, and (iv) during the Lookback Period.

(b) Recoupment Generally. Pursuant to the provisions of this Policy, if there is an Accounting Restatement, the Company must reasonably promptly recoup the full amount of the Recoverable Incentive Compensation, unless the conditions of one or more subsections of Section 4(c) of this Policy are met and the Compensation Committee, or, if such committee does not consist solely of independent directors, a majority of the independent directors serving on the Board, has made a determination that recoupment would be impracticable. Recoupment is required regardless of whether the Covered Officer engaged in any misconduct and regardless of fault, and the Company's obligation to recoup Recoverable Incentive Compensation is not dependent on whether or when any restated financial statements are filed.

(c) Impracticability of Recovery. Recoupment may be determined to be impracticable if, and only if:

(i) the direct expense paid to a third party to assist in enforcing this Policy would exceed the amount of the applicable Recoverable Incentive Compensation; provided that, before concluding that it would be impracticable to recover any amount of Recoverable Incentive Compensation based on expense of enforcement, the Company shall make a reasonable attempt to recover such Recoverable Incentive Compensation, document such reasonable attempt(s) to recover, and provide that documentation to the Exchange in accordance with the Listing Standards; or

(ii) recoupment of the applicable Recoverable Incentive Compensation would likely cause an otherwise tax-qualified retirement plan, under which benefits are broadly available to employees of the Company, to fail to meet the requirements of Code Section 401(a)(13) or Code Section 411(a) and regulations thereunder.

(d) Sources of Recoupment. To the extent permitted by applicable law, the Administrator shall, in its sole discretion, determine the timing and method for recouping Recoverable Incentive Compensation hereunder, provided that such recoupment is undertaken reasonably promptly. The Administrator may, in its discretion, seek recoupment from a Covered Officer from any of the following sources or a combination thereof, whether the applicable compensation was approved, awarded, granted, payable or paid to the Covered Officer prior to, on or after the Effective Date: (i) direct repayment of Recoverable Incentive Compensation previously paid to the Covered Officer; (ii) cancelling prior cash or equity-based awards (whether vested or unvested and whether paid or unpaid); (iii) cancelling or offsetting against any planned future cash or equity-based awards; (iv) forfeiture of deferred compensation, subject to compliance with Code Section 409A; and (v) any other method authorized by applicable law or contract. Subject to compliance with any applicable law, the Administrator may effectuate recoupment under this Policy from any amount otherwise payable to the Covered Officer, including amounts payable to such individual under any otherwise applicable Company plan or program, *e.g.*, base salary, bonuses or commissions and compensation previously deferred by the Covered Officer. The Administrator need not utilize the same method of recovery for all Covered Officers or with respect to all types of Recoverable Incentive Compensation.

(e) No Indemnification of Covered Officers. Notwithstanding any indemnification agreement, applicable insurance policy or any other agreement or provision of the Company's certificate of incorporation or bylaws to the contrary, no Covered Officer shall be entitled to indemnification or advancement of expenses in connection with any enforcement of this Policy by the Company, including paying or reimbursing such Covered Officer for insurance premiums to cover potential obligations to the Company under this Policy.

(f) Indemnification of Administrator. Any members of the Administrator, and any other members of the Board who assist in the administration of this Policy, shall not be personally liable for any action, determination or interpretation made with respect to this Policy and shall be indemnified by the Company to the fullest extent under applicable law and Company policy with respect to any such action, determination or interpretation. The foregoing sentence shall not limit any other rights to indemnification of the members of the Board under applicable law or Company policy.

(g) No "Good Reason" for Covered Officers. Any action by the Company to recoup or any recoupment of Recoverable Incentive Compensation under this Policy from a Covered Officer shall not be deemed (i) "good reason" for resignation or to serve as a basis for a claim of constructive termination under any benefits or compensation arrangement applicable to such Covered Officer, or (ii) to constitute a breach of a contract or other arrangement to which such Covered Officer is party.

5. Administration

Except as specifically set forth herein, this Policy shall be administered by the Administrator. The Administrator shall have full and final authority to make any and all determinations required under this Policy. Any determination by the Administrator with respect to this Policy shall be final, conclusive and binding on all interested parties and need not be uniform with respect to each individual covered by this Policy. In carrying out the administration of this Policy, the Administrator is authorized and directed to consult with the full Board or such other committees of the Board as may be necessary or appropriate as to matters within the scope of such other committee's responsibility and authority. Subject to applicable

law, the Administrator may authorize and empower any officer or employee of the Company to take any and all actions that the Administrator, in its sole discretion, deems necessary or appropriate to carry out the purpose and intent of this Policy (other than with respect to any recovery under this Policy involving such officer or employee).

6. Severability

If any provision of this Policy or the application of any such provision to a Covered Officer shall be adjudicated to be invalid, illegal or unenforceable in any respect, such invalidity, illegality or unenforceability shall not affect any other provisions of this Policy, and the invalid, illegal or unenforceable provisions shall be deemed amended to the minimum extent necessary to render any such provision or application enforceable.

7. No Impairment of Other Remedies

Nothing contained in this Policy, and no recoupment or recovery as contemplated herein, shall limit any claims, damages or other legal remedies the Company or any of its affiliates may have against a Covered Officer arising out of or resulting from any actions or omissions by the Covered Officer. This Policy does not preclude the Company from taking any other action to enforce a Covered Officer's obligations to the Company, including, without limitation, termination of employment and/or institution of civil proceedings. This Policy is in addition to the requirements of Section 304 of the Sarbanes-Oxley Act of 2002 ("**SOX 304**") that are applicable to the Company's Chief Executive Officer and Chief Financial Officer and to any other compensation recoupment policy and/or similar provisions in any employment, equity plan, equity award, or other individual agreement, to which the Company is a party or which the Company has adopted or may adopt and maintain from time to time; provided, however, that compensation recouped pursuant to this Policy shall not be duplicative of compensation recouped pursuant to SOX 304 or any such compensation recoupment policy and/or similar provisions in any such employment, equity plan, equity award, or other individual agreement except as may be required by law.

8. Amendment; Termination

The Administrator may amend, terminate or replace this Policy or any portion of this Policy at any time and from time to time in its sole discretion. The Administrator shall amend this Policy as it deems necessary to comply with applicable law or any Listing Standard.

9. Successors

This Policy shall be binding and enforceable against all Covered Officers and, to the extent required by Rule 10D-1 and/or the applicable Listing Standards, their beneficiaries, heirs, executors, administrators or other legal representatives.

10. Required Filings

The Company shall make any disclosures and filings with respect to this Policy that are required by law, including as required by the SEC.

* * * * *

Bionano Genomics, Inc.

Incentive Compensation Recoupment Policy

Form of Executive Acknowledgment

I, the undersigned, agree and acknowledge that I am bound by, and subject to, the Bionano Genomics, Inc. Incentive Compensation Recoupment Policy, as may be amended, restated, supplemented or otherwise modified from time to time (the "***Policy***"). In the event of any inconsistency between the Policy and the terms of any employment agreement, offer letter or other individual agreement with Bionano Genomics, Inc. (the "***Company***") to which I am a party, or the terms of any compensation plan, program or agreement, whether or not written, under which any compensation has been granted, awarded, earned or paid to me, the terms of the Policy shall govern.

In the event that the Administrator (as defined in the Policy) determines that any compensation granted, awarded, earned or paid to me must be forfeited or reimbursed to the Company pursuant to the Policy, I will promptly take any action necessary to effectuate such forfeiture and/or reimbursement. I further agree and acknowledge that I am not entitled to indemnification, and hereby waive any right to advancement of expenses, in connection with any enforcement of the Policy by the Company.

Agreed and Acknowledged:

___

Name: ___

Title: ___

Date: ___