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

FORM 10-K

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

For the fiscal year ended December 31, 2022.

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

For the transition period from ___ to ___.

Commission File Number 001-40443

Singular Genomics Systems, Inc.

(Exact name of Registrant as specified in its Charter)

Delaware	**81-2948451**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**

3010 Science Park Road
San Diego, California 92121
(858) 333-7830
(Registrant's address of principal executive offices and telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, $0.0001 par value per share	OMIC	Nasdaq Global Select Market

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 ☒

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 ☒

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

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, 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 ☒

As of June 30, 2022, the aggregate market value of the voting and non-voting common stock held by non-affiliates of the Registrant was $214 million. Shares of common stock held by each officer and director and by each person who is known to own 10% or more of the outstanding common stock have been excluded in that such persons may be deemed to be affiliates of the Company. This determination of affiliate status is not necessarily a conclusive determination for other purposes.

The number of shares of Registrant's common stock outstanding as of February 17, 2023 was 71,941,091.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive Proxy Statement for the registrant's 2023 Annual Meeting of Stockholders, which will be filed with the Securities and Exchange Commission not later than 120 days after the registrant's fiscal year ended December 31, 2022, are hereby incorporated by reference into certain information called for by Part III of this Annual Report on Form 10-K.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This filing contains forward-looking statements. All statements other than statements of historical facts contained in this report, including statements regarding our future results of operations and financial position, future revenue, business strategy, prospects, products, research and development costs, timing and likelihood of success, as well as plans and objectives of management for future operations, are forward-looking statements. These statements involve known and unknown risks, uncertainties and other important factors that are in some cases beyond our control and may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements.

The words "anticipate," "believe," contemplate," "continue," "could," "estimate," "expect," "intend," "may," "might," "plan," "potential," "predict," "project," "should," "target," "will" or "would" or the negative of these terms or other similar expressions are intended to identify forward-looking statements. Forward-looking statements contained in this report include, but are not limited to, statements about:

- estimates of our addressable market, market growth, future revenue, expenses, capital requirements and our needs for additional financing;
- our ability to timely and successfully complete the development and implement our commercialization plan for the G4 and planned PX;
- the implementation of our business model and strategic plans for the G4 and planned PX;
- our expectations regarding the rate and degree of market acceptance of the G4 and planned PX;
- our ability to compete with competitive companies and technologies in our industry;
- our ability to manage and grow our business and commercialize the G4 and planned PX;
- our ability to develop and commercialize new products and product enhancements;
- the impact of the COVID-19 pandemic and recent downward macroeconomic pressures on our business;
- our ability to establish and maintain intellectual property protection for our products or avoid or defend claims of infringement;
- our ability to fulfill our contractual commitments;
- the performance of third-party manufacturers and suppliers;
- our ability to effectively manufacture our products;
- the potential effects of government regulation;
- our ability to hire and retain key personnel and to manage our future growth effectively;
- our ability to obtain additional financing on favorable terms to us or at all;
- our expectations regarding use of proceeds from our initial public offering;
- the impact of local, regional, national and international economic conditions and events;
- our expectations about market trends; and
- our expectations regarding the period during which we will qualify as an emerging growth company under the JOBS Act.

These forward-looking statements are subject to a number of risks, uncertainties and assumptions, including those described in the section titled "Risk Factors" elsewhere in this report. Moreover, we operate in a very competitive and rapidly changing environment. New risks emerge from time to time. It is not possible for our management to predict all risks, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements we may make. In light of these risks, uncertainties and assumptions, the forward-looking events and circumstances discussed in this report may not occur and actual results could differ materially and adversely from those anticipated or implied in the forward-looking statements.

You should not rely on forward-looking statements as predictions of future events. Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee that the future results, advancements, discoveries, levels of activity, performance or events and circumstances reflected in the forward-looking statements will be achieved or occur. Moreover, except as required by law, neither we nor any other person assumes responsibility for the accuracy and completeness of the forward-looking statements. We undertake no obligation to update publicly any forward-looking statements for any reason after the date of this report to conform these statements to actual results or to changes in our expectations.

You should read this report and the documents that we reference in this report and have filed with the Securities and Exchange Commission as exhibits to this report with the understanding that our actual future results, levels of activity, performance and events and circumstances may be materially different from what we expect.

Summary of Material Risks Associated with Our Business

Our business is subject to a number of risks that if realized could materially affect our business, prospects, operating results and financial condition. These risks are discussed more fully in the "Risk Factors" section of this Annual Report on Form 10-K. These risks include the following:

- Our limited operating history makes it difficult to evaluate our future prospects and the risks and challenges we may encounter.
- We have incurred significant losses since inception, we expect to incur significant losses in the future and we may not be able to generate sufficient revenue to achieve and maintain profitability.
- We have only recently generated revenue and have very limited history in developing and commercializing our products or technology, which makes it difficult to evaluate our prospects and predict our future performance.
- The life sciences technology market is highly competitive. If we fail to compete effectively, our business and operating results will suffer.
- If we are sued for infringing, misappropriating or otherwise violating intellectual property rights of third parties, such litigation could be costly and time-consuming and could prevent or delay us from developing or commercializing our products.
- We could have disputes with contractual counterparties regarding our or their performance under those contracts, we could be unable to fulfill such contractual commitments, or our contractual obligations may exceed our current expectations.
- If our products fail to achieve early customer and scientific acceptance, we may not be able to achieve broader market acceptance for our products, and our revenues and prospects may be harmed.
- We expect to be highly dependent upon revenue generated from the sale of the G4 and planned PX, and any delay or failure by us to successfully develop and commercialize the G4 or PX could have a substantial adverse effect on our business and results of operations.
- The COVID-19 pandemic and efforts to reduce its spread have adversely impacted and may materially and adversely impact our business and operations in the future; recent macroeconomic pressures could also materially and adversely impact our business and operations.
- Our business will depend significantly on research and development spending by academic institutions and other research institutions, and any reduction in spending could limit demand for our products and adversely affect our business, results of operations, financial condition and prospects.
- Our operating results may fluctuate significantly in the future, which makes our future operating results difficult to predict and could cause our operating results to fall below expectations or any guidance we may provide.
- We have only launched one commercial product, the G4, and we may not be able to successfully commercially launch our planned PX or other products as planned.
- The G4 is sold as a research-use-only product; changes in the regulatory landscape could affect the market for such a product.
- If we are unable to obtain and maintain sufficient intellectual property protection for our products and technology, or if the scope of the intellectual property protection obtained is not sufficiently broad, our competitors could develop and commercialize products similar or identical to ours, and our ability to successfully commercialize our products may be impaired.
- We may require substantial additional funding, which may not be available to us on acceptable terms, or at all, and, if not available, may require us to delay, scale back or cease our product development programs or operations.

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PART I

Item 1. Business

Our Mission

Our mission is to empower researchers and clinicians to advance science and medicine. The genomic technologies developed over the last two decades, since the first sequencing of the human genome, have greatly improved our understanding of biology, empowered the development of novel therapies and advanced clinical diagnostics. Yet, the potential of genomics is just starting to be realized. Today's sequencing technologies have made a significant impact, but limitations remain to incorporate these tools into routine clinical practice: long analysis times, labor-intensive protocols, sample-batching requirements and high cost. We are developing powerful, fast, flexible and accurate sequencing products, along with novel applications and sample-to-result workflows, to solve these challenges.

We believe the next generation of biological discovery and translational medicine will be powered by even more advanced molecular technologies. These technologies will enable a high-resolution view of DNA, RNA and proteins in individual cells, including their spatial arrangement. This view, called multiomics, will enable greater insight into the function of cells and tissues. We are building multiomics technologies by leveraging our core DNA sequencing engine, which uses molecular biology techniques and the latest advances in high-speed, high-resolution imaging.

Our goal is to unleash the power of sequencing as a universal reader of biology, which we believe will open new frontiers in research and medicine.

Overview

We are a life science technology company that develops next-generation sequencing and multiomics technologies. The commercially available G4 Sequencing Platform (the "G4") is a powerful, highly versatile benchtop genomic sequencer designed to produce fast and accurate results. Our second product in development, the PX system (the "PX"), leverages our proprietary sequencing technology, applying it as an *in situ* readout to look at RNA and proteins in single cells and tissue. With these products, our mission is to empower researchers and clinicians to advance science and medicine.

We developed a unique and proprietary NGS technology, which we refer to as our Sequencing Engine. This Sequencing Engine is the platform technology of our products and core product tenets: power, speed, flexibility and accuracy. The core of our Sequencing Engine is comprised of unique and proprietary chemistry, including novel chemical compounds, polymers and enzymes. This chemistry is designed to produce high-accuracy sequencing and rapid cycle times that we believe can drive improvements in NGS. To take full advantage of our proprietary chemistry, we have developed and continue to develop purpose-built instrumentation consisting of high-speed, high-resolution imaging and innovative fluidic design. We believe that our Sequencing Engine, together with our proprietary innovations in molecular biology techniques, will enable differentiated applications in fast-growing markets, supported by our intellectual property portfolio.

The G4 is a benchtop next-generation sequencer designed to produce fast and accurate sequencing results. The G4 is designed to target the NGS market in particular applications that require power, speed, flexibility and accuracy. We believe the G4 will expand and accelerate the use of DNA sequencing across a wide range of applications, such as identifying cancer-associated genetic mutations, deep sequencing to detect minimum residual disease in circulating cell-free DNA, profiling the immune system, analyzing single-cell RNA transcription and rapidly sequencing exomes and whole genomes. We are executing a three-step commercialization plan for the G4 consisting of the following: (i) collaborating with select partners to conduct beta pilot tests, which we completed in 2021; (ii) collaborating with potential customers in our early access program, which we concluded in the second quarter of 2022; and (iii) offering the G4 broadly to the market. We commercially launched the G4 in December of 2021, and we began recognizing revenue on sales of the G4 in the fourth quarter of 2022.

The PX is our second product in development and is a multiomics platform designed to target the markets for single-cell, spatial analysis and proteomics. The PX will leverage our Sequencing Engine as a readout mechanism to provide a high-resolution view of biology at the single-cell and tissue level. We believe the PX, when launched, will be a high-throughput, versatile platform capable of measuring levels of RNA transcription, protein expression and sequence-specific information directly in cells and tissues. We believe the PX will have broad application across many areas of biology. We are initially focused on applications in oncology and immunology, with future expansion into other applications such as neurology. We are currently in an advanced prototype development stage for the PX. For the PX, we plan to collaborate with select partners to conduct a technology access program designed to bring samples and collaborators in-house, which we initiated in the fourth quarter of 2022 and executed our first technology access partner agreement in February 2023. Following our technology access program, we plan to expand collaborations with additional potential customers in an early access program.

Sequencing Engine

Our Sequencing Engine is the platform technology of our products. The core of the Sequencing Engine is a novel and proprietary sequencing-by-synthesis ("SBS") chemistry that enables high-accuracy sequencing and rapid cycle times that we believe will drive improvements in NGS. The Sequencing Engine enables performance of highly accurate and massively parallel sequencing at speed. We built the Sequencing Engine from the ground up, and it incorporates the following innovations:

- *Cluster amplification*: We have developed an optimized cluster amplification method that is designed to ensure generation of high-quality and high-density clusters with minimal sequence bias and high signal-to-background ratios. This enables high-accuracy sequencing regardless of the type of genetic input material.
- *Paired-read sequencing*: We have developed a novel method to read DNA from both ends of the fragment, called paired-read sequencing. We believe our method is fast and efficient with reagent usage, while providing efficient mapping and detection of gene rearrangements, higher-quality data and single-cell genomics.
- *Sequencing chemistry*: We have developed a new and proprietary sequencing chemistry. This chemistry includes novel enzymes and nucleotides. We have also designed and synthesized our own dyes to optimize performance. This new and proprietary chemistry enables fast sequencing cycle times.
- *Detection technology*: We have developed a proprietary high-speed and high-resolution imaging system. The imaging system has been designed to optimize throughput, cycle time, accuracy and efficiency.

Our Products

Our product pipeline comprises two products, each is designed to leverage the Sequencing Engine and purpose-built to address different applications. Our first product, the G4, targets the NGS market. Our second product in development, the PX, combines single cell analysis, spatial analysis, genomics and proteomics in one integrated instrument to offer a versatile multiomics solution. The G4 and PX are each comprised of an instrument and an associated menu of consumable kits.

G4

We surveyed numerous labs and key opinion leaders while developing the G4 to listen to their needs and to identify the limitations of current solutions. In parallel, we engineered an instrument around the Sequencing Engine to address those real-world needs. The G4 consists of our G4 instrument and associated consumables and is designed to seamlessly fit into existing workflows, including library preparation up front and bioinformatics on the back end. It is also designed to provide flexibility in terms of scalable sample volumes with the use of one to four flow cells in a sequencing run. We believe this design will enable customers to better manage a wide range of daily sample volume demands without sacrificing turnaround times or incurring extra expenses from inefficient reagent kit use. We are targeting applications for which we believe power, speed, flexibility and accuracy matter, and where our novel molecular biology methods offer unique advantages.

Capabilities of the G4

The G4 is designed with the following capabilities:

- *Power:* We designed the G4 with four flow cells, which we expect will be able to provide over 100 gigabase throughput on each flow cell per run depending on consumable kit and application. This is enough power to sequence a whole genome at 30x coverage on each flow cell in a single run.
- *Speed:* We optimized our novel and proprietary chemistry to achieve fast cycle times and built optics and fluidics to leverage it. The G4 is able to achieve cycle times of approximately 2.5 minutes.
- *Flexibility:* The G4 has four flow cells. No other sequencer has this type of flexibility that allows a researcher or clinician to run one, two, three or four flow cells at a time on one instrument on a daily basis.
- *Quality and Accuracy:* Q30 quality is considered to be the "gold standard" for a sequencer. The G4 provides Q30 or higher quality on 80%−90% of base reads and achieves accuracy of 99.6%−99.9% for 150 base reads.
- *Paired-read sequencing:* Our novel method currently allows for flexible read length paired-read sequencing of up to 2x150 cycles.
- *Read lengths:* The G4 can sequence in common read configurations for the most common applications and support up to 2x150 read lengths.
- *Workflow:* We have designed the G4 for customers to efficiently switch to our products. The upstream workflow and downstream analysis are compatible with many current NGS applications, and to enable this efficiency we have partnered with industry-leading library preparation and data-analysis organizations.

Specialized Applications for the G4

We believe that the G4 has broad potential application across various markets. Additional targeted applications for the G4 include multiple short-read applications with Max Read kits, rare variant detection with high-definition sequencing ("HD-Seq") and detection of gene fusions with unknown partners or breakpoints with Ring-Seq.

- *Max Read kits for single cell sequencing:* Next generation sequencing of short reads has enabled advances in a wide variety of applications, including detection and quantification of RNA in biological samples, cell-free DNA fragment detection and counting, high-throughput NGS barcode sequencing, CRISPR-screens, single-cell analysis, proteomics and others. Short-read NGS is typically performed with one set of single-end or paired-end reads on a single flow cell. Our Max Read kit in development enables multiple sets of independent single-end or paired-end reads on the same flow cell. Compared to conventional NGS formats, this workflow enables higher output of short reads for the same flow cell, without a significant impact on read quality. The Max Read kits boost the potential output of the G4 on single cell applications to an unprecedented 3.2 billion reads per run on a benchtop system.
- *Rare variant detection with HD-Seq:* We designed the G4 to support HD-Seq, a unique library prep kit and sequencing method for double-stranded DNA in order to provide higher accuracy than standard single-strand NGS sequencing methods. HD-Seq is expected to enable rare variant detection with higher efficiency and lower costs and is intended to achieve accuracy levels of Q50, which can help differentiate a real mutation from random errors. Accuracy is especially important in oncology for the detection of somatic mutations, including rare single-nucleotide polymorphisms. It is also critical in liquid biopsy where the frequency of mutations in a sample is extremely low. The development of HD-Seq kits is in our product roadmap for future release.
- *Gene fusion detection with Ring-Seq:* Gene fusions are an important and actionable type of genetic aberration in cancer. We are developing an elegant, novel method ("Ring-Seq") for the targeted detection of gene fusions, including those with unknown partners or breakpoints. The method aims to deliver the sensitivity and speed of traditional multiplex polymerase chain reaction ("PCR")–based assays, but with the ability to detect gene fusions with unknown partners or breakpoints. The method includes an innovative wild-type suppression mechanism to increase sequencing efficiency, resulting in reduced sequencing cost per sample.
- *Extended range sequencing:* Other possible applications include extended range sequencing ("XR-Seq"), which would facilitate longer gene sequence reads of up to 3,000 base pairs and support comprehensive analysis of the immune system, particularly the adaptive immune response consisting of B- and T-cells. Based on our analysis of the market opportunity for this technology, including feedback from potential customers, we have reprioritized the development efforts of our other technologies ahead of XR-Seq.

PX

The PX in development is focused on the single cell and spatial analysis markets and consists of the PX instrument and associated consumables. The PX leverages our Sequencing Engine as both a universal detection method and *in situ* sequencing to enable multiomics analysis of single cells and tissues. The PX is designed to provide high-throughput analysis of nucleic acids and proteins, while also generating high-resolution images of cellular morphology to enable analysis of cellular phenotypes together with spatial context. We believe the PX will eliminate the need for customers to employ multiple systems over several-day workflows, which is required by existing commercial methods. We believe this will enable researchers to perform large-scale experiments that may fundamentally advance our understanding of biology, and, in turn, advance human health.

Capabilities of the PX

We are designing the PX to have the following characteristics, which we believe are important differentiating characteristics of single-cell and spatial analysis approaches:

- *Multiomics detection*: We are developing the PX to identify specific RNA and proteins targets using our Sequencing Engine either as a universal detection method or for *in situ* sequencing. Additionally, we will provide imaging data of cellular morphology (in the case of single-cell analysis) and tissue organization (in the case of spatial analysis). We believe this combination of molecular and phenotypic data will provide significantly more information than is available today with current commercial technologies. The addition of the cellular morphology along with spatial organization of biomolecules within the tissue microenvironment can provide a data-rich solution across many research applications to better understand cell development, maturation and pathogenesis. We believe that the combination of these useful datasets from individual cells will provide a more complete cellular picture as it will combine both phenotypic data along with detailed molecular characterization.
- *High throughput and large scale:* We are designing the PX to be high throughput in order to enable researchers to perform large-scale studies that are currently inaccessible but are needed for a more complete characterization and understanding of biology. Current commercially available single cell technologies detect up to 1 million cells in an experiment. The PX will use a well-plate approach designed to process 10,000 to 100,000 cells per well at a throughput of 1 million to 10 million cells in a single run on its 96 well plate. We believe that this will meet the growing need in this market to study millions of cells and the large scale that is currently unattainable today. Similarly, in the spatial market, current commercially available spatial analysis instruments with similar plex (number of target analytes per panel) profiles can run an experiment involving up to 20 tissue samples per day. With the PX, we expect to run up to 96 tissue samples per day, providing researchers with the ability to run at a scale that is not possible today.
- *High resolution:* The PX will be designed to resolve molecules at the single-cell level including subcellular localization of targets. We anticipate that this will enable researchers to differentiate between single cells to truly understand cellular characterization.
- *Targeted panels*: We believe that current discovery efforts with bulk sequencing will lead to translational panels that are targeted on key genes of interest. The PX will be designed for larger-scale studies that will process a higher number of samples with these focused panels.

Applications for the PX

We are developing the PX to have a broad set of applications in single-cell and tissue analysis. Examples of applications for the PX may include and are not limited to the following:

- *Single cell gene expression and proteomics:* Targeted gene expression panels and protein panels for specific applications to measure RNA and proteins in combination with morphology data.
- *In situ RNA sequencing: In situ* sequencing of selected gene targets directly within each cell or tissue while also simultaneously providing phenotype data.
- *Spatial RNA and proteomics applications for tissue:* Targeted panels (with customization available) for specific basic and translational research applications to measure gene transcription and protein expression within tissue and then link this information to additional phenotypic data to help provide biological context.

Key Disease Areas for the PX

We are designing the PX to have broad applicability across multiple large disease areas. Although our initial applications will focus on indications across oncology and immunology, we are designing the PX to possess the foundational technology and capabilities to potentially address additional areas, including neurology and developmental biology. We believe that key existing biological challenges can be addressed through improved multiomics information, higher sample throughput and enhanced spatial context, which we intend to address through the PX. The following large disease areas are examples of where we are designing the PX to address significant challenges.

- *Oncology*: We believe the PX will be ideally suited to study blood cancers initially. We are designing the PX to enable the mapping of the progression of blood cancers as they develop, pre- and post-treatment, to fully characterize them across multiple molecular markers. The cellular phenotype, including morphology, could be valuable in helping to further characterize these cancer cells along with the molecular data of gene expression. We anticipate that the coupling of molecular data with the cellular phenotype and morphology can help to drive further understanding and identification of different types of cancer as well as provide the ability to interpret biological function.
- *Immunology*: We anticipate that our *in situ* sequencing will be valuable for identifying the paired receptor data (light and heavy chains in B-cells or alpha and beta chains in T-cells) that is currently lacking at scale today. By having a high-throughput method that will sequence and retain the linkage of the two chains of the immune receptors, we believe researchers will be able to study the immune repertoire in more depth while also correlating each cell with its cellular phenotype or studying the spatial context of the immune cells within the tumor microenvironment. Additionally, we believe that we will be able to use a DNA-conjugated antibody that recognizes the antigen to confirm the immune cell is binding to a specific antigen. We anticipate this combination of data can provide powerful information to interpret biological function as well as to further characterize immune cell types.

Markets

We believe our product pipeline targets multiple market opportunities across life sciences. Due to the comprehensive capability to analyze biology that we are designing into our products, we anticipate that much of this opportunity will be available to us. We estimate that the G4 and the PX target substantial market opportunities such as NGS, single cell, spatial analysis, proteomics and potential new markets.

We plan to initially sell and market our products for research use only ("RUO") to academic institutions, life sciences and research laboratories, and biopharmaceutical and biotechnology companies for non-diagnostic and non-clinical purposes. Additionally, CLIA-certified laboratories are able to develop laboratory developed tests ("LDTs") using RUO products. Today, a significant majority of NGS-based diagnostic tests are performed as LDTs on DNA sequencers that are labeled for RUO. While our initial products are intended for RUO, our longer-term plans include seeking U.S. Food and Drug Administration ("FDA") clearance for *in vitro* diagnostic ("IVD") products and corresponding clearances in other countries.

Commercialization

Our business model focuses on first driving customer adoption of the G4, followed by the PX. We believe customer adoption will then form a base of users who in turn drive an ongoing revenue stream by purchasing our consumables. We plan to focus our commercial efforts on: (i) expanding the installed base of the G4 and planned PX across a wide array of customer segments; and (ii) driving applications, scale of experimentation and discoveries that lead to increasing utilization of our products by our customers. Similar to our strategy of developing purpose-built products based on feedback from potential customers, we are developing a service and support organization that focuses on creating an unparalleled customer experience.

We are executing a three-step commercialization plan for the G4 consisting of the following: (i) collaborating with select partners to conduct beta pilot tests, which we completed in 2021; (ii) collaborating with potential customers in our early access program, which we concluded in the second quarter of 2022; and (iii) offering the G4 broadly to the market. We commercially launched the G4 in December of 2021, and we began recognizing revenue on sales of the G4 in the fourth quarter of 2022. For the PX, we plan to collaborate with select partners to conduct a technology access program designed to bring samples and collaborators in-house, which we initiated in the fourth quarter of 2022 and executed our first technology access partner agreement in February 2023. Following our technology access program, we plan to expand collaborations with additional potential customers in an early access program.

We have built and are continuing to expand our commercial organization to have direct commercial staff in sales, customer support, applications support, field service and marketing and communications. As we continue our commercial rollout, we will need to scale each function within our commercial organization in anticipation of demand and with the intent to deliver exceptional customer experiences. We believe that coupling customer experience with a transformative integrated solution will allow us to deliver substantial value to our customers, build long-term customer loyalty and enhance our competitive differentiation. Additionally, as part of our commercialization strategy, we plan to provide flexible purchase offerings to customers such as in the form of leases, reagent rentals and subscriptions, and we plan to provide discounts to certain customers or other sales incentives, including bulk purchases such as the G4x4, where we package four G4 instruments to be sold together at a discount.

We have initially targeted customers in North America through direct sales and customer support organizations. We also plan to expand outside North America to sell and support our products in the European Union, United Kingdom, Asia Pacific and Japan, and expect to expand access to our products in other geographies through well established distribution networks.

Competition

The life sciences market is highly competitive. There are other companies, both established and early-stage, that have indicated that they are designing, manufacturing and marketing products for, among other things, genomics analysis, single-cell analysis and spatial analysis. These companies include 10x Genomics Inc., Becton, Dickinson and Company, Bio-Rad Laboratories, Inc., Illumina Inc., MissionBio Inc., Nanostring Technologies, Inc., Oxford Nanopore Technologies Inc., Pacific Biosciences Inc., Element Biosciences, Inc., Ultima Genomics, Inc. and Thermo Fisher Scientific Inc., each of which has products or products in development that compete or could compete to varying degrees with some but not all of our product solutions, as well as a number of other emerging and established companies. Some of these companies may have substantially greater financial and other resources than us, including larger research and development staff or more established marketing and sales forces. Other competitors are in the process of developing novel technologies for the life sciences market which may lead to products that rival or replace our products. However, we believe we are significantly differentiated from our competitors for many reasons, including our novel, proprietary Sequencing Engine.

Research and Development

The goal of our research and development programs is to accelerate genomics for the advancement of science and medicine. To this end, we focus our research and development efforts on the following areas: improving the performance of our core Sequencing Engine; developing new applications for the G4; developing the PX; and enabling future instruments. Our research and development teams are located in our headquarters in San Diego, California. As of December 31, 2022, we had 134 employees in research and development.

Intellectual Property

Developing and maintaining a strong intellectual property position is an important element of our business. Our success depends in part on our ability to obtain and maintain intellectual property protection for our products, technologies and our brand. We utilize a variety of intellectual property protection strategies, including patents, trademarks, trade secrets and other methods of protecting proprietary information.

Our patent strategy seeks broad patent protection on new developments in sequencing technology in addition to new implementations and applications of our technology. The intellectual property portfolio includes patents and pending patent applications that generally relate to the following areas: chemistry (e.g., nucleotides, dyes and polymers); enzymes; nucleic acid sequencing and amplification methodologies; systems, devices and software; spatial analysis; and applications of our technology.

As of December 31, 2022, we own or exclusively license twenty-two (22) issued U.S. Utility patents, two (2) issued U.S. Design patents, sixty-four (64) pending U.S. Utility patent applications, nine (9) pending U.S. Design patent applications, eleven (11) issued European Registered Community Design Certificates, nineteen (19) pending European patent applications, one (1) issued Other International (i.e., Australia, Canada, China, Israel, and/or Japan) Design patent, fifteen (15) pending Other International patent applications, twenty-four (24) pending Patent Cooperation Treaty (PCT) patent applications, and forty-five (45) pending U.S. Provisional patent applications. The pending European patent applications were filed in the European Patent Organization (EPO), designating all thirty-eight (38) member countries. Our U.S. owned patents and patent applications, if issued, are expected to expire between 2038 and 2042, in each case without taking into account any possible patent term adjustments or extensions and assuming payment of all appropriate maintenance, renewal, annuity or other governmental fees.

Of these, we exclusively license from The Trustees of Columbia University in the City of New York (“Columbia”) one (1) issued U.S. patent, four (4) pending U.S. Utility patent applications, one (1) pending European patent application, and certain materials and technical information provided by Columbia. The pending European patent application was filed in the EPO, designating all thirty-eight (38) member countries. These patent applications are directed to compositions and methods for sequencing utilizing nucleotides containing disulfide linkers. Our in-licensed patent applications, if issued, are expected to expire in 2036 and 2037, in each case without considering any possible patent term adjustments or extensions and assuming payment of all appropriate maintenance, renewal, annuity or other governmental fees.

In addition to our reliance on patent protection for our inventions, products and technologies, we also rely on trade secrets, know-how, confidentiality agreements, and continuing technological innovation and licensing opportunities, to develop and maintain our competitive position. For example, some elements of manufacturing processes such as our nucleotide synthesis and flow cell assembly, analytic techniques and assays, imaging and optics implementations, as well as computational algorithms and related processes and software, are based on unpatented trade secrets and know-how that are not publicly disclosed. Our success will depend in part on our ability to obtain patent protection for our products and technologies, to preserve our trade secrets, to operate without infringing the proprietary rights of third parties and to acquire licenses related to enabling technology or products.

We use Singular Genomics®, G4, XR-Seq, XR/T-SEQ, HD-Seq, Max Read, Ring-Seq, and PX as trademarks in the United States and internationally. For one or more of the aforementioned trademarks, we applied for trademark registration in the United States, Australia, Brazil, Canada, China, Europe, Israel, Japan, Mexico, South Korea, Switzerland, and the United Kingdom. This disclosure contains references to our trademark and service marks and to those belonging to other entities. Solely for convenience, trademarks and trade names referred to in this disclosure, including logos, artwork and other visual displays, may appear without the ® or TM symbols, but such references are not intended to indicate in any way that we will not assert, to the fullest extent under applicable law, our rights or the rights of the applicable licensor to these trademarks and trade names. We do not intend our use or display of other entities' trade names, trademarks or service marks to imply a relationship with, or endorsement or sponsorship of us by, any other entity.

Columbia License Agreement

In August 2016, we entered into an Exclusive License Agreement (the "License Agreement") with Columbia. The License Agreement includes a number of diligence obligations that require us to use commercially reasonable efforts to research, discover, develop and market Patent Products and/or Other Products (as defined in the License Agreement) by certain dates. Under the License Agreement, we pay an annual license fee that increases each year, until it reaches a low six-digit fee for the fifth year, and for each subsequent year, for so long as the License Agreement remains in force. For any products within the scope of the License Agreement that we commercialize, we are required to pay royalties ranging from low to mid-single digits on net sales of Patent Products and low single-digit royalty rates on net sales of Other Products. We can credit our yearly annual license fee against any yearly royalty fees payable to Columbia. Additionally, if we receive any income in connection with any sublicenses, we must pay Columbia a high single-digit percentage of that income. Finally, the License Agreement provides for payments to Columbia based on our achievement of certain development and commercialization milestones, which could total up to $3.9 million over the life of the License Agreement. We have accrued approximately $0.4 million toward these milestones as of December 31, 2022. During each of the years ended December 31, 2022 and 2021, the Company paid approximately $0.1 million to Columbia pursuant to the terms of the License Agreement.

Suppliers and Manufacturing

The majority of our consumable products and instruments are manufactured in-house at our facilities in San Diego, California. These manufacturing operations include the following: instrument assembly and testing, flow cell surface synthesis and flow cell assembly, reagent formulation and cartridge filling, kit assembly and packaging as well as analytical and functional quality control testing. We obtain many components of our instruments and consumables from third-party suppliers. While some of these components are sourced from a single supplier, we have qualified second sources for several of our critical components. However, during 2022, we had experienced delays in the scale-up of our manufacturing process driven in-part by the availability of certain components from our third-party suppliers.

Human Capital

As of December 31, 2022, we had 275 full-time employees, many of whom are based at our headquarters in San Diego, California. Of these employees, 134 were in research and development, 69 were in operations, 26 were in commercial, and 46 were in general and administration. Among our full-time employees, 117 hold advanced degrees in their field of expertise, including 60 who hold doctoral degrees. None of our employees are represented by labor unions or are covered by a collective bargaining agreement with respect to their employment. We have not experienced any work stoppages and we consider our relationship with our employees to be good.

Talent Acquisition and Retention

We recognize that our employees are the primary engine of our success. We support business growth by seeking to attract, retain, and engage best-in-class talent. Our talent acquisition team uses internal and external resources to recruit highly skilled candidates across the U.S. In 2022, we were successful in hiring key positions throughout the organization that we believe will help accelerate our growth.

Compensation and Benefits

Our compensation philosophy is focused on investing in our workforce by offering competitive and fair compensation and benefits packages. We provide employees with compensation packages that include base salary, short-term incentives such as annual bonuses and commissions, and long-term equity awards. We also offer comprehensive employee benefits, such as life, disability and health insurance, health savings and flexible spending accounts, paid time off, paid parental leave, an employee stock purchase program and a 401(k) plan. We strive to be an employer of choice in our industry by providing market-competitive compensation and benefits packages.

Health, Safety and Wellness

The health, safety and wellness of our employees is a priority. We provide our employees and their families with access to a variety of flexible and convenient health and wellness programs. Program benefits are intended to provide our employees with peace of mind concerning events that may require time away from work or that may impact their financial wellbeing.

In response to the COVID-19 pandemic, we had adopted a broad approach to increased safety, including requirements for the wearing of masks and for physical distancing, increased cleaning, readily available hand sanitizing stations, providing personal protective equipment, widespread signage and messaging reminding employees of the importance of these measures and other steps. We also supported access to testing by holding on-site testing clinics available to employees and their family members. We will continue to seek health and safety programs to educate and assist employees when possible.

Diversity, Equity and Inclusion

We believe a diverse workforce is critical to our success. To this end, among other initiatives, we established our employee-led Inclusion Council in 2022. The mission of the Inclusion Council is to create a culture of belonging that fosters connectedness, encourages authentic communication and challenges biases. Through these programs, we aim to provide our employees with an inclusive working environment and opportunities for them to achieve their goals.

Training and Development

We believe in encouraging employees to become lifelong learners by providing ongoing learning and leadership training opportunities. Our scaled learning platform of on-demand and virtual classroom learning focuses on personal and professional development. We also strive to provide real-time recognition of employee performance. Additionally, our formal annual review process is used to determine pay and equity adjustments to recognize individual contributions, as well as identify areas where training and development may be needed.

Employee Communication and Engagement

We value open and direct communication with our employees about their experiences and use a variety of channels to obtain employee feedback, including employee surveys. Our annual employee survey provides us with actionable data at the company, department and managerial level, with upward feedback on performance against expectations. Each year, the input received through these surveys is used to help evolve our working environment and strengthen our culture.

Regulatory

The development, testing, manufacturing, marketing, post-market surveillance, distribution, advertising and labeling of certain of medical devices are subject to regulation in the United States by the Center for Devices and Radiological Health of the FDA under the Federal Food, Drug, and Cosmetic Act ("FDC Act") and comparable state and international agencies. The FDA defines a medical device as an instrument, apparatus, implement, machine, contrivance, implant, *in vitro* reagent or other similar or related article, including any component part or accessory, which is (i) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or (ii) intended to affect the structure or any function of the body of man or other animals and which does not achieve any of its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its primary intended purposes. Medical devices to be commercially distributed in the United States must receive from the FDA either clearance of a premarket notification, known as 510(k), premarket approval, or PMA, or authorization through a de-novo petition pursuant to the FDC Act prior to marketing, unless subject to an exemption.

We intend to label and sell our products for research use only ("RUO") and expect to sell our products to academic institutions, life sciences and research laboratories that conduct research, and biopharmaceutical and biotechnology companies for non-diagnostic and non-clinical purposes. Our products are not intended or promoted for use in clinical practice in the diagnosis of disease or other conditions, and they are labeled for research use only, not for use in diagnostic procedures. Accordingly, we believe our products, as we intend to market them, generally are not subject to regulation by the FDA. Rather, while FDA regulations require that research use only products be labeled with – "For Research Use Only. Not for use in diagnostic procedures." – the regulations do not subject such products to the FDA's jurisdiction or the broader pre- and post-market controls for medical devices.

In November 2013, the FDA issued a final guidance on RUO labeled products, which, among other things, reaffirmed that a company may not make any clinical or diagnostic claims about an RUO product, stating that merely including a labeling statement that the product is for research purposes only will not necessarily render the device exempt from the FDA's clearance, approval, or other regulatory requirements if the totality of circumstances surrounding the distribution of the product indicates that the manufacturer knows its product is being used by customers for diagnostic uses or the manufacturer intends such a use. These circumstances may include, among other things, written or verbal marketing claims regarding a product's performance in clinical diagnostic applications and a manufacturer's provision of technical support for such activities. If the FDA were to determine, based on the totality of circumstances, that our products labeled and marketed for RUO are intended for diagnostic purposes, they would be considered medical devices that will require clearance or approval prior to commercialization. Further, sales of devices for diagnostic purposes may subject us to additional healthcare regulation. We continue to monitor the changing legal and regulatory landscape to ensure our compliance with any applicable rules, laws and regulations.

In the future, certain of our products or related applications could become subject to regulation as medical devices by the FDA. If we wish to label and expand product lines to address the diagnosis of disease, regulation by governmental authorities in the United States and other countries will become an increasingly significant factor in development, testing, production and marketing. Products that we may develop in the molecular diagnostic markets, depending on their intended use, may be regulated as medical devices or *in vitro* diagnostic products ("IVDs") by the FDA and comparable agencies in other countries. In the U.S., if we market our products for use in performing clinical diagnostics, such products would be subject to regulation by the FDA under pre-market and post-market control as medical devices, unless an exemption applies, we would be required to obtain either prior 510(k) clearance or prior premarket approval from the FDA before commercializing the product. If we are required to submit our products for pre-market review by the FDA, we may be required to delay marketing and commercialization while we obtain premarket clearance or approval from the FDA. There would be no assurance that we could ever obtain such clearance or approval.

As noted above, although we intend to label and sell our products for research purposes only, the regulatory requirements related to marketing, selling and supporting such products could be uncertain and depend on the totality of circumstances. This uncertainty exists even if such use by our customers occurs without our consent. If the FDA or other regulatory authorities assert that any of our RUO products are subject to regulatory clearance or approval, our business, financial condition, or results of operations could be adversely affected. For example, in some cases, our customers may use our RUO products in their own laboratory-developed tests ("LDTs") or in other FDA-regulated products for clinical diagnostic use. The FDA has historically exercised enforcement discretion in not enforcing the medical device regulations against LDTs and LDT manufacturers. However, on October 3, 2014, the FDA issued two draft guidance documents that set forth the FDA's proposed risk-based framework for regulating LDTs, which are designed, manufactured and used within a single laboratory. In January 2017, the FDA announced that it would not issue final guidance on the oversight of LDTs and LDT manufacturers, but would seek further public discussion on an appropriate oversight approach and give Congress an opportunity to develop a legislative solution. Any restrictions on LDTs by the FDA, HHS, Congress, or state regulatory authorities may decrease the demand for our products. The adoption of new restrictions on RUOs, whether by the FDA or Congress, could adversely affect demand for our specialized reagents and instruments.

As laboratories and manufacturers develop more complex genetic tests and diagnostic software, the FDA may increase its regulation of LDTs. Any future legislative or administrative rule making or oversight of LDTs and LDT manufacturers, if and when finalized, may impact the sales of our products and how customers use our products, and may require us to change our business model in order to maintain compliance with these laws. Additionally, international sales of medical devices are subject to foreign government regulations, which vary substantially from country to country. In the future, if we decide to distribute or market our diagnostic products as IVDs in Europe, such products will be subject to regulation under the European Union ("EU") IVD Directive and/or the IVD Medical Device Regulation (IVDR) European Union (EU) 2017/746.

In the future, to the extent we develop any clinical diagnostic assays, we may pursue payment for such products through a diverse and broad range of channels and seek coverage and reimbursement by government health insurance programs and commercial third-party payors for such products. In the United States, there is no uniform coverage for clinical laboratory tests. The extent of coverage and rate of payment for covered services or items vary from payor to payor. Obtaining coverage and reimbursement for such products can be uncertain, time-consuming and expensive, and, even if favorable coverage and reimbursement status were attained for our tests, to the extent applicable, less favorable coverage policies and reimbursement rates may be implemented in the future. Changes in healthcare regulatory policies could also increase our costs and subject us to additional regulatory requirements that may interrupt commercialization of our products, decrease our revenue and adversely impact sales of, and pricing of and reimbursement for, our products.

In the event that we develop clinical diagnostic assays for which third-party reimbursement becomes available, we would also become subject to various federal and state fraud and abuse and transparency laws. Among other things, these laws may impact our arrangements with customers, as well as our consulting and other arrangements with healthcare providers and others who purchase, recommend or order our clinical diagnostic products. The federal anti-kickback statute prohibits, among other things, persons and entities from knowingly and willfully offering, paying, soliciting, or receiving remuneration, directly or indirectly, overtly or covertly, in cash or in kind, in return for or to induce or reward the purchase, lease, order, arrangement for, or recommendation of, any item or service that is reimbursable, in whole or in part, under a federal healthcare program. In addition, the federal civil and criminal false claims laws (including the civil False Claims Act, for which claims can be brought by private citizens on behalf of the government through qui tam actions), impose liability for, among other things, knowingly presenting, or causing to be presented, false or fraudulent claims for payment of federal funds, and knowingly making, or causing to be made, a false record or statement material to a false or fraudulent claim. Further, the Physician Payments Sunshine Act requires certain manufacturers of drugs, devices, biologics, and medical supplies for which reimbursement is available under certain federal health care programs to collect and report annually certain information on payments and other transfers of value to U.S.-licensed physicians (defined to include doctors, dentists, optometrists, podiatrists, and chiropractors) and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members. Violations of these laws can result in significant penalties, including civil, criminal and administrative penalties, disgorgement, monetary fines, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, imprisonment, and integrity oversight and reporting obligations.

The Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), as amended by the Health Information Technology for Economic and Clinical Health Act ("HITECH"), and their implementing regulations, impose obligations, including mandatory contractual terms, with respect to safeguarding the transmission, security and privacy of protected health information by covered entities subject to HIPAA, such as health plans, healthcare clearinghouses and certain healthcare providers and their respective business associates and covered subcontractors that access protected health information. HITECH also created new tiers of civil monetary penalties and made civil and criminal penalties directly applicable to business associates in some cases, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions.

In addition, in the U.S., numerous federal and state laws and regulations, including state data breach notification laws, state health information privacy laws state genetic privacy laws, federal and state research laws and federal and state consumer protection laws, govern the collection, use, disclosure and protection of health-related and other personal information. Further, the collection, use, storage, disclosure, transfer, or other processing of personal data regarding individuals in the European Economic Area ("EEA"), including personal health data, is subject to the GDPR, which became effective on May 25, 2018.

In addition, in the U.S. and certain foreign jurisdictions, there have been and continue to be a number of healthcare-related legislative initiatives that have significantly affected the healthcare industry. These reform initiatives may, among other things, result in modifications to the aforementioned laws and/or the implementation of new laws affecting the healthcare industry.

Environmental Matters

Our operations require the use of hazardous materials (including biological materials) that subject us to a variety of federal, state and local environmental and safety laws and regulations. Some of the regulations provide for strict liability, holding a party potentially liable without regard to fault or negligence. We could be held liable for damages and fines as a result of our or others' business operations should contamination of the environment or individual exposure to hazardous substances occur. We cannot predict how changes in laws or development of new regulations will affect our business operations or the cost of compliance.

Implications of Being an Emerging Growth Company

We are an "emerging growth company" as defined in the Jumpstart Our Business Startups Act of 2012, as amended (the "JOBS Act"). We will remain an emerging growth company until the earliest to occur of: (i) the last day of the fiscal year in which we have more than $1.07 billion in annual gross revenue; (ii) the date we qualify as a "large accelerated filer" as defined in Rule 12b-2 under the Exchange Act, with at least $700 million of equity securities held by non-affiliates; (iii) the issuance, in any three-year period, by us of more than $1.0 billion in non-convertible debt securities; or (iv) December 31, 2026. As a result of this status, we have taken advantage of certain exemptions from various reporting requirements in this report that are applicable to other publicly traded entities that are not emerging growth companies and may elect to take advantage of other exemptions from reporting requirements in our future filings with the SEC. In particular, in this report, these exemptions include:

- the option to present only two years of audited financial statements and only two years of Management's Discussion and Analysis of Financial Condition and Results of Operations;
- not being required to comply with the auditor attestation requirements of Section 404(b) of the Sarbanes-Oxley Act of 2002, as amended;
- not being required to submit certain executive compensation matters to stockholder advisory votes, such as "say-on-pay," "say-on-frequency," and "say-on-golden parachutes"; and

- not being required to disclose certain executive compensation-related items such as the correlation between executive compensation and performance and comparisons of the chief executive officer's compensation to median employee compensation.

As a result, we do not know if some investors will find our common stock less attractive. The result may be a less active trading market for our common stock, and the price of our common stock may become more volatile.

In addition, Section 107 of the JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards, delaying the adoption of these accounting standards until they would apply to private companies. We have elected to avail ourselves of this exemption and, as a result, we will adopt new or revised accounting standards on the relevant dates on which adoption of such standards is required for private companies. Accordingly, the information contained herein may be different than the information you receive from other public companies.

Facilities

As of December 31, 2022 we leased 135,311 square feet of office, laboratory and manufacturing space in San Diego, California under various leases that expire in 2024, 2026 and 2036.

In January 2022, we entered into a Lease Agreement (the "OAS Lease") with an affiliate of Alexandria Real Estate Equities, Inc. to lease two buildings ("Building 3" and "Building 4") to be constructed in connection with One Alexandria Square in La Jolla, California. Building 3 and Building 4 are comprised of 113,094 square feet and 92,572 square feet, respectively, of office and manufacturing space and will serve as the Company's future headquarters. Per the OAS Lease, the target commencement dates of Building 3 and Building 4 are estimated to be November 1, 2024 and November 1, 2025, respectively, with a base term of 144 months beginning on the commencement date of Building 3.

Corporate and Other Information

We were incorporated in Delaware in 2016. Our principal executive offices are located at 3010 Science Park Road, San Diego, California 92121. Our telephone number is (858) 333-7830. We are subject to the reporting requirements of the Exchange Act. Consequently, we are required to file reports and information with the Securities and Exchange Commission (the "SEC"), including reports on the following forms: annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Exchange Act. These reports and other information concerning us may be accessed, free of charge, through the SEC's website at www.sec.gov and our website at www.singulargenomics.com. These reports are placed on our website as soon as reasonably practicable after they are filed with the SEC. Information contained in, or that can be accessed through, our website is not incorporated by reference into, nor is it in any way a part of, this Form 10-K. We have included our website address in this Form 10-K solely as an inactive textual reference.

Singular Genomics, the Singular Genomics logo and our other registered or common law trademarks appearing in this filing are the property of Singular Genomics Systems, Inc. This filing contains references to our trademarks and service marks and to those belonging to other entities. Solely for convenience, trademarks and trade names referred to in this filing, including logos, artwork and other visual displays, may appear without the ®, TM or SM symbols, but such references are not intended to indicate in any way that we will not assert, to the fullest extent under applicable law, our rights or the rights of the applicable licensor to these trademarks and trade names. We do not intend our use or display of other entities' trade names, trademarks or service marks to imply a relationship with, or endorsement or sponsorship of us by, any other entity.

Item 1A. Risk Factors

Investing in our common stock is speculative and involves a high degree of risk. You should consider and read carefully all of the risks and uncertainties described below, together with all of the other information contained in this report, including the section titled "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our financial statements and the related notes, before investing in our common stock. The risks and uncertainties described below are not the only ones we face. Additional risks and uncertainties not currently known to us or that we currently deem to be immaterial also may materially adversely affect our business, financial condition and/or operating results. If any of the following risks occur, our business, financial condition, results of operations and future growth prospects could be materially and adversely affected. In these circumstances, the market price of our common stock could decline, and you may lose all or part of your investment. This report also contains forward-looking statements that involve risks and uncertainties. Our actual results could differ materially from those anticipated in the forward-looking statements as a result of a number of factors, including the risks described below. See "Special Note Regarding Forward-Looking Statements" elsewhere in this report.

Risks Related to Our Business and Industry

Our limited operating history makes it difficult to evaluate our future prospects and the risks and challenges we may encounter.

We operate in a highly competitive market characterized by rapid technological advances, frequent new product introductions, evolving industry standards and changing customer preferences. Our limited operating history makes it difficult to evaluate our future prospects and our ability to respond to our competitors, changes in our market and the risks and challenges we may encounter as we expand our business operations. If we fail to address the risks, uncertainties and difficulties that we face, including those described elsewhere in this "Risk Factors" section, our business, financial condition and results of operations could be adversely affected. We have encountered in the past, and will encounter in the future, risks and uncertainties frequently experienced by companies developing and introducing new products in competitive and rapidly changing markets. If our assumptions regarding these risks and uncertainties, which we use to plan and operate our business, are incorrect or change, or if we do not address these risks and uncertainties successfully, our results of operations could differ materially from our expectations, and our business, financial condition and results of operations could be adversely affected.

We have incurred significant losses since inception, we expect to incur significant losses in the future and we may not be able to generate sufficient revenue to achieve and maintain profitability.

We have incurred significant losses since we were formed in 2016 and have only recently generated revenue. We expect to continue to incur significant losses for the foreseeable future as we expand our business operations, manufacture and commercialize the G4, continue to enhance and develop our products and implement our business plans and strategies. Our net loss was $90.9 million and $98.8 million for the years ended December 31, 2022 and 2021, respectively. As of December 31, 2022, we had an accumulated deficit of $242.8 million. We expect that our losses will continue for the foreseeable future as we continue to invest significant additional funds toward the commercialization of our products and ongoing research and development. We have experienced these losses and accumulated deficit primarily due to the investments we have made in developing our proprietary technologies and products, building our team and manufacturing capabilities and commercially launching our first product, the G4. Over the next several years, we expect to continue to incur significant expenses as we continue our research and development activities, continue to commercialize the G4, finalize the development of the PX, continue to build our sales and marketing organization and increase our manufacturing and commercialization capabilities. These efforts may prove to be more costly, or take longer, than we currently anticipate. Additionally, we may encounter unforeseen expenses, product development or manufacturing delays, declines in revenue or other unknown factors that may result in losses in future periods. We have only recently generated revenue, and we may never generate revenue sufficient to offset our expenses. In addition, as a public company, we have incurred and will incur significant legal, accounting, administrative, insurance and other expenses that we did not incur as a private company. To date, we have financed our operations principally from the sale of common stock, convertible preferred stock, convertible notes and the incurrence of other indebtedness. There can be no assurance that our revenue and gross margin will increase sufficiently such that our net losses decrease, or that we attain profitability, in the future. Further, our limited operating history makes it difficult to effectively plan for and model our operating expenses and our ability to generate revenue. Our ability to achieve and then sustain profitability is based on numerous factors, many of which are beyond our control, including the impact of market acceptance of our products, product development results and timing, offerings or actions taken by our competitors, our market penetration and margins and current and future litigation. We may never be able to generate sufficient revenue to achieve or sustain profitability, which could negatively impact the value of our common stock.

We have only recently generated revenue and have limited experience developing and commercializing our products or technology, which makes it difficult to evaluate our prospects and predict our future performance.

We commercially launched our first product, the G4, in December of 2021, and we began recognizing revenue on sales of the G4 in the fourth quarter of 2022. There can be no assurance that we will be able to generate sufficient revenue in the future to support our operations and plans. Our operations to date have been focused on developing and commercializing our technologies and products, including developing and commercializing the G4 and developing the PX. The performance of our products in our beta pilot program and early access program may not be indicative of the performance our customers experience following commercial launch, and we may need to make modifications to improve our products. For example, we expect to make modifications to improve the reliability, quality and/or functionality of the G4 as we manufacture the G4 and in response to customer feedback, and we expect the G4 to improve in time as further units are sold. However, there can be no assurance that this will occur or that we will avoid delays in finalizing these improvements. There can be no assurance that we will be able to timely achieve market acceptance for the G4 in the future. We have limited experience manufacturing the G4 for commercial use, conducting sales and marketing activities at scale and managing customer support at the commercial level. Further, while we are continuing to develop the PX, we have no experience manufacturing or commercializing the PX. Consequently, predictions about our future success or viability are highly uncertain and hard to predict as a result of our limited operating history, the development stage of our products and our limited history commercializing our technologies or products. Our prospects must be considered in light of the uncertainties, risks, expenses, and difficulties frequently encountered by companies in their early stages of operations.

Further, we are transitioning from a company with a focus on research and development to a company capable of supporting both research and development and robust manufacturing and commercial activities, and we may not be successful in this transition. We have encountered in the past, and will encounter in the future, risks and uncertainties, delays and scientific setbacks frequently experienced by development stage companies with limited operating histories in competitive and rapidly changing industries, such as the genomics industry. If our assumptions regarding these risks and uncertainties, which we use to plan and operate our business, manufacturing and commercialization activities, are incorrect or change, or if we do not address these risks, delays or uncertainties successfully, our results of operations could differ materially from our expectations, and our business, financial condition and results of operations could be adversely affected.

The life sciences technology market is highly competitive. If we fail to compete effectively, our business and operating results will suffer.

We face significant competition in the life sciences technology market. More specifically, the NGS market is characterized by rapid technological changes, frequent new product introductions, established and emerging competition, extensive intellectual property disputes and litigation, price competition, aggressive marketing practices, evolving industry standards and changing customer preferences. Our primary competitors and potential competitors are large publicly traded companies or are divisions of large publicly traded companies, including 10x Genomics Inc., Becton, Dickinson and Company, Bio-Rad Laboratories, Inc., Illumina Inc., MissionBio Inc., Nanostring Technologies, Inc., Oxford Nanopore Technologies Inc., Pacific Biosciences Inc. and Thermo Fisher Scientific Inc. There are other companies, both established and early stage, such as Element Biosciences, Inc. and Ultima Genomics, Inc., who have begun commercializing NGS technologies and products to our target customers. We also face competition from companies and research institutes developing their own products or applications for omics research. This is particularly true for the largest research centers and laboratories who are continually testing and trying new technologies, whether from a third-party vendor or developed internally.

Our current competitors, including those who are large publicly traded companies, or are divisions of large publicly traded companies, enjoy a number of competitive advantages over us, including:

- greater name and brand recognition;
- greater financial and human resources;
- established and trusted commercial relationships with our target customers;
- broader product lines;
- superior product offerings, features or capabilities;
- greater pricing flexibility, including the ability to offer significant discounts and to bundle products and services;
- larger sales and customer service forces and more established distributor networks;
- substantial intellectual property portfolios;
- exclusive or long-term supply agreements with our target customers;
- approvals with the U.S. Food and Drug Administration (the "FDA") that allow our competitors to market their products for additional uses;
- numerous scientific papers and publications supporting their technologies and product claims; and

- better established, larger scale and lower cost manufacturing capabilities.

We cannot assure investors that we can successfully compete with these competitors or that the G4, our planned PX or any other technologies and products we develop can compete favorably with the offerings from such competitors. We also cannot assure investors that we can successfully defend our technologies and products from lawsuits filed by our competitors without significant expenses, the requirement to complete additional product and technology development, potential manufacturing or commercialization delays, or at all. Further, we cannot assure investors that we will be successful in the face of increasing competition from products and technologies introduced by our existing or future competitors, or developed by our customers internally. 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 offer products with greater capabilities or at lower costs than ours or that are able to run comparable experiments at a lower total experiment cost. Many of our competitors have also been able to enter into long-term, exclusive agreements with major potential customers, often by offering favorable pricing and other terms. Until these agreements expire, our ability to place our products with these customers will be limited. Even after exclusive agreements expire, we may not be able to compete with the terms offered by our competitors in their efforts to extend exclusive relationships with these major potential customers. Any failure to compete effectively could materially and adversely affect our business, financial condition and operating results.

If our products fail to achieve early customer and scientific acceptance, we may not be able to achieve broader market acceptance for our products, and our revenue and prospects may be harmed.

We cannot guarantee that customer experiences or reviews of the G4 from our customers will be favorable. Initial negative perception of the G4 by customers could irreparably damage our reputation and ability to successfully commercialize the G4, our planned PX or any of our other future products. Further, the life sciences scientific community is comprised of a small number of early adopters and key opinion leaders ("KOLs") who significantly influence the rest of the community and the marketplace in general. The success of life sciences products is due, in large part, to acceptance by the scientific community and their adoption of certain products as best practice in the applicable field of research. The current system of academic and scientific research views publishing in a peer-reviewed journal as a measure of success. In such journal publications, the researchers will describe not only their discoveries, but also the methods and typically the products used to fuel such discoveries. Mentions in peer-reviewed journal publications are a good barometer for the general acceptance of our products as best practices. Ensuring that early adopters and KOLs publish research involving the use of our products is critical to ensuring our products gain widespread acceptance and market growth. Continuing to maintain good relationships with such KOLs is vital to growing the acceptance of our products in the marketplace. If early adopters and KOLs do not favorably describe the use of our products, do not compare our products favorably to existing products and technologies, or negatively describe the use and operation of our products in publications, it may drive potential customers away from our products and prevent broader market acceptance of our products, which could harm our business, financial condition and results of operations.

We expect to be highly dependent upon revenue generated from the sale of the G4 and the planned PX and any delay or failure by us to successfully develop and commercialize the G4 or PX could have a substantial adverse effect on our business and results of operations.

We have commercially launched the G4 and began recognizing revenue on sales of the G4 in the fourth quarter of 2022. Our second planned product, the PX, is under development. For the PX, we plan to collaborate with select partners to conduct a technology access program designed to bring samples and collaborators in-house, which we initiated in the fourth quarter of 2022 and executed our first technology access partner agreement in February 2023. Following our technology access program, we plan to expand collaborations with additional potential customers in an early access program. As a result, we expect to generate substantially all of our revenue in the near term from the sale of the G4 and, in the future, from the sale of the G4 and planned PX. There can be no assurance of the following: that the G4 will meet the expectations of our customers, including those relating to cost, reliability, performance and features, or otherwise gain market acceptance; that we can manufacture the G4 in commercial quantities; that we will be able to successfully commercialize the G4; or that we will be able to service and maintain the G4 products that we have sold. Further, there is no assurance that we will be able to successfully complete the development of, or commercialize, our planned PX or any other future products or product enhancements we elect to pursue. To date, we have limited experience simultaneously designing, testing, manufacturing and selling products and there can be no assurances we will be successful in doing so or doing so on our intended timelines. In addition, as technologies change in the life sciences research tools marketplace in general, and in the omics technologies marketplace specifically, we will be expected to upgrade or adapt our products in order to keep up with the latest technology. Further, our competitors may offer or develop products or technologies that cause the G4 or our planned PX to not be commercially attractive to our customers.

Our future financial performance will be dependent on our ability to increase penetration and utilization in our existing markets.

Our financial performance will be driven by, and a key factor to our future success will be, the rate of commercial adoption of the G4 and planned PX. In addition, our financial performance will be dependent on our ability to increase customer utilization of our products, and thereby, increase sales of our consumables and any other associated products and services we offer. There is no assurance that we will be successful in demonstrating our product performance claims and value proposition to potential customers. There also is no assurance that our direct sales and marketing organization in the United States or our direct or distributor sales and marketing efforts in markets outside the United States will drive broad customer adoption of our products. Further, we may not be successful in increasing our customers' usage of our products, or their associated purchase of our consumables and other products and services. Any failure to establish a broad installed base of the G4 and our planned PX among our target customers, or failure to increase the usage of our products and the associated sales of our consumables and other products and services, will limit our revenue growth and harm our results of operations and financial performance.

Our business will depend significantly on research and development spending by academic institutions and other research institutions, and any reduction in spending could limit demand for our products and adversely affect our business, results of operations, financial condition and prospects.

We are initially targeting customers who are already familiar with genomic analysis, including academic institutions, genomic research centers/core labs and government laboratories, as well as pharmaceutical, clinical research organizations ("CROs"), biotechnology, consumer genomics, commercial molecular diagnostic laboratories and agrigenomics companies. We believe that a substantial amount of our sales revenue in the near term will be generated from sales to academic and other research institutions. Therefore, we expect much of these customers' funding will be, in turn, provided by various state, federal and international governmental agencies. As a result, the demand for the G4, our planned PX and any other product or product enhancements we elect to develop in the future may depend in part upon the research and development budgets of these customers, which are impacted by factors beyond our control, such as:

- decreases in government funding of research and development;
- changes to programs that provide funding to research laboratories and institutions, including changes in the amount of funds allocated to different areas of research or changes that have the effect of increasing the length of the funding process;
- macroeconomic conditions and the political climate;
- scientists' and customers' opinions of the utility of new products or services;
- researchers' opinions of the utility of the G4, our planned PX or any other product or product enhancements we elect to develop in the future;
- citation of the G4 and planned PX in published research;
- potential changes in the regulatory environment;
- differences in budgetary cycles, especially government- or grant-funded customers, whose cycles often coincide with government fiscal year ends;
- competitor product offerings or pricing;
- the effect of inflation on budgets of our potential customers;
- market acceptance of new technologies; and
- market driven pressures to consolidate operations and reduce costs.

In addition, various state, federal and international agencies that provide grants and other funding may be subject to stringent budgetary constraints that could result in spending reductions, reduced grant making, reduced allocations or budget cutbacks, which could jeopardize the ability of these customers, or the customers to whom they provide funding, to purchase our products. For example, congressional appropriations to the National Institutes of Health (the "NIH") have generally increased year-over-year for the last 20 years, but the NIH also experiences occasional year-over-year decreases in appropriations, including as recently as 2013. There is no guarantee that NIH appropriations will not decrease in the future. A decrease in the amount of, or delay in the approval of, appropriations to NIH or other similar United States or international organizations, such as the Medical Research Council in the United Kingdom, could result in fewer grants benefiting life sciences research. These reductions or delays could also result in a decrease in the aggregate amount of grants awarded for life sciences research or the redirection of existing funding to other projects or priorities, any of which in turn could cause our customers and potential customers to reduce or delay purchases of our products. Our operating results may fluctuate substantially due to any such reductions and delays. Any decrease in our customers' budgets or expenditures, or in the size, scope or frequency of their capital or operating expenditures, could materially and adversely affect our business, results of operations, financial condition and prospects.

Our operating results may fluctuate significantly in the future, which makes our future operating results difficult to predict and could cause our operating results to fall below expectations or any guidance we may provide.

We have very limited operating history in manufacturing, commercializing and providing customer support for our first product, the G4 and have limited history in developing our PX. As a result, our quarterly and annual operating results may fluctuate significantly as we finalize the development of the G4 and begin or continue these new manufacturing, commercialization and customer support activities and continue the development of the PX, which makes it difficult for us to predict our future operating results. These fluctuations may occur due to a variety of factors, many of which are outside of our control, including but not limited to:

- our ability to successfully manufacture and commercialize the G4 on our anticipated timelines and costs;
- our ability to continue the development and successfully manufacture and commercialize the PX or other products and technologies on our anticipated timelines and costs;
- the timing and cost of, and level of investment in, research and development, manufacturing and commercialization activities relating to our products and technologies, which may change from time to time;
- the level of demand for any products or product enhancements we are able to commercialize, particularly the G4 and our planned PX, which may vary significantly from period to period;
- market acceptance of our products, especially by early adopters and KOLs;
- our ability to drive adoption of our products and technologies, including the G4 and our planned PX, in our target markets and our ability to expand into any future target markets;
- the prices at which we will be able to sell our products and technologies;
- our ability to lower the cost of manufacturing our products and product enhancements;
- the availability and cost of components and raw materials;
- actions taken by our competitors, including new product introductions, pricing changes, product bundling and aggressive marketing practices;
- intellectual property disputes and litigation;
- the outcomes of and related rulings in litigation and administrative proceedings in which we may in the future become involved in;
- the operating performance and financial results of our competitors;
- the volume and mix of our sales between the G4 and our planned PX and other products and technologies, including consumables, or changes in the manufacturing or sales costs related to our products;
- the utilization of our instruments and the volume and mix of the sales of our consumables;
- the length of time of the sales cycle for purchases of our products and technologies, including the G4 and our planned PX;
- the timing and amount of expenditures that we may incur to develop, commercialize or acquire additional products and technologies or for other purposes, such as the expansion of our facilities;
- changes in governmental funding of life sciences research and development or changes that impact budgets or budget cycles;
- the timing of when we recognize revenue;
- future accounting pronouncements or changes in our accounting policies;
- the outcome of any future governmental investigations involving us, our industry or both;
- higher than anticipated service, replacement and warranty costs;
- the impact of the COVID-19 pandemic on the economy, our business and operations, investment in life sciences and research industries, and resources and operations of our customers, suppliers and distributors;
- general industry, economic and market conditions and other factors, including factors unrelated to our operating performance or the operating performance of our competitors; and
- the other factors described in this “Risk Factors” section.

The cumulative effects of the factors discussed above could result in large fluctuations and unpredictability in our quarterly and annual operating results. As a result, comparing our operating results on a period-to-period basis may not be meaningful. Investors should not rely on our past results as an indication of our future performance. This variability and unpredictability could also result in our failing to meet the expectations of industry or financial analysts or investors for any period. If we are unable to commercialize products or generate sufficient revenue, or if our 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, it could cause the market price of our common stock to decline.

We expect to continue to incur substantial operating expenses in the future, which will negatively impact our ability to achieve or maintain profitability.

We have experienced net losses and negative cash flows from operations since our formation in 2016. As of December 31, 2022, we had an accumulated deficit of $242.8 million. Over the next several years, we expect to continue to incur significant expenses as we continue to build our sales and marketing organization, increase our manufacturing and commercialization capabilities, continue our research and development activities and continue the development and enhancement of our products. These efforts may prove to be more costly, or take longer, than we currently anticipate. We have only recently recognized revenue, and we may never generate revenue sufficient to offset our expenses. If our revenue does not eventually grow to a level that exceeds our expenses, we will not be able to achieve or maintain profitability. Additionally, we may encounter unexpected development delays, unforeseen expenses, operating delays, declines in revenue or other unknown factors that may result in losses in future periods. If we are unable to achieve and maintain sustained profitability, our business, results of operations, financial condition and prospects will be materially harmed.

The COVID-19 pandemic and efforts to reduce its spread have adversely impacted and may materially and adversely impact our business and operations; recent downward macroeconomic pressures could also materially and adversely impact our business and operations.

The COVID-19 pandemic spread worldwide, and caused many governments to implement measures to slow the spread of the outbreak through quarantines, travel restrictions, heightened border scrutiny and other measures. In addition, in response to the COVID-19 pandemic, many state, local and foreign governments put in place quarantines, executive orders, shelter-in-place orders and similar government orders and restrictions in order to control the spread of the disease. Such orders or restrictions resulted in business closures, work stoppages, slowdowns and delays, work-from-home policies, travel restrictions and cancellation of events, among other effects that impacted our business, personnel, personnel at third-party manufacturing facilities and the availability or cost of materials.

For instance, there were previously standing "stay-at-home" orders in California, and specifically in San Diego County, where our headquarters is located. We have continued to operate within the rules applicable to our business; however, while these mandates have generally expired, a reinstatement of these governmental mandates or institution of other mandates could impact our ability to operate effectively and conduct ongoing research and development or other activities. Additionally, we have experienced longer lead times from our suppliers of components used in our product development and manufacturing operations, including due to supply chain challenges currently being experienced generally in the economy. Further, our operating costs have increased, and may continue to increase, due to the recent growth in inflation, which could have an adverse effect on our results of operation and financial condition. Existing pandemic precautions and preventative measures or such precautions or preventative measures that are reinstituted could also impact our commercialization plans due to restrictions on our customers' ability to access laboratories, causing delays in the delivery and installation of our products, training such customers on our products and their ability to conduct research. The ongoing build-out of our new headquarters and manufacturing facilities may also be delayed by the reinstitution of COVID-19 related restrictions. The COVID-19 pandemic has also had an adverse effect on our ability to attract, recruit, interview and hire at the pace we would typically expect to support our rapidly expanding operations. To the extent that any governmental authority imposes additional regulatory requirements or re-imposes regulatory requirements or changes existing laws, regulations and policies that apply to our business and operations, such as additional workplace safety measures, our product development plans may be delayed, and we may incur further costs in bringing our business and operations into compliance with new laws, regulations and policies.

In the near term, we expect that a substantial amount of our revenue will be derived from sales of the G4 to academic and research institutions. Our ability to drive the adoption of our products will depend on our ability to visit customer sites to install and train customers on the G4, and the ability of our customers to access laboratories and conduct research in light of the COVID-19 pandemic. While we don't believe our customers have experienced substantial issues in accessing laboratories to conduct research, we cannot be certain they won't experience difficulties in the future. Additionally, the research and development budgets of these customers, the ability of such customers to receive funding for research, and the ability of such customers to receive instrument installations and visitors to their facilities and to travel to our facilities, other laboratories and industry events, will become increasingly important to the adoption of the G4. All of these activities have been impacted by the COVID-19 pandemic in multiple ways, such as:

- reductions in capacity or shutdowns of laboratories and other institutions as well as other impacts stemming from the COVID-19 pandemic, such as reduced or delayed spending on instruments or consumables as a result of such delays and shutdowns;
- re-allocation of resources by potential customers toward COVID-19 research, testing or treatment;
- delays in or the inability to obtain supplies and materials used to produce our products;
- decreases in government funding of research and development; and
- changes to programs that provide funding to research laboratories and institutions, including changes in the amount of funds allocated to different areas of research and changes that have the effect of increasing the length of the funding process.

The ultimate impact of the COVID-19 pandemic is highly uncertain and subject to sudden change, despite expiration of most of the mandates and a waning effect of the pandemic. Any future impacts could have a material, adverse impact on our liquidity, capital resources, operations and business and those of the third parties we rely on, and could worsen over time. The extent to which the COVID-19 pandemic impacts our results will depend on future developments, which are highly uncertain and cannot be predicted, including new information that may emerge concerning the severity of COVID-19 and the actions to contain COVID-19 or treat its impact, among others. While we do not yet know the full extent of the potential future impacts on our business, any of these occurrences could significantly harm our business, results of operations and financial condition.

Further, the COVID-19 pandemic and its related affects has resulted in, and may continue to result in, downward pressure, extreme volatility, and disruptions in the capital and credit markets, reducing our ability to raise additional capital through equity, equity-linked or debt financings, which could negatively impact our short-term and long-term liquidity and our ability to operate in accordance with our operating plan, or at all. Additionally, the economy has recently begun to experience a downturn. A severe or prolonged economic downturn could result in a variety of risks to our business, including weakened demand for our products and technologies and our ability to raise additional capital when needed on favorable terms, if at all. A weak or declining economy could strain our customers' budgets or cause delays in their payments to us. Any of the foregoing could harm our business and results of operations, and we cannot anticipate all of the ways in which the current economic climate and financial market conditions could adversely impact our business, results of operations, financial condition or our ability to raise capital.

Risks Related to the Development and Commercialization of Our Products

Our efforts to manufacture and commercialize the G4 and to finalize the development and commercially launch our planned PX may not be successful.

With respect to the G4, we completed our beta pilot program, have concluded our early access program, and have commercially launched the G4. We began recognizing revenue on sales of the G4 in the fourth quarter of 2022. With respect to our planned PX, we are currently in an advanced prototype development stage for the initial products. For the PX, we plan to collaborate with select partners to conduct a technology access program designed to bring samples and collaborators in-house, which we initiated in the fourth quarter of 2022 and executed our first technology access partner agreement in February 2023. Following our technology access program, we plan to expand collaborations with additional potential customers in an early access program. Our commercialization and product development plans may not progress as planned or meet our expected timelines or may not be successful due to:

- the level of customer demand for the G4;
- the ability of our commercial products to regularly meet target specifications;
- our ability to manufacture and ship the G4 efficiently and at sufficient commercial scale to meet demand;
- potential delays in completing development of our planned PX or future products;
- our ability to complete the development and manufacture our planned PX;
- our inability to establish the capabilities and value proposition of our products with KOLs and early adopters in a timely fashion, including through information included in scientific publications and presentations;
- our inability to establish broad scientific acceptance of our products;
- potential litigation brought by our competitors against our products, technology or intellectual property;
- the continued effect and lasting impact of the COVID-19 pandemic and recent downward macroeconomic pressure;
- our inability to overcome the long-term relationships, including exclusive agreements, that our competitors have established with our target customers;
- actions taken by our competitors, including new product introductions and the ability to offer significant discounts and to bundle products and services to our target customers;
- our customers' willingness and ability to adopt new products and workflows, including in light of commercial pressures applied by our competitors and pre-existing long-term contracts with our competitors;
- our ability to demonstrate that the G4 and our planned PX provide meaningful advantages over competing products and technologies;
- the prices we charge for the G4 and planned PX and other products and technologies;
- our ability to develop new products and workflows and solutions for customers, and the impact of our investments in product innovation and commercial growth;
- our ability to provide service and maintain the products we have sold;
- changing industry or market conditions, customer expectations or requirements;
- delays in building out our sales, customer support and marketing organization as needed for our commercial launch plans; and
- delays in ramping up manufacturing, including obtaining required materials and components from third-party suppliers, to meet expected or actual demand for our products.

We cannot assure you that we will be successful in addressing each of the risks and uncertainties that might affect the development and market acceptance of any products we commercialize. Initial negative perception of the G4 by customers could irreparably damage our reputation and ability to successfully commercialize the G4 or our planned PX or future products. In addition, as we continue to commercialize the G4 we will also need to continue to make corresponding improvements to other operational functions, such as our customer support, service and billing systems, compliance programs and our internal quality assurance programs. We cannot assure you that any increases in scale, required manufacturing improvements and quality assurance will be successfully implemented or that appropriate personnel will be available. To the extent any of our commercial plans and related activities are delayed, unsuccessful or more expensive than we currently anticipate, our financial results may be adversely impacted and we may never generate sufficient revenue to achieve and maintain profitability.

If we are unable to establish sales and marketing capabilities, we may not be successful in commercializing the G4 or our planned PX.

We have limited experience commercializing our products, and our ability to achieve profitability depends on being able to successfully commercialize the G4 and our planned PX. Although members of our management team have considerable industry experience, we are in the process of expanding our sales, marketing, distribution and customer service and support capabilities with the appropriate technical expertise. To perform sales, marketing, distribution, and customer service and support successfully, we will face a number of risks, including:

- our ability to attract, train, retain and manage the sales, marketing and customer service and support force necessary to commercialize and gain market acceptance for our products and train and support our customers in the use of our systems;
- our ability to adopt successful marketing and pricing strategies;
- the time and cost of establishing a specialized sales, marketing and customer service and support force; and
- our sales, marketing and customer service and support force may be unable to initiate and execute successful commercialization activities.

We may seek to enlist one or more third parties to assist with sales, distribution and customer service and support globally or in certain regions of the world. There is no guarantee, if we do seek to enter into such arrangements, that we will be successful in attracting desirable sales and distribution partners or that we will be able to enter into such arrangements on favorable terms. If our sales and marketing efforts, or those of any third-party sales and distribution partners, are not successful, the G4 or our planned PX may not gain market acceptance, which could materially impact our business and results of operations.

Our products could fail to achieve key performance metrics we are targeting and our prospects could be harmed.

We believe our Sequencing Engine can impart commercially marketable capabilities to our products, including power, speed, flexibility and accuracy. To successfully commercialize our products, we are targeting certain performance metrics, including cycle times for each base, accuracy for base reads, quality scores and the number of independent flow cells that can run concurrently. If our Sequencing Engine or our products are unable to meet and to consistently achieve key performance metrics, including once commercially deployed, or, if the data supporting our preliminary achievement of certain key performance metrics are incorrect or not viewed favorably by KOLs or potential customers, demand for the G4 and planned PX may not develop as anticipated, which could adversely affect our revenue and our results of operations.

If we fail to continue to expand the capabilities of the G4 and complete the development of the PX, our revenue and our prospects could be harmed.

We completed our beta pilot program, have concluded our early access program, and have commercially launched the G4. We began recognizing revenue on sales of the G4 in the fourth quarter of 2022. We are working to expand the capabilities of the G4 by providing novel kits for targeted applications. Any delay or failure by us to successfully develop and release these enhancements could have a substantial adverse effect on our business and results of operations.

Our planned PX is in the development phase and is subject to all the risks and uncertainties associated with product development of highly complex and novel life sciences instruments. We have not met a number of technical and performance metrics that we believe will be necessary to achieve prior to commercialization. If we do not achieve the required technical specifications and performance metrics for our planned PX or if development work is not performed according to our planned schedule, then we may not be successful in finalizing our planned PX and its commercial launch may be adversely affected, delayed or not occur at all. Additionally, our planned PX could be subject to redesign or further improvements, and result in delays in finalizing development and commencing commercialization, after feedback from beta collaborators, collaborators in our early access program, and KOLs. Any delay or failure by us to successfully develop, release, commercialize and maintain the PX could have a substantial adverse effect on our business and results of operations.

If we fail to continue to improve our planned products or, introduce compelling new products, product enhancements or product configurations, our revenue and our prospects could be harmed.

Our ability to attract customers and earn revenue will depend in large part on our ability to continue to enhance and improve our products and to introduce compelling new products and product capabilities. The success of any enhancements to the G4 or our planned PX, or the introduction of any new products and product capabilities depends on several factors, including timely completion and delivery of such enhancements and products, competitive pricing, adequate quality testing, integration with existing products and technologies, appropriately timed and staged introduction, overall market acceptance and our ability to properly manufacture, service and maintain these products. Any new products or enhancements that we develop may not be introduced in a timely or cost effective manner, may contain defects, errors, vulnerabilities or bugs, or may not achieve the market acceptance necessary to increase our revenue and improve our operating results. Further, if we are unable to successfully develop any new products, enhance the capabilities of our existing products to meet evolving customer requirements and demands, compete with alternative products and technologies, or otherwise gain and maintain market acceptance, our business, results of operations and financial condition could be harmed.

The sizes of the markets for our products and technologies may be smaller or grow slower 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.

The market for NGS, single-cell, spatial and proteomics 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. In particular, while we believe that our target markets may be underserved by existing genomics products and technologies and that our target customers will recognize the value proposition offered by our products, we cannot be certain that our target customers will recognize enough value from our products to purchase our products in place of, or in addition to, tools and technologies they already use. Further, we cannot be certain that our target customers will view our products as competitive alternatives to existing tools and technologies in our target markets, especially given that our competitors have long relationships, including exclusive arrangements, with our target customers and may be able to offer significant discounts and/or buddle products or offerings to our target customers.

While we believe our assumptions and the data underlying our estimates of the total annual addressable market for our products and technologies are reasonable, these assumptions and estimates may not be correct and the conditions supporting our assumptions or estimates, or those underlying the third-party data we have used, may change at any time, thereby reducing the accuracy of our estimates. As a result, our estimates of the annual total addressable market for our products and technologies may be incorrect. Further, the future growth of the market for our current and future products depends on many factors beyond our control, and if the markets for our current and future products are smaller than estimated or do not develop as we expect, our growth may be limited and our business, financial condition and operational results of operations could be adversely affected.

We expect to commercialize the G4 and our planned PX outside of the United States, which could expose us to business, regulatory, political, operational, financial and economic risks associated with doing business outside of the United States.

Engaging in international business inherently involves a number of difficulties and risks, including:

- required compliance with existing and changing foreign regulatory requirements and laws that are or may be applicable to our business in the future, such as the European Union's ("EU") General Data Protection Regulation ("GDPR") and other data privacy requirements, labor and employment regulations, anti-competition regulations, the U.K. Bribery Act of 2010 and other anti-corruption laws, regulations relating to the use of certain hazardous substances or chemicals in commercial products, and require the collection, reuse, and recycling of waste from products we manufacture;
- required compliance with U.S. laws such as the Foreign Corrupt Practices Act, and other U.S. federal laws and regulations established by the office of Foreign Asset Control;
- export requirements and import or trade restrictions;
- laws and business practices favoring local companies;
- foreign currency exchange, longer payment cycles and difficulties in enforcing agreements and collecting receivables through certain foreign legal systems;
- changes in social, economic, and political conditions or in laws, regulations and policies governing foreign trade, manufacturing, research and development, and investment both domestically as well as in the other countries and jurisdictions in which we operate and into which we may sell our products including as a result of the separation of the United Kingdom from the European Union ("Brexit");
- potentially adverse tax consequences, tariffs, customs charges, bureaucratic requirements and other trade barriers;
- difficulties and costs of staffing and managing foreign operations; and
- difficulties protecting, maintaining, enforcing or procuring intellectual property rights.

If one or more of these risks occurs, it could require us to dedicate significant resources to remedy such occurrence, and if we are unsuccessful in finding a solution, our financial results will suffer.

Risks Related to Our Financial Position and Need for Additional Capital

We may require substantial additional funding, which may not be available to us on acceptable terms, or at all, and, if not available, may require us to delay, scale back, or cease our product development or commercialization activities.

Based on our current plans, we believe that our current cash and cash equivalents, short-term investments and anticipated cash flow from operations, if any, will be sufficient to meet our anticipated cash requirements for at least 12 months from the date of this report. If our available cash resources and anticipated cash flows from operations, if any, are insufficient to satisfy our liquidity requirements, we may be required to raise significant additional capital to support our continued operations and the implementation of our business plans. Our future funding requirements will depend on many factors, including but not limited to:

- our rate of progress in commercializing and scaling the manufacturing of the G4;
- the costs of the sales and marketing activities associated with establishing adoption of the G4;
- the effect of competing technological and market developments, including any requirement to provide discounts for the G4 because of competitive pressures;
- litigation expenses we incur to defend against claims, including claims that we infringe the intellectual property of others or judgments we must pay to satisfy such claims;
- contractual obligations to third parties;
- our rate of progress in developing, launching and commercializing our planned PX and any new products or product enhancements we pursue;
- our ability to control our manufacturing and operating costs;
- our ability to satisfy our outstanding debt obligations; and
- the costs of responding to the other risks and uncertainties described in this report.

We may also be required to raise additional capital in the future to expand our business and operations to pursue strategic investments or for other reasons, including but not limited to:

- increasing our sales and marketing and other commercialization efforts to drive market adoption of the G4;
- commercializing our planned PX;
- scaling up our manufacturing and customer support capabilities;
- funding development and marketing efforts of our other future products and product enhancements;
- expanding our technologies into additional markets;
- acquiring, licensing or investing in technologies and other intellectual property rights;
- acquiring or investing in complementary businesses or assets; and
- financing capital expenditures and general and administrative expenses.

We may seek required funding through issuances of equity or convertible debt securities, entering into additional loan facilities or drawing down additional funds under our SVB Loan. Each of the various ways we could raise additional capital carry potential risks. If we raise funds by issuing equity securities, dilution to our stockholders would result. If we raise funds by issuing additional debt securities, those debt securities would have rights, preferences and privileges senior to those of holders of our common stock. Our SVB Loan restricts our ability to pursue certain transactions that we may believe to be in our best interest, including incurring additional indebtedness without the prior written consent of the lender under the SVB Loan. If we raise funds through collaborations or licensing arrangements, we might be required to relinquish significant rights to our technologies or products or grant licenses on terms that are not favorable to us.

If we are unable to obtain adequate financing or financing on terms satisfactory to us, if we require it, our ability to continue to pursue our business objectives and to respond to business opportunities, challenges, or unforeseen circumstances could be significantly limited and could have a material adverse effect on our business, financial condition, results of operations and prospects.

Our results of operations could be materially harmed if we are unable to accurately forecast customer demand for the G4, our planned PX if and once developed and commercialized, and any other future products and product enhancements we elect to pursue.

To ensure adequate supply of the G4 to meet demand, we must forecast our future inventory needs and appropriately scale-up our manufacturing operations and personnel. We must also place orders with our third-party suppliers based on such forecasts. Our ability to accurately forecast demand for the G4 could be negatively affected by many factors, including: our ability to timely scale our manufacturing operations and capabilities; the success of our sales and marketing activities; customer acceptance of the G4; and potential adverse impacts resulting from the COVID-19 pandemic and related matters, including supply delays and shortages. These same risks and uncertainties will also apply to our planned PX and any other future products and product enhancements we elect to pursue.

Inventory levels in excess of customer demand may result in inventory write-downs or write-offs, which would cause our gross margin to be adversely affected and could impair the strength of our brand. Similarly, a portion of our inventory could become obsolete or expire, which could have a material and adverse effect on our earnings and cash flows due to the resulting costs associated with inventory impairment charges and costs required to replace obsolete inventory. Any of these occurrences could negatively impact our financial performance.

Conversely, if we underestimate customer demand for the G4, our planned PX or any other future products and product enhancements we elect to pursue, we may not be able to deliver sufficient products to meet our customer requirements, which could result in damage to our reputation and customer relationships. In addition, if we experience a significant increase in demand, we may not be able to increase our manufacturing capacity on a timely basis. Further, we may not be able to obtain the components for our products when required on terms that are acceptable to us, or at all, which could have an adverse effect on our ability to meet customer demand and harm our business and results of operations.

Our existing indebtedness may limit our flexibility in financing and operating our business and adversely affect our business, financial condition and results of operations.

As of December 31, 2022, there was $10.5 million of principal owed under our SVB Loan (as defined in Note 8 to our financial statements included in Item 8). In addition to this outstanding amount, we may borrow substantial funds in the future to provide a portion of the capital needed in our business and may secure the repayment of such borrowings by placing additional liens or other encumbrances on our assets. Our SVB Loan contains customary conditions to borrowing, events of default and affirmative and negative covenants, including covenants that restrict our ability (and the ability of certain of our subsidiaries) to incur additional indebtedness, grant liens, make certain fundamental changes and asset sales, pay dividends or make other distributions to holders of our stock, make investments or engage in transactions with our affiliates. Such restrictions could limit our ability to take certain actions could reduce our flexibility to run and manage our business which could have an adverse effect on our results of operations. The obligations under the SVB Loan are also secured by liens on substantially all of our assets, excluding our intellectual property on which there is a negative pledge, subject to customary exceptions. If we were unable to repay amounts due under the SVB Loan, Silicon Valley Bank could proceed against such assets. Any declaration by Silicon Valley Bank of an event of default could significantly harm our business and prospects and could cause the price of our common shares to decline.

Our ability to use our net operating loss carryforwards and certain other tax attributes may be limited.

We have incurred substantial losses during our history, which we expect to continue for the foreseeable future, and we may never achieve profitability. As of December 31, 2022, we had federal and California tax loss carryforwards of approximately $148.6 million and $126.7 million, respectively. As of December 31, 2022, we had federal and state tax credit carry forwards of approximately $6.0 million and $5.8 million, respectively. Under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, (the "Code"), if a corporation undergoes an "ownership change," generally defined as a greater than 50 percentage point change (by value) in its equity ownership by certain stockholders over a three-year period, the corporation's ability to use its pre-change net operating loss carryforwards ("NOLs"), and other pre-change tax attributes (such as research tax credits) to offset its post-change income or taxes may be limited. We have not yet completed an ownership change analysis. If a requisite ownership change occurs, the amount of remaining tax attribute carryforwards available to offset taxable income and reduce income tax expense in future years may be restricted or eliminated. Similar provisions of state tax law may also apply to limit our use of accumulated state tax attributes. In addition, at the state level, there may be periods during which the use of NOLs is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed. As a result, even if we attain profitability, we may be unable to use a material portion of our NOLs and other tax attributes based on restrictions in the Code, which could adversely affect our future cash flows and results of operations.

U.S. federal income tax reform and the implementation of such reforms could adversely affect us.

On December 22, 2017, the United States enacted the Tax Cuts and Jobs Act (the "TCJA") that significantly reformed the Code. The TCJA, among other things, contained significant changes to corporate taxation, including a reduction of the corporate tax rate from a top marginal rate of 35% to a flat rate of 21%, the limitation of the tax deduction for net interest expense to 30% of adjusted earnings (except for certain small businesses), the limitation of the deduction for NOLs arising in taxable years beginning after December 31, 2017 to 80% of current year taxable income and elimination of NOL carrybacks for losses arising in taxable years ending after December 31, 2017 (though any such NOLs may be carried forward indefinitely), the imposition of a one-time taxation of offshore earnings at reduced rates regardless of whether they are repatriated, the elimination of U.S. tax on foreign earnings (subject to certain important exceptions), the allowance of immediate deductions for certain new investments instead of deductions for depreciation expense over time, and the modification or repeal of many business deductions and credits. The financial statements contained herein reflect the effects of the TCJA based on current guidance. However, there remain uncertainties and ambiguities in the application of certain provisions of the TCJA, and, as a result, we made certain judgments and assumptions in the interpretation thereof.

As part of Congress's response to the COVID-19 pandemic, the Families First Coronavirus Response Act (the "FFCR Act"), was enacted on March 18, 2020, and the Coronavirus Aid, Relief, and Economic Security Act, (the "CARES Act"), was enacted on March 27, 2020. Both contain numerous tax provisions. In particular, the CARES Act retroactively and temporarily (for taxable years beginning before January 1, 2021) suspends application of the 80%-of-income limitation on the use of NOLs, which was enacted as part of the TCJA. It also provides that NOLs arising in any taxable year beginning after December 31, 2017 and before January 1, 2021 are generally eligible to be carried back up to five years. The CARES Act also temporarily (for taxable years beginning in 2019 or 2020) relaxes the limitation of the tax deductibility for net interest expense by increasing the limitation from 30% to 50% of adjusted taxable income.

Risks Related to Manufacturing Our Products

We may be unable to manufacture the G4 to meet our commercialization plans on a timely or cost effective basis.

We must successfully increase our manufacturing output to meet our long-term commercialization plans. We currently manufacture the G4 in our facilities in San Diego, California. We have signed a lease for a manufacturing facility that is being constructed at a new location in La Jolla, California to support our growth and commercialization plans. In order to manufacture sufficient G4 instruments and consumables to meet our commercialization plans, we will need to hire and train a sufficient number of manufacturing, engineering and quality personnel. Manufacturing the G4 requires complex processes, and depends on the skill and experience of our manufacturing personnel. The manufacturing process for the G4 also includes sourcing components from various third-party suppliers and then assembling and testing the final product offerings. We must manufacture the G4 in compliance with our demanding specifications in a timely and efficient manner and at an acceptable cost in order to achieve and maintain profitability. We have a limited history of manufacturing and assembling the G4, and, as a result, we may have difficulty manufacturing and assembling sufficient quantities of such products in a timely and cost-effective manner. For example, we had previously experienced delays in the scale-up of our manufacturing process when producing our first commercial units of the G4, and we have since improved this process. In addition, to manage our manufacturing operations and the supply of components from our third-party suppliers, we will need to forecast anticipated demand to predict our inventory needs from six months to a year in advance and enter into purchase orders on the basis of these requirements. Our limited manufacturing history may not provide us with enough data to allow us to accurately and effectively predict our manufacturing capacity requirements or our need for components from our third-party suppliers, including appropriately anticipating supply shortages or unavailability and fluctuations in the pricing of required components. We may experience delays in obtaining components required for the G4, including due to recent supply chain challenges being experienced in the economy generally, or not have sufficient manufacturing capabilities and personnel for such products, which could impede our ability to manufacture and assemble these products on our expected timeline. As a result of this or any other delays, we may encounter difficulties in production of the G4, including problems with quality control and assurance, component supply shortages or surpluses, increased costs, shortages of qualified personnel and difficulties associated with compliance with local, state, federal and foreign regulatory requirements. Our costs may also significantly increase as a result of inflation, and we may not be able to offset those higher costs by increasing our prices to our customers to the extent we have generated sales. Our operating costs have increased, and may continue to increase, due to the recent growth in inflation, which could have an adverse effect on our results of operation and financial condition.

We are dependent on single source suppliers for some components to our consumables and the loss of any of these suppliers could harm our business.

We do not have long-term contracts with third-party suppliers from whom we obtain some components to manufacture the G4. We are, therefore, subject to the risk that these third-party suppliers will not continue to provide us with components that meet our specifications, quality standards and delivery schedules. Factors that could impact our suppliers' willingness and ability to continue to provide us with the required components include disruption at or affecting our suppliers' facilities, such as work stoppages or natural disasters, demand for and availability of raw materials and subcomponents, adverse weather or other conditions that affect their supply, the financial condition of our suppliers and deterioration in our relationships with these suppliers. In addition, we cannot be sure that we will be able to obtain these components on satisfactory terms. Any increase in component costs could reduce any potential future sales and harm our gross margins.

While we have qualified second sources for several of our critical components, including flow cells, optics and oligonucleotides, we do not have qualified secondary sources for all components that we source through a single supplier and we cannot assure investors that the qualification of a secondary supplier will prevent future supply issues. Disruption in the supply of materials or components would impair our ability to sell our products and meet customer demand, and also could delay the launch of new products, any of which could harm our business and results of operations. If we were to have to change suppliers, the new supplier may not be able to provide us components in a timely manner and in adequate quantities that are consistent with our quality standards and on satisfactory pricing terms. In addition, alternative sources of supply may not be available for components for which there are a limited number of suppliers which could result in a requirement to redesign certain aspects of our products. Further, supply shortages could require us to redesign our products to be compatible with components that are more readily available, which could lead to manufacturing and commercialization delays.

We have limited experience manufacturing the G4, and we may be unable to consistently manufacture or supply the G4 to the necessary specifications or in quantities necessary to meet demand on a timely basis and at acceptable performance and cost levels.

The G4 is a complex product with many different components that must work together to obtain the desired results. As such, a quality defect in a single component can compromise the performance of the entire product. In order to successfully generate sufficient revenue from the G4, we need to supply our customers with products that meet their expectations for quality and functionality in accordance with established specifications on a timely basis. Given the complexity of the G4, individual G4 units may require additional installation and service time prior to becoming available for customer use and we may be required to replace lots of reagents or consumables.

We manufacture the G4 at our existing facilities in San Diego, California. We procure certain components of the G4 from third-party suppliers, which include both commonly available raw materials and custom components. Many of these manufacturing processes are complex. For example, we had previously experienced delays in the scale-up of our manufacturing process when producing our first commercial units of the G4, and we have since improved this process. If we are not able to repeatedly produce the G4 at commercial scale and source required components from third-party suppliers, our business will be adversely impacted.

We have limited manufacturing experience and there is no assurance that we will be able to manufacture our products so that they repeatedly provide accurate results consistent with product specifications. Further, our consumables have a limited shelf life, after which their performance is not ensured. Shipment of consumables that effectively expire early or shipment of defective instruments or consumables to customers may result in recalls and warranty replacements, which would increase our costs, and depending upon our inventory levels and the availability and lead time for additional inventory, could lead to availability issues. As we develop additional products, we may need to bring new equipment on-line, implement new systems, technology, controls and procedures and hire personnel with different qualifications. Any future design issues, unforeseen manufacturing problems, equipment malfunctions, aging components, quality issues with components and materials sourced from third-party suppliers, or failures to strictly follow procedures or meet specifications, may have a material adverse effect on our brand, business, results of operations and financial condition.

The G4 could have defects or errors, which may give rise to claims against us, adversely affect market adoption and adversely affect our business, financial condition, and results of operations.

The G4 utilizes novel and complex technologies and may develop or contain undetected defects or errors. We cannot assure you that material performance problems, defects, or errors will not arise, and as we commercialize our products, these risks may increase. We provide and expect to continue to provide warranties that our products will meet performance expectations and will be free from defects. The costs incurred in correcting any defects or errors may be substantial and could adversely affect our operating margins.

In manufacturing the G4, we depend on third parties for the supply of various components, many of which require a significant degree of technical expertise to produce. If our suppliers fail to produce our components to specification or provide defective products to us and our quality control tests and procedures fail to detect such errors or defects, or if we or our suppliers use defective materials or workmanship in the manufacturing process, the reliability and performance of our products will be compromised.

If the G4 contains defects, we may experience:

- a failure to achieve market acceptance for our products or increased sales;
- loss of customer orders or delays in order fulfillment;
- damage to our brand reputation;
- increased warranty and customer service and support costs due to product repair or replacement;
- product recalls or replacements;
- inability to attract new customers or gain market acceptance;
- diversion of resources from our manufacturing and research and development departments into our service department; and
- legal claims against us, including product liability claims, which could be costly and time consuming to defend and result in substantial damages.

In addition, we expect that the G4 will be used with our customers' and potential customers' own lab equipment and third-party products, and the performance of such equipment and products is outside of our control. If our customers' equipment or the third-party products they utilize are not produced to specification, are produced in accordance with modified specifications, or are defective, they may not be compatible with or perform as intended with the G4. In such case, the reliability, results and performance of the G4 may be compromised. The occurrence of any one or more of the foregoing could negatively affect our business, financial condition, and results of operations. Additionally, we expect that we will need to train our customers on properly using the G4. If we are unable to adequately train our customers to use the G4 or they fail to follow our training and protocols we have established, the performance of the G4 may be compromised.

Our ability to achieve profitability will depend, in part, on our ability to reduce the per unit manufacturing costs of the G4.

To achieve our operating and strategic goals, we will need to, among other things, reduce the per unit manufacturing cost of the G4. Manufacturing the G4 involves complex processes, and depends on the skills and experience of our manufacturing personnel. For example, we had previously experienced delays in the scale-up of our manufacturing process when producing our first commercial units of the G4, and we have since improved this process. We may in the future experience delays or low manufacturing yields for the G4. In addition, we will need to continually focus on reducing the per unit manufacturing cost of the G4, which cannot be achieved without increasing the volume of components that we purchase in order to take advantage of volume-based pricing discounts, improving our manufacturing efficiency or increasing our volumes to leverage manufacturing overhead costs. For example, gross margin for the year ended December 31, 2022 is negative as a result of both additional incentives we provided to certain customers for their early adoption of the G4 sequencing platform, as well as higher direct costs for "white-glove" services to our initial customers, and we will need to improve our gross margins in the future, which we may be unable to achieve. If we are unable to improve our manufacturing efficiency and reduce our manufacturing overhead costs per unit, our ability to achieve profitability will be severely constrained. Any increase in manufacturing volumes is dependent upon a corresponding increase in sales. Our costs may also significantly increase as a result of inflation, and we may not be able to offset those higher costs by increasing our prices to our customers. The occurrence of one or more factors that negatively impact the manufacturing or sales of the G4 or reduce our manufacturing efficiency may prevent us from achieving our desired reduction in manufacturing costs, which would negatively affect our operating results and may prevent us from attaining profitability.

If our facilities or our third-party suppliers' facilities become unavailable or inoperable, our research and development program and commercialization launch plan could be adversely impacted and manufacturing of the G4 could be interrupted.

Our existing facilities in San Diego, California house our corporate, research and development, manufacturing, sales and marketing, customer support and quality assurance teams. Our facilities and those of our third-party suppliers are vulnerable to natural disasters, public health crises, including the impact of the COVID-19 pandemic, civil unrest, wars and other catastrophic events. For example, our San Diego facilities are located near earthquake fault zones and are vulnerable to damage from earthquakes as well as other types of disasters, including fires, floods, power loss, communications failures and similar events. If any disaster, any new or continuing public health crisis or catastrophic event were to occur, our ability to operate our business would be seriously, or potentially completely, impaired. If our facilities or our third-party suppliers' facilities become unavailable for any reason, we cannot provide assurances that we will be able to secure alternative facilities with the necessary capabilities and equipment or alternative suppliers on acceptable terms, if at all. We may encounter particular difficulties in replacing our San Diego facilities given the specialized equipment housed within it. The inability to manufacture the G4, combined with our limited inventory of such manufactured products, may result in the loss of future customers or harm our reputation, and we may be unable to re-establish relationships with those customers in the future. Because our consumables are perishable and must be kept in temperature controlled storage, the loss of power to our facilities, mechanical or other issues with our storage facilities or other events that impact our temperature controlled storage could result in the loss of some or all of such products, and we may not be able to replace them without disruption to our customers or at all.

If our business operations are disrupted by a disaster, war or other catastrophe, the launch of the G4 and our planned PX, and the timing of improvements to such products could be significantly delayed and could adversely impact our ability to compete with other available products and solutions. If our or our third-party suppliers' capabilities are impaired, we may not be able to manufacture and ship our products in a timely manner, which would adversely impact our business. Although we possess insurance for damage to our property and the disruption of our business, this insurance may not be sufficient to cover all of our potential losses and may not continue to be available to us on acceptable terms, or at all.

The costs to maintain and provide customer support for the G4, and any future products or product enhancements that we commercialize, may exceed our expectations.

As we continue to commercialize the G4, we are building a commercial organization and infrastructure to support the following activities:

- installing the G4 in customer locations;
- training customers on the use of the G4;
- providing customer support services; and
- providing maintenance, repair and warranty services.

We may not be successful in developing the organization or commercial infrastructure necessary to provide these customer support activities in a timely manner to meet commercial demand, and on a cost effective basis. Any failure to provide our customers with a superior customer experience, to timely respond to their requests and questions and to provide maintenance and warranty services, may adversely affect our brand and our results of operations.

Risks Related to Our Planned Growth

If we do not successfully manage our current and anticipated growth, our business and prospects will be harmed.

From December 31, 2021 to December 31, 2022, the number of our full-time employees increased from 221to 275. Since that time, we have continued to increase our employee headcount and expand our operations and expect to continue to do so as we commercialize the G4 and develop the PX. Our recent growth has placed significant strains on our management, financial systems and internal controls. We expect that the growth associated with the commercial launch of the G4 and the development and commercial launch of our planned PX will also strain our operational and manufacturing systems and processes, sales and marketing team, financial systems and internal controls and other aspects of our business. Commercializing the G4, and continuing to develop our planned PX and then commercializing our planned PX, will require us to hire and retain scientific, sales and marketing, software, manufacturing, customer service and quality assurance personnel. In addition, we expect that we will need to hire additional accounting, finance and other personnel in connection with our becoming, and our efforts to comply with the requirements of being, a public company. As a public company, our management and other personnel devote a substantial amount of time toward maintaining compliance with these requirements and effectively manage these growth activities. We have faced challenges integrating, developing and motivating our rapidly growing employee base, especially during the COVID-19 pandemic, and may continue to face related challenges as we continue to grow. To effectively manage our growth, we must continue to improve our operational and manufacturing systems and processes, our financial systems and internal controls and other aspects of our business and continue to effectively expand, train and manage our personnel in a virtual environment during the COVID-19 pandemic and related governmental work from home mandates. Our ability to successfully manage our expected growth is uncertain given the fact that we have been in operation only since 2016. As our organization continues to grow, we will be required to implement more complex organizational management structures, and may find it increasingly difficult to maintain the benefits of our corporate culture, including our ability to quickly develop and launch new and innovative products and technologies. If we do not successfully manage our anticipated growth, our business, results of operations, financial condition and prospects will be harmed.

We depend on our senior management team, and the loss of one or more of our key employees or an inability to attract and retain highly skilled employees, particularly in this highly competitive labor market, will negatively affect our business, financial condition and results of operations.

Our future success depends upon our ability to recruit, train, retain and motivate our senior management team and our other highly qualified personnel. Our senior management team, including Andrew Spaventa, our founder, Chief Executive Officer and Chairperson of the Board, and Eli Glezer, our founder and Chief Scientific Officer, is critical to our vision, strategic direction, product development and commercialization efforts. The departure of one or more of these individuals or any of our other executive officers, senior management team members, or other key employees could be disruptive to our business until we are able to hire qualified successors. We do not have long-term employment contracts or maintain "key man" life insurance on our senior management team.

Our continued growth and ability to successfully transition from a company primarily focused on research and development to commercialization depends, in part, on attracting, retaining and motivating qualified personnel, including highly-trained sales and marketing personnel with the necessary scientific background and ability to understand our products at a technical level to effectively identify, market and sell to potential new customers. New hires will require significant training and, in most cases, take significant time before they achieve full productivity. Our failure to successfully integrate these key personnel into our business could adversely affect our business. In addition, competition for qualified personnel in the life sciences space is intense and has recently become even more intense, particularly in the San Diego metropolitan area. Recently, the labor market to retain and replace highly skilled personnel has become even more competitive. We compete for qualified scientific and information technology personnel with other life science and information technology companies as well as academic institutions and research institutions. Some of our scientific personnel are qualified foreign nationals whose ability to live and work in the United States is contingent upon the continued availability of appropriate visas. Due to the competition for qualified personnel, particularly in the current labor market and in the San Diego metropolitan area, we expect to continue to utilize foreign nationals to fill part of our recruiting needs. As a result, changes to United States immigration policies could restrain the flow of technical and professional talent into the United States and may inhibit our ability to hire qualified personnel.

We do not maintain fixed term employment contracts with any of our employees, including the members of our senior management team. As a result, our executives and other key employees could leave our company with little or no prior notice and would be free to work for a competitor. The failure to properly manage succession plans, develop leadership talent or replace the loss of services of senior management or other key employees and qualified personnel, could significantly delay or prevent the achievement of our objectives.

We may acquire or invest in other companies or technologies, which could divert our management's attention, result in additional dilution to our stockholders and otherwise disrupt our operations and harm our operating results.

We may in the future seek to acquire or invest in businesses, applications or technologies that we believe could complement or expand the G4, our planned PX or any other future products and product enhancements we elect to pursue. We may also pursue acquisitions or investments to expand our technical capabilities or otherwise offer growth opportunities. The pursuit of potential acquisitions or investments may divert the attention of management and cause us to incur various costs and expenses in identifying, investigating and pursuing suitable acquisitions or investments, whether or not they are consummated. We may not be able to identify desirable acquisition targets or be successful in entering into an agreement with any particular target or obtain the expected benefits of any acquisition or investment.

To date, the growth of our operations has been organic, and we have limited experience in acquiring or investing in other businesses or technologies. We may not be able to successfully integrate acquired personnel, operations and technologies, or effectively manage the combined business following an acquisition. Acquisitions could also result in dilutive issuances of equity securities, the use of our available cash, or the incurrence of debt, which could harm our operating results. In addition, if an acquired business fails to meet our expectations, our operating results, business and financial condition may suffer. Also, our SVB Loan may restrict our ability to pursue certain mergers, acquisitions, amalgamations or consolidations without obtaining the prior consent of Silicon Valley Bank or repaying our outstanding loan amounts. Additionally, future acquisitions or investments could result in potentially dilutive issuances of our equity securities, the incurrence of debt, contingent liabilities or amortization expenses or write-offs of goodwill, any of which could harm our financial condition.

If we experience a disruption in our information technology systems or breaches of data security, our business could be adversely affected.

We rely on information technology systems to keep financial records, facilitate our research and development initiatives, manage our manufacturing operations, maintain quality control, fulfill customer orders, maintain corporate records, communicate with staff and external parties and operate other critical functions. Our information technology systems and those of our vendors and partners are potentially vulnerable to disruption due to breakdown, malicious intrusion and computer viruses or other disruptive events, including, but not limited to, natural disasters and catastrophes. Cyberattacks and other malicious internet-based activity continue to increase and cloud-based platform providers of services have been and are expected to continue to be targeted. Methods of attacks on information technology systems and data security breaches change frequently, are increasingly complex and sophisticated, including social engineering and phishing scams, and can originate from a wide variety of sources. In addition to traditional computer "hackers," malicious code, such as viruses and worms, stolen or fraudulently obtained log-in credentials, employee errors, actions, inaction, theft, or misuse, and denial-of-service attacks, there are sophisticated nation-state and nation-state supported actors that now engage in attacks, including advanced persistent threat intrusions. Our information technology and data security procedures continue to evolve and therefore, our information technology systems may be more susceptible to cybersecurity attacks. Despite any of our current or future efforts to protect against cybersecurity attacks and data security breaches, there is no guarantee that our efforts are adequate to safeguard against all such attacks and breaches. Moreover, it is possible that we may not be able to anticipate, detect, appropriately react and respond to, or implement effective preventative measures against, all cybersecurity incidents.

If our security measures, or those of our vendors and partners, are compromised due to any cybersecurity attacks or data security breaches, our business and reputation may be harmed, we could become subject to litigation and we could incur significant liability. If we were to experience a prolonged system disruption in our information technology systems or those of certain of our vendors and partners, it could negatively impact our ability to serve our customers, which could adversely impact our business, financial condition, results of operations and prospects. If operations at our facilities were disrupted, it may cause a material disruption in our business if we are not capable of restoring functionality in an acceptable timeframe. In addition, our information technology systems, and those of our vendors and partners, are potentially vulnerable to data security breaches and supply chain attacks, whether by internal bad actors, such as employees or other third parties with legitimate access to our or our third-party providers' systems, or external bad actors, which could lead to the exposure of personal data, sensitive data and confidential information to unauthorized persons. Further, due to the political uncertainty involving Russia and Ukraine resulting from Russia's invasion of Ukraine, there is also an increased likelihood that escalation of tensions could result in cyber-attacks or cybersecurity incidents that could either directly or indirectly impact our operations. Any such data security breaches or cyber-attacks could lead to the loss of trade secrets or other intellectual property, or could lead to the exposure of personal information, including sensitive personal information, of our employees, customers and others, any of which could have a material adverse effect on our business, reputation, financial condition and results of operations.

In addition, any such access, disclosure or other loss or unauthorized use of information or data could result in legal claims or proceedings, regulatory investigations or actions, and other types of liability under laws that protect the privacy and security of personal information, including federal, state and foreign data protection and privacy regulations, violations of which could result in significant penalties and fines. Further, defending a suit, regardless of its merit, could be costly, divert management's attention and harm our reputation. In addition, although we seek to detect and investigate all data security incidents, security breaches and other incidents of unauthorized access to our information technology systems and data can be difficult to detect and any delay in identifying such breaches or incidents may lead to increased harm and legal exposure of the type described above. Moreover, there could be public announcements regarding any cybersecurity incidents and any steps we take to respond to or remediate such incidents, and if securities analysts or investors perceive these announcements to be negative, it could, among other things, have a material adverse effect on the price of our common stock.

The cost of protecting against, investigating, mitigating and responding to potential breaches of our information technology systems and data security breaches and complying with applicable breach notification obligations to individuals, regulators, partners and others can be significant. As cybersecurity incidents continue to evolve, we may be required to expend significant additional resources to continue to modify or enhance our protective measures or to investigate and remediate any information security vulnerabilities. The inability to implement, maintain and upgrade adequate safeguards could have a material adverse effect on our business, financial condition, results of operations and prospects. Our insurance policies may not be adequate to compensate us for the potential costs and other losses arising from such disruptions, failures or security breaches. In addition, such insurance may not be available to us in the future on economically reasonable terms, or at all, or that any insurer will not deny coverage as to any future claim. The successful assertion of one or more large claims against us that exceed available insurance coverage, or the occurrence of changes in our insurance policies, including premium increases or the imposition of large deductible or co-insurance requirements, could have a material adverse effect on our business, financial condition, results of operations and prospects.

Risks Related to our Intellectual Property

If we are sued for infringing, misappropriating or otherwise violating intellectual property rights of third parties, such litigation could be costly and time consuming and could prevent or delay us from developing or commercializing our products.

Our commercial success depends on our ability to develop, manufacture, market and sell our products and use our products and technologies without infringing, misappropriating or otherwise violating the intellectual property rights of third parties. We operate in a crowded technology area in which there are numerous issued patents and patent applications and in which there has been substantial litigation regarding patent and other intellectual property rights. There also is a substantial number of administrative proceedings for challenging patents, including interference, derivation, *inter partes* review ("IPR"), post grant review, and reexamination proceedings before the United States Patent and Trademark Office ("USPTO"), or oppositions and other comparable proceedings in foreign jurisdictions. We expect to be exposed to, or threatened with, future litigation by third parties, including our primary competitors, who have patent and other intellectual property rights and may allege that our research and development activities, products, manufacturing methods, software and/or technologies infringe, misappropriate or otherwise violate their intellectual property rights. Our competitors have numerous issued patents and pending patent applications in the fields covered by our products and in which we are developing our products and technologies. It is not always clear to industry participants, including us, the claim scope that may issue from pending patent applications owned by third parties or which patents cover various types of products, technologies or their methods of use or manufacture. In addition, many patent applications are unpublished for up to 18 months from their first filing date and are not accessible to us. We expect that our competitors may, either in connection with our launch of the G4, our planned PX or other product offerings, assert that we are infringing, or have in the past infringed as part of our research and development activities, their patent and other intellectual property rights and that we are employing their proprietary technology without authorization.

If third parties, including our competitors, believe that our products or technologies infringe, misappropriate or otherwise violate their intellectual property, such third parties may seek to enforce their intellectual property, including patents, against us by filing an intellectual property-related lawsuit, including a patent infringement lawsuit, against us. There is no assurance that a court would find in our favor on questions of infringement, validity, enforceability, or priority. If any of our competitors, or any other third parties, were to assert their patents against us and we are unable to successfully defend against any such assertion, we may be required, including by court order, to cease the development and commercialization of the infringing products or technology and we may be required to redesign such products and technologies so they do not infringe such patents, which may not be possible or may require substantial monetary expenditures and time. We could also be required to pay damages, which could be significant, including treble damages and attorneys' fees if we are found to have willfully infringed such patents. We could also be required to obtain a license to such patents in order to continue the development and commercialization of the infringing product or technology, which may not be on commercially reasonable terms or may not be obtainable at all. Even if such license were available, it may require substantial payments or cross-licenses under our intellectual property rights, and it may only be available on a nonexclusive basis, in which case third parties, including our competitors, could use the same licensed intellectual property to compete with us. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operation or prospects.

We may choose to challenge the patentability, validity or enforceability of any third-party patent that we believe may have applicability in our field, and any other third-party patent that may be asserted against us. Such challenges may be brought either in court or by requesting that the USPTO, or other foreign patent offices review the patent claims. However, there can be no assurance that any such challenge will be successful and if not successful, we may be estopped from asserting in a district court any grounds already raised or that could have been raised in certain proceedings, such as IPR at the USPTO. Even if such proceedings are successful, these proceedings are expensive and may consume our time or other resources, distract our management and technical personnel.

Third parties, including our existing and future competitors, may be infringing, misappropriating or otherwise violating our owned and in-licensed intellectual property rights. Monitoring unauthorized use of our intellectual property will be difficult and costly. We may not be able to detect unauthorized use of, or take appropriate steps to enforce, our intellectual property rights. From time to time, we seek to analyze our competitors' products and services, and may in the future seek to enforce our rights against potential infringement, misappropriation or violation of our intellectual property. However, the steps we have taken to protect our intellectual property rights may not be adequate to enforce our rights. Any inability to meaningfully enforce our intellectual property rights could harm our ability to compete and reduce demand for our products and technologies.

Litigation proceedings may be necessary for us to enforce our patent and other intellectual property rights. We may not be successful in such proceedings. Further, in such proceedings, the defendant could counterclaim that our intellectual property is invalid or unenforceable and the court may agree, in which case we could lose valuable intellectual property rights. The outcome in any such proceedings are unpredictable. Third parties may also bring challenges to our patents in the USPTO or foreign patent offices seeking to invalidate them.

Regardless of whether we are defending against or asserting any intellectual property-related proceeding, any such intellectual property-related proceeding that may be necessary in the future, regardless of outcome, could result in substantial costs and diversion of resources and could have a material adverse effect on our business, financial condition, results of operations and prospects. Further, 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. In addition, there could be public announcements of the results of such ongoing litigation, and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock. Some of our competitors and other third parties may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources and more mature and developed intellectual property portfolios. We may not have sufficient financial or other resources to adequately conduct these types of litigation or proceedings. Any of the foregoing, or any uncertainties resulting from the initiation, continuation and results of any litigation, could have a material adverse effect on our ability to raise the funds necessary to continue our operations or could otherwise have a material adverse effect on our business, financial condition, results of operations and prospects. Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar adverse effect on our business, financial condition, results of operations and prospects.

If we are unable to obtain and maintain sufficient intellectual property protection for our products and technology, or if the scope of the intellectual property protection obtained is not sufficiently broad, our competitors could develop and commercialize products similar or identical to ours, and our ability to successfully commercialize our products may be impaired.

We rely on patent, trademark, copyright, trade secret and other intellectual property rights and contractual restrictions to protect our proprietary products and 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 currently have three issued patents covering our proprietary next-generation sequencing technology. If we fail to obtain additional patent protection for our products and technology and maintain and protect our intellectual property rights, third parties may be able to compete more effectively against us. In addition, we may incur substantial litigation costs in our attempts to recover or restrict use of our intellectual property. Further, if we are unable to obtain and maintain sufficient intellectual property protection for our products and technology, or if the scope of the intellectual property protection obtained is not sufficiently broad, our ability to successfully commercialize our products may be impaired.

We have and intend to continue to apply for patents covering our products and technologies and uses thereof, as we deem appropriate. However, obtaining and enforcing patents is costly, time-consuming and complex, and we may fail to apply for patents on important products and technologies in a timely fashion or at all, or we may fail to apply for patents in potentially relevant jurisdictions. We may not be able to file and prosecute all necessary or desirable patent applications, or maintain, enforce and license any patents that may issue from such patent applications, at a reasonable cost or in a timely manner or in all jurisdictions. It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. Moreover, we may not develop additional proprietary products, methods and technologies that are patentable. We may not have the right to control the preparation, filing and prosecution of patent applications, or to maintain the rights to patents licensed from or to third parties. Therefore, these patents and applications may not be prosecuted and enforced by such third parties in a manner consistent with the best interests of our business.

In addition, the patent position of life sciences technology companies such as ours is generally highly uncertain, involves complex legal and factual questions, and our industry has been to widespread and intense litigation in recent years. Changes in either the patent laws or in interpretations of patent laws in the United States or other countries or regions may diminish the value of our intellectual property. As a result, the issuance, scope, validity, enforceability, and commercial value of our patent rights are highly uncertain. It is possible that none of our pending patent applications will result in issued patents in a timely fashion or at all, and even if patents are granted, they may not provide a basis for intellectual property protection of commercially viable products or technologies, may not provide us with any competitive advantages, or may be challenged, narrowed and invalidated by third parties. We cannot predict the breadth of claims that may be allowed or enforced in our patents or in third-party patents. It is possible that third parties will design around our current or future patents such that we cannot prevent such third parties from using similar technologies and commercializing similar products to compete with us. Some of our owned or licensed patents or patent applications may be challenged at a future point in time and we may not be successful in defending any such challenges made against our patents or patent applications. Any successful third-party challenge to our patents could result in the narrowing, unenforceability or invalidity of such patents and increased competition to our business. The outcome of patent litigation or other proceeding can be uncertain, and any attempt by us to enforce our patent rights against others or to challenge the patent rights of others may not be successful, or, regardless of success, may take substantial time and result in substantial cost, and may divert our efforts and attention from other aspects of our business. Any of the foregoing events could have a material adverse effect on our business, financial condition and results of operations.

We cannot ensure that patent rights relating to inventions described and claimed in our pending patent applications will issue and will provide sufficient protection for our products and technologies. We also cannot ensure that our patents or patents based on our patent applications will not be challenged and rendered invalid and/or unenforceable.

Our success depends in large part on our ability to obtain and maintain intellectual property protection, particularly patents, for our products and technologies in the both the United States and other foreign countries. Patents are of national or regional effect, and filing, prosecuting and defending patents on all of our products and technologies throughout the world would be prohibitively expensive, and the laws of foreign countries may not protect our rights to the same extent as the laws of the United States. As such, 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. Further, the legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets and other intellectual property protection, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally. As such, 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. Further, certain foreign and developing countries, including China and India, have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In those countries, we and our licensors may have limited remedies if patents are infringed or if we or our licensors are compelled to grant a license to a third-party, which could materially diminish the value of those patents. This could limit our potential revenue opportunities. 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. We have pending U.S. and foreign patent applications in our portfolio, however, we cannot predict:

- if and when patents may issue based on our patent applications;
- the scope of protection of any patent issuing based on our patent applications;
- whether the claims of any patent issuing based on our patent applications will provide protection against competitors;
- whether or not third parties will find ways to invalidate or circumvent our patent rights;
- whether or not others will obtain patents claiming aspects similar to those covered by our patents and patent applications;
- whether we will need to initiate litigation or administrative proceedings to enforce and/or defend our patent rights which will be costly whether we win or lose; and/or
- whether the patent applications that we own or in-license will result in issued patents with claims that cover our product candidates or uses thereof in the United States or in other foreign countries.

We cannot be certain that the claims in our pending patent applications directed to our product candidates and/or technologies will be considered patentable by the USPTO or by patent offices in foreign countries. One aspect of the determination of patentability of our inventions depends on the scope and content of the "prior art," information that was or is deemed available to a person of skill in the relevant art prior to the priority date of the claimed invention. There may be prior art of which we are not aware that may affect the patentability of our patent claims or, if issued, affect the validity or enforceability of a patent claim. Even if the patents do issue based on our patent applications, third parties may challenge the validity, enforceability or scope thereof, which may result in such patents being narrowed, invalidated or held unenforceable. Further, even if they are unchallenged, patents in our portfolio may not adequately exclude third parties from practicing relevant technology or prevent others from designing around our claims. If the breadth or strength of our intellectual property position with respect to our product candidates is threatened, it could dissuade companies from collaborating with us to develop and threaten our ability to commercialize our product candidates. In the event of litigation or administrative proceedings, we cannot be certain that the claims in any of our issued patents will be considered valid by courts in the United States or foreign countries.

We may be subject to claims that our employees, consultants or independent contractors have wrongfully used or disclosed confidential information of third parties.

We have employed and expect to employ individuals who were previously employed at universities, research institutions or other companies, including our competitors or potential competitors. Although we seek to protect our ownership of intellectual property rights by ensuring that our agreements with our employees, collaborators, and other third parties with whom we do business include provisions requiring such parties to not disclose the confidential information of their previous employers or other third parties, we may be subject to claims that we or our employees, consultants or independent contractors have inadvertently or otherwise used or disclosed confidential information of our employees' former employers or other third parties. We or our licensors may also be subject to claims that former employers or other third parties have an ownership interest in our patents. Litigation may be necessary to defend against these claims. There is no guarantee of success in defending these claims, and if we or our licensors fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, valuable intellectual property. Even if we are successful, litigation could result in substantial cost and be a distraction to our management and other employees.

If we are unable to protect the confidentiality of our trade secrets, the value of our technology could be materially adversely affected and our business could be harmed.

We rely heavily on trade secrets and confidentiality agreements to protect our unpatented know-how, technology and other proprietary information, including the design and features of the G4 and our planned PX, and to maintain our competitive position. However, trade secrets and know-how can be difficult to protect. In particular, we anticipate that with respect to our technologies, these trade secrets and know how will over time be disseminated within the industry through independent development, the publication of journal articles describing the methodology, and the movement of personnel from academic to industry scientific positions.

In addition to pursuing patents on our technology, we take steps to protect our intellectual property and proprietary technology by entering into agreements, including confidentiality agreements, non-disclosure agreements and intellectual property assignment agreements, with our employees, consultants, academic institutions, corporate partners and, when needed, our advisers. However, we cannot be certain that such agreements have been entered into with all relevant parties, and we cannot be certain that our trade secrets and other confidential proprietary information will not be disclosed or that competitors or other third parties will not otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. For example, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Such agreements may not be enforceable or may not provide meaningful protection for our trade secrets 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, which could adversely impact our ability to establish or maintain a competitive advantage in the market, business, financial condition, results of operations and prospects.

Monitoring unauthorized 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 wrongfully obtained and was using our trade secrets, it would be expensive and time-consuming, it could distract our personnel, and the outcome would be unpredictable. In addition, courts outside the United States may be less willing to protect trade secrets.

We also seek to preserve the integrity and confidentiality of our confidential proprietary information by maintaining physical security of our premises and physical and electronic security of our information technology systems, but it is possible that these security measures could be breached. If any of our confidential proprietary information were to be lawfully obtained or independently developed by a competitor or other third-party, absent patent protection, we would have no right to prevent such competitor from using that technology or information to compete with us, which could harm our competitive position. Competitors or third parties could purchase our products and attempt to replicate some or all of the competitive advantages we derive from our development efforts, design around our protected technology, develop their own competitive technologies that fall outside the scope of our intellectual property rights or independently develop our technologies without reference to our trade secrets. If any of our trade secrets were to be disclosed to or independently discovered by a competitor or other third-party, it could materially and adversely affect our business, financial condition, results of operations and prospects.

We could have disputes with contractual counterparties regarding our or their performance under those contracts or we could be unable to fulfill such contractual commitments. For example, we in-licensed certain patents and other intellectual property rights from The Trustees of Columbia University in the City of New York ("Columbia"). If we fail to comply with the terms of our agreement with Columbia or have a disagreement with Columbia regarding our obligations thereunder, we may be subject to breach of contract claims or other actions by Columbia, which could harm our business, results of operations and financial condition.

We could have disputes with contractual counterparties regarding our or their performance under those contracts or could be unable to fulfill such contractual commitments. For example, in August 2016, we entered into an Exclusive License Agreement with Columbia, which was subsequently amended in September 2016, November 2016 and June 2017 (the "License Agreement"). Under the License Agreement, we received (i) an exclusive, sublicensable, worldwide license under certain patents owned by Columbia to discover, develop, make and sell products or services covered by the claims of such licensed patents (the "Patent Products"), and (ii) an exclusive, sublicensable, worldwide license under certain materials and technical information provided by Columbia to discover, develop, make and sell products or services that directly use or incorporate such materials or information (the "Other Products"). Under the License Agreement, we are required to use commercially reasonable efforts to research, discover, develop and market Patent Products and/or Other Products and to achieve certain fundraising and development milestone events. For any products within the scope of the License Agreement that we commercialize, we are required to pay royalties ranging from low to mid-single digits on net sales of Patent Products and low single-digit royalty rates on net sales of Other Products. We are also required to make milestone payments to Columbia upon our achievement of certain development and commercialization milestones, which could total up to $3.9 million over the life of the License Agreement.

The License Agreement includes a number of diligence obligations that require us to use commercially reasonable efforts to research, discover, develop and market Patent Products and/or Other Products by certain dates. Columbia could take the position that the License Agreement should convert to a non-exclusive license or pursue actions to terminate the License Agreement alleging that we have not satisfied our diligence obligations. Columbia could also disagree with our interpretation of our milestone and royalty obligations under the License Agreement and contend that we are in breach of the License Agreement.

Columbia has a right to pursue a termination of the License Agreement in the event we become insolvent or otherwise cease operations, in the event we materially breach our obligations under the License Agreement, or in the event we assert any claim challenging the validity or enforceability of any patent licensed to us by Columbia under the License Agreement. For example, Columbia may assert that we have breached the License Agreement if it disagrees with our interpretation regarding the application of the License Agreement to the G4 and PX instruments and the associated consumables. Columbia may take the position that we have not complied with our diligence obligations under the License Agreement. There is no assurance that we can satisfy our obligations under the License Agreement, or that we and Columbia will agree on whether or not we have satisfied our obligations under the License Agreement, including whether any royalty or milestones, or the amount thereof, are payable under the terms of the License Agreement or whether we have satisfied our diligence obligations. If we fail to comply with our obligations, or if we and Columbia do not agree on whether we have satisfied our obligations under the License Agreement, Columbia could exercise its right to assert a breach of contract, convert the License Agreement to a non-exclusive license and/or pursue actions to terminate the License Agreement. If we are required to defend against breach of contract or other claims and actions asserted by Columbia or if Columbia is successful in terminating the License Agreement or converting the License Agreement to a non-exclusive license, our business may be adversely affected. Further, if we are required to make additional milestone payments or pay Columbia royalties on the G4 and PX Instruments, and the consumables we have developed to date, beyond what we believe would be due under the License Agreement, our resulting operations and financial condition may be adversely affected. If we are unable to fulfill our contractual commitments with Columbia or other parties, or if we have disputes with Columbia or other contractual counterparties regarding our or their performance under those contracts, our results of operations and financial condition may be adversely affected.

Patent terms may be inadequate to protect our competitive position on our products for an adequate amount of time.

Patents have a limited lifespan. In the United States, if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest U.S. non-provisional filing date. While extensions may be available, the life of a patent, and the protection it affords, is limited. In the United States, a patent's term may, in certain cases, be lengthened by patent term adjustment, which compensates a patentee for administrative delays by the USPTO in examining and granting a patent, or may be shortened if a patent is terminally disclaimed over a commonly owned patent or a patent naming a common inventor and having an earlier expiration date. Even if patents covering our products are obtained, once the patent life has expired, we may be open to competition from competitive products. If one of our products requires extended development, testing and/or regulatory review, patents protecting such products might expire before or shortly after such products are commercialized. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours, which could have a material adverse effect on our business, financial condition and results of operations.

We may not be able to protect and enforce our trademarks and trade names, or build name recognition in our markets of interest thereby harming our competitive position.

The registered or unregistered trademarks or trade names that we own may be challenged, infringed, circumvented, declared generic, lapsed or determined to be infringing on or dilutive of other marks. We may not be able to protect our rights in these trademarks and trade names, which we need in order to build name recognition. In addition, third parties have filed, and may in the future file, for registration of trademarks similar or identical to our trademarks, 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 or trademarks that incorporate variations of our registered or unregistered trademarks or trade names. Further, we may in the future enter into agreements with owners of such third-party trade names or trademarks to avoid potential trademark litigation which may limit our ability to use our trade names or trademarks in certain fields of business. 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, financial condition, results of operations and prospects may be adversely affected. Our efforts to enforce or protect our proprietary rights related to trademarks, trade secrets, domain names, copyrights or other intellectual property may be ineffective and could result in substantial costs and diversion of resources. Any of the foregoing events could have a material adverse effect on our business, financial condition and results of operations.

The U.S. law relating to the patentability of certain inventions in the life sciences technology industry is uncertain and rapidly changing, which may adversely impact our existing patents or our ability to obtain patents in the future.

Changes in either the patent laws or interpretation of the patent laws in the United States or in other jurisdictions could increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents. For instance, under the Leahy-Smith America Invents Act, or the America Invents Act, enacted in September 2011, the United States transitioned to a first inventor to file system in which, assuming that other requirements for patentability are met, the first inventor to file a patent application is entitled to the patent on an invention regardless of whether a third-party was the first to invent the claimed invention. These changes include allowing third-party submission of prior art to the USPTO during patent prosecution and additional procedures to challenge the validity of a patent by USPTO administered post-grant proceedings, including post-grant review, *inter partes* review and derivation proceedings. The America Invents Act 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, all of which could have a material adverse effect on our business, financial condition, results of operations and prospects.

Various courts, including the U.S. Supreme Court, have rendered decisions that impact the scope of patentability of certain inventions or discoveries relating to the life sciences technology. Specifically, these decisions stand for the proposition that patent claims that recite laws of nature are not themselves patentable unless those patent claims have sufficient additional features that provide practical assurance that the processes are genuine inventive applications of those laws rather than patent drafting efforts designed to monopolize the law of nature itself. What constitutes a "sufficient" additional feature is uncertain. Further, in view of these decisions, since December 2014, the USPTO has published and continues to publish revised guidelines for patent examiners to apply when examining process claims for patent eligibility.

In addition, U.S. Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events may create uncertainty with respect to the value of patents, once obtained. 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 may have a material adverse effect on our ability to obtain new patents and to defend and enforce our existing patents and patents that we might obtain in the future.

We cannot be certain that our patent portfolio will not be negatively impacted by the current uncertain state of the law, new court rulings or changes in guidance or procedures issued by the USPTO or other similar patent offices around the world. From time to time, the U.S. Supreme Court, other federal courts, the U.S. Congress or the USPTO may change the standards of patentability, scope and validity of patents within the life sciences technology and any such changes, or any similar adverse changes in the patent laws of other jurisdictions, could have a negative impact on our business, financial condition, prospects and results of operations.

If we cannot license rights to use technologies on reasonable terms, we may not be able to commercialize new products in the future.

We may identify third-party technology that we may need to license or acquire in order to develop or commercialize our products or technologies. However, we may be unable to secure such licenses or acquisitions. The licensing or acquisition of third-party intellectual property rights is a competitive area, and several more established companies may pursue strategies to license or acquire third-party intellectual property rights that we may consider attractive or necessary. These established companies may have a competitive advantage over us due to their size, capital resources and greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us.

We also may be unable to license or acquire third-party intellectual property rights on terms that would allow us to make an appropriate return on our investment or at all. In return for the use of a third-party's technology, we may agree to pay the licensor royalties based on sales of our products or services. Royalties are a component of cost of products or technologies and affect the margins on our products. We may also need to negotiate licenses to patents or patent applications before or after introducing a commercial product. We may not be able to obtain necessary licenses to patents or patent applications, the commercial release of our products could be delayed and our business may suffer if we are unable to enter into the necessary licenses on acceptable terms or at all, if any necessary licenses are subsequently terminated, if the licensor fails to abide by the terms of the license or fails to prevent infringement by third parties, or if the licensed intellectual property rights are found to be invalid or unenforceable.

Certain of our future owned and in-licensed patents may be subject to a reservation of rights by one or more third parties, including government march-in rights, which may limit our ability to exclude third parties from commercializing products similar or identical to ours.

Our future in-licensed patents may be subject to a reservation of rights by one or more third parties. For example, when new technologies are developed with government funding, in order to secure ownership of such patent rights, the recipient of such funding is required to comply with certain government regulations, including timely disclosing the inventions claimed in such patent rights to the U.S. government and timely electing title to such inventions. Any failure to timely elect title to such inventions may provide the U.S. government to, at any time, take title such inventions. Additionally, the U.S. government generally obtains certain rights in any resulting patents, including a non-exclusive license authorizing the government to use the invention or to have others use the invention on its behalf. If the government decides to exercise these rights, it is not required to engage us as its contractor in connection with doing so. These rights may permit the U.S. government to disclose our confidential information to third parties and to exercise march-in rights to use or allow third parties to use our licensed technology. The U.S. government can exercise its march-in rights if it determines that action is necessary because we fail to achieve practical application of the government-funded technology, because action is necessary to alleviate health or safety needs, to meet requirements of federal regulations, or to give preference to U.S. industry. In addition, our rights in such inventions may be subject to certain requirements to manufacture products embodying such inventions in the United States. Any exercise by the government of any of the foregoing rights could have a material adverse effect on our business, financial condition, results of operations and prospects.

Our use of open source software may pose particular risks to our proprietary software and systems.

We use open source software in our products and anticipate that we will continue to use open source software in the future. The licenses applicable to our use of open source software may require that source code that is developed using open source software be made available to the public and that any modifications or derivative works to certain open source software continue to be licensed under open source licenses. From time to time, we may face claims from third parties claiming infringement of their intellectual property rights, or demanding the release or license of the open source software or derivative works that we developed using such software (which could include our proprietary source code) or otherwise seeking to enforce the terms of the applicable open source license. These claims could result in litigation and could require us to purchase a costly license, publicly release the affected portions of our source code, be limited in or cease using the implicated software unless and until we can re-engineer such software to avoid infringement or change the use of, or remove, the implicated open source software. Our use of open source software may also present additional security risks because the source code for open source software is publicly available. Any of these risks could be difficult to eliminate or manage, and, if not addressed, could have a material adverse effect on our business, results of operations, financial condition, and prospects.

Risks Related to Regulatory and Legal Compliance Matters

If we elect to label and promote any of our products as clinical diagnostics tests or medical devices, we would be required to obtain prior approval or clearance by the FDA, which would take significant time and expense and could fail to result in FDA clearance or approval for the intended uses we believe are commercially attractive.

We intend to market and sell the G4 and our planned PX primarily to academic and research institutions and research companies, government laboratories, hospitals, and biotechnology, consumer genomics and proteomics, commercial molecular diagnostic laboratories, and agrigenomics companies as research use only ("RUO") products. Our products are not currently designed, or intended to be used, for clinical diagnostic tests or as medical devices. If we elect to label and market our products for use as, or in the performance of, clinical diagnostics in the United States, thereby subjecting them to U.S. Food and Drug Administration ("FDA") regulation as medical devices, we would be required to obtain premarket 510(k) clearance or premarket approval from the FDA, unless an exception applies.

We may in the future register with the FDA as a medical device manufacturer and list some of our products with the FDA pursuant to an FDA Class I listing for general purpose laboratory equipment. While this regulatory classification is exempt from certain FDA requirements, such as the need to submit a premarket notification commonly known as a 510(k), and some of the requirements of the FDA's Quality System Regulations ("QSRs"), we would be subject to ongoing FDA "general controls," which include compliance with FDA regulations for labeling, inspections by the FDA, complaint evaluation, corrections and removals reporting, promotional restrictions, reporting adverse events or malfunctions for our products, and general prohibitions against misbranding and adulteration.

In addition, we may in the future submit 510(k) premarket notifications to the FDA to obtain FDA clearance of certain of our products on a selective basis. It is possible, in the event we elect to submit 510(k) applications for certain of our products, that the FDA would take the position that a more burdensome premarket application, such as a premarket approval application (PMA) or a de novo application is required for some of our products. If such applications were required, greater time and investment would be required to obtain FDA approval. Even if the FDA agreed that a 510(k) was appropriate, FDA clearance can be expensive and time consuming. It generally takes a significant amount of time to prepare a 510(k), including conducting appropriate testing on our products, and several months to years for the FDA to review a submission. Notwithstanding the effort and expense, FDA clearance or approval could be denied for some or all of our products for which we choose to market as a medical device or a clinical diagnostic device. Even if we were to seek and obtain regulatory approval or clearance, it may not be for the intended uses we request or that we believe are important or commercially attractive. There can be no assurance that future products for which we may seek premarket clearance or approval will be approved or cleared by FDA or a comparable foreign regulatory authority on a timely basis, if at all, nor can there be assurance that labeling claims will be consistent with our anticipated claims or adequate to support continued adoption of such products. Compliance with FDA or comparable foreign regulatory authority regulations will require substantial costs, and subject us to heightened scrutiny by regulators and substantial penalties for failure to comply with such requirements or the inability to market our products. The lengthy and unpredictable premarket clearance or approval process, as well as the unpredictability of the results of any required clinical studies, may result in our failing to obtain regulatory clearance or approval to market such products, which would significantly harm our business, results of operations, reputation, and prospects.

If we sought and received regulatory clearance or approval for certain of our products, we would be subject to ongoing FDA obligations and continued regulatory oversight and review, including the general controls listed above and the FDA's QSRs for our development and manufacturing operations. In addition, we would be required to obtain a new 510(k) clearance before we could introduce subsequent modifications or improvements to such products. We could also be subject to additional FDA post-marketing obligations for such products, any or all of which would increase our costs and divert resources away from other projects. If we sought and received regulatory clearance or approval and are not able to maintain regulatory compliance with applicable laws, we could be prohibited from marketing our products for use as, or in the performance of, clinical diagnostics and/or could be subject to enforcement actions, including warning letters and adverse publicity, fines, injunctions and civil penalties, recall or seizure of products, operating restrictions and criminal prosecution.

In addition, we could decide to seek regulatory clearance or approval for certain of our products in countries outside of the United States. Sales of such products outside the United States will likely be subject to foreign regulatory requirements, which can vary greatly from country to country. As a result, the time required to obtain clearances or approvals outside the United States may differ from that required to obtain FDA clearance or approval and we may not be able to obtain foreign regulatory approvals on a timely basis or at all. For example, in Europe we would need to comply with the new Medical Device Regulation 2017/745 and In Vitro Diagnostic Regulation 2017/746, which became effective May 26, 2017, with application dates of May 26, 2021 (postponed from 2020) and May 26, 2022 respectively. This will increase the difficulty of regulatory approvals in Europe in the future. In addition, the FDA regulates exports of medical devices. Failure to comply with these regulatory requirements or obtain and maintain required approvals, clearances and certifications could impair our ability to commercialize our products for diagnostic use outside of the United States.

The G4 is sold as an RUO product; changes in the regulatory landscape could affect the market for such a product. Our products could become subject to government regulation as medical devices by the FDA and other regulatory agencies even if we do not elect to seek regulatory clearance or approval to market our products for diagnostic purposes, which would adversely impact our ability to market and sell our products and harm our business. If our products become subject to FDA regulation, the regulatory clearance or approval and the maintenance of continued and post-market regulatory compliance for such products will be expensive, time-consuming, and uncertain both in timing and in outcome.

The G4 is sold as an RUO product, and we do not currently expect either the G4 or our planned PX to be subject to the clearance or approval of the FDA, as they are not intended to be used for the diagnosis, treatment or prevention of disease. However, as we expand our product line and the applications and uses of our products into new fields, certain of our future products could become subject to regulation by the FDA, or comparable international agencies, including requirements for regulatory clearance or approval of such products before they can be marketed. Also, even if our products are labeled, promoted, and intended as RUO, the FDA or comparable agencies of other countries could disagree with our conclusion that our products are intended for RUO or deem our sales, marketing and promotional efforts as being inconsistent with RUO products. For example, our customers may independently elect to use our RUO labeled products in their own laboratory developed tests ("LDTs") for clinical diagnostic use, which could subject our products to government regulation, and the regulatory clearance or approval and maintenance process for such products may be uncertain, expensive and time-consuming. Regulatory requirements related to marketing, selling and distribution of RUO products could change or be uncertain, even if clinical uses of our RUO products by our customers were done without our consent. Further, regulations may change causing RUO products to be subject to regulatory clearance or approval. If the FDA or other regulatory authorities assert that any of our RUO products are subject to regulatory clearance or approval, our business, financial condition, or results of operations could be adversely affected.

The FDA has historically exercised enforcement discretion in not enforcing the medical device regulations against laboratories offering LDTs. However, on October 3, 2014, the FDA issued two draft guidance documents that set forth the FDA's proposed risk-based framework for regulating LDTs, which are designed, manufactured, and used within a single laboratory. The draft guidance documents provide the anticipated details through which the FDA would propose to establish an LDT oversight framework, including premarket review for higher-risk LDTs, such as those that have the same intended use as FDA-approved or cleared companion diagnostic tests currently on the market. In January 2017, the FDA announced that it would not issue final guidance on the oversight of LDTs and manufacturers of products used for LDTs, but would seek further public discussion on an appropriate oversight approach, and give Congress an opportunity to develop a legislative solution. More recently, the FDA has issued warning letters to certain genomics labs for illegally marketing genetic tests that claim to predict patients' responses to specific medications, noting that the FDA has not created a legal "carve-out" for LDTs and retains discretion to take action when appropriate, such as when certain genomic tests raise significant public health concerns.

As manufacturers develop more complex diagnostic tests and diagnostic software, the FDA may increase its regulation of LDTs. Any future legislative or administrative rule making or oversight of LDTs, if and when finalized, may impact the sales of our products and how customers use our products, and may require us to change our business model in order to maintain compliance with these laws. We cannot predict how these various efforts will be resolved, how Congress or the FDA will regulate LDTs in the future, or how that regulatory system will impact our business. Changes to the current regulatory framework, including the imposition of additional or new regulations, including regulation of our products, 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. Further, sales of devices for diagnostic purposes may subject us to additional healthcare regulation and enforcement by the applicable government agencies. Such laws include, without limitation, state and federal anti-kickback or anti-referral laws, healthcare fraud and abuse laws, false claims laws, privacy and security laws, Physician Payments Sunshine Act and related transparency and manufacturer reporting laws, and other laws and regulations applicable to medical device manufacturers. Our operations may subject us to certain of these health care laws through our customers who use our platform for the development or sale of diagnostic tests. Failure to comply with such laws and regulations, as applicable, may result in substantial penalties.

Additionally, on November 25, 2013, the FDA issued Final Guidance "Distribution of In Vitro Diagnostic Products Labeled for Research Use Only." The guidance emphasizes that the FDA will review the totality of the circumstances when it comes to evaluating whether equipment and testing components are properly labeled as RUO. The final guidance states that merely including a labeling statement that the product is for RUO will not necessarily render the device exempt from the FDA's clearance, approval, and other regulatory requirements if the circumstances surrounding the distribution, marketing and promotional practices indicate that the manufacturer knows its products are, or intends for its products to be, used for clinical diagnostic purposes. These circumstances may include written or verbal sales and marketing claims or links to articles regarding a product's performance in clinical applications and a manufacturer's provision of technical support for clinical applications.

As part of the previous Administration's efforts to combat COVID-19 and consistent with former President Trump's direction in Executive Orders 13771 and 13924, the Department of Health and Human Services (HHS) announced rescission of guidance and other informal issuances of the FDA regarding premarket review of LDT absent notice-and-comment rulemaking, stating that, absent notice-and-comment rulemaking, those seeking approval or clearance of, or an emergency use authorization, for an LDT may nonetheless voluntarily submit a premarket approval application, premarket notification or an Emergency Use Authorization request, respectively, but are not required to do so. However, laboratories opting to use LDTs without FDA premarket review or authorization would not be eligible for liability protection under the Public Readiness and Emergency Preparedness Act. While this action by HHS is expected to reduce the regulatory burden on clinical laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 that develop LDTs, it is unclear how this action as well as future legislation by federal and state governments and the FDA will impact the industry, including our business and that of our customers. Such HHS measure may compel the FDA to formalize earlier enforcement discretionary policies and informal guidance through notice-and-comment rulemaking and/or impose further restrictions on LDTs. HHS' rescission policy may change over time and we cannot be certain if the new administration will withdraw Executive Orders 13771 and 13924. Congress could also enact legislation restricting LDTs. Any restrictions on LDTs by the FDA, HHS, Congress, or state regulatory authorities may decrease the demand for our products. The adoption of new restrictions on RUO products, whether by the FDA or Congress, could adversely affect demand for our specialized reagents and instruments. Further, we could be required to obtain premarket clearance or approval before we can sell our products to certain customers.

Additionally, in the United States and some foreign jurisdictions there have been, and continue to be, several legislative and regulatory changes and proposed reforms of the healthcare system in an effort to contain costs, improve quality, and expand access to care. Further, third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for medications and other health care products and services. Our ability to commercialize any of our products successfully, and our customers' ability to commercialize their products successfully, will depend in part on the extent to which coverage and adequate reimbursement for these products and will be available from third-party payors. As such, cost containment reform efforts may result in an adverse effect on our operations.

We are currently subject to, and may in the future become subject to additional, U.S. federal and state laws and regulations imposing obligations on how we collect, store and process personal information. Our actual or perceived failure to comply with such obligations could harm our business. Ensuring compliance with such laws could also impair our efforts to maintain and expand our future customer base, and thereby decrease our revenue.

In the ordinary course of our business, we currently, and in the future will, collect, store, transfer, use or process sensitive data, including personally identifiable information of employees, and intellectual property and proprietary business information owned or controlled by ourselves and other parties. The secure processing, storage, maintenance, and transmission of this critical information is vital to our operations and business strategy. We are, and may increasingly become, subject to various laws and regulations, as well as contractual obligations, relating to data privacy and security in the jurisdictions in which we operate. The regulatory environment related to data privacy and security is increasingly rigorous, with new and constantly changing requirements applicable to our business, and enforcement practices are likely to remain uncertain for the foreseeable future. These laws and regulations may be interpreted and applied differently and inconsistently over time and from jurisdiction to jurisdiction, and it is possible that they will be interpreted and applied in ways that may have a material adverse effect on our business, financial condition, results of operations and prospects.

In the United States, various federal and state regulators, including governmental agencies like the Consumer Financial Protection Bureau and the Federal Trade Commission, have adopted, or are considering adopting, laws and regulations concerning personal information and data security. Certain state laws may be more stringent or broader in scope, or offer greater individual rights, with respect to personal information than federal, international or other state laws, and such laws may differ from each other, all of which may complicate compliance efforts. For example, the California Consumer Privacy Act ("CCPA"), which increases privacy rights for California residents and imposes obligations on companies that process their personal information, came into effect on January 1, 2020. Among other things, the CCPA requires covered companies to provide new disclosures to California consumers and provide such consumers new data protection and privacy rights, including the ability to opt-out of certain sales of personal information. The CCPA provides for civil penalties for violations, as well as a private right of action for certain data breaches that result in the loss of personal information. This private right of action may increase the likelihood of, and risks associated with, data breach litigation. In addition, laws in all 50 U.S. states require businesses to provide notice to consumers whose personal information has been disclosed as a result of a data breach. State laws are changing rapidly and there is discussion in the U.S. Congress of a new comprehensive federal data privacy law to which we would become subject if it is enacted. Additionally, California voters approved a new privacy law, the California Privacy Rights Act ("CPRA"), in the November 3, 2020 election. Effective starting on January 1, 2023, the CPRA will significantly modify the CCPA, including by expanding consumers' rights with respect to certain sensitive personal information. The CPRA also creates a new state agency that will be vested with authority to implement and enforce the CCPA and the CPRA. New legislation proposed or enacted in various other states will continue to shape the data privacy environment nationally. Certain state laws may be more stringent or broader in scope, or offer greater individual rights, with respect to confidential, sensitive and personal information than federal, international or other state laws, and such laws may differ from each other, which may complicate compliance efforts.

Further, regulations promulgated pursuant to the Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), establish privacy and security standards that limit the use and disclosure of individually identifiable health information (known as "protected health information" or "PHI") and require the implementation of administrative, physical and technological safeguards to protect the privacy of PHI and ensure the confidentiality, integrity and availability of electronic PHI. Determining whether protected health information has been handled in compliance with applicable privacy standards and our contractual obligations can require complex factual and statistical analyses and may be subject to changing interpretation. Although we take measures to protect sensitive data from unauthorized access, use or disclosure, our information technology and infrastructure may be vulnerable to attacks by hackers or viruses or breached due to employee error, malfeasance or other malicious or inadvertent disruptions. Any such breach or interruption could compromise our networks and the information stored there could be accessed by unauthorized parties, manipulated, publicly disclosed, lost or stolen. Any such access, breach or other loss of information could result in legal claims or proceedings, liability under federal or state laws that protect the privacy of personal information (such as the HIPAA and the Health Information Technology for Economic and Clinical Health Act ("HITECH"), and regulatory penalties. Notice of breaches must be made to affected individuals, the Secretary of the Department of Health and Human Services, and for extensive breaches, notice may need to be made to the media or State Attorneys General. Such a notice could harm our reputation and our ability to compete.

In Europe, the collection, use, storage, disclosure, transfer, or other processing of personal data regarding individuals in the European Economic Area ("EEA"), including personal health data, is subject to the GDPR, which became effective on May 25, 2018. The GDPR is wide-ranging in scope and imposes numerous requirements on companies that process personal data, including requirements relating to processing health and other sensitive data, obtaining consent of the individuals to whom the personal data relates, providing information to individuals regarding data processing activities, implementing safeguards to protect the security and confidentiality of personal data, providing notification of data breaches and taking certain measures when engaging third-party processors. The GDPR also imposes strict rules on the transfer of personal data to countries outside the EEA, including the United States, and permits data protection authorities to impose large penalties for violations of the GDPR, including potential fines of up to €20 million or 4% of annual global revenues, whichever is greater. The GDPR also confers a private right of action on data subjects and consumer associations to lodge complaints with supervisory authorities, seek judicial remedies and obtain compensation for damages resulting from violations of the GDPR. In addition, the GDPR includes restrictions on cross-border data transfers. The GDPR may increase our responsibility and liability in relation to personal data that we process where such processing is subject to the GDPR, and we may be required to put in place additional mechanisms to ensure compliance with the GDPR, including as implemented by individual countries. Compliance with the GDPR will be a rigorous and time- intensive process that may increase our cost of doing business or require us to change our business practices, and despite those efforts, there is a risk that we may be subject to fines and penalties, litigation and reputational harm in connection with our European activities.

The exit of the United Kingdom ("UK") from the EU, often referred to as Brexit, also has created uncertainty with regard to data protection regulation in the UK. Specifically, the UK exited the EU on January 1, 2020, subject to a transition period that ended December 31, 2020. Under the post-Brexit Trade and Cooperation Agreement between the EU and the UK, the UK and EU have agreed that transfers of personal data to the UK from EEA member states will not be treated as 'restricted transfers' to a non-EEA country for a period of up to four months from January 1, 2021, plus a potential further two months extension (the "Extended Adequacy Assessment Period"). Although the current maximum duration of the Extended Adequacy Assessment Period is six months, it may end sooner, for example, in the event that the European Commission adopts an adequacy decision in respect of the UK, or the UK amends the UK GDPR and/or makes certain changes regarding data transfers under the UK GDPR/Data Protection Act 2018 without the consent of the EU (unless those amendments or decisions are made simply to keep relevant UK laws aligned with the EU's data protection regime). If the European Commission does not adopt an 'adequacy decision' in respect of the UK prior to the expiry of the Extended Adequacy Assessment Period, from that point onwards the UK will be an 'inadequate third country' under the GDPR and transfers of personal data from the EEA to the UK will require a 'transfer mechanism' such as the Standard Contractual Clauses.

Further, the European Court of Justice ("ECJ") invalidated the EU-U.S. Privacy Shield, which had enabled the transfer of personal data from the EU to the U.S. for companies that had self-certified to the Privacy Shield in July 2020. The ECJ decision also raised questions about the continued validity of one of the primary alternatives to the EU-U.S. Privacy Shield, namely the European Commission's Standard Contractual Clauses, and EU regulators have issued additional guidance regarding considerations and requirements that we and other companies must consider and undertake when using the Standard Contractual Clauses. Although the EU has presented a new draft set of contractual clauses, at present, there are few, if any, viable alternatives to the EU-U.S. Privacy Shield and the Standard Contractual Clauses. To the extent that we were to rely on the EU-U.S. or Swiss-U.S. Privacy Shield programs, we will not be able to do so in the future, and the ECJ's decision and other regulatory guidance or developments otherwise may impose additional obligations with respect to the transfer of personal data from the EU and Switzerland to the U.S., each of which could restrict our activities in those jurisdictions, limit our ability to provide our products and services in those jurisdictions, or increase our costs and obligations and impose limitations upon our ability to efficiently transfer personal data from the EU and Switzerland to the U.S.

We are in the process of evaluating compliance needs, and are still finalizing formal policies and procedures related to the storage, collection and processing of information, and still need to conduct internal or external data privacy audits, to ensure our compliance with all applicable data protection laws and regulations. Additionally, we still need to assess our third-party vendors' compliance with applicable data protection laws and regulations. All of these evolving compliance and operational requirements impose significant costs, such as costs related to organizational changes, implementing additional protection technologies, training employees and engaging consultants, which are likely to increase over time. In addition, such requirements may require us to modify our data processing practices and policies, distract management or divert resources from other initiatives and projects, all of which could have a material adverse effect on our business, financial condition, results of operations and prospects. Any failure or perceived failure by us or our third-party vendors, collaborators, contractors and consultants to comply with any applicable federal, state or similar foreign laws and regulations relating to data privacy and security, or could result in damage to our reputation, as well as proceedings or litigation by governmental agencies or other third parties, including class action privacy litigation in certain jurisdictions, which could subject us to significant fines, sanctions, awards, penalties or judgments, all of which could have a material adverse effect on our business, financial condition, results of operations and prospects.

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 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. Our operations involve the use of hazardous and flammable materials, including chemicals and biological and radioactive materials. Our research and development and manufacturing operations also produce hazardous waste products. We generally contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risks 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, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties.

Although we maintain general liability insurance as well as 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.

In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our research and development. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

Further, with respect to the operations of our any future third-party contract manufacturers, it is possible that if they fail to operate in compliance with applicable environmental, health and safety laws and regulations or properly dispose of wastes associated with our products, we could be held liable for any resulting damages, suffer reputational harm or experience a disruption in the manufacture and supply of our product candidates or products. In addition, our supply chain may be adversely impacted if any of our third-party contract manufacturers become subject to injunctions or other sanctions as a result of their non-compliance with environmental, health and safety laws and regulations.

We are subject to U.S. and certain foreign export and import controls, sanctions, embargoes, anti-corruption laws, and anti-money laundering laws and regulations. Compliance with these legal standards could impair our ability to compete in domestic and international markets. We can face criminal liability and other serious consequences for violations, which can harm our business.

We are subject to export control and import laws and regulations, including the U.S. Export Administration Regulations, U.S. Customs regulations, various economic and trade sanctions regulations administered by the U.S. Treasury Department's Office of Foreign Assets Controls, the U.S. Foreign Corrupt Practices Act of 1977, as amended, ("FCPA"), the U.S. domestic bribery statute contained in 18 U.S.C. § 201, the U.S. Travel Act, the USA PATRIOT Act, and other state and national anti-bribery and anti-money laundering laws in the countries in which we conduct activities. Anti- corruption laws are interpreted broadly and prohibit companies and their employees, agents, contractors, and other collaborators from authorizing, promising, offering, or providing, directly or indirectly, improper payments or anything else of value to recipients in the public or private sector. We may engage third parties to sell our products outside the United States, to conduct clinical trials, and/or to obtain necessary permits, licenses, patent registrations, and other regulatory approvals. We have direct or indirect interactions with officials and employees of government agencies or government-affiliated hospitals, universities, and other organizations. We can be held liable for the corrupt or other illegal activities of our employees, agents, contractors, and other collaborators, even if we do not explicitly authorize or have actual knowledge of such activities. Any violations of the laws and regulations described above may result in substantial civil and criminal fines and penalties, imprisonment, the loss of export or import privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm and other consequences.

Risks Related to Ownership of our Common Stock

We have a limited market for our common stock. The stock price of our common stock has been and may continue to be volatile or may decline regardless of our operating performance.

While our common stock is traded on the Nasdaq Global Select Market, we currently have a limited trading history and an active trading market may not be sustained. The market price of our common stock has fluctuated and declined substantially and may continue to do so significantly in response to numerous factors, many of which are beyond our control, including:

- the timing of our launch and commercialization of our products and degree to which such launch and commercialization meets the expectations of securities analysts and investors;
- actual or anticipated fluctuations in our operating results, including fluctuations in our quarterly and annual results;
- operating and research and development expenses exceed our plans and expectations;
- the failure or discontinuation of any of our product development and research programs;
- changes in the structure or funding of research at academic and research laboratories and institutions, including changes that would affect their ability to purchase our instruments or consumables;

- our ability to reduce the per unit cost of our commercialized products;
- financing or other corporate transactions, or inability to obtain additional funding;
- sales by us of a substantial number of shares of our capital stock or other securities to raise capital;
- variations in the financial results of competitive companies;
- the introduction and success of existing or new competitive businesses or technologies;
- announcements about new research programs or products by us or our competitors;
- announcements of new pricing or product bundling terms offered by our competitors;
- intellectual property litigation or developments in disputes concerning infringement of patents or other proprietary rights;
- the recruitment or departure of key personnel;
- litigation and governmental investigations involving us, our industry or both;
- regulatory or legal developments in the United States and other countries;
- volatility and variations in market conditions in the life sciences technology sector generally, or the genomics and proteomics sectors specifically;
- investor perceptions of us or our industry;
- the level of expenses related to any of our research and development programs or future products or product enhancements;
- actual or anticipated changes in our estimates as to our financial results or development timelines;
- changes in estimates or recommendations by securities analysts, if any, that cover our common stock or companies that are perceived to be similar to us;
- whether our financial results meet the expectations of securities analysts or investors;
- the effect of inflation on our business;
- the announcement or expectation of additional financing efforts;
- sales of our common stock by us or sales of our common stock or common stock by our insiders or other stockholders;
- the expiration of market standoff or lock-up agreements;
- the COVID-19 pandemic, natural disasters or major catastrophic events; and
- general economic, industry and market conditions.

The concentration of our stock ownership will likely limit your ability to influence corporate matters, including the ability to influence the outcome of director elections and other matters requiring stockholder approval.

As of December 31, 2022, our officers, directors and the holders of more than 5% of our outstanding common stock collectively beneficially own approximately 44% of our common stock. As a result, these stockholders, acting together, will have significant influence over all matters that require approval by our stockholders, including the election of directors and approval of significant corporate transactions. Corporate actions might be taken even if many other stockholders oppose them. This concentration of ownership might also have the effect of delaying or preventing a change of control of our company that many other stockholders may view as beneficial.

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 common stock.

The preparation of financial statements in conformity with U.S. 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 estimates 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. For example, in connection with the implementation of revenue accounting standards, management makes judgments and assumptions based on our interpretations of these standards. The revenue standards are principle-based and interpretation of those principles may vary from company to company based on their unique circumstances. It is possible that interpretation, industry practice and guidance may evolve as we apply revenue accounting standards. 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 common stock.

We are an "emerging growth company," and we cannot be certain if the reduced reporting requirements applicable to emerging growth companies will make our common stock less attractive to investors.

We are an "emerging growth company" as defined in the JOBS Act and we intend to take advantage of some of the exemptions from reporting requirements that are applicable to other public companies that are not emerging growth companies, including:

- the option to present only two years of audited financial statements, in addition to any required unaudited interim financial statements, with correspondingly reduced "Management's Discussion and Analysis of Financial Condition and Results of Operations" disclosure;
- not being required to comply with the auditor attestation requirements of Section 404(b) of the Sarbanes Oxley Act;
- not being required to comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements;
- not being required to disclose certain executive compensation-related items such as the correlation between executive compensation and performance and comparisons of the chief executive officer's compensation to median employee compensation; and
- not being required to submit certain executive compensation matters to stockholder advisory votes, such as "say-on-pay," "say-on-frequency," and "say-on-golden parachutes."

The JOBS Act permits an "emerging growth company" such as us to take advantage of an extended transition period to comply with new or revised accounting standards applicable to public companies. We have elected to avail ourselves of this exemption and, as a result, we will adopt new or revised accounting standards on the relevant dates on which adoption of such standards is required for private companies.

We cannot predict if investors will find our common stock less attractive because we will rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile. We may take advantage of these reporting exemptions until we are no longer an emerging growth company. We will remain an emerging growth company until the earlier of (1) the last day of the fiscal year (a) following the fifth anniversary of the completion of our IPO, (b) in which we have total annual gross revenue of at least $1.07 billion or (c) in which we are deemed to be a large accelerated filer, which means the market value of our common stock that is held by non-affiliates exceeds $700 million as of the prior September 30th and (2) the date on which we have issued more than $1.0 billion in non-convertible debt during the prior three-year period. Even after we no longer qualify as an emerging growth company, we may qualify as a "smaller reporting company," which would allow us to take advantage of many of the same exemptions from disclosure requirements including reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, if either (i) the market value of our stock held by non-affiliates is less than $250 million or (ii) our annual revenue is less than $100 million during the most recently completed fiscal year and the market value of our stock held by non-affiliates is less than $700 million.

We do not intend to pay dividends for the foreseeable future.

We have never declared nor paid cash dividends on our capital stock. We currently intend to retain any future earnings to finance the operation and expansion of our business, and we do not expect to declare or pay any dividends in the foreseeable future. The SVB Loan also contains a negative covenant that prohibits us from paying dividends subject to limited exceptions. Consequently, stockholders must rely on sales of their common stock after price appreciation, which may never occur, as the only way to realize any future gains on their investment.

Delaware law and provisions in our amended and restated certificate of incorporation and amended and restated bylaws could make a merger, tender offer or proxy contest difficult, thereby depressing the trading price of our common stock.

Our status as a Delaware corporation and the anti-takeover provisions of the Delaware General Corporation Law may discourage, delay or prevent a change in control by prohibiting us from engaging in a business combination with an interested stockholder for a period of three years after the person becomes an interested stockholder, even if a change of control would be beneficial to our existing stockholders. In addition, our amended and restated certificate of incorporation and amended and restated bylaws contain provisions that may make the acquisition of our company more difficult, including the following:

- a classified board of directors with three-year staggered terms, which could delay the ability of stockholders to change the membership of a majority of our board of directors;
- the ability of our board of directors to issue shares of preferred stock and to determine the price and other terms of those shares, including preferences and voting rights, without stockholder approval, which could be used to significantly dilute the ownership of a hostile acquirer;

- the exclusive right of our board of directors to elect a director to fill a vacancy created by the expansion of our board of directors or the resignation, death or removal of a director, which prevents stockholders from being able to fill vacancies on our board of directors;
- a prohibition on stockholder action by written consent, which forces stockholder action to be taken at an annual or special meeting of our stockholders;
- the requirement that a special meeting of stockholders may be called only by a majority vote of our entire board of directors, the chair of our board of directors or our chief executive officer, which could delay the ability of our stockholders to force consideration of a proposal or to take action, including the removal of directors;
- the requirement for the affirmative vote of holders of at least 66 2/3% of the voting power of all of the then-outstanding shares of the voting stock, voting together as a single class, to amend the provisions of our amended and restated certificate of incorporation or our amended and restated bylaws, which may inhibit the ability of an acquirer to effect such amendments to facilitate an unsolicited takeover attempt; and
- advance notice procedures with which stockholders must comply to nominate candidates to our board of directors or to propose matters to be acted upon at a stockholders' meeting, which may discourage or deter a potential acquirer from conducting a solicitation of proxies to elect the acquirer's own slate of directors or otherwise attempting to obtain control of us.

In addition, as a Delaware corporation, we are subject to Section 203 of the Delaware General Corporation Law. These provisions may prohibit large stockholders, in particular those owning 15% or more of our outstanding voting stock, from merging or combining with us for a certain period of time. A Delaware corporation may opt out of this provision by express provision in its original certificate of incorporation or by amendment to its certificate of incorporation or bylaws approved by its stockholders. However, we have not opted out of this provision.

These and other provisions in our amended and restated certificate of incorporation, amended and restated bylaws and Delaware law 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 our then-current board of directors, including delay or impede a merger, tender offer or proxy contest involving our company. The existence of these provisions could negatively affect the price of our common stock and limit opportunities for you to realize value in a corporate transaction.

Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware and the U.S. federal district courts are 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 employees.

Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware is the exclusive forum for 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 pursuant to the Delaware General Corporation Law, our certificate of incorporation or our bylaws or 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. Further, 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 certificate of incorporation further provides that the U.S. federal district courts will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act, including all causes of action asserted against any defendant named in such complaint. For the avoidance of doubt, this provision is intended to benefit and may be enforced by us, our officers and directors, the underwriters to any offering giving rise to such complaint, and any other professional entity whose profession gives authority to a statement made by that person or entity and who has prepared or certified any part of the documents underlying the offering. 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 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.

This choice of forum provision 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 and may discourage these types of lawsuits. Alternatively, if a court were to find the choice of forum provision contained in our amended and restated certificate of incorporation to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions.

Sales of a substantial number of shares of our common stock in the public market could cause the price of our common stock to fall.

Sales of a substantial number of shares of our common stock in the public market could cause our stock price to decline. Sales of a substantial number of shares of our common stock could occur at any time. These sales, or the perception in the market that the holders of a large number of shares intend to sell shares, could reduce the market price of our common stock.

On July 19, 2022 we filed a shelf registration statement (the "Shelf Registration Statement") on Form S-3 with the Securities and Exchange Commission ("SEC") (that was declared effective on July 27, 2022), which permits us to offer up to an aggregate of $250.0 million of our common stock, preferred stock, debt securities and warrants in one or more offerings and in any combination, including units from time to time. Our Shelf Registration Statement is intended to provide us with additional flexibility to raise capital in the future for general corporate purposes. As part of this Shelf Registration Statement, we also entered into a sales agreement with Cowen and Company, LLC ("Cowen and Company"), pursuant to which we may offer and sell common stock through Cowen and Company from time to time up to an aggregate offering price of $100.0 million (The "Sales Agreement"). Through the date of this filing, we have not sold any shares of our common stock in "at the market" transactions pursuant to the Sales Agreement. Depending upon market liquidity at the time, sales of shares of our common stock under the Shelf Registration Statement or the Sales Agreement may cause the trading price of our common stock to decline and may result in substantial dilution to the interests of other holders of our common stock.

Further, we have registered and intend to continue to register all shares of common stock that we may issue under our equity plans. Once we register these shares, they can be freely sold in the public market upon issuance, subject to volume limitations applicable to affiliates. We cannot predict what effect, if any, sales of our shares in the public market or the availability of shares for sale will have on the market price of our common stock. However, future sales of substantial amounts of our common stock in the public market, including shares issued upon exercise of our outstanding options, or the perception that such sales may occur, could adversely affect the market price of our common stock.

We expect that significant additional capital may be needed in the future to continue our planned operations. To raise capital, we may sell common stock, convertible securities or other equity securities in one or more transactions at prices and in a manner we determine from time to time, including through our existing Shelf Registration Statement and Sales Agreement with Cowen and Company. To the extent that additional capital is raised through the sale and issuance of shares or other securities convertible into shares, our stockholders will be diluted. These sales, or the perception in the market that the holders of a large number of shares intend to sell shares, could reduce the market price of our common stock. Sales of a substantial number of shares of our common stock in the public market could cause our stock price to decline. Sales of a substantial number of shares of our common stock in the public market could occur at any time. These sales, or the perception in the market that the holders of a large number of shares intend to sell shares, could reduce the market price of our common stock. We cannot predict what effect, if any, sales of our shares in the public market or the availability of shares for sale will have on the market price of our common stock. However, future sales of substantial amounts of our common stock in the public market, or the perception that such sales may occur, could adversely affect the market price of our common stock.

General Risk Factors

If securities or industry analysts cease publishing research or publish inaccurate or unfavorable research about our business, our stock price and trading volume could decline.

The trading market for our common stock will depend in part on the research and reports published by securities or industry analysts about us or our business. Securities and industry analysts currently publish research on our company. If analysts cease coverage of us, the trading price for our common stock could be negatively affected. If one or more of the analysts who cover us downgrade our common stock or publish inaccurate or unfavorable research about our business, our common stock price would likely decline. If one or more of these analysts cease coverage of us or fail to publish reports on us regularly, demand for our common stock could decrease, which might cause our common stock price and trading volume to decline.

We could be subject to securities class action litigation.

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 our stock price has declined since our IPO, and life science technology companies have experienced significant stock price volatility in recent years. If we face such litigation, it could result in substantial costs and a diversion of management's attention and resources, which could harm our business.

Requirements associated with being a public company have increased and will increase our costs significantly, as well as divert significant company resources and management attention.

We are subject to the reporting requirements of the Exchange Act, or the other rules and regulations of the SEC, or any securities exchange relating to public companies. Compliance with the various reporting and other requirements applicable to public companies requires considerable time and attention of management and we will incur significant legal, accounting and other expenses that we did not incur as a private company. We cannot assure you that we will satisfy our obligations as a public company on a timely basis.

In addition, as a public company, it may be more difficult or more costly for us to obtain certain types of insurance, including directors' and officers' liability insurance, and we may be forced to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. The impact of these events could also make it more difficult for us to attract and retain qualified personnel to serve on our board of directors, our board committees or as executive officers.

If we fail to maintain proper and effective internal controls, our ability to produce accurate and timely financial statements could be impaired, which could result in sanctions or other penalties that would harm our business.

We are subject to the reporting requirements of the Exchange Act, the Sarbanes-Oxley Act and the rules and regulations of the Nasdaq Global Select Market. The Sarbanes Oxley Act requires, among other things, that we maintain effective disclosure controls and procedures and internal controls over financial reporting. Commencing in 2022, we must perform system and process design evaluation and testing of the effectiveness of our internal controls over financial reporting to allow management to report on the effectiveness of our internal controls over financial reporting in our Form 10-K filing for the year ended December 31, 2022, as required by Section 404 of the Sarbanes-Oxley Act. To achieve compliance with Section 404 within the prescribed period, we will be engaged in a process to document and evaluate our internal control over financial reporting, which is both costly and challenging. In this regard, we will need to continue to dedicate internal resources, including through hiring additional financial and accounting personnel, potentially engage outside consultants and adopt a detailed work plan to assess and document the adequacy of internal control over financial reporting, continue steps to improve control processes as appropriate, validate through testing that controls are functioning as documented and implement a continuous reporting and improvement process for internal control over financial reporting. This will require that we incur substantial additional professional fees and internal costs to expand our accounting and finance functions and that we expend significant management efforts. Prior to our IPO, we have never been required to test our internal controls within a specified period and, as a result, we may experience difficulty in meeting these reporting requirements in a timely manner.

We may discover weaknesses in our system of internal financial and accounting controls and procedures that could result in a material misstatement of our financial statements. Our internal control over financial reporting will not prevent or detect all errors and all fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system's objectives will be met. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud will be detected.

If we are not able to comply with the requirements of Section 404 of the Sarbanes-Oxley Act in a timely manner, or if we are unable to maintain proper and effective internal controls over financial reporting, we may not be able to produce timely and accurate financial statements. If that were to happen, our investors could lose confidence in our reported financial information, the market price of our stock could decline and we could be subject to sanctions or investigations by the SEC or other regulatory authorities including equivalent foreign authorities.

Item 1B. Unresolved Staff Comments

None.

Item 2. Properties

As of December 31, 2022, we leased 135,311 square feet of office, laboratory and manufacturing space in San Diego, California under various leases that expire in 2024, 2026 and 2036.

In January 2022, we entered into a Lease Agreement (the "OAS Lease") with an affiliate of Alexandria Real Estate Equities, Inc. to lease two buildings ("Building 3" and "Building 4") to be constructed in connection with One Alexandria Square in La Jolla, California. Building 3 and Building 4 are comprised of 113,094 square feet and 92,572 square feet, respectively, of office and manufacturing space and will serve as the Company's future headquarters. Per the OAS Lease, the target commencement dates of Building 3 and Building 4 are estimated to be November 1, 2024 and November 1, 2025, respectively, with a base term of 144 months beginning on the commencement date of Building 3.

We believe that the facilities under our leases are sufficient to meet our needs for the foreseeable future.

Item 3. Legal Proceedings

We are not currently a party to any material legal proceedings. From time to time, we may become involved in legal proceedings arising in the ordinary course of our business. Regardless of outcome, litigation can have an adverse impact on us due to defense and settlement costs, diversion of management resources, negative publicity, reputational harm and other factors.

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

Shares of our common stock are traded on the Nasdaq Global Select Market under the symbol "OMIC."

Holders of Record

As of January 31, 2023, we had 46 holders of record. Certain shares of common stock are held in "street" name, and, accordingly, the number of beneficial owners of such shares of common stock is not known or included in the foregoing number. This number of holders of record also does not include shareholders whose shares may be held in trust by other entities.

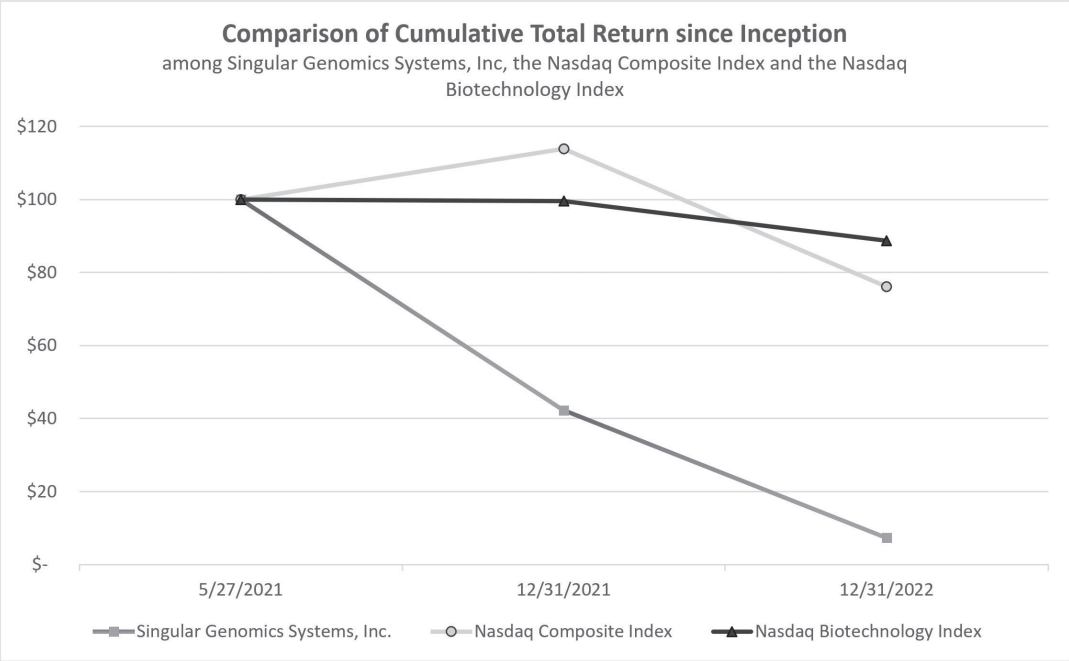
Dividend Policy

We have never declared or paid any cash dividends on our capital stock and we do not currently intend to pay any cash dividends on our capital stock for the foreseeable future. We currently intend to retain all available funds and any future earnings to support operations and to finance the growth and development of our business. Any future determination to declare and pay dividends will be made at the discretion of our board of directors subject to applicable laws and will depend on, among other factors, our results of operations, financial condition, business prospects, contractual restrictions, capital requirements and other factors our board of directors may deem relevant. Additionally, our Loan Agreement with Silicon Valley Bank contains customary covenants, including restrictions on our ability to pay cash dividends.

Stock Performance Graph

This graph below is not "soliciting material" or deemed "filed" with the Securities and Exchange Commission for purposes of Section 18 of the Exchange Act or otherwise subject to liabilities under that section, and shall not be deemed incorporated by reference into this Annual Report or into any other filing of Singular Genomics Systems, Inc. under the Securities Act except to the extent that we specifically incorporate this information by reference therein, whether made before or after the date hereof and irrespective of any general incorporation language in any such filing.

The following graph compares the cumulative total return on our common stock relative to the cumulative total returns of the Nasdaq Composite Index and the Nasdaq Biotechnology Composite Index. An investment of $100 is assumed to have been made in our common stock and each index at market close on May 27, 2021 (the first day of trading of our common stock), and its relative performance is tracked through December 31, 2022. Pursuant to applicable Securities and Exchange Commission ("SEC") rules, all values assume reinvestment of the full amount of all dividends; however, no dividends have been declared on our common stock to date. The stockholder returns shown on the graph below are based on historical results and are not indicative of future performance, and we do not make or endorse any predictions as to future stockholder returns.



Securities Authorized for Issuance under Equity Compensation Plans

The information required by this item will be contained in the definitive Proxy Statement for the 2023 Annual Meeting of Stockholders to be filed with the SEC no later than May 1, 2023.

Use of Proceeds

On May 26, 2021, our Registration Statement on Form S-1 (File No. 333-255912) ("Registration Statement") relating to the initial public offering of our common stock ("IPO") was declared effective by the SEC. Pursuant to such Registration Statement, we sold an aggregate of 11,730,000 shares of our common stock, which includes 1,530,000 shares sold pursuant to the underwriters' full exercise of their option to purchase additional shares, at a price to the public of $22.00 per share. The aggregate offering price for shares sold in the offering was $258.1 million. On June 1, 2021, we closed the sale of such shares, resulting in aggregate cash proceeds to us of approximately $237.2 million, net of underwriting discounts, commissions and offering expenses paid or payable by us. No offering expenses were paid or are payable, directly or indirectly, to our directors or officers, to persons owning 10% or more of any class of our equity securities or to any of our affiliates. There has been no material change in the planned use of proceeds from our IPO as described in the final prospectus, dated May 26, 2021, filed with the SEC on May 28, 2021, pursuant to Rule 424(b) of the Securities Act.

Unregistered Sale of Equity Securities

We had no sales of unregistered equity securities during the period covered by this report that were not previously reported in a Quarterly Report on Form 10-Q or a Current Report on Form 8-K.

Item 6. [Reserved]

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our financial statements and the related notes to those statements included in Item 8 of this report. In addition to historical financial information, the following discussion and analysis contains forward-looking statements that involve risks, uncertainties and assumptions. Our actual results and timing of selected events may differ materially from those anticipated in these forward-looking statements as a result of many factors, including, but not limited to, those discussed under the section titled "Risk Factors" elsewhere in this report. See the section titled "Special Note Regarding Forward-Looking Statements" elsewhere in this report.

Overview

We are a life science technology company that develops next-generation sequencing and multiomics technologies. The commercially available G4 Sequencing Platform is a powerful, highly versatile benchtop genomic sequencer designed to produce fast and accurate results. In development, the PX system leverages our proprietary sequencing technology, applying it as an *in situ* readout to look at RNA and proteins in single cells and tissue. With these products, our mission is to empower researchers and clinicians to advance science and medicine.

We developed a unique and proprietary NGS technology, which we refer to as our Sequencing Engine. This Sequencing Engine is the platform technology of our products and core product tenets: power, speed, flexibility and accuracy. The core of our Sequencing Engine is comprised of unique and proprietary chemistry, including novel chemical compounds, polymers and enzymes. This chemistry is designed to produce high-accuracy sequencing and rapid cycle times that we believe can drive improvements in NGS. To take full advantage of our proprietary chemistry, we have developed and continue to develop purpose-built instrumentation consisting of high-speed, high-resolution imaging and innovative fluidic design. We believe that our Sequencing Engine, together with our proprietary innovations in molecular biology techniques, will enable differentiated applications in fast-growing markets, supported by our intellectual property portfolio.

The G4 is a benchtop next-generation sequencer designed to produce fast and accurate sequencing results. The G4 is designed to target the NGS market in particular applications that require power, speed, flexibility and accuracy. We believe the G4 will expand and accelerate the use of DNA sequencing across a wide range of applications, such as identifying cancer-associated genetic mutations, deep sequencing to detect minimum residual disease in circulating cell-free DNA, profiling the immune system, analyzing single-cell RNA transcription and rapidly sequencing exomes and whole genomes. We are executing a three-step commercialization plan for the G4 consisting of the following: (i) collaborating with select partners to conduct beta pilot tests, which we completed in 2021; (ii) collaborating with potential customers in our early access program, which we concluded in the second quarter of 2022; and (iii) offering the G4 broadly to the market. We commercially launched the G4 in December of 2021, and we began recognizing revenue on sales of the G4 in the fourth quarter of 2022.

The PX is our second product in development and is a multiomics platform designed to target the markets for single-cell, spatial analysis and proteomics. The PX will leverage our Sequencing Engine as a readout mechanism to provide a high-resolution view of biology at the single-cell and tissue level. We believe the PX, when launched, will be a high-throughput, versatile platform capable of measuring levels of RNA transcription, protein expression and sequence-specific information directly in cells and tissues. We believe the PX will have broad application across many areas of biology. We are initially focused on applications in oncology and immunology, with future expansion into other applications such as neurology. We are currently in an advanced prototype development stage for the PX. For the PX, we plan to collaborate with select partners to conduct a technology access program designed to bring samples and collaborators in-house, which we initiated in the fourth quarter of 2022 and executed our first technology access partner agreement in February 2023. Following our technology access program, we plan to expand collaborations with additional potential customers in an early access program.

Corporate and Financial Overview

Since we were incorporated in 2016, we have devoted substantially all of our resources to research and product development activities, initiating our commercialization plans, establishing and maintaining our intellectual property portfolio, hiring personnel, raising capital, building our commercial infrastructure and providing general and administrative support for these activities. Since our incorporation, we have incurred significant losses and negative cash flows from operations. During the year ended December 31, 2022, we incurred a net loss of $90.9 million and used $87.1 million of cash in our operations. As of December 31, 2022, we had an accumulated deficit of $242.8 million. We expect to continue to incur significant and increasing losses and do not expect positive cash flows from operations for the foreseeable future, and our net losses may fluctuate significantly from period to period depending on the timing of and expenditures on our planned commercialization and research and development activities.

On June 1, 2021, we closed our initial public offering ("IPO") in which we sold 11,730,000 shares of our common stock (which includes 1,530,000 shares that were offered and sold pursuant to the full exercise of the underwriters' option to purchase additional shares) at a public offering price of $22.00 per share, resulting in net proceeds of approximately $237.2 million after deducting offering costs, underwriting discounts and commissions of $20.9 million.

From the date of our incorporation through December 31, 2022, we have financed our operations primarily through private placements of convertible preferred stock, convertible promissory notes and the net proceeds from our IPO. We have raised aggregate net proceeds of approximately $447.4 million, net of issuance costs, including the $130.5 million we raised through the issuance of convertible promissory notes in February 2021 (the "2021 Convertible Notes"), and including $10.5 million of advances on our loan agreement with Silicon Valley Bank (the "Loan Agreement"). As of December 31, 2022, we had cash, cash equivalents and short-term investments of $244.6 million.

We expect our expenses to increase significantly in connection with our ongoing activities as we:

- continue to commercialize and enhance the G4;
- continue to develop our planned PX;
- attract, hire and retain qualified personnel;
- continue to expand our sales, marketing, service, support and distribution infrastructure to support our commercialization plans and engage in commercialization activities;
- build-out and expand our in-house manufacturing capabilities and engage in larger scale manufacturing activities;
- continue to engage in research and development of other products and enhancements;
- implement operational, financial and management information systems; and
- obtain, maintain, expand and protect our intellectual property portfolio.

Key Factors Affecting Our Performance

We believe that our financial performance is and will continue to be driven primarily by the factors below. While each of these factors presents significant opportunities for our business, they also pose important challenges that we must successfully address in order to grow our business and improve our results of operations. Our ability to successfully address the factors below is subject to various risks and uncertainties, including those described under the section titled "Risk Factors" elsewhere in this report.

Commercial adoption of the G4 and planned PX

Our financial performance will be driven by, and a key factor to our future success will be, the rate of commercial adoption of the G4 and planned PX. We have commercially launched the G4 through a direct sales and marketing organization in the United States. In the future, we plan sell and support our products in the European Union, United Kingdom, Asia Pacific and Japan, either through direct sales or through established distribution networks. Throughout our commercial rollout, we aim to grow our sales and marketing team to foster deep customer relationships and to establish and grow distribution networks capable of deploying our products in select areas of the world. We also expect to offer different access options, including lease options, for our products to meet each customer's needs. As a result, we will aim to increase the installed base of the G4 and our planned PX.

Utilization by our customers of the G4 and planned PX

The utilization of our products and the corresponding purchases of consumables and other products and services will represent a source of potential recurring revenue from our customers. We plan to drive utilization of the G4 and planned PX by engaging with customers to help them advance through the adoption cycle from early stage validation to the plug-and-play integration of our products with their existing NGS workflows.

Expansion of the G4 and PX beyond initial applications

The rate of growth of our revenue will rely in part on our ability to expand our market opportunity. We aim to continually innovate and develop new products, applications, workflows and analysis tools that may potentially lead to new end markets, applications and business models. We believe that the capabilities offered by our products and future products may potentially lead to additional or complementary addressable markets and may expand our market opportunity.

Revenue mix between our instruments and consumables, and gross margin

The revenue we have generated and any revenue we generate in the future was and will be derived from sales of our instruments, consumables and services. Initially, our revenue has been and will be derived principally from sales of instruments. As we drive utilization of the G4, and customers begin utilizing more of our consumables, we estimate that the portion of our revenue from sales of our consumables will grow over time. We expect the revenue contribution from our consumables to vary on a quarterly basis due to several factors, including the timing and number of publications of scientific papers demonstrating the value of our consumables, the availability of grants to fund research, budgetary timing and our introduction of new product features and new consumables offerings. Additionally, we expect the mix and variance of sales between our instruments and consumables to cause our gross margin to vary on a quarterly basis.

Rate of investment in our growth

As we continue to commercialize the G4 and, once developed and commercially launched, the PX, we expect to continue investing in our manufacturing capabilities and commercial infrastructure. Additionally, we plan to further invest in research and development as we hire employees with the necessary scientific and technical backgrounds to enhance and expand our existing products and help us bring new products to market, and we expect to incur additional research and development expenses as a result. We also plan to invest in sales and marketing activities and expect to incur additional general and administrative expenses as we support our growth and our operations as a commercial-stage company.

Expansion of our geographic presence

We are initially building our commercial infrastructure to sell and support our products directly in the United States and Canada. We also have plans to sell and support our products in the European Union, United Kingdom, Asia Pacific and Japawn, either through direct sales or through well established distribution networks. We expect to incur expenses as we expand our geographic presence and generate revenue either through direct sales or through distribution networks. Our expenses and revenue will fluctuate depending on the extent to which we pursue direct sales or distribution arrangements outside the United States and Canada.

Columbia License Agreement

In August 2016, we entered into an Exclusive License Agreement (the "License Agreement") with Columbia. The License Agreement includes a number of diligence obligations that require us to use commercially reasonable efforts to research, discover, develop and market Patent Products and/or Other Products (as defined in the License Agreement) by certain dates. Under the License Agreement, we pay an annual license fee that increases each year, until it reaches a low six-digit fee for the fifth year, and for each subsequent year, for so long as the License Agreement remains in force. For any products within the scope of the License Agreement that we commercialize, we are required to pay royalties ranging from low to mid-single digits on net sales of Patent Products and low single-digit royalty rates on net sales of Other Products. We can credit our yearly annual license fee against any yearly royalty fees payable to Columbia. Additionally, if we receive any income in connection with any sublicenses, we must pay Columbia a high single-digit percentage of that income. Finally, the License Agreement provides for payments to Columbia based on our achievement of certain development and commercialization milestones, which could total up to $3.9 million over the life of the License Agreement.

COVID-19 Pandemic

We are continuing to assess the impact of the COVID-19 pandemic on our current and future business and operations, as well as on our industry and the healthcare system. The COVID-19 pandemic and efforts to reduce its spread adversely impacted our business and operations, and depending on further outbreaks and related responses, may impact our business in the future. We have continued to operate within the rules applicable to our business; however, while many of these mandates have expired, an extended implementation of these governmental mandates or institution of other mandates could further impact our ability to operate effectively and conduct ongoing research and development or other activities. Additionally, we have experienced longer lead times from our suppliers of components used in our product development and manufacturing operations, including due to supply chain challenges currently being experienced generally in the economy. Any pandemic precautions and preventative measures still in effect may also impact our commercialization plans due to restrictions on our customers' ability to access laboratories, causing delays in the delivery and installation of our products, training such customers on our products and their ability to conduct research. The ongoing build-out of our planned future headquarters and manufacturing facilities may also be delayed by COVID-19 related restrictions that remain in effect. The COVID-19 pandemic also had an adverse effect on our ability to attract, recruit, interview and hire at the pace we would typically expect to support our rapidly expanding operations. To the extent that any governmental authority imposes additional regulatory requirements, or continues to maintain regulatory requirements or changes existing laws, regulations and policies that apply to our business and operations, such as additional workplace safety measures, our product development plans may be delayed, and we may incur further costs in bringing our business and operations into compliance with new laws, regulations and policies.

Results and Components of Operations

The following table summarizes our results of operations for the periods indicated:

	Year Ended December 31,			
	2022	2021	$ Change	% Change
	(in thousands)			
Revenue	$ 765	$ -	$ 765	100%
Cost of revenue	789		789	100%
Gross margin	(24)	-	(24)	-100%
Operating expenses:				
Research and development	46,199	32,655	13,544	41%
Selling, general and administrative	47,264	28,624	18,640	65%
Total operating expenses	93,463	61,279	32,184	53%
Loss from operations	(93,487)	(61,279)	(32,208)	53%
Other income (expense):				
Interest expense	(763)	(846)	83	-10%
Change in fair value of convertible promissory notes	-	(35,199)	35,199	-100%
Change in fair value of warrant liability	-	(2,180)	2,180	-100%
Interest and other income	3,371	733	2,638	360%
Total other income (expense)	2,608	(37,492)	40,100	-107%
Net loss	$ (90,879)	$ (98,771)	$ 7,892	8%

Revenue, Cost of Revenue and Gross Margin

We generate revenue from sales of products which consist of the G4 instrument, related consumable flow cell kits and services. Revenue from instrument sales is recognized generally upon customer acceptance. Once the Company generates sufficient history of successful customer acceptances for instruments, the Company intends to recognize revenue for instruments generally upon shipment to the customer. Revenue from consumables sales is recognized generally upon shipment to the customer. Revenue from services, which are primarily comprised of extended warranty–type services, is recognized over the applicable service period. When we sell multiple products, also referred to as performance obligations, in one contract, revenue is allocated to each of those performance obligations. This results in revenue being deferred for performance obligations to be satisfied in the future, such as services and discounted consumables. During the year ended December 31, 2022 we recognized revenue on instruments and consumables of approximately $748,000 and approximately $17,000, respectively. We did not recognize service revenue for the year ended December 31, 2022.

Cost of revenue consists primarily of the direct costs of the materials and labor to build our products, overhead such as facilities and indirect labor that support manufacturing, shipping costs, and the labor and direct costs to install the G4. Cost of revenue also includes estimated costs to satisfy customary assurance-type warranties.

Our gross margin for the year ended December 31, 2022 is negative as a result of both additional incentives we provided to certain customers for their early adoption of the G4 sequencing platform, as well as higher direct costs for “white-glove” services to our initial customers. We expect our gross margins to improve over time both as we phase-out incentives and enhanced services for early customers and as we increase our manufacturing efficiency.

The following tables summarizes our revenue, cost of revenue and gross margin for the periods indicated:

	Year Ended December 31,			
	2022	2021	$ Change	% Change
	(in thousands)			
Revenue	$ 765	$ -	$ 765	100%
Cost of revenue	789		789	100%
Gross margin	$ (24)	$ -	$ (24)	100%

Research and Development Expense

Research and development expenses consist primarily of the following: salaries, payroll taxes, employee benefits and stock-based compensation for personnel engaged in research and development activities; consultant fees; fees incurred under intellectual property license agreements; laboratory supplies and development compound materials; and allocated facilities and depreciation costs. All research and development costs are charged to expense as incurred.

We plan to continue to increase our investment in our research and development efforts related to our product development pipeline and our proprietary technology, including related to the G4 and planned PX. Therefore, we expect our research and development expenses will increase as we incur expenses associated with hiring additional personnel and purchasing supplies and materials to support our research and development efforts.

The following table summarizes our research and development expense for the periods indicated:

	Year Ended December 31,			
	2022	2021	$ Change	% Change
	(in thousands)			
Research and development	$ 46,199	$ 32,655	$ 13,544	41%

Research and development expense increased by $13.5 million, or 41%, in the year ended December 31, 2022 compared to the same period in 2021. The increase was primarily due to an increase of $6.7 million in employee compensation costs, including $1.6 million of stock-based compensation, to support the development efforts of the G4 and our beta development of the PX. Other increases include $1.1 million in laboratory materials, supplies and reagents used for in-house research, $4.7 million related to the expansion of our facilities and increase in information technology spend, $0.8 million related to increase in depreciation and $0.2 million related to other various research and development activities.

Selling, General and Administrative Expense

Selling, general and administrative expenses consist primarily of the following: salaries, payroll taxes, employee benefits and stock-based compensation for personnel in our executive management, finance, administration and human resources functions; professional service fees, including for legal, accounting, patent, auditing and other services; allocated facilities and depreciation costs; and other costs to support our operations.

We plan to continue to increase our investment in our personnel as we grow, particularly in the areas of sales and customer support and expect that are expenses related to our growth in sales personnel and customer support will continue to increase. We also have incurred and expect to continue to incur additional costs as a result of operating as a public company. As a result of our continued investment in our personnel, we expect our selling, general and administrative expenses will increase in future periods.

The following table summarizes our selling, general and administrative expense for the periods indicated:

	Year Ended December 31,			
	2022	2021	$ Change	% Change
	(in thousands)			
Selling, general and administrative	$ 47,264	$ 28,624	$ 18,640	65%

Selling, general and administrative expenses increased by $18.6 million, or 65%, in the year ended December 31, 2022 compared to the same period in 2021. The increase was primarily due to an $11.6 million increase in employee compensation costs, including $2.8 million of stock-based compensation costs, as a result of hiring personnel to support our growth and commercialization. Other increases include $2.3 million related to the expansion of our facilities and increase in information technology spend, $0.5 million related to an increase in depreciation, $2.4 million in professional and consulting fees related to insurance, legal, audit, marketing services, and other costs associated with becoming a public company, and $1.8 million of various other administrative expenses to support growing headcount.

Other Income (Expense)

Other income (expense) primarily consists of interest income, interest expense, and expenses recorded for the changes in fair value of our convertible notes and warrant liability incurred prior to and up to our IPO.

Interest Expense—Interest expense consists of interest related to our Loan Agreement with Silicon Valley Bank, including amortization of the debt issuance cost.

Change in Fair Value of Convertible Promissory Notes—Prior to the IPO, we accounted for the convertible promissory notes (the "2021 Convertible Notes") in accordance with the provisions of Accounting Standards Codification ("ASC") 480, *Distinguishing Liabilities from Equity* and ASU 2020-06, *Debt—Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging—Contracts in Entity's Own Equity (Subtopic 815-40): Accounting for Convertible Instruments and Contracts in an Entity's Own Equity*. We adjusted the carrying value of the liability for the 2021 Convertible Notes to its estimated fair value at the end of each reporting period through conversion, with increases in fair value recorded as other income or expense in the statements of operations.

Change in Fair Value of Warrant Liability—Prior to the IPO, we accounted for the warrant for preferred stock (the "SVB Warrant", see Note 8 to our financial statements included in Item 8) in accordance with the provisions of ASC 480, *Distinguishing Liabilities from Equity*, which requires that warrants for the purchase of shares in contingently redeemable instruments be accounted for as liabilities. We adjusted the carrying value of such warrant liability to its estimated fair value at the end of each reporting period through conversion, with increases or decreases in fair value recorded as other income or expense in the statements of operations.

Interest and Other Income—Interest income consists of interest earned on cash, cash equivalents and short-term investments primarily from holdings in corporate notes, government notes and money market funds. Other income primarily includes certain tax credits received.

The following table summarizes our other income (expense) for the periods indicated:

	Year Ended December 31,			
	2022	2021	$ Change	% Change
	(in thousands)			
Interest expense	$ (763)	$ (846)	$ 83	-10%
Change in fair value of convertible promissory notes	-	(35,199)	35,199	-100%
Change in fair value of warrant liability	-	(2,180)	2,180	-100%
Interest and other income	3,371	733	2,638	360%
Total	$ 2,608	$ (37,492)	$ 40,100	-107%

Other expense decreased by $40.1 million in the year ended December 31, 2022 compared to the same period in 2021, resulting in $2.6 million of other income in 2022, primarily due to the exclusion of the $37.4 million of changes in fair value of our convertible promissory notes and warrant liability in the current year, as these instruments were converted in connection with the IPO in 2021. Additionally, we earned an additional $2.6 million of interest income in 2022 compared to 2021 due to increases in interest rates during 2022.

Liquidity and Capital Resources

Since we were incorporated in 2016, we have devoted substantially all of our resources to research and product development activities, initiating commercialization of our G4, establishing and maintaining our intellectual property portfolio, hiring personnel, raising capital, building our commercial infrastructure and providing general and administrative support for these activities. Since our incorporation, we have incurred significant operating losses and negative cash flows from operations and have only recently recognized any revenue from product sales. From incorporation in June 2016 through December 31, 2022, we have financed our operations primarily through private placements of convertible preferred stock and convertible promissory notes and the net proceeds from our IPO. We expect to continue to incur significant and increasing losses and do not expect positive cash flows from operations for the foreseeable future, and our net losses may fluctuate significantly from period to period depending on the timing of and expenditures on our commercialization and research and development activities. In particular, we expect to incur increasing costs in the near term in connection with the commercialization of the G4, which includes, among others, increasing our sales and marketing and other commercialization efforts to drive market adoption and scaling our manufacturing and customer support capabilities. During the year ended December 31, 2022, we incurred a net loss of $90.9 million and used $87.1 million of cash in operations. As of December 31, 2022, we had an accumulated deficit of $242.8 million. As of December 31, 2022, we had cash, cash equivalents and short-term investments of $244.6 million.

Our capital obligations include minimum lease payments and minimum payments under our Loan Agreement with Silicon Valley Bank totaling $7.4 million in 2023 and $10.4 million in 2024. Our capital obligations also include payments under our License Agreement with Columbia. Under the License Agreement, we will pay a low six-digit annual license fee for so long as the License Agreement remains in force. For any products within the scope of the License Agreement that we commercialize, we are required to pay royalties ranging from low to mid-single digits on net sales of Patent Products and low single digit royalty rates on net sales of Other Products, as such terms are defined in the License Agreement. We can credit our yearly annual license fee against any yearly royalty fees payable to Columbia. Additionally, if we receive any income in connection with any sublicenses, we must pay Columbia a high single-digit percentage of that income. Finally, the License Agreement provides for payments to Columbia based on our achievement of certain development and commercialization milestones, which could total up to $3.9 million over the life of the License Agreement. We have accrued approximately $0.4 million toward these milestones as of December 31, 2022. Our leases and the License Agreement are further described in Note 9 to the audited financial statements contained elsewhere in this report. The Loan Agreement is further described in Note 8 to the audited financial statements contained elsewhere in this report.

Our future capital requirements will depend on many factors including executing on our commercialization plans, continuing to invest into our research and development projects and other factors described in the section titled “Risk Factors” elsewhere in this report. Based on our current operating plan, we believe our existing cash, cash equivalents and short-term investments will enable us to fund our planned operations for at least 12 months from the issuance date this report. We have based our estimate of capital requirements on assumptions that may prove to be incorrect, and, as we continue to face challenges and uncertainties, our available capital resources may be consumed more rapidly than currently expected due to a variety of factors, including those factors described in the section titled “Risk Factors” elsewhere in this report.

We may need to seek additional financing in the future to support our operations, research and development activities and commercialization plans. If we are not able to generate sufficient revenue to finance our cash requirements, if the maximum availability of $35.5 million under our Loan Agreement is not sufficient to finance our cash requirements, or if we are not able to raise additional capital or enter into financing agreements or arrangements when required on favorable terms, or at all, we may have to delay, reduce the scope of, or discontinue one or more development programs, delay potential commercialization or reduce the scope of sales or marketing activities and pursue other cost cutting measures, including the reduction of headcount, scope of operations and planned capital expenditures, which may have a material adverse effect on our business, results of operations, financial condition or ability to fund our scheduled obligations on a timely basis or continue as a going concern. We cannot assure you that we will ever be profitable or generate positive cash flow from operating activities or that, if we achieve profitability, we will be able to sustain it.

On July 19, 2022, we filed a shelf registration statement (the “Shelf Registration Statement”) on Form S-3 with the Securities and Exchange Commission (“SEC”) (that was declared effective by the SEC on July 27, 2022), which permits us to offer up to $250 million of common stock, preferred stock, debt securities and warrants in one or more offerings and in any combination, including in units from time to time. Our Shelf Registration Statement is intended to provide us with additional flexibility to raise capital in the future for general corporate purposes. As part of this Shelf Registration Statement, we also filed a sales agreement prospectus covering the “at the market” offerings, pursuant to which we may offer and sell up to $100 million of our common stock under a sales agreement (the “Sales Agreement”) with Cowen and Company, LLC. Through the date of this filing, we have not sold any shares of our common stock in “at the market” transactions pursuant to the Sales Agreement.

Cash Flows

The following table sets forth the primary sources and uses of cash, cash equivalents and restricted cash for each of the periods presented below:

	Year Ended December 31,	
	2022	2021
	(in thousands)	
Net cash provided by (used in):		
Operating activities	$ (87,094)	$ (51,701)
Investing activities	(39,566)	(130,861)
Financing activities	901	372,128
Net (decrease) increase in cash and cash equivalents and restricted cash	$ (125,759)	$ 189,566

Operating Activities

During the year ended December 31, 2022, cash used in operating activities was $87.1 million attributable to a net loss of $90.9 million and a net increase in our working capital of $16.8 million primarily due to increased inventory to support projected demand, offset by non-cash charges of $20.6 million. Non-cash charges primarily consisted of $13.7 million of stock-based compensation expense, $3.6 million of amortization of our right-of-use lease assets and $2.4 million of depreciation.

During the year ended December 31, 2021, cash used in operating activities was $51.7 million attributable to a net loss of $98.8 million and a net change in our working capital of $2.9 million, offset by non-cash charges of $50.0 million Non-cash charges primarily consisted of a $35.2 million change in the fair value of the 2021 Convertible Notes, $9.2 million of stock-based compensation expense, and a $2.2 million change in the fair value of warrants.

Investing Activities

During the year ended December 31, 2022, cash used in investing activities was $39.6 million, which related to purchases of available-for-sale securities of $174.7 million, net of proceeds from maturities and sales of available-for-sale securities of $141.2 million, in addition to $4.9 million in payments related to purchases of property and equipment.

During the year ended December 31, 2021, cash used in investing activities was $130.9 million, which related to purchases of available-for-sale securities of $195.7 million, net of proceeds from maturities and sales of available-for-sale securities of $69.7 million, in addition to $4.9 million in payments related to purchases of property and equipment.

Financing Activities

During the year ended December 31, 2022, cash provided by financing activities was approximately $0.9 million, which was primarily related to proceeds from the issuance of common stock under the Company's employee stock purchase plan of $1.2 million, offset by repurchases under the Company's equity incentive plan, net of proceeds, of $0.3 million.

During the year ended December 31, 2021, cash provided by financing activities was $372.1 million, which was primarily related to the net proceeds from our IPO of $237.2 million, proceeds from the issuance of the 2021 Convertible Notes of $130.5 million and cash received related to exercise of stock options of $3.7 million.

Indebtedness

In November 2019, we entered into a loan and security agreement with Silicon Valley Bank pursuant to which Silicon Valley Bank agreed to lend us up to $15.0 million in a series of term loans (the "2019 SVB Loan"). Contemporaneously, we borrowed $2.5 million in the first of three draw-downs available under the 2019 SVB Loan. In March 2020, we borrowed an additional $7.5 million as a second draw. The 2019 SVB Loan was previously set to mature on September 1, 2023 and bore interest at an annual rate equal to the greater of (a) 0.65% above the prime rate or (b) 5.90%. Payment on the 2019 SVB Loan was for interest only through September 30, 2021. In addition, a final payment equal to the original principal amount of each advance multiplied by 5.50% was to be due on the maturity date.

On September 30, 2021, we refinanced our 2019 SVB Loan. In connection with the refinancing, we entered into the Loan Agreement (the "2021 SVB" Loan together with the 2019 SVB Loan, the "SVB Loans") with Silicon Valley Bank. The 2021 SVB Loan provides for term loans in an aggregate principal amount of up to $35.5 million to be delivered in three tranches. The tranches consist of: (i) a term loan advance to us in an aggregate principal amount of $10.5 million on the loan closing date (the "First Tranche"); (ii) an additional term loan advance available to us through September 30, 2022 in an aggregate principal amount of $15.0 million; and (iii) subject to Silicon Valley Bank's approval, our right to request that Silicon Valley Bank make an additional term loan advance in an aggregate principal amount of $10.0 million. The proceeds from the First Tranche were used to repay in full the existing indebtedness under the 2019 SVB Loan. The 2021 SVB Loan matures on September 1, 2026 and bears interest at an annual rate equal to the greater of (a) 0.75% plus the prime rate as reported in The Wall Street Journal and (b) 4.00%. The 2021 SVB Loan has an initial interest-only period of 36 months. In addition, a final payment ("Final Payment Fee") equal to the original principal amount of each advance multiplied by 4.00% will be due on the maturity date.

On September 30, 2022, the Company entered into an amendment to the 2021 SVB Loan (the "2022 SVB Loan Amendment"). The 2022 SVB Loan Amendment extended the period to draw down the additional tranches totaling $25.0 million from September 30, 2022 to March 31, 2024, provided that in order for the Company to access the Second Tranche availability the Company must achieve a six-month trailing revenue hurdle. The 2022 SVB Loan Amendment was accounted for as a debt modification, rather than an extinguishment, based on a comparison between the present value of the cash flows under the terms of the debt immediately before and after the amendment, which resulted in a change of such cash flows of less than 10%.

We are subject to customary affirmative and restrictive covenants under the Loan Agreement. Our obligations under the Loan Agreement are secured by a first priority security interest in substantially all of our current and future assets, other than intellectual property. We have agreed not to encumber our intellectual property assets, except as permitted by the Loan Agreement. The Loan Agreement provides for events of default customary for term loan facilities of this type, including but not limited to: non-payment; breaches or defaults in the performance of covenants or representations and warranties; bankruptcy and other insolvency events; and the occurrence of a material adverse change as defined in the SVB Loan. After the occurrence of an event of default, Silicon Valley Bank may, among other remedies, accelerate payment of all obligations.

Critical Accounting Policies, Significant Judgments and Use of Estimates

Our management's discussion and analysis of our financial condition and results of operations is based on our financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles ("GAAP"). The preparation of financial statements requires us to make estimates and judgements that affect the reported amounts of assets, liabilities, costs and expenses and related disclosures. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances. Changes in estimates are reflected in reported results for the period in which they become known. Actual results could differ significantly from the estimates we make.

Leases

We adopted Accounting Standards Codification ("ASC") Topic 842, Leases ("ASC 842"), effective January 1, 2022. ASC 842 requires us to recognize on the balance sheet lease liabilities and corresponding right-of-use ("ROU") lease assets for our operating leases where we are the lessee.

We determine if an arrangement is or contains a lease at contract inception. Lease liabilities represent our obligation to make payments under our operating leases. ROU lease assets represent our right to use assets under our operating leases. We determine the value of lease liabilities and ROU lease assets on a lease-by-lease basis. A lease liability is recognized at the commencement date of an operating lease based on the present value of the future lease payments over the expected lease term. A corresponding ROU lease asset is recognized at the commencement date of an operating lease based on the value of the lease liability, adjusted for any lease incentives received, any initial direct costs incurred and any lease payments made at or before the lease commencement date.

We calculate the present value of lease payments using the discount rate implicit in the lease, unless that rate cannot be readily determined. In that case, we use our incremental borrowing rate based on information available at the date of lease commencement. The incremental borrowing rate is the estimated rate of interest that we would pay to borrow, on a collateralized basis, an amount equal to the lease payments over the expected lease term. Determining the incremental borrowing rate requires using assumptions that require management's judgment. The assumptions used in estimating the incremental borrowing rate include our recent borrowing activity and industry data for loans with similar terms. Changes to any of these assumptions would impact our estimate of our incremental borrowing rate and thus could significantly impact the value recorded for our lease liabilities and ROU lease assets.

Stock-based Compensation

We account for stock-based compensation by measuring and recognizing compensation expense for all stock-based awards made to employees and non-employees based on estimated grant-date fair values. We use the straight-line method to recognize compensation cost over the required service period of the award, which is generally the vesting period of the award. We recognize actual forfeitures by reducing the stock-based compensation in the same period that the forfeitures occur. We estimate the fair value of stock-based option awards using the Black-Scholes option pricing model. The Black-Scholes option pricing model requires the input of subjective assumptions, including the fair value of common stock, expected term, expected volatility, risk-free interest rate and expected dividend yield, which are described in greater detail below.

Inputs to the Black-Scholes option pricing model are subjective and generally require the use of judgment. Changes in the assumptions can materially affect how much stock-based compensation is recognized. These inputs are as follows:

- *Fair value of common stock*—For awards granted prior to the IPO, when there was no public market for our common stock, the grant date fair value of our common stock was determined by our board of directors based in part on valuations of our common stock prepared by a third-party valuation specialist. For awards granted after the IPO, the fair value of common stock is the closing price per share of our common stock on the grant date as reported on the Nasdaq Global Select Market.
- *Expected term*—The expected term represents the average period that options granted are expected to be outstanding and is determined using the simplified method (based on the mid-point between the weighted-average vesting period and the end of the contractual term). We use the simplified method because we have concluded that our historical option exercise experience does not provide a reasonable basis to estimate expected term.
- *Expected volatility*—We had no publicly available stock price information prior to our IPO and have limited publicly available stock price information since our IPO; therefore, we used the historical volatility of the stock price of similar publicly traded companies. The historical volatility is calculated based on a period of time commensurate with the expected term.
- *Risk-free interest rate*—The risk-free interest rate is based on the U.S. Treasury zero coupon issues in effect at the time of grant for periods corresponding with the expected term.
- *Expected dividend yield*—We have never paid dividends and do not intend to pay dividends in the foreseeable future. Therefore, we used an expected dividend yield of zero.

Assumptions we used in applying the Black-Scholes option pricing model to determine the estimated fair value of our stock options granted involve inherent uncertainties and the application of significant judgment. As a result, if factors or expected outcomes change and we use significantly different assumptions or estimates, our equity-based compensation could be materially different.

We expect to continue to grant stock options and may grant other stock-based awards in the future, and to the extent that we do, our stock-based compensation expense recognized in future periods will increase.

Recent Accounting Pronouncements

A description of recent accounting pronouncements that may potentially impact our financial position, results of operations or cash flows is disclosed in Note 2 to our financial statements included elsewhere in this report.

Off–Balance Sheet Arrangements

Since our inception, we have not engaged in any off–balance sheet arrangements, as such term is defined in the rules and regulations of the SEC.

JOBS Act

We are an "emerging growth company" as defined in the Jumpstart Our Business Startups Act of 2012, as amended (the "JOBS Act"). We will remain an emerging growth company until the earliest to occur of: (i) the last day of the fiscal year in which we have more than $1.07 billion in annual gross revenue; (ii) the date we qualify as a "large accelerated filer" as defined in Rule 12b-2 under the Exchange Act, with at least $700 million of equity securities held by non-affiliates; (iii) the issuance, in any three-year period, by us of more than $1.0 billion in non-convertible debt securities; or (iv) December 31, 2026. As a result of this status, we have taken advantage of certain exemptions from various reporting requirements in this report that are applicable to other publicly traded entities that are not emerging growth companies and may elect to take advantage of other exemptions from reporting requirements in our future filings with the SEC. In particular, in this report, these exemptions include:

- the option to present only two years of audited financial statements and only two years of Management's Discussion and Analysis of Financial Condition and Results of Operations;
- not being required to comply with the auditor attestation requirements of Section 404(b) of the Sarbanes-Oxley Act of 2002, as amended;
- not being required to submit certain executive compensation matters to stockholder advisory votes, such as "say-on-pay," "say-on-frequency," and "say-on-golden parachutes"; and
- not being required to disclose certain executive compensation-related items such as the correlation between executive compensation and performance and comparisons of the chief executive officer's compensation to median employee compensation.

As a result, we do not know if some investors will find our common stock less attractive. The result may be a less active trading market for our common stock, and the price of our common stock may become more volatile.

In addition, Section 107 of the JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards, delaying the adoption of these accounting standards until they would apply to private companies. We have elected to avail ourselves of this exemption and, as a result, we will adopt new or revised accounting standards on the relevant dates on which adoption of such standards is required for private companies. Accordingly, the information contained herein may be different than the information you receive from other public companies.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk

We are exposed to various market risks, including changes in commodity prices and interest rates. Market risk is the potential loss arising from adverse changes in market rates and prices. Prices for our products are largely denominated in U.S. dollars and, as a result, we do not face significant risk with respect to foreign currency exchange rates.

Interest Rate Risk

Generally, our exposure to market risk has been primarily limited to interest income sensitivity, which is affected by changes in the general level of U.S. interest rates, particularly because the majority of our investments are in short-term debt securities. The primary objective of our investment activities is to preserve principal while at the same time maximizing the income we receive without significantly increasing risk. To minimize risk, we maintain our portfolio of cash, cash equivalents and short-term investments in a variety of interest-bearing instruments, which have included U.S. government and agency securities, high-grade U.S. corporate bonds, asset-backed securities and money market funds. Declines in interest rates, however, would reduce future investment income. A 10% relative change in interest rates during any of the periods presented would not have had a material impact on our financial statements.

Inflation Risk

We do not believe that inflation has had a material adverse effect on our business, financial condition or results of operations. 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 adversely affect our business, financial condition and results of operations.

Item 8. Financial Statements and Supplementary Data

Index to Financial Statements

Report of Independent Registered Public Accounting Firm

To the Stockholders and the Board of Directors of Singular Genomics Systems, Inc.

Opinion on the Financial Statements

We have audited the accompanying balance sheets of Singular Genomics Systems, Inc. (the Company) as of December 31, 2022 and 2021, the related statements of operations and comprehensive loss, preferred stock and stockholders' equity (deficit), and cash flows for each of the two years in the period ended December 31, 2022, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2022 and 2021, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2022, in conformity with U.S. generally accepted accounting principles.

Adoption of ASU No. 2016-02

As discussed in Note 2 to the financial statements, the Company changed its method of accounting for leases in 2022 due to the adoption of Accounting Standards Update (ASU) No. 2016-02, Leases (Topic 842), and the related amendments.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. 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 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 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 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 financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ Ernst & Young LLP

We have served as the Company's auditor since 2018.

San Diego, California
March 2, 2023

Singular Genomics Systems, Inc.

Balance Sheets
(In thousands, except share and par value amounts)

	December 31,	
	2022	**2021**
Assets		
Current assets:		
Cash and cash equivalents	$ 74,266	$ 201,049
Short-term investments	170,310	138,174
Accounts receivable	913	-
Inventory	18,221	3,011
Prepaid expenses and other current assets	4,722	5,526
Total current assets	268,432	347,760
Right-of-use lease assets	45,896	-
Property and equipment, net	10,784	6,072
Restricted cash	1,711	687
Other noncurrent assets	1,152	1,129
Total assets	$ 327,975	$ 355,648
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 3,099	$ 2,348
Accrued expenses	4,583	4,278
Lease liabilities, current	6,323	-
Other current liabilities	113	118
Total current liabilities	14,118	6,744
Lease liabilities, noncurrent	42,456	-
Long-term debt, net of issuance costs	10,065	9,904
Other noncurrent liabilities	1,015	2,827
Total liabilities	67,654	19,475
Commitments and contingencies (Note 9)		
Stockholders' equity:		
Series A common stock equivalent convertible preferred stock, $0.0001 par value; 7,000 shares authorized, 2,500 and no shares issued and outstanding at December 31, 2022 and December 31, 2021, respectively	-	-
Common stock, $0.0001 par value; 400,000,000 shares authorized, 71,854,688 and 72,438,742 shares outstanding at December 31, 2022 and December 31, 2021, respectively	7	7
Additional paid-in capital	503,926	488,200
Accumulated other comprehensive loss	(837)	(138)
Accumulated deficit	(242,775)	(151,896)
Total stockholders' equity	260,321	336,173
Total liabilities and stockholders' equity	$ 327,975	$ 355,648

The accompanying notes are an integral part of these financial statements.

Singular Genomics Systems, Inc.

Statements of Operations
(In thousands, except share and per share amounts)

	Year Ended December 31,	
	2022	**2021**
Revenue	$ 765	$ -
Cost of revenue	789	-
Gross margin	(24)	-
Operating expenses:		
Research and development	46,199	32,655
Selling, general and administrative	47,264	28,624
Total operating expenses	93,463	61,279
Loss from operations	(93,487)	(61,279)
Other income (expense):		
Interest expense	(763)	(846)
Change in fair value of convertible promissory notes	-	(35,199)
Change in fair value of warrant liability	-	(2,180)
Interest and other income	3,371	733
Total other income (expense)	2,608	(37,492)
Net loss	$ (90,879)	$ (98,771)
Net loss per share:		
Basic and diluted net loss per share	$ (1.28)	$ (2.10)
Weighted-average shares used to compute basic and diluted net loss per share	71,148,076	47,023,048

The accompanying notes are an integral part of these financial statements.

Singular Genomics Systems, Inc.

Statements of Comprehensive Loss
(In thousands)

	Year Ended December 31,	
	2022	**2021**
Net loss	$ (90,879)	$ (98,771)
Other comprehensive loss:		
Unrealized loss on available-for-sale securities	(699)	(155)
Comprehensive loss	$ (91,578)	$ (98,926)

The accompanying notes are an integral part of these financial statements.

Singular Genomics Systems, Inc.

Statements of Preferred Stock and Stockholders' Equity (Deficit)

(In thousands, except share data)

	Series Seed Convertible Preferred Stock		Series A Convertible Preferred Stock		Series B Convertible Preferred Stock		Preferred Stock		Common Stock		Additional Paid-In	Accumulated Other Comprehensive	Accumulated	Total Stockholders' Equity
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Capital	Gain (Loss)	Deficit	(Deficit)
Balance at December 31, 2020	6,520,790	$ 4,486	12,932,429	$ 19,908	19,373,169	$ 44,790	-	$ -	10,816,937	$ 1	$ 1,552	$ 17	$ (53,125)	$ (51,555)
Vesting of common stock issued for early exercise of stock options							-	-	1,279,865	-	798	-	-	798
Issuance of common stock in connection with exercise of stock options							-	-	2,077,291	-	1,160	-	-	1,160
Stock-based compensation									-	-	9,231	-	-	9,231
Conversion of preferred stock into common stock	(6,520,790)	(4,486)	(12,932,429)	(19,908)	(19,373,169)	(44,790)	-	-	38,826,388	4	69,180	-	-	69,184
Conversion of the convertible promissory notes into common stock							-	-	7,531,777	1	165,698	-	-	165,699
Issuance of common stock upon initial public offering, net of issuance costs									11,730,000	1	237,198	-	-	237,199
Cashless exercise of common stock warrant							-	-	117,088	-	2,631	-	-	2,631
Unrealized loss on available- for-sale marketable securities							-	-	-	-	-	(155)	-	(155)
Issuance of common stock in connection with Employee Stock Purchase Program									59,396	-	752	-	-	752
Net loss							-	-	-	-	-	-	(98,771)	(98,771)
Balance at December 30, 2021	-	$ -	-	$ -	-	$ -	-	$ -	72,438,742	$ 7	$ 488,200	$ (138)	$ (151,896)	$ 336,173
Exchange of common stock for Series A common stock equivalent convertible preferred stock							2,500	-	(2,500,000)	-	-	-	-	-
Vesting of common stock issued for early exercise of stock options	-	-	-	-	-	-	-	-	1,015,695	-	705	-	-	705
Issuance of common stock in connection with exercise of stock options	-	-	-	-	-	-	-	-	385,824	-	172	-	-	172
Issuance of common stock in connection with Employee Stock Purchase Program	-	-	-	-	-	-	-	-	514,427	-	1,180	-	-	1,180
Stock-based compensation	-	-	-	-	-	-	-	-	-	-	13,669	-	-	13,669
Unrealized loss on available- for-sale marketable securities	-	-	-	-	-	-	-	-	-	-	-	(699)	-	(699)
Net loss	-	-	-	-	-	-	-	-	-	-	-	-	(90,879)	(90,879)
Balance at December 30, 2022	-	$ -	-	$ -	-	$ -	2,500	$ -	71,854,688	$ 7	$ 503,926	$ (837)	$ (242,775)	$ 260,321

The accompanying notes are an integral part of these financial statements.

Singular Genomics Systems, Inc.

Statements of Cash Flows
(In thousands)

	Year Ended December 31,	
	2022	**2021**
Operating activities		
Net loss	$ (90,879)	$ (98,771)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	13,669	9,231
Amortization of right-of-use lease assets	3,601	-
Amortization of premium on short-term investments	676	1,865
Depreciation	2,431	1,133
Accretion of debt issuance costs	165	279
Loss on disposal of property and equipment	60	94
Change in fair value of convertible promissory notes	-	35,199
Change in fair value of warrant liability	-	2,180
Changes in operating assets and liabilities:		
Accounts receivable	(913)	-
Inventory	(13,487)	-
Prepaid expenses and other current assets	604	(6,851)
Other noncurrent assets	(892)	(1,048)
Accounts payable	(1,168)	1,854
Accrued expenses	79	2,686
Other current liabilities	81	(176)
Lease liabilities	(1,208)	-
Other noncurrent liabilities	87	624
Net cash used in operating activities	(87,094)	(51,701)
Investing activities		
Purchases of short-term investments	(174,713)	(195,684)
Maturities of short-term investments	119,647	33,688
Sales of short-term investments	21,522	35,999
Purchases of property and equipment	(6,022)	(4,864)
Net cash used in investing activities	(39,566)	(130,861)
Financing activities		
Proceeds from issuance of common stock under employee stock purchase plan	1,180	752
Proceeds from issuance of common stock under equity incentive plans	171	3,615
Repurchases of common stock under equity incentive plans	(450)	(38)
Proceeds from initial public offering, net of issuance costs	-	237,199
Proceeds from issuance of convertible promissory notes	-	130,500
Proceeds from issuance of debt	-	10,500
Repayments of debt principal and issuance costs in connection with refinancing	-	(10,400)
Net cash provided by financing activities	901	372,128
Net (decrease) increase in cash and cash equivalents and restricted cash	(125,759)	189,566
Cash and cash equivalents and restricted cash, beginning of year	201,736	12,170
Cash and cash equivalents and restricted cash, end of year	$ 75,977	$ 201,736
Supplemental disclosure for cash activities		
Interest paid	$ 561	$ 569
Supplemental disclosure for non-cash activities		
Initial lease liability recognized upon lease commencements during the period	$ 43,231	$ -
Initial lease liability recognized upon adoption of ASC 842	$ 7,074	$ -
Purchases of inventory included in accounts payable	$ 1,601	$ -
Noncurrent deposit transferred to property and equipment	$ 759	$ -
Vesting of common stock issued for early exercise of stock options	$ 705	$ 798
Reduction of lease liability for lease termination	$ 334	$ -
Purchases of property and equipment included in accounts payable	$ 318	$ 67
Purchases of inventory included in accrued expenses	$ 226	$ -
Inventory transferred to property and equipment	$ 104	$ -
Conversion of convertible promissory notes to common stock	$ -	$ 165,699
Conversion of preferred stock to common stock	$ -	$ 69,184
Cashless warrant exercise	$ -	$ 300

The accompanying notes are an integral part of these financial statements.

Singular Genomics Systems, Inc.

Notes to Financial Statements

1. Business

Description of Business

Singular Genomics Systems, Inc. (the "Company") is a life science technology company that develops next-generation sequencing and multiomics technologies. The commercially available G4 Sequencing Platform is a powerful, highly versatile benchtop genomic sequencer designed to produce fast and accurate results. In development, the PX system leverages the Company's proprietary sequencing technology, applying it as an *in situ* readout to look at RNA and proteins in single cells and tissue. With these products, the Company's mission is to empower researchers and clinicians to advance science and medicine.

The Company was incorporated in the state of Delaware in June 2016 and has its principal operations in San Diego, California.

Initial Public Offering

On June 1, 2021, the Company closed its initial public offering ("IPO") in which it sold 11,730,000 shares of common stock (which included 1,530,000 shares that were sold pursuant to the full exercise of the IPO underwriters' option to purchase additional shares) at a public offering price of $22.00 per share. The Company received net proceeds of approximately $237.2 million after deducting offering costs, underwriting discounts and commissions of $20.9 million.

Concurrent with the closing of the IPO:

- 38,826,388 outstanding shares of convertible preferred stock converted into an equivalent number of shares of common stock;
- the outstanding principal and interest amount of convertible promissory notes (the "2021 Convertible Notes") converted into 7,531,777 shares of common stock; and
- a warrant to purchase 129,156 shares of convertible preferred stock (the "SVB Warrant") was automatically adjusted to become a warrant to purchase an equivalent number of shares of common stock.

Liquidity and Capital Resources

The Company has incurred net losses since inception and, as of December 31, 2022 and December 31, 2021, had an accumulated deficit of $242.8 million and $151.9 million, respectively. The Company has a limited operating history and the revenue and income potential of the Company's business are unproven. From incorporation in June 2016 through December 31, 2022, substantially all of the Company's operations have been funded by the sales of equity securities and issuances of debt. As of December 31, 2022, the Company had cash, cash equivalents and short-term investments of $244.6 million. The Company believes that its cash, cash equivalents and short-term investments as of December 31, 2022 are sufficient to fund its operations for at least 12 months from the issuance date of the accompanying financial statements.

2. Basis of Presentation and Summary of Significant Accounting Policies

Basis of Presentation and Use of Estimates

The accompanying financial statements have been prepared in accordance with U.S. generally accepted accounting principles ("GAAP"). The preparation of the Company's financial statements requires management to make estimates and assumptions that impact the reported amounts of assets, liabilities and expenses and the disclosure of contingent assets and liabilities in the Company's financial statements and accompanying notes. Although these estimates are based on the Company's knowledge of current events and actions it may undertake in the future, actual results may significantly differ from these estimates and assumptions. For the year ended December 31, 2021, significant estimates and assumptions include the fair value of the 2021 Convertible Notes, the fair value of the liability for the SVB Warrant, the fair value of the Company's preferred and common stock and stock-based compensation. After December 31, 2021, significant estimates and assumptions include the value of lease liabilities and right-of-use lease assets.

Cash, Cash Equivalents and Restricted Cash

Cash and Cash Equivalents

Cash and cash equivalents include cash readily available in checking, savings, money market funds and sweep accounts. The Company considers all highly liquid investments with an original maturity of three months or less at the date of purchase to be cash equivalents.

Restricted Cash

Restricted cash is held in a separate restricted bank account as the collateral for the security deposits on three executed lease agreements. The Company has classified restricted cash as noncurrent on its balance sheets.

The following table provides a summary of cash, cash equivalents and restricted cash reported within the balance sheets (in thousands):

	December 31,	
	2022	2021
Cash and cash equivalents	$ 74,266	$ 201,049
Restricted cash	1,711	687
Total	$ 75,977	$ 201,736

Concentration of Credit Risk

Financial instruments, which potentially subject the Company to a concentration of credit risk, consist primarily of cash, cash equivalents and short-term investments. The Company maintains deposits in federally insured 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 institutions in which those deposits are held.

Short-term Investments

As of December 31, 2022 and December 31, 2021, short-term investments primarily consisted of U.S. Treasury securities, asset-backed securities and corporate debt securities. The Company classifies its investments in securities as available-for-sale because, for accounting purposes, they are not considered to be either held-to-maturity securities or trading securities. They are not considered to be held-to-maturity securities because the Company does not have the positive intent to hold those securities to maturity. They are not considered trading securities because they are not acquired with the intent of selling them within hours or days. The Company's investments in securities are classified as current as they are available to use to fund current operations, and the Company has the ability and intent to do so. Short-term investments are carried at fair value with the unrealized gains and losses included in other comprehensive income (loss) as a component of stockholders' equity until realized. The amortized cost of debt securities is adjusted for amortization of premiums and accretion of discounts to maturity and recorded as interest income. Realized gains and losses are determined using the specific identification method and are included in other income (expense).

The Company evaluates its investments in securities that are in an unrealized loss position quarterly to determine if those securities are other-than-temporarily impaired. If the Company intends to sell or if it is more likely than not that the Company will be required to sell those securities prior to the recovery of their book value, then those securities would be considered other-than-temporarily-impaired, and the Company would record this impairment as a loss through other income (expense). During the years ended December 31, 2022 and 2021, the Company concluded that none of its investments in securities were other-than-temporarily-impaired and thus recorded no impairment losses for its investments in securities.

The following tables summarize the short-term investments held at December 31, 2022 and December 31, 2021 (in thousands):

	December 31, 2022		
	Amortized Cost	Gross Unrealized Losses	Estimated Fair Value
U.S. treasury securities	$ 62,776	$ (244)	$ 62,532
Asset-backed securities	6,351	(40)	6,311
Corporate debt securities	102,020	(553)	101,467
Total	$ 171,147	$ (837)	$ 170,310

	December 31, 2021		
	Amortized Cost	Gross Unrealized Losses	Estimated Fair Value
Asset-backed securities	$ 21,172	$ (25)	$ 21,147
Corporate debt securities	117,140	(113)	117,027
Total	$ 138,312	$ (138)	$ 138,174

The following table summarizes contractual maturities of available-for-sale securities held at December 31, 2022 and December 31, 2021 (in thousands):

	December 31,	
	2022	2021
Due within one year	$ 155,920	$ 94,085
After one but within five years	14,390	44,089
Total	$ 170,310	$ 138,174

Property and Equipment, Net

Property and equipment, net, which consists of lab equipment, computers and software, furniture and fixtures, leasehold improvements and construction in process, are stated at cost less accumulated depreciation. Depreciation is calculated using the straight-line method over the estimated useful lives of the assets (generally three to five years). Leasehold improvements are amortized over the remaining life of the lease or the useful life of the asset, whichever is shorter. Construction in process is not depreciated until placed into service. Repairs and maintenance costs are charged to expense as incurred.

Inventory

Inventory includes raw materials, which are goods to be consumed directly or indirectly in production, work in process, which are goods in the course of production, and finished goods, which are goods awaiting sale. Inventory is recorded at the lower of cost or net realizable value. Costs are based on standard costs that are adjusted regularly to reflect current conditions so that at the balance-sheet date standard costs reasonably approximate costs under a first-in, first-out basis. Standard costs include acquisition and production costs. Raw materials include inventories that may be used in research and development activities, and such items are expensed as consumed or capitalized as property and equipment and depreciated.

Inventory in the prior year's financial statements have been reclassified to conform to the current presentation on the balance sheets and statements of cash flows. No subtotals in the prior year financial statements were impacted as a result.

Impairment of Long-lived Assets

Long-lived assets consist primarily of property and equipment and right-of-use lease assets. The Company reviews long-lived assets for impairment whenever events or changes in circumstances indicate the carrying amount of an asset may not be recoverable. Recoverability of assets to be held and used is measured by a comparison of the carrying amount of an asset to the future undiscounted net cash flows expected to be generated by the asset. If such assets are considered to be impaired, the impairment to be recognized is measured as the amount by which the carrying amount of the assets exceeds the fair value of the assets. Fair value would be assessed using discounted cash flows or other appropriate measures of fair value. The Company did not recognize any impairment losses for the year ended December 31, 2022 and December 31, 2021, respectively.

Fair Value Measurements

Certain assets and liabilities are carried at fair value under GAAP and consist primarily of cash, cash equivalents, short-term investments, restricted cash, accounts payable, accrued liabilities, the 2021 Convertible Notes and the SVB Warrant. The carrying amounts of cash, cash equivalents, accounts payable, and accrued liabilities approximate their fair values due to the short-term nature of these instruments. None of the Company's non-financial assets or liabilities are recorded at fair value on a recurring basis.

As permitted under Accounting Standards Codification ("ASC") 825, *Financial Instruments* ("ASC 825"), the Company elected the fair value option to account for its 2021 Convertible Notes and SVB Warrant. Changes in the fair value of the 2021 Convertible Notes and the SVB Warrant were recorded in the statements of operations. As a result of applying the fair value option, direct costs and fees related to the 2021 Convertible Notes were recognized as incurred and not deferred. In June 2021, in connection with the IPO completion, the 2021 Convertible Notes converted into the Company's common stock and the SVB Warrant was automatically adjusted into a warrant to purchase an equivalent number of shares of common stock.

There are significant judgments and estimates inherent in the determination of the fair value of these liabilities. If the Company had made different assumptions including, among others, those related to the timing and probability of various corporate scenarios, discount rates, volatilities and exit valuations, the carrying values of the 2021 Convertible Notes and SVB Warrant, and net loss and net loss per share, could have been significantly different.

Leases

The Company adopted Accounting Standards Codification ("ASC") Topic 842, *Leases* ("ASC 842"), effective January 1, 2022. ASC 842 requires the Company to recognize on the balance sheet lease liabilities and corresponding right-of-use ("ROU") lease assets for its operating leases where the Company is the lessee. The initial impact of the adoption is discussed below in the section titled "Recent Accounting Pronouncements—Adopted."

The Company determines if an arrangement is or contains a lease at contract inception. Lease liabilities represent the Company's obligation to make payments under its operating leases. ROU lease assets represent the Company's right to use assets under its operating leases. The Company determines the value of lease liabilities and ROU lease assets on a lease-by-lease basis. A lease liability is recognized at the commencement date of an operating lease based on the present value of the future lease payments over the expected lease term. A corresponding ROU lease asset is recognized at the commencement date of an operating lease based on the value of the lease liability, adjusted for any lease incentives received, any initial direct costs incurred and any lease payments made at or before the lease commencement date. The Company made a policy election to not recognize lease liabilities and ROU lease assets for operating leases with an expected lease term of twelve months or less.

The Company calculates the present value of lease payments using the discount rate implicit in the lease, unless that rate cannot be readily determined. In that case, the Company uses its incremental borrowing rate based on information available at the date of lease commencement. The incremental borrowing rate is the estimated rate of interest that the Company would pay to borrow, on a collateralized basis, an amount equal to the lease payments over the expected lease term.

After lease commencement, the Company measures its operating leases as follows: (i) the lease liability based on the present value of the remaining lease payments using the incremental borrowing rate determined at lease commencement; and (ii) the ROU lease asset based on the remeasured lease liability, adjusted for any unamortized lease incentives received, any unamortized initial direct costs and the cumulative difference between lease expense and amounts paid under the lease. Lease expense is recognized on a straight-line basis over the expected lease term. Any lease incentives received and any initial direct costs are amortized on a straight-line basis over the expected lease term. Variable lease payments such as those related to property taxes, insurance and common area maintenance are recognized as expense when incurred.

Revenue Recognition

The Company generates revenue from sales of products which consist of the G4 instrument, related consumable flow cell kits and services. Revenue from instrument sales is recognized generally upon customer acceptance. Revenue from consumables sales is recognized generally upon shipment to the customer. Revenue from services, which are primarily comprised of assurance-type services, is recognized over the applicable service period.

Revenue is recorded net of discounts and sales taxes. The Company invoices its customers for instruments generally upon acceptance, for consumables generally on delivery, and for services generally in advance of the service period. Invoice terms are generally net 30 days. Cash received from customers in advance of revenue recognition is recorded as a contract liability. The Company's contracts with its customers generally do not include rights of return or a significant financing component.

The Company regularly enters into contracts that include a combination of products and services, which are distinct within the context of the contract and are accounted for as separate performance obligations. The transaction price is allocated to each performance obligation in proportion to its standalone selling price. Until the Company has sufficient volume of historical sales data for each performance obligation, the Company determines the standalone selling price using observable prices when available and with consideration of current market conditions which is primarily based on prices set by management, adjusted for applicable discounts. The Company then recognizes revenue for each performance obligation as that performance obligations is satisfied as discussed above.

For the year ended December 31, 2022 and 2021, the Company recognized $0.8 million and $0 of revenue related to sales of instruments and consumables products. Contract liabilities, which consists of deferred revenue, as of December 31, 2022 and December 31, 2021 were $0.1 million and $0, respectively, were recorded as other noncurrent liabilities. Deferred revenue represents the value of performance obligations that have been invoiced but for which revenue has not yet been earned.

For the year ended December 31, 2022, all of the Company's revenue was generated within the United Sates. During the period, the Company generated all of its revenue from three customers.

Cost of Revenue

Cost of revenue consists primarily of the direct costs of the materials and labor to build our products, overhead such as facilities and indirect labor that support manufacturing, shipping and handling costs, and the labor and direct costs to install the G4. Cost of revenue also includes estimated costs to satisfy customary assurance-type warranty provisions.

Research and Development Expense

The Company's research and development expense consists primarily of the following: salaries, payroll taxes, employee benefits and stock-based compensation for personnel engaged in research and development activities; fees paid to consultants; license fees paid to third parties for use of their intellectual property, laboratory supplies and development materials; allocated information technology and facilities costs; and depreciation. Research and development costs are charged to expense as incurred.

Patent Costs

Costs related to filing and pursuing patent applications are recorded as selling, general and administrative expenses within the Company's statements of operations and expensed as incurred since recoverability of such expenditures is uncertain.

Issuance Costs Related to Equity and Debt

The Company allocates issuance costs between the individual freestanding instruments identified on the same basis as proceeds were allocated. Issuance costs associated with the issuance of debt is recorded as a direct reduction of the carrying amount of the debt liability, limited to the notional value of the debt. The Company accounts for the Silicon Valley Bank loan (see Note 8) as a liability measured at amortized cost and amortizes the related debt discount to interest expense using the effective interest method over the expected term of the debt.

Stock-based Compensation

The Company accounts for stock-based compensation by measuring and recognizing compensation expense for all stock-based awards made to employees and non-employees based on estimated grant-date fair values. The Company uses the straight-line method to recognize compensation cost over the required service period of the award, which is generally the vesting period of the award. The Company recognizes actual forfeitures by reducing the stock-based compensation in the same period that the forfeitures occur. The Company estimates the fair value of stock-based option awards to employees and non-employees using the Black-Scholes option pricing model. The Black-Scholes option pricing model requires the input of subjective assumptions, including the fair value of common stock, expected term, expected volatility, risk-free interest rate and expected dividend yield, which are described in greater detail below.

Inputs to the Black-Scholes option pricing model are subjective and generally require the use of judgment. Changes in the assumptions can materially affect how much stock-based compensation is recognized. These inputs are as follows:

- *Fair value of common stock*— For awards granted prior to the IPO, when there was no public market for the Company's common stock, the grant date fair value of the Company's common stock was determined by the Company's board of directors based in part on valuations of the Company's common stock prepared by a third-party valuation specialist. For awards granted after the IPO, the fair value of common stock is the closing price per share of the Company's common stock on the grant date as reported on the Nasdaq Global Select Market.
- *Expected term*—The expected term represents the average period that options granted are expected to be outstanding and is determined using the simplified method (based on the mid-point between the weighted-average vesting period and the end of the contractual term). The Company uses the simplified method because the Company has concluded that its historical option exercise experience does not provide a reasonable basis to estimate expected term.
- *Expected volatility*—The Company had no publicly available stock price information prior to its IPO and limited publicly available stock price information after its IPO; therefore, the Company used the historical volatility of the stock price of similar publicly traded companies. The historical volatility is calculated based on a period of time commensurate with the expected term.
- *Risk-free interest rate*—The risk-free interest rate is based on the U.S. Treasury zero coupon issues in effect at the time of grant for periods corresponding with the expected term.
- *Expected dividend yield*—The Company has never paid dividends and does not intend to pay dividends in the foreseeable future. Therefore, the Company used an expected dividend yield of zero.

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 the 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 as income or expense in the period that includes the enactment date.

The Company recognizes net 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 net recorded amount, management would make an adjustment to the deferred tax asset valuation allowance, which would reduce any provision for income taxes.

The Company records uncertain tax positions on the basis of a two-step process whereby: (i) management determines whether it is more likely than not that the tax positions will be sustained on the basis of the technical merits of the position; and (ii) for those tax positions that meet the more-likely-than-not recognition threshold, management recognizes the largest amount of tax benefit that is more than 50% likely to be realized upon ultimate settlement with the related tax authority. The Company will recognize interest and penalties related to unrecognized tax benefits within income tax expense.

Other Comprehensive Loss

Other comprehensive loss is defined as a change in equity during a period from transactions and other events and circumstances from non-owner sources. The only component of other comprehensive loss is unrealized loss on available-for-sale securities, which have been reflected in the statements of comprehensive loss and as a separate component in the statements of preferred stock and stockholders' equity (deficit).

Net Loss per Share

In periods of net loss, basic net loss per share is computed by dividing net loss available to common stockholders by the weighted-average number of shares of common stock outstanding during the period, without consideration for potentially dilutive securities. Outstanding stock options, convertible preferred stock and shares of common stock subject to repurchase by the Company are excluded from the calculation of diluted net loss per common share for the periods presented as their effect would be anti-dilutive. Thus, for all periods presented, there is no difference in the number of shares used to calculate basic and diluted net loss per share.

Segment Information

Operating segments are components of a public entity that: (i) engage in business activities from which they may recognize revenues and incur expenses; (ii) have operating results that are regularly reviewed by the chief operating decision maker to make decisions about resources to be allocated to the segment and assess its performance; and (iii) have discrete financial information available. The Company views its operations and manages its business as one operating segment, and thus has one reportable segment. The Company's long-lived assets are located in the United States.

Recent Accounting Pronouncements—Adopted

In February 2016, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") No. 2016-02, *Leases* ("ASU 2016-02"), codified as ASC 842. ASC 842 requires the Company to recognize on the balance sheet lease liabilities and corresponding ROU lease assets for its operating leases where the Company is the lessee. The Company adopted this standard effective January 1, 2022 using the modified retrospective method by applying the new standard to all leases existing as of January 1, 2022 and not restating any prior comparative periods. The Company elected the practical expedients to carry forward its historical lease classification, not reassess whether any expired or existing contracts are or contain leases and not reassess initial direct costs for existing leases. On January 1, 2022, the Company recorded operating lease liabilities of $7.1 million, ROU lease assets of $6.4 million, and derecognized deferred rent of $0.7 million. The additional disclosures required by the standard have been included in the section above titled "Leases" and in Note 9. Prior comparative periods have not been adjusted and continue to be reported under ASC 840.

Recent Accounting Pronouncements—Not Yet Adopted

In June 2016, the FASB issued ASU No. 2016-13, *Financial Instruments–Credit Losses: Measurement of Credit Losses on Financial Instruments* ("ASU 2016-13"), which amends the impairment model by requiring entities to use a forward-looking approach based on expected losses to estimate credit losses on certain types of financial instruments, including trade receivables and available-for-sale debt securities. ASU 2016-13 is effective for the Company's annual periods beginning after December 15, 2022, with early adoption permitted. The Company does not anticipate adoption of this standard will have a material impact on its financial statements as the Company's trade receivables balance is not material to the financial statements as a whole, and the Company's investment portfolio is composed of diversified investment-grade securities that the Company believes present a lower credit loss risk. Further, the Company does not presently intend to sell, nor is more likely than not that the Company will be required to sell, securities in an unrealized loss position prior to the recovery of their book value.

3. Fair Value Measurements

For accounting purposes, fair value is defined as an exit price representing the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants. As such, fair value is a market-based measurement that should be determined based on assumptions that market participants would use in pricing an asset or liability. As a basis for considering such assumptions, the accounting guidance establishes a three-tier fair value hierarchy, which prioritizes the inputs used in measuring fair value as follows:

Level 1: Observable inputs such as quoted prices in active markets.

Level 2: Inputs, other than the quoted prices in active markets, that are observable either directly or indirectly.

Level 3: Unobservable inputs in which there is little or no market data, which require the reporting entity to develop its own assumptions.

When quoted market prices are available in active markets, the fair value of assets and liabilities is estimated within Level 1 of the valuation hierarchy. If quoted prices are not available, then fair values are estimated by using pricing models, quoted prices of assets and liabilities with similar characteristics, or discounted cash flows, within Level 2 of the valuation hierarchy. In cases where Level 1 or Level 2 inputs are not available, the fair values are estimated by using inputs within Level 3 of the hierarchy.

None of the Company's assets or liabilities are recorded at fair value on a recurring basis other than cash and cash equivalents, short-term investments. No transfers between levels occurred during the periods presented. The fair value of short-term investments is based on market prices quoted on the last day of the fiscal period or other observable market inputs.

The following tables summarize the Company's assets measured at fair value on a recurring basis as of December 31, 2022 and December 31, 2021 (in thousands):

	December 31, 2022			
	Level 1	Level 2	Level 3	Total
Cash and cash equivalents				
Cash	$ 48,690	$ -	$ -	$ 48,690
Money market funds	25,576	-	-	25,576
Total cash and cash equivalents	74,266	-	-	74,266
Short-term investments				
U.S. Treasury securities	62,532	-	-	62,532
Corporate debt securities	-	101,467	-	101,467
Asset-backed securities	-	6,311	-	6,311
Total short-term investments	62,532	107,778	-	170,310
Total cash and cash equivalents and short-term investments	$ 136,798	$ 107,778	$ -	$ 244,576

	December 31, 2021			
	Level 1	Level 2	Level 3	Total
Cash and cash equivalents				
Cash	$ 26,037	$ -	$ -	$ 26,037
Money market funds	175,012	-	-	175,012
Total cash and cash equivalents	201,049	-	-	201,049
Short-term investments				
Corporate debt securities	-	117,027	-	117,027
Asset-backed securities	-	21,147	-	21,147
Total short-term investments	-	138,174	-	138,174
Total cash and cash equivalents and short-term investments	$ 201,049	$ 138,174	$ -	$ 339,223

4. Inventory

Inventory consisted of the following (in thousands):

	December 31,	
	2022	2021
Raw materials	$ 14,508	$ 2,565
Work in process	3,276	446
Finished goods	437	-
Total inventory	$ 18,221	$ 3,011

5. Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets consisted of the following (in thousands):

	December 31,	
	2022	2021
Prepaid expenses	$ 3,003	$ 3,715
Interest receivable	1,099	1,050
Current deposits and other current assets	620	761
Total prepaid expenses and other current assets	$ 4,722	$ 5,526

6. Property and Equipment, Net

Property and equipment, net, consisted of the following (in thousands):

		December 31,	
	Useful Life	2022	2021
Equipment	5 years	$ 8,656	$ 4,433
Computers and software	3 years	2,705	2,136
Leasehold improvements	14 years or less	2,127	1,041
Furniture and fixtures	5 years or less	1,854	75
Construction in progress	N/A	-	574
Total property and equipment, gross		15,342	8,259
Less: accumulated depreciation		(4,558)	(2,187)
Total property and equipment, net		$ 10,784	$ 6,072

7. Accrued Expenses

Accrued expenses consisted of the following (in thousands):

	December 31,	
	2022	2021
Accrued compensation and other employee benefits	$ 3,580	$ 3,516
Accrued research and development expenses	360	41
Accrued professional services	204	200
Accrued other expenses	439	521
Total accrued expenses	$ 4,583	$ 4,278

8. Long-term Debt

Silicon Valley Bank Loan

In November 2019, the Company entered into a loan and security agreement with Silicon Valley Bank ("SVB") pursuant to which SVB agreed to lend to the Company up to $15.0 million in a series of term loans (the "2019 SVB Loan"). Contemporaneously, the Company borrowed $2.5 million in the first of three draw-downs available under the 2019 SVB Loan. In March 2020, the Company borrowed an additional $7.5 million as a second draw. The 2019 SVB Loan was to mature on September 1, 2023 and bore interest at an annual rate equal to the greater of (i) 0.65% above the prime rate or (ii) 5.90%. Payment on the 2019 SVB Loan was for interest only through September 30, 2021. In addition, a final payment equal to the original principal amount of each advance multiplied by 5.50% was to be due on the maturity date. In connection with the 2019 SVB Loan, SVB entered into the SVB Warrant agreement with the Company to purchase shares of Series B convertible preferred stock at an exercise price of $2.3228 per share (see section titled "SVB Warrant" below).

On September 30, 2021, the Company refinanced its 2019 SVB Loan. In connection with the refinancing, the Company entered into an Amended and Restated Loan and Security Agreement (the "2021 SVB Loan," together with the 2022 SVB Loan Amendment (defined below), the "SVB Loan") with SVB. The 2021 SVB Loan provided for term loans in an aggregate principal amount of up to $35.5 million to be delivered in three tranches. The tranches consisted of: (i) a term loan advance to the Company in an aggregate principal amount of $10.5 million on the loan closing date (the "First Tranche"); (ii) an additional term loan advance available to the Company through September 30, 2022 in an aggregate principal amount of $15.0 million (the "Second Tranche"); and (iii) subject to SVB's approval, a right of the Company to request that SVB make an additional term loan advance in an aggregate principal amount of $10.0 million. The proceeds from the First Tranche were used to repay in full the existing indebtedness under the 2019 SVB Loan. The SVB Loan matures on September 1, 2026 and bears interest at an annual rate equal to the greater of (i) 0.75% plus the prime rate as reported in *The Wall Street Journal* and (ii) 4.00%. As of December 31, 2022, the SVB Loan bears interest at an annual rate of 8.25%. The SVB Loan has an initial interest-only period of 36 months. In addition, a final payment (the "Final Payment Fee") equal to the original principal amount of each advance multiplied by 4.00% will be due on the maturity date. The Final Payment Fee is recorded in other noncurrent liabilities on the balance sheet. As of December 31, 2022, the SVB Loan is recorded as noncurrent.

The 2021 SVB Loan was accounted for as a debt modification, rather than an extinguishment, based on a comparison of the present value of the cash flows under the terms of the debt immediately before and after the amendment, which resulted in a change of such cash flows of less than 10%. Unamortized debt issuance costs as of the date of modification and incremental issuance costs incurred in connection with the 2021 SVB Loan will be amortized to interest expense using the effective interest method over the repayment term.

On September 30, 2022, the Company entered into an amendment to the 2021 SVB Loan (the "2022 SVB Loan Amendment"). The 2022 SVB Loan Amendment extended the period to draw down the additional tranches totaling $25.0 million from September 30, 2022 to March 31, 2024, provided that in order for the Company to access the Second Tranche availability the Company must achieve a six-month trailing revenue hurdle. The 2022 SVB Loan Amendment was accounted for as a debt modification, rather than an extinguishment, based on a comparison between the present value of the cash flows under the terms of the debt immediately before and after the amendment, which resulted in a change of such cash flows of less than 10%. Unamortized debt issuance costs as of the date of modification and incremental issuance costs incurred in connection with the 2022 SVB Loan Amendment will be amortized to interest expense using the effective interest method over the repayment term.

As of December 31, 2022 and December 31, 2021, the unamortized debt issuance costs related to the SVB Loan were $0.4 million and $0.6 million, respectively. Debt issuance costs include the initial fair value of the SVB Warrant. The debt issuance costs are amortized to interest expense over the term of the loan using the effective interest method.

The SVB Loan and unamortized discount balances as of December 31, 2022 and December 31, 2021 are shown below (in thousands):

	December 31,	
	2022	2021
Long-term debt	$ 10,500	$ 10,500
Less: issuance costs	(435)	(596)
Total long-term debt, net of issuance costs	$ 10,065	$ 9,904

Future minimum payments of outstanding principal and interest under the 2021 SVB Loan are as follows (in thousands):

As of December 31, 2022	
2023	804
2024	2,612
2025	5,780
2026	4,029
Total future minimum payments	13,225
Less: interest, Final Payment fee	(2,725)
Long-term debt	10,500
Less: issuance costs	(435)
Long-term debt, net of issuance costs	$ 10,065

The Company is subject to customary affirmative and restrictive covenants under the SVB Loan. The Company's obligations under the SVB Loan are secured by a first priority security interest in substantially all of the Company's current and future assets, other than intellectual property. The Company has agreed not to encumber its intellectual property assets, except as permitted by the SVB Loan.

The SVB Loan provides for events of default customary for term loan facilities of this type, including but not limited to: non-payment; breaches or defaults in the performance of covenants or representations and warranties; bankruptcy and other insolvency events of the Company; and the occurrence of a material adverse change as defined in the SVB Loan. After the occurrence of an event of default, SVB may, among other remedies, accelerate payment of all obligations.

As of December 31, 2022 and December 31, 2021, the Company was in compliance with all covenants under the SVB Loan and 2019 SVB Loan, respectively, and there had been no events of default.

SVB Warrant

In November 2019, simultaneously with the first draw-down under its 2019 SVB Loan, SVB entered into a warrant agreement with the Company to purchase 32,289 shares of Series B convertible preferred stock of the Company at an exercise price of $2.3228 per share (as amended, the "SVB Warrant"). In March 2020, in connection with the Company's second draw-down under the 2019 SVB Loan, the SVB Warrant was amended to increase the number of shares of Series B convertible preferred stock of the Company by 96,867, to a total of 129,156 shares. In connection with the completion of the Company's IPO, in accordance with the original terms the warrant instrument, the SVB Warrant was automatically adjusted into a warrant to purchase an equivalent number of shares of common stock. In June 2021, after the IPO, SVB net exercised the SVB Warrant into 117,088 shares of common stock of the Company, and the SVB Warrant is no longer outstanding as of December 31, 2022.

The fair value of the SVB Warrant liability was remeasured at each financial reporting period with any changes in fair value recognized as other income (expense) in the statements of operations. The fair value for the warrant liability for the SVB Warrant was based on the Black-Scholes option pricing valuation model using significant inputs not observable in the market and was thus classified within Level 3 of the fair value hierarchy. The change in fair value of the warrant for the year ended December 31, 2022 and 2021 was $0 and $2.2 million, respectively, and recorded as "Change in fair value of warrant liability" in the statements of operations. When, in connection with the IPO, the SVB Warrant was automatically adjusted into a warrant to purchase an equivalent number of shares of common stock, the warrant liability was reclassified from current liabilities to equity as the warrant met the definition of an equity instrument. Additionally, at that time, the Company recorded the final valuation of the warrant liability for the SVB Warrant.

2021 Convertible Notes

In February 2021, the Company sold and issued approximately $130.5 million aggregate principal of 2021 Convertible Notes in a private placement transaction. Of this amount, $48.5 million was issued to certain investors affiliated with members of the Company's board of directors. The 2021 Convertible Notes accrued 6% interest per annum. The Company elected as of the issuance date to account for the 2021 Convertible Notes at fair value. Management believes that the fair value option better reflected the underlying economics of the 2021 Convertible Notes, which contained multiple embedded derivatives. Under the fair value election, changes in fair value are reported as "Change in fair value of convertible promissory notes" in the statements of operations in each reporting period after the issuance through the conversion of the 2021 Convertible Notes. The Company measured the fair value of the 2021 Convertible Notes using the probability weighted "as-converted" plus Black-Scholes option pricing model based on inputs such as the probability of IPO vs. non-IPO scenarios, fair value of the common stock price, discount yield, risk-free rate, equity volatility, expected term, number of converted shares and price negotiation adjustment for the calibration. In connection with the IPO, the 2021 Convertible Notes converted into 7,531,777 shares of the Company's common stock. Based on the terms of the agreement, the 2021 Convertible Notes converted at a 20% discount to the public offering price in the IPO. At the time of the conversion, the Company recorded a final fair value adjustment of the 2021 Convertible Notes using the Company's common stock price at the IPO.

9. Commitments and Contingencies

Columbia License Agreement

In 2016, the Company entered into an Exclusive License Agreement (the "License Agreement") with The Trustees of Columbia University ("Columbia"). Under the License Agreement, the Company acquired the exclusive right to use certain patents, materials and information. The License Agreement includes a number of diligence obligations that requires the Company to use commercially reasonable efforts to research, discover, develop and market Patent Products and/or Other Products (as defined in the License Agreement) by certain dates. Under the License Agreement, the Company pays an annual license fee that increases each year, until it reaches a low six-digit fee for the fifth year, and for each subsequent year, for so long as the License Agreement remains in force. The license fee was immaterial for all periods presented. For any products within the scope of the License Agreement that the Company commercializes, the Company is required to pay royalties ranging from low to mid-single digits on net sales of Patent Products and low single-digit royalty rates on net sales of Other Products. The Company can credit the yearly annual license fee against any yearly royalty fees payable to Columbia. Additionally, if the Company receives any income in connection with any sublicenses, the Company must pay Columbia a high single-digit percentage of that income. Finally, the License Agreement provides for payments to Columbia based on the Company's achievement of certain development and commercialization milestones, which could total up to $3.9 million over the life of the License Agreement. As of December 31, 2022 the Company accrued $0.4 million related to the milestones. During each of the years ended December 31, 2022 and 2021, the Company paid approximately $0.1 million to Columbia pursuant to the terms of the License Agreement.

Operating Leases

Overview of Operating Leases

In November 2017, the Company entered into a non-cancelable operating lease in La Jolla, California for its prior headquarters, which expired in May 2022 upon commencement of the New HQ Lease (defined below). The lease included certain rent escalations and additional charges for common area maintenance and other costs. The Company gained access to the leased space and began recognizing rent expense under this lease in February 2018.

In November 2019, the Company entered into a lease agreement for office space in San Diego, California (the "3033 Lease"). The Company gained access to the leased space and began recognizing rent expense under this lease in May 2020. The Company has since amended the 3033 Lease to extend the lease and expand the existing premises for certain rent escalations. The term of the 3033 Lease will end 30 days following the Commencement Date of the OAS Lease (defined below).

In December 2019, the Company entered into a 5-year lease agreement for additional office space in San Diego, California (the "SV Lease"). The lease included certain rent escalations and additional charges for common area maintenance and other costs. The Company gained access to the leased space and began recognizing rent expense under this lease in January 2020. The Company terminated this lease as of September 30, 2022 and recognized approximately $35,000 for both termination costs and the write-off of the applicable right-of-use asset during the year ended December 31, 2022.

In June 2020, the Company entered into a lease agreement with ARE-SD Region No. 27, LLC (the "Landlord") for new office and laboratory space in San Diego, California ("New HQ Lease"). The New HQ Lease term ends at the same time the OAS Lease term ends (defined below). The Landlord shall make available to the Company for use within 12 months after the commencement date a tenant improvement allowance ("TI Allowance"), which the Company will repay to the Landlord as additional rent over the base term and shall accrue interest at a rate of 8% per annum. Upon commencement, the contractual base rent will be charged, subject to partial rent abatement, annual base rent adjustments, the Company's share of operating expenses and additional rent for the TI Allowance actually disbursed by the Landlord. The Company gained access to the New HQ Lease space and began recognizing rent expense under this lease in April 2022.

In April 2021, the Company entered into a 62-month lease agreement for additional office and manufacturing space in San Diego, California (the "MR Lease"). The lease includes certain rent escalations and additional charges for common area maintenance and other costs. The Company gained access to the leased space in June 2021 and began recognizing rent expense under this lease at that time.

In January 2022, the Company entered into a Lease Agreement (the "OAS Lease") with an affiliate of Alexandria Real Estate Equities, Inc. ("ARE") to lease two buildings ("Building 3" and "Building 4") to be constructed in connection with One Alexandria Square in La Jolla, California. The two buildings are comprised of office and manufacturing space and are intended to serve as the Company's future headquarters. The term of the OAS Lease will commence when ARE's work for Building 3 is substantially complete, which was estimated to be November 1, 2024 (the "Commencement Date"). The Company's obligation to pay rent for Building 3 will begin approximately seven months following the Commencement Date. The Company's obligation to pay rent for Building 4 will begin 12 months following the Commencement Date, subject to the substantial completion of ARE's work on Building 4. The Company has an option to accelerate the construction and delivery of Building 4 to be the same date as the Commencement Date for Building 3 and will receive 12 months of base rent abatement on Building 4 if it exercises this option. The initial term of the OAS Lease is 144 months following the Commencement Date. The Company has the one-time option to extend the term of the OAS Lease by 60 months upon prior notice to ARE. The annual base rent under the OAS Lease is initially based on $64.80 per square foot per year, or approximately $7.3 million per year for Building 3 and $6.0 million per year for Building 4, subject to annual increases of 3% and certain other adjustments, and includes tenant improvement and warm shell allowances. Maximum tenant improvement and warm shell allowances total approximately $32.9 million. The Company is also obligated to pay for an estimated $23.7 million of certain tenant improvements plus 7% interest per year amortized in equal monthly payments over the term of the OAS Lease. At the time of entering into the OAS Lease, the Company paid ARE $1.1 million as prepayment for rent and, as a security deposit, provided ARE with a $1.1 million standby letter of credit.

Accounting for Operating Leases

On January 1, 2022, the Company adopted ASC 842 (see Note 2). As of January 1, 2022, the remaining weighted-average lease term was 2.9 years and the weighted-average incremental borrowing rate used to determine the operating lease liabilities was 3.6%. Cash payments included in the measurement of lease liabilities totaled $7.5 million. As of December 31, 2022, the remaining weighted-average lease term was 12.7 years and the weighted-average incremental borrowing rate used to determine the operating lease liabilities was 9.1%. Cash payments included in the measurement of lease liabilities totaled $86.7 million.

During the year ended December 31, 2022, the Company incurred $9.3 million of lease costs, of which $0.1 million is related to the Company's short-term leases, $2.7 million is related to variable lease payments, which are primarily comprised of common area maintenance, and $6.5 million is related to straight-line operating lease expense. The Company recorded straight-line operating lease expense of $2.2 million for the year ended December 31, 2021.

Future minimum payments under the Company's non-cancelable operating leases that have commenced as of December 31, 2022 are as follows (in thousands):

2023	6,552
2024	7,765
2025	5,560
2026	5,565
2027	5,447
Thereafter	55,803
Future non-cancelable minimum lease payments	86,692
Less: discount	(37,913)
Total lease liabilities	48,779
Less: current portion	6,323
Lease liabilities, noncurrent	$ 42,456

The total undiscounted future minimum lease payments associated with the OAS Lease are approximately $179.0 million and are not included in the table above. The Company did not recognize lease liabilities or corresponding ROU lease assets for the OAS Lease as its lease term had not yet commenced as of December 31, 2022.

Future minimum payments under all of the Company's non-cancelable operating leases, including those that have not yet commenced, are as follows:

2023	6,552
2024	7,765
2025	10,902
2026	19,346
2027	19,657
Thereafter	201,322
Total	$ 265,544

Indemnification

As permitted under Delaware law and in accordance with the Company's bylaws, the Company indemnifies its officers and directors for certain events or occurrences while the officers or directors are or were serving in such capacity. The Company is also party to indemnification agreements with its officers and directors. The Company considers the fair value of the indemnification rights and agreements as minimal. Accordingly, the Company has not recorded any liabilities for these indemnification rights and agreements as of December 31, 2022.

Other Contingencies

We are not currently a party to any material legal proceedings. From time to time, we may become involved in legal proceedings arising in the ordinary course of our business. Regardless of outcome, litigation can have an adverse impact on us due to defense and settlement costs, diversion of management resources, negative publicity, reputational harm and other factors.

10. Series A Common Stock Equivalent Convertible Preferred Stock

In January 2022, the Company entered into an Exchange Agreement (the "Exchange Agreement") with Deerfield Private Design Fund IV, L.P. (the "Deerfield Holder"), pursuant to which the Deerfield Holder exchanged an aggregate of 2,500,000 shares of the Company's common stock held by the Deerfield Holder for 2,500 shares of a newly created class of non-voting preferred stock designated as Series A Common Stock Equivalent Convertible Preferred Stock. Additionally, in connection with the issuance of the Series A Common Stock Equivalent Convertible Preferred Stock, the Company filed a Certificate of Designation, Preferences and Rights of Series A Common Stock Equivalent Convertible Preferred Stock, par value $0.0001 per share, of the Company with the Secretary of State of the State of Delaware. Each outstanding share of Series A Common Stock Equivalent Convertible Preferred Stock is entitled to a *de minimis* liquidation preference of $0.0001 per share. The Series A Common Stock Equivalent Convertible Preferred Stock is convertible into 1,000 shares of common stock for each share of Series A Common Stock Equivalent Convertible Preferred Stock at the option of the holder. Additionally, the ability of a holder to convert non-voting Series A Common Stock Equivalent Convertible Preferred Stock into common stock is prohibited to the extent that, upon such conversion, such holder, its affiliates and other persons whose ownership of common stock would be aggregated with that of such holder for purposes of Section 13(d) of the Securities Exchange Act of 1934, as amended, would exceed 4.9% of the total number of shares of common stock then outstanding.

The Company classifies Series A Common Stock Equivalent Convertible Preferred Stock as permanent equity on the balance sheet because it is not redeemable for cash or other assets of the Company and is not considered debt under ASC 480. There are no features of the Series A Common Stock Equivalent Convertible Preferred Stock that require bifurcation and separate accounting under ASC 815. Series A Common Stock Equivalent Convertible Preferred Stock is considered a participating security for purposes of calculating earnings per share under ASC 260 because it participates in dividends ratably on an as-converted basis with common stock.

11. Stock Incentive Plans

2021 and 2016 Equity Incentive Plans

The Company's Board of Directors and stockholders adopted and approved the Company's 2021 Equity Incentive Plan (the "2021 Plan") in May 2021, which was amended in July 2022. The 2021 Plan replaced the Company's 2016 Equity Incentive Plan adopted in September 2016 (the "2016 Plan"); however, awards outstanding under the 2016 Plan will continue to be governed by their existing terms. The number of shares of the Company's common stock that were initially available for issuance under the 2021 Plan equaled the sum of 7,500,000 shares plus 585,720 shares that were then available for issuance under the 2016 Plan. The 2021 Plan provides for the following types of awards: incentive and nonqualified stock options, stock appreciation rights, restricted shares and restricted stock units. As of December 31, 2022, 6,832,428 shares of common stock remained available for future grants under the 2021 Plan.

The number of shares of common stock reserved for issuance under the 2021 Plan are increased automatically on the first business day of each fiscal year, commencing in 2022 and ending in 2031, by a number equal to the lesser of: (i) 5% of the shares of common stock outstanding on the last business day of the prior fiscal year; or (ii) the number of shares determined by the Company's Board of Directors. In general, to the extent that any awards under the 2021 Plan are forfeited, terminated, expired or lapsed without the issuance of shares, or if the Company reacquires the shares subject to awards granted under the 2021 Plan, those shares will again become available for issuance under the 2021 Plan, as will shares applied to pay the exercise or purchase price of an award or to satisfy tax withholding obligations related to an award.

Stock-based awards are governed by agreements between the Company and the recipients. Incentive stock options and nonqualified stock options may be granted under the 2021 Plan (and previously the 2016 Plan) at an exercise price of not less than 100% of the fair market value of the Company's common stock on the date of grant. The grant date is the date the terms of the award are formally approved by the Company's Board of Directors or its designee.

In August 2022, the Company completed an exchange of 984,291 options owned by eligible non-executive employees with exercise prices ranging from $10.99 to $26.23 for the same number of options with an exercise price of $3.60. The requisite service period and the contractual term of the new options were not changed from the exchanged options, and the exchanged options were cancelled. The exercise price of $3.60 was the volume-weighted average price of the Company's common stock for the 20-day period immediately prior to the exchange. The exchange was treated as an option modification under GAAP, and the total incremental expense resulting from the exchange will be $1.2 million, of which $0.4 million was recognized in 2022, and the remaining will be recognized over a weighted-average period of approximately 2.6 years. The Company will continue to recognize the grant-date fair value of the exchanged options over the remaining service period.

The following table summarizes stock option activity under all equity plans for the year ended December 31, 2022:

	Number of Options	Weighted-Average Exercise Price (per Share)	Weighted-Average Remaining Contract Term (in Years)	Aggregate intrinsic value (in thousands)
Outstanding at December 31, 2021	5,322,314	$ 6.75		
Exercisable at December 31, 2021	3,296,183	3.03		
Granted	6,587,419	6.00		
Exercised	(392,824)	0.47		
Canceled or forfeited	(1,879,887)	12.63		
Outstanding at December 31, 2022	9,637,022	5.35	8.5	$ 3,223
Exercisable at December 31, 2022	4,066,881	4.17	7.7	$ 3,220

Options outstanding as of December 31, 2022 consist of options vested and expected to vest. Aggregate intrinsic value in the table above is the total in-the-money value of the options above as of December 31, 2022, which is the aggregate of the difference between the Company's last closing stock price per share of $2.01 as of December 31, 2022 and the exercise price of each option that has an exercise price of lower than $2.01.

The intrinsic value of options exercised during the years ended December 31, 2022 and 2021, calculated based on the stock price on the date of each exercise, was $1.3 million and $74.6 million, respectively.

The 2016 Plan allows for the early exercise of awards to plan participants subject to the right of repurchase by the Company at the lower of the original exercise price or fair market value for unvested awards. As of December 31, 2022 and December 31, 2021, the Company had a liability for the cash received from the early exercise of stock options in the amount of $0.5 million and $1.7 million, respectively. The Company reduces the liability as the underlying shares vest in accordance with the vesting terms of the awards or when the Company repurchases unvested awards.

At December 31, 2022 and December 31, 2021, there were 526,660 and 2,198,933, respectively, of early exercised stock options that remain subject to the Company's repurchase right.

Employee Stock Purchase Plan

In May 2021, the Company's Board of Directors approved the 2021 Employee Stock Purchase Plan (the "ESPP"). A total of 730,000 shares of common stock was initially reserved for issuance under the ESPP. The price at which common stock is purchased by employees under the ESPP is equal to 85% of the fair market value of the common stock on the first day of the offering period or purchase date, whichever is lower.

During the year ended December 31, 2022, 514,427 shares of common stock were issued under the ESPP.

Stock-based Compensation Summary

The classification of stock-based compensation expense is summarized as follows (in thousands):

	Year Ended December 31,	
	2022	2021
Research and development	$ 3,970	$ 2,468
Selling, general and administrative	9,699	6,763
Total stock-based compensation expense	$ 13,669	$ 9,231

As of December 31, 2022, total unrecognized stock-based compensation expense was $27.3 million and is expected to be recognized over the weighted-average period of approximately 2.7 years.

The following table shows the weighted-average assumptions used to compute the fair value of the awards granted to employees and nonemployees using the Black-Scholes option pricing model during the periods below:

	Year Ended December 31,	
Assumption	**2022**	**2021**
Expected volatility	57.56%	77.22%
Expected term (years)	5.2−6.1	5.5−6.1
Expected dividend yield	0.00%	0.00%
Risk-free interest rate	1.98%	0.91%

Common stock reserved for future issuance under equity incentive plans consisted of the following as of December 31, 2022:

Stock options issued and outstanding under all Plans	9,637,022
Authorized for future grants under the 2021 Plan	6,832,428
Authorized for future grants under the ESPP	880,564
Total as of December 31, 2022	17,350,014

The table above does not include 526,660 of common stock for early exercised stock options that remain subject to the Company's repurchase right.

12. Income Taxes

Due to its net losses for the years ended December 31, 2022 and December 31, 2021, and since it has a full valuation allowance against deferred tax assets, the Company did not record any provision or benefit for income taxes. There were no components of current or deferred federal, state or foreign tax provisions for the year ended December 31, 2022 or 2021.

The difference between income taxes computed using the U.S. federal income statutory tax rate and the provision for income taxes is as follows (in thousands):

	December 31,	
	2022	2021
Income taxes at statutory rates	$ (19,085)	$ (20,742)
State income tax, net of federal benefit	(2,615)	(3,305)
Permanent items	49	1,373
Convertible debt revaluation	-	7,392
Research credit	(3,434)	(3,072)
Change in valuation allowance	24,423	17,861
Other	662	493
	$ -	$ -

Significant components of the Company's deferred tax assets and deferred tax liabilities are as follows (in thousands):

	December 31,	
	2022	2021
Deferred tax assets:		
Net operating loss carryforward	$ 40,101	$ 27,560
Credits	9,433	6,005
Lease liability	11,673	39
Section 174 capitalized research and development	7,408	-
Other	3,972	1,355
Total deferred tax assets	72,587	34,959
Valuation allowance	(59,435)	(34,844)
Net deferred tax assets	13,152	115
Deferred tax liabilities:		
Right-of-use lease assets	(10,983)	-
Fixed assets	(2,169)	(115)
Total deferred tax liabilities	(13,152)	(115)
Total net deferred taxes	$ -	$ -

At December 31, 2022 the Company had federal and California tax loss carryforwards of approximately $148.6 million and $126.7 million, respectively. The federal net operating loss generated prior to 2018 and state net operating loss carryforwards begin to expire in 2036, if unused. The federal net operating loss carryover includes $144.8 million of net operating losses generated from 2018 through the current period which, under current tax law, will carryover indefinitely.

At December 31, 2022, the Company had federal and state tax credit carry forwards of approximately $6.0 million and $5.8 million, respectively. The Company has not performed a formal research and development credit study with respect to these credits. The federal credits will begin to expire in 2037, if unused, and the state credits carry forward indefinitely.

Due to the Company's history of losses and uncertainty regarding future earnings, a valuation allowance has been recorded against the Company's deferred tax assets, as it is more likely than not that such assets will not be realized. The net change in the total valuation allowance for the years ended December 31, 2022 and December 31, 2021 was $24.6 million and $17.9 million, respectively.

Pursuant to Internal Revenue Code of 1986, as amended ("IRC"), specifically IRC §382 and IRC §383, the Company's ability to use net operating loss and research and development tax credit carryforwards ("tax attribute carryforwards") to offset future taxable income is limited if the Company experiences a cumulative change in ownership of more than 50% within a three-year testing period. The Company has not completed an ownership change analysis pursuant to IRC Section 382. If ownership changes within the meaning of IRC Section 382 are identified as having occurred, the amount of remaining tax attribute carryforwards available to offset future taxable income and income tax expense in future years may be significantly restricted or eliminated. Any limitation may result in the expiration of a portion of the net operating loss or research credit carryforwards before utilization.

The Company recognizes a tax benefit from an uncertain tax position when it is more likely than not that the position will be sustained upon examination, including resolutions of any related appeals or litigation processes, based on the technical merits. Income tax positions must meet a more likely than not recognition threshold to be recognized. The Company's practice is to recognize interest and/or penalties related to income tax matters in income tax expense. The Company had no accrual for interest and penalties on the Company's balance sheets and has not recognized interest and/or penalties in the statements of operations and comprehensive loss for the years ended December 31, 2022 and 2021.

The following table summarizes the changes to the Company's unrecognized tax benefits for the periods presented (in thousands):

	December 31,	
	2022	2021
Balance at beginning of year	$ 866	$ 493
Increases related to prior year tax positions	(50)	18
Increases related to current year tax positions	421	355
Balance at end of year	$ 1,237	$ 866

If recognized, these amounts would not affect the Company's effective tax rate, since they would be offset by an equal corresponding adjustment in the deferred tax asset valuation allowance. The Company does not anticipate there will be a significant change in unrecognized tax benefits within the next twelve months.

The Company is subject to taxation in the United States and California. The U.S. federal and California returns are open to examination for all years since inception. The Company has not been, nor is it currently, under examination by any federal or state tax authority.

13. Net Loss per Share

The Company's preferred stock were considered participating securities for purposes of calculating earnings per share because they had a right to participate in dividends with common stock. However, because the Company's preferred stock do not have a contractual obligation to share in the losses of the Company on a basis that is objectively determinable, they were excluded from the calculation of basic net loss per share.

The following common stock equivalents were excluded from the computation of diluted net loss per share for the periods presented because including them would have had an anti-dilutive effect:

	December 31,	
	2022	2021
Employee stock options issued and outstanding	9,637,022	5,322,314
Series A Common Stock Equivalent Convertible Preferred Stock	2,500,000	-
Common stock subject to the Company's right of repurchase	526,660	2,198,933
Total	12,663,682	7,521,247

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure

None.

Item 9A. Controls and Procedures

Management's Evaluation of our Disclosure Controls and Procedures

Our management, with the participation of our principal executive officer and our principal financial officer, evaluated, as of the end of the period covered by this Annual Report on Form 10-K, the effectiveness of our disclosure controls and procedures. Based on that evaluation of our disclosure controls and procedures as of December 31, 2022, our principal executive officer and principal financial officer concluded that our disclosure controls and procedures as of such date are effective at the reasonable assurance level. The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934 (the "Exchange Act"), means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act are recorded, processed, summarized and reported within the time periods specified in the U.S. Securities and Exchange Commission'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 we file or submit under the Exchange Act is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives, and our management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

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 defined in Rules 13a-15(f) under the Exchange Act). Internal control over financial reporting is a process designed under the supervision and with the participation of our management, including our principal executive officer and our principal financial officer, 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 in the U.S.

As of December 31, 2022, our management assessed the effectiveness of our internal control over financial reporting using the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission in Internal Control-Integrated Framework ("2013 Framework"). Based on this assessment, our management concluded that our internal control over financial reporting was effective as of December 31, 2022.

This Annual Report on Form 10-K does not include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. Our auditors will not be required to opine on the effectiveness of our internal control over financial reporting pursuant to Section 404(b) of the Sarbanes-Oxley Act of 2002 until we are no longer an emerging growth company, as defined in the Jumpstart Our Business Startups Act of 2012.

Changes in Internal Control over Financial Reporting

There was no change in our internal control over financial reporting that occurred during the quarter ended December 31, 2022 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Inherent Limitations on Effectiveness of Disclosure Controls and Procedures

Our management, including our principal executive officer and principal financial officer, does not expect that our disclosure controls and procedures or our internal control over financial reporting will prevent all errors and all fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, have been detected. These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of a simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by management override of the controls. The design of any system of controls is also based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions; over time, controls may become inadequate because of changes in conditions, or the degree of compliance with policies or procedures may deteriorate. Due to inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected.

Item 9B. Other Information

The Company's General Counsel, Daralyn Durie, resigned from her position as General Counsel effective February 28, 2023 (the "Separation Date"). Ms. Durie's resignation follows the merger of her law firm, Durie Tangri, LLP, with Morrison & Foerster LLP. The Company has retained Morrison & Foerster and expects to continue to receive services and advice from Ms. Durie. In connection with her separation, the Company has entered into a Separation and Release Agreement (the "Separation Agreement") with Ms. Durie. Pursuant to the terms of, and in consideration of Ms. Durie executing, the Separation Agreement (including customary release provisions), Ms. Durie will receive the following benefits: (i) the post-termination exercise period with respect to 250,000 shares of common stock underlying outstanding options that Ms. Durie has vested in as of the Separation Date has been extended until March 24, 2031, and (ii) subject to Ms. Durie's continued compliance with her obligations under the Separation Agreement, an option to purchase 80,000 shares of common stock will continue to vest until fully-vested in February 2025, and the post-termination exercise period for this option has been extended until March 24, 2031. The foregoing description of the material terms of the Separation Agreement does not purport to be complete and is qualified in its entirety by reference to the full text of the Separation Agreement, a copy of which is filed as an exhibit to this Annual Report.

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 is incorporated by reference from the definitive Proxy Statement for the 2023 Annual Meeting of Stockholders to be filed with the U.S. Securities and Exchange Commission no later than May 1, 2023.

We have adopted a Code of Conduct that applies to all our directors, officers and employees, including our principal executive officer and principal financial officer. Our Code of Conduct is available on the Governance section of the Company's investor relations website at https://investor.singulargenomics.com/. We intend to disclose any material future amendments to provisions of the Code of Conduct, and waivers of the Code of Conduct granted to executive officers and directors, on the website within four business days following the date of the amendment or waiver.

Item 11. Executive Compensation

The information required by this item is incorporated by reference from the definitive Proxy Statement for the 2023 Annual Meeting of Stockholders to be filed with the U.S. Securities and Exchange Commission no later than May 1, 2023.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters

The information required by this item is incorporated by reference from the definitive Proxy Statement for the 2023 Annual Meeting of Stockholders to be filed with the U.S. Securities and Exchange Commission no later than May 1, 2023.

Item 13. Certain Relationships and Related Transactions, and Director Independence

The information required by this item is incorporated by reference from the definitive Proxy Statement for the 2023 Annual Meeting of Stockholders to be filed with the U.S. Securities and Exchange Commission no later than May 1, 2023.

Item 14. Principal Accounting Fees and Services

The information required by this item is incorporated by reference from the definitive Proxy Statement for the 2023 Annual Meeting of Stockholders to be filed with the U.S. Securities and Exchange Commission no later than May 1, 2023.

PART IV

Item 15. Exhibits, Financial Statement Schedules

(a)(1) Financial Statements

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

(a)(2) Financial Statement Schedules

No financial statement schedules are provided because this information is not required or is shown in the financial statements or the notes thereto.

(a)(3) Exhibits

The following exhibits are included herein or incorporated herein by reference:

Exhibit Number	Description
3.1	Amended and Restated Certificate of Incorporation of Registrant. (filed as Exhibit 3.1 to the Registrant's Current Report on Form 8-K filed with the SEC on June 1, 2021 and incorporated herein by reference (File No. 001-40443)).
3.2	Amended and Restated Bylaws of Registrant. (filed as Exhibit 3.2 to the Registrant's Current Report on Form 8-K filed with the SEC on June 1, 2021 and incorporated herein by reference (File No. 001-40443)).
3.3	Certificate of Designation of Preferences, Rights and Limitations of the Series A Preferred Stock, par value $0.0001 per share, of the Company (filed as Exhibit 3.1 of the Registrant's Current Report on Form 8-K on January 26, 2022 and incorporated herein by reference (File No. 001-40443)).
4.1	Form of Registrant's Common Stock Certificate (filed as Exhibit 4.1 to the Registration Statement on Form S-1/A, filed with the SEC on May 24, 2021 and incorporated herein by reference (File No. 333-255912)).
4.2	Description of the Registrant's Securities registered pursuant to Section 12 of the Securities Exchange Act of 1934. (filed as Exhibit 4.2 to the Registrant's Form 10-K for the fiscal year ended December 31, 2021 filed with the SEC on March 14, 2022 and incorporated herein by reference (File No. 001-40443)
4.3	Amended and Restated Investors' Rights Agreement, dated June 27, 2019, as amended, by and among the Registrant and the other parties thereto (filed as Exhibit 4.2 to the Registration Statement on Form S-1, filed with the SEC on May 7, 2021 and incorporated herein by reference (File No. 333-255912)).
10.1	Form of Indemnification Agreement between the Registrant and each of its directors and executive officers (filed as Exhibit 10.1 to the Registration Statement on Form S-1/A, filed with the SEC on May 24, 2021 and incorporated herein by reference (File No. 333-255912)).
10.2#	Singular Genomics Systems, Inc. 2016 Stock Plan, as amended, and forms of agreements thereunder (filed as Exhibit 10.2 to the Registration Statement on Form S-1, filed with the SEC on May 7, 2021 and incorporated herein by reference (File No. 333-255912)).
10.3#	Singular Genomics Systems, Inc. 2021 Equity Incentive Plan as amended and restated, and form of agreements thereunder (filed as Exhibit 10.1 to the Registrant's Current Report on Form 8-K, filed with the SEC on July 25, 2022 and incorporated herein by reference (File No. 001-40443)).
10.4#	Singular Genomics Systems, Inc. 2021 Employee Stock Purchase Plan (filed as Exhibit 10.4 to the Registration Statement on Form S-1/A, filed with the SEC on May 24, 2021 and incorporated herein by reference (File No. 333-255912)).
10.5	Lease Agreement, dated November 1, 2017, by and between ARE-10933 North Torrey Pines, LLC and the Registrant (filed as Exhibit 10.5 to the Registration Statement on Form S-1, filed with the SEC on May 7, 2021 and incorporated herein by reference (File No. 333-255912)).
10.6	Lease Agreement, dated June 26, 2020, by and between ARE-SD Region No. 27, LLC and the Registrant (filed as Exhibit 10.6 to the Registration Statement on Form S-1, filed with the SEC on May 7, 2021 and incorporated herein by reference (File No. 333-255912)).

10.7	Sublease, dated June 15, 2020, by and between the Registrant and Gossamer Bio, Inc. (filed as Exhibit 10.7 to the Registration Statement on Form S-1, filed with the SEC on May 7, 2021 and incorporated herein by reference (File No. 333-255912)).
10.8#	Amended and Restated Offer Letter, dated January 7, 2020, by and between the Registrant and Andrew Spaventa (filed as Exhibit 10.8 to the Registration Statement on Form S-1, filed with the SEC on May 7, 2021 and incorporated herein by reference (File No. 333-255912)).
10.9#	Amended and Restated Offer Letter, dated January 11, 2020, by and between the Registrant and Eli Glezer (filed as Exhibit 10.9 to the Registration Statement on Form S-1, filed with the SEC on May 7, 2021 and incorporated herein by reference (File No. 333-255912)).
10.10#	Offer Letter, dated September 25, 2019, by and between the Registrant and Dalen Meeter (filed as Exhibit 10.10 to the Registration Statement on Form S-1, filed with the SEC on May 7, 2021 and incorporated herein by reference (File No. 333-255912)).
10.11†	Exclusive License Agreement, date August 12, 2016, as amended, by and between the Registrant and The Trustees of Columbia University in the City of New York (filed as Exhibit 10.12 to the Registration Statement on Form S-1, filed with the SEC on May 7, 2021 and incorporated herein by reference (File No. 333-255912)).
10.12#	Management Cash Incentive Plan (filed as Exhibit 10.13 to the Registration Statement on Form S-1/A, filed with the SEC on May 24, 2021 and incorporated herein by reference (File No. 333-255912)).
10.13#	Executive Severance Plan (filed as Exhibit 10.14 to the Registration Statement on Form S-1/A, filed with the SEC on May 24, 2021 and incorporated herein by reference (File No. 333-255912)).
10.14	Amended and Restated Loan and Security Agreement, dated September 30, 2021, by and between the Registrant and Silicon Valley Bank (filed as Exhibit 10.1 to the Quarterly Report on Form 10-Q for the quarter ended September 30, 2021, filed with the SEC on November 9, 2021 and incorporated herein by reference (File No. 001-40443)).
10.15	Exchange Agreement, dated as of January 26, 2022, by and between the Company and Deerfield Private Design Fund IV, L.P. (filed as Exhibit 10.1 of the Registrant's Current Report on Form 8-K on January 26, 2022 and incorporated herein by reference (File No. 001-40443)).
10.16	First Amendment to Amended and Restated Loan and Security Agreement, dated September 30, 2022, by and between the Company and Silicon Valley Bank (filed as Exhibit 10.1 of the Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 2022, filed with the SEC on November 7, 2022 and incorporated herein by reference (File No. 001-40443).
10.17	Lease Agreement, dated January 19, 2022, by and between the Registrant and ARE-10933 North Torrey Pines, LLC (filed as Exhibit 10.1 of the Registrant's Quarterly Report on Form 10-Q for the Quarter ended March 31, 2922, filed with the SEC on May 10, 2022 and incorporated herein by reference (File No. 001-40443)).
10.18#*	Separation and Release Agreement, dated as of February 28, 2023, by and between the Registrant and Daralyn Durie.
23.1*	Consent of Independent Registered Public Accounting Firm.
24.1*	Power of Attorney (included in the signature page to this Annual Report on Form 10-K).
31.1*	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2*	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
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.
101.INS*	Inline XBRL Instance Document – the instance document does not appear in the Interactive Data File because XBRL tags are embedded within the Inline XBRL document.
101.SCH*	Inline XBRL Taxonomy Extension Schema Document
101.CAL*	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF*	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB*	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE*	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

* Filed herewith.

† Pursuant to Item 601(b)(10) of Regulation S-K, certain confidential portions of this exhibit have been omitted by means of marking such portions with asterisks as the identified confidential portions (i) are not material and (ii) would likely cause competitive harm to the registrant if publicly disclosed.

# Indicates a management contract or compensatory plan.

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 report to be signed on its behalf by the undersigned, thereunto duly authorized**.**

Singular Genomics Systems, Inc.

Date: March 2, 2023

By: /s/ Dalen Meeter
Dalen Meeter
Chief Financial Officer

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each individual whose signature appears below hereby constitutes and appoints Andrew Spaventa and Dalen Meeter, and each of them, the true and lawful attorneys-in-fact and agents of the undersigned, with full power of substitution and resubstitution, for and in the name, place and stead of the undersigned, to sign in any and all capacities (including, without limitation, the capacities listed below), with respect to this Annual Report on Form 10-K, and any and all amendments thereto, and to file the same, with all exhibits thereto, and all other documents in connection therewith, with the U.S. Securities and Exchange Commission (the "SEC"), and hereby grants to such attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and anything necessary to be done to enable Singular Genomics Systems, Inc. to comply with the provisions of the Securities Exchange Act of 1934 (the "Exchange Act") and all the requirements of the SEC, as fully to all intents and purposes as the undersigned might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents, or any of them, or their or his or her substitute, or substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Exchange Act, this report has been signed by the following persons in the capacities set forth opposite their names and on the dates indicated below.

Name	Title	Date
/s/ Andrew Spaventa **Andrew Spaventa**	Chief Executive Officer and Chair of the Board of Directors *(Principal Executive Officer)*	March 2, 2023
/s/ Dalen Meeter **Dalen Meeter**	Chief Financial Officer *(Principal Financial Officer and Principal Accounting Officer)*	March 2, 2023
/s/ David Barker **David Barker**	Director	March 2, 2023
/s/ Kim Kamdar **Kim Kamdar**	Director	March 2, 2023
/s/ Elaine Mardis **Elaine Mardis**	Director	March 2, 2023
/s/ Michael Pellini **Michael Pellini**	Lead Independent Director	March 2, 2023
/s/ Jason Ryan **Jason Ryan**	Director	March 2, 2023