UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2018

OR

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

Commission File Number 001-38613

Bionano Genomics, Inc.

(Exact name of Registrant as specified in its Charter)

Delaware	**26-1756290**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
9640 Towne Centre Drive, Suite 100, San Diego, CA	**92121**
(Address of principal executive offices)	(Zip Code)

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

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

Title of Each Class	**Name of Each Exchange on which Registered**
Common Stock, $0.0001 par value	The Nasdaq Stock Market, LLC
Warrants to purchase Common Stock	The Nasdaq Stock Market, LLC

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

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

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

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

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

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§229.405) is not contained herein, and will not be contained, to the best of Registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ☐

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	x	Smaller reporting company	x
Emerging growth company	x		

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 is a shell company (as defined in Rule 12b-2 of the Exchange Act). YES ☐ NO x

The registrant was not a public company as of the last business day of its most recently completed second fiscal quarter and therefore, cannot calculate the aggregate market value of its voting and non-voting common equity held by non-affiliates as of such date.

As of March 11, 2019, the registrant had 10,096,407 shares of common stock, $0.0001 par value per share, outstanding.

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As used in this Form 10-K, "Bionano," the "Company," "we," "our," and "us" refer to Bionano Genomics, Inc., a Delaware corporation.

Note Regarding Forward-Looking Statements

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

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

- the size and growth potential of the markets for our products, and our ability to serve those markets;
- the rate and degree of market acceptance of our products;
- ability to expand our sales organization to address effectively existing and new markets that we intend to target;
- impact from future regulatory, judicial, and legislative changes or developments in the U.S. and foreign countries;
- ability to compete effectively in a competitive industry;
- the success of competing technologies that are or may become available;
- the performance of our third-party contract sales organizations, suppliers and manufacturers;
- our ability to attract and retain key scientific or management personnel;
- the accuracy of our estimates regarding expenses, future revenues, reimbursement rates, capital requirements and needs for additional financing;
- our ability to obtain funding for our operations; and
- our ability to attract collaborators and strategic partnerships;

You should not rely on forward-looking statements as predictions of future events. We have based the forward-looking statements contained in this Annual Report primarily on our current expectations and projections about future events and trends that we believe may affect our business, financial condition, results of operations and prospects. The outcome of the events described in these forward-looking statements is subject to risks, uncertainties and other factors described in Part I, Item 1A Risk Factors and elsewhere in this Annual Report. Moreover, we operate in a very competitive and rapidly changing environment. New risks and uncertainties emerge from time to time, and it is not possible for us to predict all risks and uncertainties that could have an impact on the forward-looking statements contained in this Annual Report.

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

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

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

PART I

Item 1. Business.

Overview

We are a life sciences instrumentation company in the genome analysis space. We develop and market the Saphyr system, a platform for ultra-sensitive and ultra-specific structural variation detection that enables researchers and clinicians to accelerate the search for new diagnostics and therapeutic targets and to streamline the study of changes in chromosomes, which is known as cytogenetics. Our Saphyr system comprises an instrument, chip consumables, reagents and a suite of data analysis tools.

Structural variation refers to large-scale structural differences in the genomic DNA of one individual compared to another. Each structural variation involves the rearrangement or repetition of as few as hundreds to as many as tens of millions of DNA base pairs. Those rearrangements may be insertions, deletions, duplications, inversions or translocations of segments of one or more chromosomes. Structural variations may be inherited or arise spontaneously, and many cause genetic disorders and diseases. Until our commercial launch of the Saphyr system in February 2017, and since, we believe no products existed or exist that could more comprehensively and cost and time-efficiently detect structural variation.

Our customers include researchers and clinicians who seek to uncover and understand the biological or clinical impact of genome variation to improve the diagnosis and treatment of patients with better clinical tests and new medicines or to replace existing cytogenetic tests that are expensive, slow and labor-intense, with a modern solution that simplifies workflow and reduces costs and that has the potential to significantly increase diagnostic yields across the industry. Our customers also include researchers in non-human segments such as agricultural genomics where they seek to advance their understanding of how structural variation impacts industrial applications of plants and animals. We have established relationships with key opinion leaders in genomics research and clinical applications, including rare diseases and oncology, and our installed base of over 110 systems made up of Saphyr and its predecessor system includes some of the world's most prominent clinical, translational research, basic research, academic and government institutions as well as leading pharmaceutical and diagnostic companies. Examples include Children's National Health System, DuPont Pioneer, Garvan Institute of Medical Research, Genentech, Icahn School of Medicine at Mount Sinai, McDonnell Genome Institute at Washington University, National Institutes of Health, Pennsylvania State University and Salk Institute for Biological Studies. Our revenues in 2017 were $9.5 million, representing approximately 40% growth over the prior year, and for 2018 our revenues were $12 million representing approximately 26% growth over the prior year comparable period.

Approximately 6,000 research use only, or RUO, high throughput sequencers are currently installed worldwide. These sequencers are developed and sold almost entirely by Illumina and are owned by an estimated 3,000 unique customers. Sequencing is very good at detecting genome differences involving just a few base pairs or single-nucleotide variations, which Saphyr cannot detect, but sequencing including next-generation sequencing, or NGS, cannot reliably detect the larger structural variations that our Saphyr system can detect. Therefore, Saphyr is being adopted alongside this installed base of sequencers as a complement that gives users the ability to see a much wider scope of genome variation than ever before.

The Saphyr system, which is for RUO, is also beginning to be adopted by cytogenetics labs that seek to use it in commercial clinical tests of its patients as a laboratory-developed test, or LDT. These labs currently rely on existing methods such as karyotyping, fluorescence in situ hybridization, or FISH, and microarrays for clinical tests and research that look at chromosomal structure, location and function in cells. Major guidelines for oncology and genetic disease clinical diagnostics recommend first-line structural variation testing by these existing methods. The organizations issuing these guidelines include, among many others, World Health Organization (WHO), National Comprehensive Cancer Network (NCCN), American College of Medical Genetics (ACMG) and American College of Obstetricians & Gynecologists (ACOG).

Saphyr and its predecessor system, which we collectively refer to as our system in this Annual Report, have been cited by researchers and clinicians in hundreds of publications covering structural variations in areas of high unmet medical need and research interest, such as rare and undiagnosed pediatric diseases, muscular diseases, developmental delays and disorders, prostate cancer and leukemia. Importantly, Saphyr can be used alone to provide comprehensive detection of structural variations and enable diagnostic calls without the need for any sequencing or cytogenetic technology.

Industry Background

Genome analysis is the process of extracting biological information from DNA. DNA is the code that is found in all living cells and determines the characteristics and health of all living organisms. Although each organism's DNA order is unique, all DNA is composed of the same four nucleotides that come in pairs, which are referred to as base pairs. The human genome is composed of six billion of these base pairs (three billion of which are the maternal copy and three billion of which are the paternal copy of the genome), distributed

across 23 pairs of chromosomes ranging in size from approximately 50 million to approximately 250 million base pairs. Genome variation is defined as at least one base pair differing in a comparison of sequence against a reference standard and can be as large as tens of millions of base pairs.

It had long been believed by the scientific community that all problems in genome analysis could be addressed by DNA sequencing, which is a method of determining the precise order of the bases adenine (A), guanine (G), cytosine (C) and thymine (T) in a genome. Many in the industry felt that the only bottlenecks for sequencing companies to address were the cost per genome and the throughput of the sequencers. If these issues could be addressed, it was generally believed that sequencing would usher in a new wave of medical-grade genome analysis that would give rise to an abundance of highly impactful discoveries in medicine. These discoveries would lead to novel therapies and patient management pathways driven by exquisitely specific and sensitive diagnostic tests.

In recent years, however, it has become evident that sequencing is not completely fulfilling the needs of researchers and clinicians. For example, after 10 years with next-generation sequencing in use, the diagnostic yields of the leading genetic testing laboratories in the world continue to hover around only 50%, which is where they have been for at least two decades, meaning that only half of patients receive a confirmed pathogenic diagnosis. Researchers and clinicians now agree that despite major advances in the speed and cost-effectiveness of sequencing, it fails to reliably detect structural variations, which represent an entire class of genome variation.

Structural variation is one of the most biologically important aspects of the human genome. It is the underlying driver of many known human diseases, including numerous genetic disorders, inherited diseases and cancer. Structural variations occur when relatively large groups of base pairs change their existence or position in the genome relative to a normal standard. Structural variations can be as small as a few hundred base pairs or as large as tens of millions of base pairs and can be confined to one chromosome or can unfold between chromosomes. The changes can be rearrangements in location, order or orientation, and they can involve the insertion, deletion or duplication of entire blocks of base pairs. As an example of the importance of structural variations, thousands of base pairs can be rearranged and result in the ABL gene from one chromosome joining the BCR gene on an entirely different chromosome to form BCR-ABL, an oncogenic fusion gene which causes certain leukemias.

We believe the available methods to detect structural variations for research and clinical applications, other than Saphyr, are antiquated and cumbersome and can only detect a small proportion of the structural variations across an entire genome. These methods therefore have very limited utility in population research studies that seek to discover new structural variations to explain pathology. Without additional tools, researchers and clinicians cannot comprehensively study the genome, which will ultimately result in the failure of genomics to deliver on its full promise of new therapies and diagnostics.

The Saphyr system provides a solution for comprehensive structural variation analysis. The Saphyr system is a proprietary, sample-to-result platform based on physical mapping of the genome, which is the process of assigning the chromosomal location, order and orientation of the functional elements of the genome. We believe that Saphyr is the only product capable of detecting structural variations at high sensitivity and specificity with a workflow that is cost-effective and time-efficient. A complete and accurate physical map of the genome enables the user to much more readily and systematically detect the structural variations that sequencing and cytogenetics technologies miss. Our mapping makes it possible for researchers and clinicians to more comprehensively detect structural variations and measure the complete scope of genome variation present in their study populations.

Market Opportunity

According to Research and Markets, the worldwide market for genomics products and services is expected to reach approximately $23.9 billion by 2022, up from approximately $14.7 billion in 2017, representing a compound annual growth rate of 10.2%. We believe that the market opportunity is predominantly split among three regions: North America, Europe and Asia. Within Asia, one of the fastest growing genomics markets is China, where adoption of genome analysis technology has been growing at approximately 20% per year.

The two segments of the genomics market that are driving the uptake of our product are:

- ***Sequencing for Discovery Research.*** In discovery research across patient cohorts, sequencing is primarily used to find single nucleotide variations responsible for disease or therapeutic response. Sequencing alone, however, is significantly limited due to its inability to reveal structural variations. Our Saphyr system has been expanding this market segment by complementing sequencing to expand the scope of genome variation that can be analyzed in a study and achieve a more comprehensive view of the genome.
- ***Cytogenetics.*** To provide a clinical diagnosis, cytogenetic tests detect known variations that are linked to specific diseases or therapeutic responses. The technologies used for detecting structural variations are expensive and involve cumbersome workflows with relatively limited ability to scale to higher volumes or more complex testing panels. Sequencers tend not to be used for cytogenetics due to their inability to reliably detect structural variations. Cytogenetics laboratories are beginning to adopt Saphyr as a more effective and efficient approach to finding the structural variations relevant to cytogenetics. For

this segment, Saphyr is used alone to provide comprehensive detection of structural variations and enable diagnostic calls without the need for any sequencing or cytogenetic technology.

We believe that the discovery research and cytogenetics segments together comprise an addressable opportunity for us to sell up to approximately 8,500 Saphyr systems, representing a current total instrument market opportunity of approximately $2.1 billion. Importantly, we expect this market opportunity to expand at the rate of adoption of new RUO high throughput sequencers which we estimate is over 15% per year. While we do not expect the number of cytogenetics labs to increase significantly, we do expect our growth in this market to be driven by conversion of traditional cytogenetics methodologies to our Saphyr system.

In addition to the instrument sales opportunity, Saphyr instruments generate recurring revenue from chip consumables that are used on a per-sample basis. We believe each Saphyr instrument has the potential to create recurring revenue in a range of approximately $75,000 to approximately $150,000 per year, suggesting a potential annual recurring revenue opportunity of approximately $0.6 billion to approximately $1.3 billion.

Therefore, we believe that our currently addressable portion of the genome analysis market is estimated to be between $2.7 billion and $3.4 billion.

Existing Technologies and Their Limitations

Existing technologies fail to adequately address the need for structural variation detection because they do not overcome the inherent complexity of the genome or they are not capable of providing a cost-effective, scalable solution to meet the increasing demands of genomics research and clinical applications.

The Genome Is Complex

Genome composition itself makes the measurement of genome structure and structural variation inherently difficult. Genome sequence is built from combinations of only the A, G, C and T nucleotides. The nucleotides have a natural pairing system in which A pairs with T and G pairs with C. Each pair of nucleotides is referred to as a base pair. In humans, the approximately six billion base pairs are distributed across 23 pairs of chromosomes. A chromosome is an organizational unit that biology has evolved to compartmentalize genomic information. One set of 23 chromosomes (three billion base pairs) is inherited from each parent. Within each chromosome, the base pairs are organized into functional elements such as genes, which code for protein production, and other elements that regulate how and when the genes are expressed for protein production.

The six billion base pairs that make up the human genome cannot be read by any existing technology in a simple linear, contiguous fashion. Due in part to only four unique nucleotides being available to write the entire genetic code, it is very common for stretches of sequence to be identical either within the same chromosome or between chromosomes. As much as two-thirds of the human genome is made up of repetitive DNA sequences. This repetition tends to cause structural variations to be flanked by sequences that are identical to sequences in other parts of the genome which further complicates structural variation detection.

The Genome Orchestrates Life and Genome Structure Is Key

Genome structure is the way in which the functional elements are organized. Namely, the location on each chromosome where the gene or functional regulatory elements are found, what order and orientation they are in and how many of each element are present. This organization is an essential part of the instructions that the organism uses in every one of its cells to develop and differentiate and to react and respond to its environment over its lifetime. When this critical location, order, orientation or quantity vary, it is termed structural variation.

Even though both single nucleotide variation and structural variation are each very common, a much larger number of variant nucleotides in the average human genome are found in structural variations as compared to single nucleotide variations. A recent study showed that 30 million base pairs, on average, in the human genome are part of structural variations while only 10 million are single nucleotide variations. Most variations are inconsequential and make up the background variation responsible for the diversity of life. Over time, these variations can randomly affect genes and proteins which, through natural selection, drive diversity and evolution across species and diversity within them. Variations can also cause disease.

Relative to single nucleotide variations, structural variations are much more apt to be profoundly disruptive. They often cause a tectonic shift in the genome. These genomic shifts can have devastating effects on the health of a human. Examples where structural variations caused a disruption of genes resulting in disease include:

- dystrophin gene variation – structural variation disrupting dystrophin production that is found in Duchenne Muscular Dystrophy;

- 9pminus variation – deletion found in a rare developmental syndrome in children;
- TMPRSS2-ERG fusion – gene fusion found in prostate cancer;
- EML4-ALK fusion – gene fusion found in lung cancer; and
- BCR-ABL fusion (Philadelphia chromosome) – gene fusion found in leukemias such as chronic myelogenous leukemia, acute lymphoblastic leukemia and acute myelogenous leukemia.

It is important to detect these structural variations and the potentially thousands of other structural variations in each individual. Sequencing and cytogenetics simply do not elucidate comprehensive structural variations in a systematic and cost- and time-efficient manner. Most structural variations found to date that have been implicated in disease, such as those listed above, were discovered through laborious, expensive, unindustrialized and non-comprehensive methods over the course of many years. Thousands of additional important structural variations are believed to exist and are expected to be found with a systematic structural variation detection tool such as our Saphyr.

The Limitations of Sequencing

As the first complete draft of the human genome was being assembled in 2000, the belief arose that most questions in genome analysis could be addressed by sequencing. Over the course of over 15 years, sequencing proliferated across the entire genome analysis community with Illumina becoming the clear sequencing industry leader. As more sequencing data emerged, it became apparent that sequencing alone would not adequately elucidate the causes of human disease. The promise of sequencing was not fully delivered due to sequencing's inability to address the complexities of genome composition.

Nearly all genome sequencing, including next-generation sequencing, uses a method called sequencing by synthesis. Sequencing by synthesis is an in-vitro process for synthesizing a copy of DNA, one base at a time in a way that makes it possible to measure the identity of each base as it is incorporated into the growing DNA copy. Sequencing by synthesis involves cutting genomic DNA into small pieces of a few hundred base pairs each, amplifying these pieces many times and anchoring them to a solid support where they are copied by a polymerase using fluorescently labeled bases. These copies are called sequencing reads. Illumina, which is the world leader in next-generation sequencing technology, markets systems that provide average read lengths that are 100 to 300 base pairs long. These short reads are matched by computer programs to a reference genome in a process called alignment. The reference is meant to represent the "standard" human genome in a normal, non-diseased state. It is the result of billions of dollars spent on the Human Genome Project and other initiatives begun in the late 1990s and early 2000s to put together the first complete set of human DNA code. When a patient's genome is sequenced today, the short reads are compared against the reference as a template. Using this approach, sequencing attempts to reconstruct, or "resequence," the genome and infer genome variations.

The read lengths typical for next-generation sequencing are often too short to determine the right location and orientation of a reading frame in the genome because many of the reads from one chromosome are identical to reads from either another chromosome or even another location on the same chromosome. When reads are indistinguishable from one another, computations cannot be performed to place the reads in the correct location in the genome.

The other significant limitation with next-generation sequencing is that the genome fragments used as templates in the copying process are also very short. This fragmentation is a result of the methods used for DNA isolation from the cell and the use of polymerase chain reaction, or PCR. These short lengths disconnect and destroy most of the structural information of the original genome and make next-generation sequencing unable to reliably detect genomic variations larger than a few hundred base pairs.

If the sequencing reads were accurate, on the order of hundreds of thousands of base pairs long and from templates that were even longer, they would overcome the redundancy of genome composition and every read would have a unique position in the genome. It would then be possible to assemble a structurally accurate picture of the genome. Accurate structural variation would be revealed upon comparing structurally accurate assemblies of genomes across a population to determine the structural changes that are driving the observed pathology or physiology.

The recognition of the need for greater lengths of sequence reads to determine genome structure, birthed the so-called long-read sequencing submarket. Because of the need for long-read sequencing, Pacific Biosciences of California developed a system that uses another alternative form of sequencing by synthesis, while Oxford Nanopore Technologies developed a system that uses nanopore technology. These systems provide users with average read lengths in the tens of thousands of base pairs. However, these read lengths have proven not to be long enough to reliably and comprehensively detect structural variations. Pacific Biosciences' polymerases cannot regularly produce reads that are the necessary hundreds of thousands of base pairs in length. In addition, Oxford Nanopore's system has difficulty reliably feeding molecules that are, on average, hundreds of thousands of base pairs in length through each nanopore. The time and cost of providing a comprehensive whole genome analysis of a patient in a clinical setting is prohibitive when using these longer-read technologies.

In summary, all existing sequencing technologies, whether short or long, do no provide a solution for integrating structural variation into patient diagnosis and management.

The Limitations of Cytogenetics

Cytogenetics is the study of chromosomal structure and how structural variations impact health. The field has historically relied on karyotyping, FISH and more recently, microarrays. These methods each can detect some structural variations, but they are all inadequate solutions for high volume and low cost genetic testing for structural variations and none is an approach that can comprehensively detect structural variations with the ultra-high sensitivity and ultra-high specificity of the Saphyr system.

Karyotyping

Karyotyping is the gross optical examination of the chromosomes using a microscope. It is a laboratory technique, modernized in the 1960s, whereby the chromosomes from one cell are stained and visualized by a pathologist or technician to investigate the total number and structure of chromosomes.

Karyotyping has many limitations. It is cell culture dependent and therefore requires live and actively dividing cells. Karyotyping has extremely low resolution and is therefore only sensitive for very large structural variations that are unambiguous to identify. Given that chromosomes are being directly viewed on a slide by a pathologist with a microscope, resolution tends to be limited to structural events that are larger than five million base pairs. When karyotyping is used to diagnose unknown genetic disease, only about 5% of karyotyping tests result in a confirmed pathogenic finding. The test is costly, and its results are subject to each pathologist's interpretation which introduces variability in diagnostic calls and makes the methodology not amenable to automation.

FISH

FISH is a molecular cytogenetic technique that is used to detect chromosomal aberrations. FISH is based on the idea of using a specifically developed probe to detect a particular gene abnormality that is suspected to be in the genome. When the probe finds targeted variation, it binds to it and generates a fluorescent signal which is observed with a fluorescence microscope.

Several characteristics of FISH limit its productivity and efficiency for use in structural variation detection. Like karyotyping, it is cell culture dependent and therefore requires live and actively dividing cells. Also, FISH is limited to known targets and cannot be used for discovery. Every FISH test performed needs to be chosen to look for a specific genetic marker that the clinician anticipates may be found based on the clinical symptoms of the patient. In addition, the test results can be ambiguous and inconclusive, and reproducibility and variability among users can be a significant issue. Like karyotyping, FISH's diagnostic yield is very low when used to diagnose unknown genetic disease with only an estimated 7% of FISH providing a confirmed pathogenic finding. In addition, FISH is expensive, especially for the limited amount of information that it provides.

Microarrays

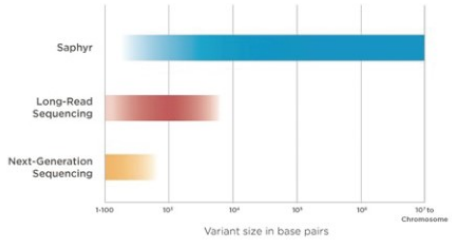
Chromosomal microarrays and SNP (single nucleotide polymorphism) arrays are tests consisting of slides that contain thousands of spots of DNA fragments that bind to the DNA of the sample. Microarrays detect gains and losses of specifically chosen DNA sequence and can also infer gene expression levels. Microarrays interrogate thousands of genes simultaneously that are known to be associated with presumed genetic disorders of interest to the user. Probe coverage is typically highly focused in regions of known clinical significance.

Microarrays have limited utility as a diagnostic tool as they are only useful when there are gains and losses of base pairs within the sample's genome that are specific to the probes that are populated on the array. Microarrays are also limited in their ability to provide specific locations of gains or losses on a chromosome, or even identify on which chromosome that the gains or losses occur. In addition, microarrays have low resolution as they cannot reliably detect structural variants smaller than 50,000 base pairs. Also, the diagnostic yield of microarrays is low. Only an estimated 20% of microarray tests provide a confirmed pathogenic finding when used to diagnose unknown genetic disease.

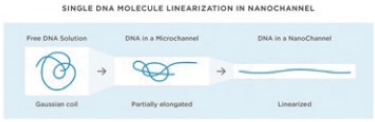
Our Solution

Our approach to measuring genome structure and structural variation is novel and highly differentiated. Most efforts in the genomic industry to address structural variation have been based on taking sequencing by synthesis as the starting point and attempting to overcome its deficiencies to make it applicable to structural variation analysis. In contrast, the Saphyr system directly observes extremely long genomic DNA without any amplification to construct a physical map that accurately assigns the chromosomal location, order, orientation and quantity of all the genome's functional elements. Our solution is built upon four key elements:

- **Extremely long molecules for analysis.** Structural accuracy can only come from analysis of extremely long chromosomal fragments. The Saphyr system is capable of analyzing single molecules that are on average approximately 250,000 base pairs long. Such fragments will contain enough unique sequence information that they are distinguishable from other fragments. These lengths are over 1,000 times longer than the average read length with Illumina systems and approximately 10 times longer than the average read lengths with Pacific Biosciences and Oxford Nanopore systems. Building a picture of the genome with massive building blocks overcomes the inherent challenge of genome complexity and is the key to Saphyr's unprecedented sensitivity and specificity.



- **Proprietary nanotechnology for massively parallel linearization and analysis of long molecules with single molecule imaging.** Analyzing these extremely long chromosomal fragments required invention. Molecules of this size are more like balls of yarn in a test tube and must be unraveled for meaningful analysis. We invented, patented, developed and commercialized nanochannel arrays to capture them from solution and unwind and linearize them for structural variation analysis. Each molecule is imaged separately, making it possible to deconvolute complex mixtures including haplotypes and heterogeneous tumors, as shown in the graphic below.



- **DNA labeling chemistry specifically for physical mapping.** The detailed analysis of sequence we use is also highly unique and novel. Instead of identifying the sequence of every base pair in these long fragments, we label and detect specific sequence patterns or motifs that occur universally across every genome with an average frequency of approximately one site for every few thousand base pairs. The key to our method entails introducing fluorescent tags at the sequence-specific site using highly specific and robust enzymatic chemistry along the extremely long fragments. These fragments, stretched out in nanochannels, are then directly imaged allowing us to measure the distance between labels with high accuracy. The pattern of labels detected on all these fragments can then be related to the pattern of sequence motif sites in a reference genome for comparison. Changes in the pattern indicate structural variation.
- **Bioinformatic tools for structural variation analysis.** Finally, our approach includes a novel bioinformatics platform that we developed from the ground-up to take advantage of the unique benefits of our solution. It comprises proprietary algorithms for the construction of a structurally accurate physical map of the genome without using a reference genome in assignment of structure. Physical maps of a test subject are then compared in cross-mapping analysis that allows our system to detect genome wide structural variation, including the most complex balanced events. Our system can do so by comparing one physical map against a common reference, or against the maps of a mother and father in the case of an afflicted child with an undiagnosed disease for example, or against maps of normal blood when studying solid tumor cancers. This comparative approach uses our proprietary database of healthy individuals to filter out the non-disease causing structural variants found in the general healthy population.

Our Focus Areas

Our Saphyr system serves many segments of the genomics market seeking to find and understand structural variation. We have identified focus areas where we concentrate our resources to ensure robust adoption of our system and frequent utilization of consumables. We have selected these segments because of their urgent need to detect structural variations and the significant economic opportunity they represent. Our current focus areas are human genetic diseases, including rare diseases and oncology. Our Saphyr system, which is for RUO, is being used for basic and translational research and also beginning to be adopted by cytogenetics labs that seek to use it in commercial clinical tests of its patients as an LDT.

Rare Diseases

In genetic disease, existing tools have reached a plateau where almost half of patients with genetic disease who are tested in clinical laboratories fail to receive a molecular diagnosis. In order to increase diagnostic yield, a massive increase in the understanding of the complete structure and variation of the genome is essential. We believe the various studies presented below illustrate how Saphyr is essential to achieving this objective.

Example: Undiagnosed Diseases Network Patient

The National Institutes of Health funded Undiagnosed Diseases Network, or UDN, brings together top clinical and genomics teams from several key institutes in the U.S. to study the most difficult to diagnose genetic disease patients. Through a collaboration with UCLA, Dr. Eric Vilain of Children's National Medical Center runs all UDN patients of the UCLA cohort on Saphyr to identify pathogenic variants that go undetected using sequencing or cytogenetics in known or novel genes.

While data collection and a full analysis of the cohort is ongoing, at the American Society of Human Genetics, or ASHG, annual meeting, Dr. Vilain's team presented preliminary results on the first 12 UDN patients and their parents analyzed with Saphyr. In each family, Saphyr detected thousands of variants of which more than 100 were rare, and typically three to seven structural variations that were new to the patient, referred to as de novo structural variations, were identified. In one case presented at ASHG, whole genome sequencing and chromosomal microarray on the DNA of a girl with developmental delay, autism, poor sleep and self-mutilation failed to identify pathogenic variants. Saphyr was able to detect a 2,500-base pair insertion inherited from the father in a gene where whole genome sequencing had picked up a random mutation inherited from the mother. Together, the two variants create a compound heterozygous mutation in a gene with a known phenotype that includes poor sleep, developmental delay and autism with self-mutilation. Large heterozygous insertions like the one presented here are seldomly detected by next-generation sequencing and are too small for microarrays. The diagnosis of this patient was only possible by the combination of next-generation sequencing and Saphyr.

Based on Dr. Vilain's results, including a study on patients with Duchenne Muscular Dystrophy published in Genome Medicine, Saphyr targets the 40% to 70% of genetics patients who cannot be diagnosed with exome or whole genome sequencing. Saphyr has the power to replace multiple tests for genetic disorders, including microarrays, PCR tests and chromosomal cytogenetic tests. Each existing test requires a patient to visit a clinician and most often provides an inconclusive result. Dr. Vilain showed evidence that integration of Saphyr into existing diagnostic regimens can help to change the way that medicine is practiced.

Example: Rare Familial Cancer

A rare cancer, occurring in approximately one in one million people, was found in four members of a single extended family. A team at MD Anderson Cancer Center had used all standard clinical tools and whole genome sequencing on the affected family members but failed to identify any causative variants. Using Saphyr data, a 38,000-base pair sequence was found in these patients in six tandem copies, while unaffected family members had a single copy of this sequence. The duplication was found to be upstream of an important gene in the pathway known to be upregulated in this rare cancer. The identification of this mutation could be useful for pre-implantation embryo analysis and targeted treatments.

Example: Repeat Expansion Disorder

In a study by Dr. Eric Wang of the University of Florida, Saphyr was able to precisely count the number of times that a sequence segment was repeated in muscle cells derived from a patient with Myotonic Dystrophy. This devastating disease is a repeat expansion disorder, caused by the extreme lengthening of short repeat array in the genome. Other diseases in this category include ALS, Huntington's Disease, and Fragile-X disease. Current methods that do not utilize our Saphyr system cannot measure the length of such repeat arrays accurately. Saphyr's ability to measure the normal and expanded repeat with unprecedented accuracy and detail on single molecules could help allow the development of better targeted tests and medicines.

Example: Greenwood Genetic Center

Greenwood Genetic Center, based in South Carolina, has acquired Saphyr as part of a project to increase the diagnostic yield for patients with genetic disorders and cancer. As one of the first centers in the world to introduce next-generation sequencing in a diagnostic setting, Greenwood Genetic Center aims to introduce a lab developed test, or LDT, based on Saphyr. As such, a number of patients with a variety of birth defects and developmental disorders are being analyzed on Saphyr.

In genetic disease, the standard of care consists usually of a combination of both phenotype-dependent targeted tests, and whole-genome analysis approaches. Targeted tests can consist of Multiple Ligation Probe Amplification, or MLPA, to test for the presence or absence of specific exons, PCR amplification and Sanger sequencing of candidate genes and multiple FISH probes to pick up specific structural variants common to the expected disease. For whole genome approaches, first tier diagnostic tools include karyotyping techniques like metaphase chromosome spreads and in some cases microarrays. More recently, whole exome sequencing or whole genome sequencing are increasingly being introduced.

A future workflow in which Saphyr replaces the large majority of FISH and MLPA tests for a genetics clinic such as Greenwood Genetic Center would rely on Saphyr to detect all structural variants larger than 500 base pairs, and on next-generation sequencing to detect all single nucleotide variants and other variants smaller than 500 base pairs. Since up to numerous FISH and MLPA tests are often performed, Saphyr's single whole genome analysis provides a cost effective solution that saves significant amounts of time, labor and analysis in lieu of such tests.

Oncology

In cancer, each patient has a unique disease with a complex pattern of genome changes. Traditional and recently-developed treatments do not attack the individual changes in each patient's tumor. Recent personalized medicine programs aim to provide clinicians with individual treatments specifically targeting the mutations found in each patient's cancer. For personalized cancer medicine to be successful, all variants in the cancer genome need to be detected, which is not feasible with cytogenetic or whole genome sequencing approaches. The studies presented below demonstrate that Saphyr is critical for a complete understanding of a cancer genome, which is essential to enable truly targeted treatments.

Example: Hematologic Malignancies

In a study to be published in Nature Genetics, Dr. James Broach, Director of the Penn State Institute for Personalized Medicine, presented system's ability to detect large rearrangements in leukemia, with a strong focus on translocations. In his research, our system detected all known translocations identified with standard clinical tools and, importantly, many structural variations never before identified in cancer, plus hundreds of structural variations that could not be seen by other methodologies.

Attempts by Dr. Broach to detect translocations using next-generation sequencing were unsuccessful because of the large number of false positive translocation calls. Because of the highly repetitive nature of the human genome, many remote genomic regions have high sequence homology, and short-read sequencing often fails to correctly map reads to the correct genomic origin, leading to excessive false positive calls. The extremely long molecules that our system analyzes span long repetitive segments of sequence and can anchor sequences into the correct genomic context, leading to extremely few false positive calls.

Given the high speed, low cost, industry-leading sensitivity and high reliability of our system displayed in this study, Dr. Broach showed evidence that our system is well positioned to eventually become the primary tool for clinical detection of genomic structural variation.

Example: Prostate Cancer

In a study published in Oncotarget, Dr. Vanessa Hayes at the Garvan Institute of Medical Research in Australia presented a complete tumor-normal comparison from a primary prostate cancer. Dr. Hayes' team identified 85 large somatic deletions and insertions, of which half directly impact potentially oncogenic genes or regions. Only 11% of these large structural variations were detected using high-coverage, short-read next-generation sequencing and bioinformatics analyses using a combination of the leading structural variation calling algorithms for next-generation sequencing data. Many structural variations detected with our system were flanked by repetitive sequences, making them undetectable to short-read sequencing.

In subsequent studies presented at the Advances in Genome Biology and Technology annual meeting, Dr. Hayes detected several oncogenic driver mutations in metastasized prostate cancer samples. Several of the reported mutations were variants previously found in other cancer types but never before reported in prostate cancer, and for which effective treatments are available. Existing gene panels or FISH tests performed on cancer samples only test for expected variants. Our system's whole genome analysis approach is the only molecular method that is capable of identifying all major structural variants in a cancer genome with sufficiently high sensitivity. To

make existing targeted cancer therapies more effective and to discover new ones, a complete characterization of the genome is important, making our system valuable in personalized cancer medicine.

Our Products

We develop and market the Saphyr system, a complete sample-to-result solution for structural variation analysis that empowers comprehensive genome analysis and facilitates a deeper understanding of genetic variation and function. We believe it is the only solution capable of addressing the needs for structural variation analysis because it is:

- **Highly sensitive.** We believe Saphyr is the most sensitive structural variation detector currently on the market in that it can identify structural variations that no other system can.
- **Highly specific.** The structural variations found by Saphyr are found by direct observation rather than inference. Saphyr has a very low false positive rate, typically less than 2%.
- **Cost effective.** We expect the cost per sample to continue to decline to less than $300 per sample in 2019 and less than $100 per sample in 2020.
- **Fast.** Saphyr generates greater than 640 giga base pairs of information per day, on par with some of the faster short-read sequencers in the market. For highly sensitive structural variation detection, this allows Saphyr to process two human samples per day. We expect Saphyr's throughput to increase to six per day by the first half of 2019 and 12 per day by the end of 2020. Over this same period, we expect to continuously improve the automation of sample prep and bioinformatics to help drive efficiencies of workflow.

Saphyr is being adopted across an extensive base of customers in world-class clinical, translational research, basic research, academic and governmental institutions as well as pharmaceutical and biotechnology companies. We began marketing the Saphyr system in February 2017 after previously marketing Irys, our first-generation system, which was a slower system. We sell through a direct sales force and support organizations in North America and Europe, and through distribution partners in the Asia-Pacific and other regions of the world. We have sold more than 110 of our systems globally. We continually seek to expand our product offerings to meet the needs of our customers.

When customers adopt the Saphyr system, they acquire one or more instruments, chips, reagents for DNA isolation and labeling and a suite of bioinformatics tools. The chips and reagents are used on a recurring basis. We also sell them ancillary solutions such as servers, reagents and other non-proprietary components used with the system. We designed Saphyr to accommodate performance upgrades without the need for replacement of the entire instrument. We intend for these performance enhancements to be delivered through software upgrades, purchased hardware upgrades and new chips and reagents.

The Saphyr Instrument

The Saphyr instrument is a single-molecule imager that includes high performance optics, automated sample loading based on machine learning algorithms and computational hardware and control software. The instrument's high-performance optics simultaneously image DNA linearized in hundreds of thousands of nanochannels. The instrument's control interface is the user's primary control center to design and monitor experiments as they occur in real time. The computational hardware is responsible for the secondary processing of the image data being produced on the Saphyr.

The Saphyr instrument currently analyzes one Saphyr chip, containing up to two samples, per day with statistically relevant depth of coverage across each whole genome. An upgrade of the capability of the Saphyr instrument to process two chips, instead of one, per run is planned for the first half of 2019. This instrument upgrade along with the planned improvements to the chip mentioned below will enable Saphyr to process up to six human samples per day by the first half of 2019 and 12 per day by the end of 2020.

The Saphyr Chip

The Saphyr chip is the consumable that packages the nanochannel arrays for use in genome analysis. In its current form, each Saphyr chip has two flow cells. Each flow cell contains approximately 120,000 nanochannels that are roughly 50 nanometers wide and can hold a unique sample, which enables a researcher to analyze two samples per chip per day. We plan to offer a new chip to our customers in the first half of 2019 that will have three flow cells which, combined with the instrument upgrade mentioned above, will allow Saphyr to process six human samples per day. In 2020, we expect to offer a 12-flow cell version of the chip. The instrument at that time will be able to run two chips per run; however, given the increased processing load of the 12-flow cell chip relative to the three-flow cell chip, Saphyr is expected to take two days to process two 12-flow cell chips, thereby enabling a throughput of 12 samples per day in 2020.

To manufacture the arrays, we use photolithography in a semiconductor fabrication facility to print hundreds of thousands of tiny grooves on silicon wafers and then dice the wafers into individual chips. Our chips are inexpensive to manufacture and highly scalable. The fluidic environment in each channel allows individual molecules to move swiftly utilizing only the charge of DNA. Our nanochannels allow only a single linearized molecule at a time to enter a given channel while preventing the molecule from tangling or folding back on itself. Importantly, hundreds of thousands of molecules can move through hundreds of thousands of parallel nanochannels simultaneously, enabling extremely high-throughput processing on a single-molecule basis.

Saphyr Sample Prep and Labeling Kits

Our Bionano Prep Kits™ and labeling kits provide the critical reagents and protocols needed to extract and label high molecular weight, or HMW, DNA for use with the Saphyr™ system. These kits are optimized for performing our genome mapping applications on a variety of sample types.

Our workflow begins with the isolation of ultra-high molecular weight DNA. Our sample prep kits are optimized for isolating and purifying ultra-high molecular weight DNA in a process that is gentler than existing DNA extraction methods. The resulting purified DNA is millions of base pairs long and optimal for use with our systems. Each Bionano Prep Kit allows customers to perform five to 10 HMW DNA preps. Our kits and protocols enable the extraction of HMW DNA from a variety of sample types including soft or fibrous animal tissue, plant tissue, cell lines and human blood.

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

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

Data Solutions

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

Bionano Access is our web-based hub for Saphyr operations. It provides all the software that our customers need for experiment management and our structural variation analysis in one place. With Bionano Access our customers can:

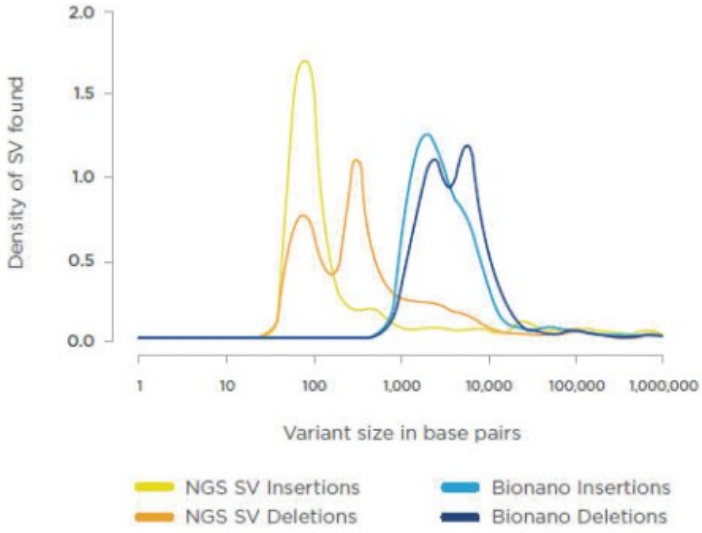
- set up runs and monitor real-time data quality metrics remotely to flag potential sample quality issues early;
- automatically start de novo assemblies and structural variation analysis when the desired amount of data has been collected;
- visualize and manipulate maps and structural variants; and
- analyze trios and clinical samples by filtering through uncommon variants to identify inherited and de novo variants, and export in a file format that is used consistently throughout the industry.

We have a suite of proprietary algorithms and databases that fully enable our proprietary bioinformatic and structural variation analysis pipelines. Using pairwise alignment of the single molecule images, consensus genome maps are constructed, refined, extended and merged. Molecules are then clustered into two alleles, and a diploid assembly is created to allow for heterozygous structural variation detection. Genome maps typically span entire chromosome arms in single, contiguous maps. Comparative analysis of maps reveals structural variation. Our customers use our variant annotation workflow to specifically uncover rare and sample-specific mutations. For example, to help a customer determine genomic variant frequency in a tumor, Saphyr compares the cancer sample structural calls against over 600,000 structural variations from over 160 humans with no evidence of diseases. To identify somatic mutations, the workflow can run comparisons of the tumor specimen against a control sample to determine whether the cancer mutations are present in low abundance among the control’s genome. Using this high through-put pipeline approach we can efficiently focus on dozens of clinically significant structural candidates for further analysis.

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

The Saphyr System's Industry-Leading Sensitivity and Specificity

Our Saphyr system detects structural variations that Illumina's systems miss. As shown in the graphic below, the Garvan Institute of Medical Research generated data that we expect to be published which shows the density of structural variations found relative to the size of the structural variation found for our system (blue lines) against next-generation sequencing (Illumina; orange lines). Next-generation sequencing has a very significant deficiency in detecting structural variations. Given our system's ability to detect structural variations, it picks up essentially where next-generation sequencing drops off, as shown below.



Retaining long-range contiguity throughout the genome mapping process is critical for any comprehensive study of genome structure and function, particularly for the analysis of structural variation in complex genomes. Saphyr offers unmatched sensitivity for the detection of large structural variations greater than 500 base pairs. Saphyr's specific sensitivity percentages from recent studies are shown below:

- 99% sensitivity for homozygous insertions/deletions larger than 500 base pairs;
- 95% sensitivity for heterozygous insertions/deletions larger than 500 base pairs;
- 95% sensitivity for balanced and unbalanced translocations larger than 50,000 base pairs;
- 99% sensitivity for inversions larger than 30,000 base pairs;
- 97% sensitivity for duplications larger than 30,000 base pairs; and
- 97% sensitivity for copy number variants larger than 500,000 base pairs.

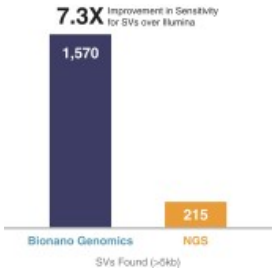
A study of Pacific Biosciences' long-read sequencing's ability to detect homozygous and heterozygous insertions and deletions was published recently. The sensitivity to detect homozygous structural variations using Pacific Biosciences was 87%, compared to 99% using Saphyr. The sensitivity to detect heterozygous structural variations using Pacific Biosciences was only 41%, which is less than half the 84% sensitivity for heterozygous structural variation detection using Saphyr. Even when the Pacific Biosciences structural variation calls were limited to insertions and deletions larger than 500 base pairs, the sensitivity for homozygous structural variations was only 81%, and for heterozygous structural variations was only 49%.

SV Sensitivity*		
	Bionano Genomics	Pacific Biosciences
Insertions		
Homozygous	99.3%	80.4%
Heterozygous	81.2%	39.7%
Deletions		
Homozygous	98.8%	82.4%
Heterozygous	87.9%	62.0%

*Sensitivity for variations >500 base pairs

Saphyr detects duplications over 30,000 base pairs, in direct or inverse orientation, with a sensitivity of 97%. Saphyr detects 99% of inversions of that same size range. Inversions are the invisible variants and have traditionally been the hardest to detect structural events. They are balanced, without gain or loss of sequence, and unlike translocations they do not create easily visible changes in genomic context. Inversions often escape detection by traditional cytogenetic techniques. Chromosomal microarrays cannot identify balanced events, and metaphase chromosome spreads can only visualize some megabase-size inversions. Next-generation sequencing approaches tend to miss inversions because reads from inside the inversion tend to map back to the reference without any indication that the orientation of the sequence has changed. Detection of the breakpoints often fails, especially if the inversion is flanked by segmental duplications, repeat sequences or other non-unique sequences. Saphyr's imaging of extremely long molecules overcomes these obstacles to identifying inversions.

In a separate study, our system detected seven times more structural variations larger than 5,000 base pairs compared to next-generation sequencing. Dr. Pui-Yan Kwok at the University of California, San Francisco, demonstrated the robustness of our system for genome-wide discovery of structural variations in a trio from the 1000 Genomes Project. Using our system, hundreds of insertions, deletions, and inversions greater than 5,000 base pairs were uncovered amounting to 7.3 times more than the large structural variation events detected by next-generation sequencing. Importantly, many of the structural variations that were found were in regions believed to contain functional elements leading to disruption of gene function or regulation.



Our Strengths

We have established ourselves as one of the leaders in the field of genome analysis, and we believe we are the industry's performance leader in structural variation detection. Below are our strengths that we believe will enable us to capture a significant portion of the genome analysis market and retain our leadership position in structural variation:

- ***Highly differentiated technology platform enables researchers and clinicians to obtain information that cannot be had systematically and cost efficiently from traditional technologies.*** Saphyr's unique ability to systematically and cost efficiently see structural variations across the genome from 500 base pairs to tens of millions of base pairs is unique in the industry. We believe this greater insight will facilitate a paradigm shift in healthcare from an emphasis on treatment with

relatively untargeted therapies to a focus on earlier detection, more precise diagnosis and treatment with better targeted therapies.

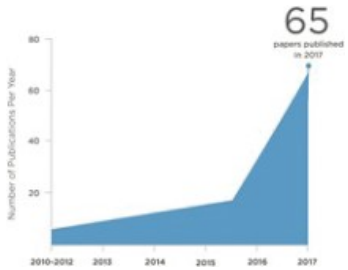
- ***Validated solution recognized industry-wide.*** We have deep and expanding scientific validation. Our system has been cited in hundreds of publications, and we believe our technology is becoming a vital tool in cutting-edge life sciences research.
- ***Strong installed base of premier customers.*** We have sold more than 110 of our systems globally. Our customers include some of the world's most prominent clinical, translational research, basic research, academic and government institutions as well as leading pharmaceutical and diagnostic companies. Examples include Examples include Children's National Health System, DuPont Pioneer, Garvan Institute of Medical Research, Genentech, Icahn School of Medicine at Mount Sinai, McDonnell Genome Institute at Washington University, National Cancer Institute, National Institutes of Health, Pennsylvania State University and Salk Institute for Biological Studies.
- ***Attractive business model with a growing, high-margin recurring revenue component.*** As we continue to grow our installed base of Saphyr systems, optimize workflows and expand our structural variation detection capabilities, we expect to rapidly increase our high-margin revenues derived from consumables. The successful integration of our technology into our customers' projects provides ongoing sales of assays and consumables.
- ***Industry-leading intellectual property portfolio.*** We have developed a global patent portfolio that includes 43 issued patents across 14 patent families and an exclusively licensed portfolio of patents and applications from Princeton University, which includes 22 patents across two families. This global patent portfolio has filing dates ranging from 2001 to 2017. We have robust intellectual property protection surrounding our devices, systems, and methods for macromolecular analysis. Our ideation stems from our highly active research programs and results in our patent portfolio continually expanding at a significant pace.
- ***Highly experienced senior management team.*** We are led by a dedicated and highly experienced senior management team with significant industry experience and proven ability to develop novel solutions. Each of the members of our senior management has more than 20 years of relevant experience.

Our Strategy

Our goal is to enable new research in genomics to allow greater insight into their role in human health in ways that have not been possible with any other current research and diagnostic technologies.

Our strategy to achieve this includes:

- ***Drive adoption of Saphyr in discovery research and cytogenetics markets.*** Saphyr has the potential to significantly expand the life science research market and genomics-based diagnostics market because of its unrivaled sensitivity, by enabling researchers to perform studies on structural variations that they were previously unable to perform. We believe Saphyr has the capability to enable the development of a new category of diagnostic tests and tools.
- ***Support the publication of findings with Saphyr by our customers beyond the over 130 papers published to date.*** The chart below shows the annual number of publications released since 2010 which featured data generated by Saphyr and its predecessor system. Recently, the overall number of these publications has grown significantly. For example, of the over 130 papers published to date, approximately half were published in 2017 alone. We will continue to support and foster our customer base to help grow the number of publications featuring our systems' data. We believe that these publications are impactful as our customers' studies cover structural variations in areas of high unmet medical need, such as rare and undiagnosed pediatric diseases, muscular diseases, developmental delays and disorders, prostate cancer and leukemia.



- ***Expand gross margins through economies of scale and growing sales of consumables.*** Our overall gross margin has historically been driven by our instrument gross margin as the sales of our instruments have constituted the vast majority

of our total revenues to date. Our instrument gross margin is significantly lower than our consumables gross margin. We expect our overall gross margin to expand in 2019 and beyond as:

- We further negotiate with silicon fabrication manufacturers for better contract pricing of our consumables. As our manufacturing lot volumes increase, we expect to have lower costs of goods sold. This is driven by the pass along of some of the economies of scale of contract manufacturers that mainly operate in the ultra-high-volume silicon computer chip industry.

- Consumables sales continue to represent the fastest growing component of overall revenues. As consumables growth continues to outpace instrument growth, we expect the proportion of our product mix which is higher gross margin to increase, thereby expanding our overall gross margin.

- ***Continue to innovate our products and technologies.*** We designed Saphyr to accommodate performance enhancements without the need for replacement of the entire instrument. For example, hardware upgrades and new consumables are made available to purchase by customers. We intend for these performance enhancements to be delivered on a regular basis. In addition, we periodically make available software upgrades to customers through download at no charge. We will continue to develop and refine our technologies to improve the ease of use of our Saphyr system and enable our existing installed systems to meaningfully increase sample throughput and sensitivity and specificity of structural variation detection.

- ***Partner with industry-leading companies and laboratories to accelerate adoption in clinical markets.*** Establish additional collaborations with customers to help drive validating studies. Expand partnership efforts with clinical diagnostic companies to commercialize LDTs in the U.S. as well as LDTs and approved tests outside the U.S.

Sales and Marketing

Our commercial team includes 16 individuals, including seven salespeople, two marketing personnel, and seven sales support personnel, including customer solutions personnel, field specialists and application specialists.

This commercial staff is primarily located in North America and Europe. Most of our sales support team is located at our headquarters in San Diego and some work remotely throughout the U.S., Europe and China.

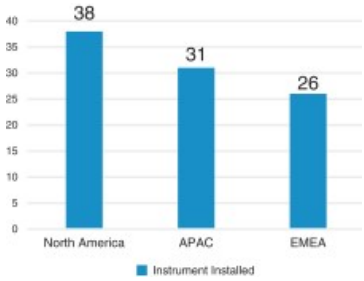
We sell our products through a direct sales force in North America and Europe. Our sales strategy involves the use of a combination of sales managers, sales representatives and field application specialists. Our direct sales force includes four salespeople located in the U.S. and three located in Europe. We expect to increase our sales force as we expand our business.

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

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

In addition, we maintain an applications lab team in San Diego, California composed of scientific experts who can transfer knowledge from the research and development team to the field application specialists. The applications lab team also runs foundational scientific collaborations and proof of principle studies, which help demonstrate the value of our product offering to prospective customers.

Our domestic and international sales force informs our current and potential customers of current product offerings, new product and new assay introductions, and technological advances in Saphyr systems, workflows, and notable research being performed by our customers or ourselves. As our primary point of contact in the marketplace, our sales force focuses on delivering a consistent marketing message and high level of customer service, while also attempting to help us better understand evolving market and customer needs.



We intend to significantly expand our sales, support, and marketing efforts in the future by expanding our direct footprint in North America and Europe as well as developing a more comprehensive support network in China where significant market opportunities exist. Additionally, we believe that there is significant opportunity in other European, South American, Asia-Pacific and Middle Eastern regions. We plan to expand into these regions via initial penetration with distributors.

Our sales and marketing efforts are targeted at key opinion leaders, laboratory directors and principal investigators at leading translational research, clinical institutions, governmental research institutions and pharmaceutical companies. In addition to our selling activities, we align with key opinion leaders at leading institutions and clinical research laboratories to help increase scientific and commercial awareness of our technology, demonstrate its benefits relative to existing technologies and accelerate its adoption. We also seek to increase awareness of our products through participation at trade shows, academic conferences, online webinars and dedicated scientific events attended by prominent users and prospective customers.

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

Manufacturing and Supply

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

Instruments

Our Saphyr instrument is manufactured by a third party medical device manufacturer. Nearly complete Saphyr instruments are shipped by the manufacturer to us for final assembly and quality control testing. Upon completion, we ship directly to our customers' locations globally, or distributors' locations in the case of certain systems sold in the Asia-Pacific region. Installation of, and training on, our products is provided by our employees in the markets where we conduct direct sales, and by distributors in those markets where we operate with distributors.

We believe this manufacturing strategy is efficient and conserves capital. However, in the event it becomes necessary to utilize a different contract manufacturer for Saphyr, we would experience additional costs, delays and difficulties in doing so, and our business could be harmed.

This manufacturer actively manages obsolescence of all components in our system. This is done through their supply management process where we get notified of any parts that will become obsolete with enough lead time to identify alternatives.

Consumables

All of our chip consumables are produced by a third party manufacturer at its facility; however, we have established procedures for a replacement manufacturer if required. We complete final assembly and quality control assessments of our chips at our headquarters in San Diego.

Our reagents are sourced from a limited number of suppliers, including certain single source suppliers. Reagents include all components required to run a sample on Saphyr, such as capture and detector reagents, enzyme reagents and enzyme substrate. Although we believe that alternatives would be available, it would take time to identify and validate replacement reagents for our assay kits, which

could negatively affect our ability to supply assay kits on a timely basis. Reagents are supplied through a single source supplier. This supplier requires a sufficient notification period to allow for supply continuity and the identification and technology transfer to a new supplier in the event either party wishes to terminate the relationship.

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

Key Agreements

License Agreement with Princeton University

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

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

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

Agreement for the Manufacture of Our Instruments

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

Agreement for the Manufacture of Our Chip Consumables

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

Berry Genomics Agreement

We have entered into a collaboration agreement, or the Berry Agreement, with Berry Genomics Co., Ltd, or Berry. Under the terms of the Berry Agreement, Berry agreed to develop, market and commercialize a Berry-branded in-vitro diagnostic, or IVD, system (which is comprised of both kits and instruments) in the People's Republic of China, or the PRC, in certain specified fields, as well as for clinical use by its partners. Pursuant to the Berry Agreement, Berry agreed to purchase certain of our components for use exclusively within the kits and instruments that make up the IVD system. Berry is then responsible for manufacturing the finished system, as well as for obtaining regulatory approvals for the sale of our components in the PRC. Per the Berry Agreement, we are obligated to provide the necessary support and documentation for the components, as well as provide training to enable Berry's after-sales installation and support for the IVD system.

Pursuant to the terms of the Berry Agreement, we granted to Berry and its affiliates, an irrevocable, exclusive, sublicensable, fully paid-up, royalty-free, license during the term of the agreement, solely to seek and obtain CFDA registration, manufacture, market, distribute and sell IVD kits and IVD instruments. We also have the right to all IVD system improvements. We have the first right, but not obligation,

to take any measures we deem appropriate to enforce our intellectual property rights. We also agree to provide reasonable assistance related to such enforcement actions as Berry may request at the cost and expenses of Berry.

The Berry Agreement may be renewed by either party upon 90 days written notice and subject to the negotiation of an agreement facilitating such renewal. Either party may terminate the agreement for a material breach if such breach remains uncured for 30 days, or immediately if the breach is not curable. We may also immediately terminate the Berry Agreement if Berry fails to fulfill its minimum quantity purchase requirements.

Intellectual Property

Our core technology for nucleic acid research is related to methods and devices for non-sequencing based analysis of macromolecules such as nucleic acids. Using this technology, long (high-molecular weight) nucleic acids can be suitably labeled and elongated in order to ascertain structural information such as scaffold organization, copy number, and de novo analysis of genomic repeats that is not readily obtained with current sequencing-based approaches. We have secured and continue to pursue intellectual property rights globally, including rights related to analysis of nucleic acid molecules, as well as innovations in the molecular biology and bioinformatics spaces.

We have developed a global patent portfolio that includes 43 issued patents across 14 patent families and an exclusively licensed portfolio of patents and applications from Princeton University, which includes 22 patents across two families. This global patent portfolio has filing dates ranging from 2001 to 2017. The owned and licensed families contain issued patents and pending applications that relate to devices, systems, and methods for macromolecular analysis, and reflect our active and ongoing research programs. The commercial foci of these patent families are discussed below.

Commercial Focus	Number of Issued and Pending Patents
Nanochannel devices and systems	70
Methods of macromolecule analysis using nanochannel arrays	62
Methods of genetic detection and copy number analysis	28
Method of genomic sequence and epigenomic analysis.	48
Biomolecule isolation and processing for use in nanochannel analysis	3
Method of optimizing nanochannel analysis	6
Next-generation products	11

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

Government Regulation

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

The FDA's 2013 Guidance for Industry and Food and Drug Administration Staff on "Distribution of In Vitro Diagnostic Products Labeled for Research Use Only or Investigational Use Only," or, the RUO/IUO Guidance, provides the FDA's thinking on when IVD products are properly labeled for RUO or for IUO. The RUO/IUO Guidance explains that the FDA will review the totality of the circumstances when evaluating whether equipment and testing components are properly labeled as RUO. Merely including a labeling statement that a product is intended for research use only will not necessarily exempt the device from the FDA's 510(k) clearance, premarket approval, or other requirements, if the circumstances surrounding the distribution of the product indicate that the manufacturer intends its product to be used for clinical diagnostic use. These circumstances may include written or verbal marketing claims or links to articles regarding a product's performance in clinical applications, a manufacturer's provision of technical support for clinical validation or clinical applications, or solicitation of business from clinical laboratories, all of which could be considered evidence of intended uses that conflict with RUO labeling.

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

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

510(k) Clearance Pathway

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

Premarket Approval Pathway

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

Clinical Trials

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

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

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

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

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

Laboratory Developed Tests

Although the FDA has statutory authority to regulate medical devices, the FDA has historically exercised its enforcement discretion and not enforced applicable provisions of the FDC Act and FDA regulations with respect to laboratory developed tests, or LDTs, which are a subset of in vitro diagnostic tests that are intended for clinical use and designed, manufactured and used entirely within a single laboratory. The FDA does not consider devices to be LDTs if they are designed or manufactured completely, or partly, outside of the laboratory that offers and uses them. We sell our Saphyr system on an RUO basis to CLIA certified cytogenetics laboratories, which may use the system to develop LDTs.

At various times since 2006, the FDA has issued documents outlining its intent to require varying levels of FDA oversight of many types of LDTs. In October 2014, the FDA issued draft guidance that sets forth a proposed risk-based regulatory framework that would apply such oversight to LDTs. The FDA has indicated that it does not intend to implement its proposed framework until the draft guidance documents are finalized. It is unclear at this time if or when the FDA will finalize its plans to end enforcement discretion for LDTs, and even then, whether the new regulatory requirements are expected to be phased-in over time. However, the FDA may decide to regulate certain LDTs on a case-by-case basis at any time. A significant change in the way that the FDA regulates any LDTs that we, our collaborators or our customers develop using our technology could affect our business. If the FDA requires laboratories to undergo premarket review and comply with other applicable FDA requirements in the future, the cost and time required to commercialize an LDT will increase substantially, and may reduce the financial incentive for laboratories to develop LDTs, which could reduce demand for our instruments and our other products. In addition, if the FDA were to change the way that it regulates LDTs to require that we undergo pre-market review or comply with other applicable FDA requirements before we can sell our instruments or our other products to clinical cytogenics laboratories, our ability to sell our instruments and other products to this addressable market would be delayed, thereby impeding our ability to penetrate this market and generate revenue from sales of our instruments and our other products.

Europe/Rest of World Government Regulation

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

Other Governmental Regulation

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

Coverage and Reimbursement

Currently, our product is for research use only, but clinical laboratories may acquire our instrumentation through a capital purchase or capital lease and use the Saphyr and direct label stain chemistry to create their own potentially reimbursable products, such as laboratory developed tests for in vitro diagnostics. Our customers may generate revenue for these testing services by seeking the necessary approval

of their product from the FDA or the Centers for Medicare & Medicaid Services, or CMS, along with coverage and reimbursement from third-party payors, including government health programs and private health plans. The ability of our customers to commercialize diagnostic tests based on our technology will depend in part on the extent to which coverage and reimbursement for these tests will be available from such third-party payors.

In the U.S., molecular testing laboratories have multiple options for reimbursement coding, but we expect that the primary codes used will be the genomic sequencing procedure codes, or GSPs. The American Medical Association, or AMA, added GSPs to its clinical laboratory fee schedule in 2015. In addition, CMS recently issued a coverage determination providing for the reimbursement of next-generation sequencing for certain cancer diagnostics using an FDA-approved in vitro diagnostic test. Private health plans often follow CMS coverage and reimbursement guidelines to a substantial degree, and it is difficult to predict what CMS will decide with respect to the coverage and reimbursement of any products our customers try to commercialize.

In Europe, coverage for molecular diagnostic testing is varied. Countries with statutory health insurance (e.g., Germany, France, The Netherlands) tend to be more progressive in technology adoption with favorable reimbursement for molecular diagnostic testing. In countries such as the United Kingdom with tax-based insurance, adoption and reimbursement for molecular diagnostic testing is not uniform and is influenced by local budgets.

Ultimately, coverage and reimbursement of new products is uncertain, and whether laboratories that use our instruments to develop their own products will attain coverage and adequate reimbursement is unknown. In the U.S., there is no uniform policy for determining coverage and reimbursement. Coverage can differ from payor to payor, and the process for determining whether a payor will provide coverage may be separate from the process for setting the reimbursement rate. In addition, the U.S. government, state legislatures and foreign governments have shown significant interest in implementing cost containment programs to limit the growth of government-paid healthcare costs, including price controls and restrictions on reimbursement.

Healthcare Reform

In the U.S. and abroad, there have been and continue to be a number of legislative initiatives to contain healthcare costs and change the way healthcare is financed. By way of example, in March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, collectively, the ACA, became law. The ACA is a sweeping law intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add new transparency requirements for the healthcare and health insurance industries, impose new taxes and fees on the health industry and impose additional health policy reforms. The ACA’s provisions of importance to our business include, but are not limited to, a 2.3% excise tax on certain entities that manufactures or imports medical devices offered for sale in the U.S., which has been suspended, but due to subsequent legislative amendments, will be automatically reinstated for medical device sales beginning January 1, 2020, unless Congress takes additional action to delay the implementation of the tax.

Some of the provisions of the ACA have yet to be implemented, and there have been judicial and Congressional challenges to certain aspects of the ACA, as well as efforts by the Trump administration to repeal or replace certain aspects of the ACA. Since January 2017, President Trump has signed two Executive Orders and other directives designed to delay the implementation of certain provisions of the ACA or otherwise circumvent some of the requirements for health insurance mandated by the ACA. Concurrently, Congress has considered legislation that would repeal or repeal and replace all or part of the ACA. While Congress has not passed comprehensive repeal legislation, it has enacted laws that modify certain provisions of the ACA, such as removing penalties, effective January 1, 2019, for not comploying with the ACA's individual mandate to carry heal and insurance and delaying the implementation of certain ACA-mandated fees including, without limitation, the medical device excise tax. On December 14, 2018, a Texas U.S. District Court Judge ruled that the ACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress as part of Legislation enacted in 2017 (H.R. 1, "An Act to provide for reconciliation pursuant to titles II and V of the concurrent resolution on the budget for fiscal year 2018"), informally titled the Tax Cuts and Jobs Act. While the Texas U.S. District Court Judge, as well as the Trump administration and CMS, have stated that the ruling will have have no immediate effect pending appeal of the decision, it is unclear how this decision, subsequent appeals, and other efforts to repeal and replace the ACA will impact the ACA.

Further, other legislative changes have been proposed and adopted since the ACA was enacted. For example, on April 1, 2014, the Protecting Access to Medicare Act of 2014, or PAMA, was signed into law, which, among other things, significantly altered the payment methodology under the Medicare Clinical Laboratory Fee Schedule, or CLFS. PAMA requires certain laboratories performing clinical diagnostic laboratory tests to report to CMS the amounts paid by private payors for laboratory tests. Beginning on January 1, 2018, CMS has begun using reported private payor pricing to periodically revise payment rates under the CLFS.

We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services. In addition, sales of our tests outside of the U.S. will subject us to foreign regulatory requirements, which may also change over time.

Other Healthcare Laws

Our operations are directly or indirectly, through our customers, subject to various federal and state fraud and abuse laws, including, without limitation, the federal and state anti-kickback statutes and false claims laws. These laws may impact, among other things, our sales and marketing and education programs, and our financial and business relationships with researchers who use our instruments to develop marketed products. By way of example: the federal Anti-Kickback Statute prohibits, among other things, any person or entity from, among other things, knowingly and willfully soliciting, receiving, offering or paying any remuneration, directly or indirectly, to induce, or in return for, purchasing, leasing, ordering, or arranging for or recommending the purchase, lease, or order of any good, facility, item, or service reimbursable, in whole or in part, under a federal healthcare program; and the federal false claims laws, including, without limitation the federal civil False Claims Act, prohibit, among other things, anyone from knowingly and willingly presenting, or causing to be presented for payment, to the federal government (including Medicare and Medicaid) claims for reimbursement for, among other things, drugs or services that are false or fraudulent, claims for items or services not provided as claimed, or claims for medically unnecessary items or services. The ACA, among other things, amended the intent requirement of the federal Anti-Kickback Statute to clarify that a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a crime. In addition, the ACA clarifies that the government may assert that a claim that includes items or service resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act.

In addition, we may be subject to HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act and their implementing regulations, which imposes certain requirements relating to the privacy, security and transmission of individually identifiable health information without appropriate authorization by entities subject to the rule, such as health plans, healthcare clearinghouses and certain healthcare providers and their business associates who create, use or disclose individually identifiable health information on their behalf. We may also be subject to state and foreign laws that govern the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

If our operations are found to be in violation of any of these laws, we may be subject to significant penalties, including, without limitation, civil, criminal, and administrative penalties, damages, fines, disgorgement, the curtailment or restructuring of our operations, exclusion from participation in federal and state healthcare programs, additional integrity oversight and reporting obligations, imprisonment, contractual damages, and reputational harm.

Employees

As of December 31, 2018, we had 77 employees, of which 33 work in sales, sales support and marketing, 31 work in research and development, six work in manufacturing and operations and seven work in general and administrative. As of December 31, 2018, of our 77 employees, 67 were located in the U.S. and 10 were employed outside the U.S. None of our employees are represented by a labor union or are subject to a collective bargaining agreement.

Facilities

We lease approximately 16,521 square feet of office, laboratory, and manufacturing space at our headquarters in San Diego, California, under a lease that expires on December 31, 2020. We believe that we will need additional space as we grow our operations, but believe that suitable additional or substitute space will be available to accommodate future growth of our business. We believe that our existing office, laboratory and manufacturing space will be sufficient to meet our needs in the interim.

Corporate Information

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

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

We are an “emerging growth company” as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act. We may take advantage of certain exemptions from various public company reporting requirements, including not being required to have our internal control over financial reporting audited by our independent registered public accounting firm under Section 404 of the Sarbanes-

Oxley Act of 2002, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and any golden parachute payments. We may take advantage of these exemptions for up to five years or until we are no longer an "emerging growth company," whichever is earlier. In particular, in this Annual Report, we have provided only two years of audited financial statements and have not included all of the executive compensation related information that would be required if we were not an emerging growth company. Accordingly, the information contained herein may be different than the information you receive from other public companies in which you hold stock.

In addition, 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. This provision allows an emerging growth company to delay the adoption of new or revised accounting standards that have different transition dates for public and private companies until those standards would otherwise apply to private companies. We have elected to use this extended transition period. As a result of this election, our timeline to comply with these standards will in many cases be delayed as compared to other public companies that are not eligible to take advantage of this election or have not made this election. Therefore, our financial statements may not be comparable to those of companies that comply with the public company effective dates for these standards.

Item 1A. Risk Factors.

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

Risks related to our financial condition and need for additional capital

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

We incurred net losses of $18.5 million and $23.4 million and cash used in operations of $19.9 million and $20.8 million for the years ended December 31, 2018 and 2017, respectively. As of December 31, 2018, we had an accumulated deficit of $72.8 million. We cannot predict if we will achieve sustained profitability in the near future or at all. We expect that our losses will continue for the foreseeable future as we plan to invest significant additional funds toward expansion of our commercial organization and the development of our technology. In addition, as a public company, we will incur significant legal, accounting, and other expenses that we did not incur as a private company. These increased expenses will make it harder for us to achieve and sustain future profitability. We may incur significant losses in the future for a number of reasons, many of which are beyond our control, including the other risks described in this Annual Report, the market acceptance of our products, future product development and our market penetration and margins.

Our quarterly and annual operating results and cash flows have fluctuated in the past and might continue to fluctuate, which could cause the market price of our securities to decline substantially.

Numerous factors, many of which are outside our control, may cause or contribute to significant fluctuations in our quarterly and annual operating results. These fluctuations may make financial planning and forecasting uncertain. In addition, these fluctuations may result in unanticipated decreases in our available cash, which could negatively affect our business and prospects. In addition, one or more of such factors may cause our revenue or operating expenses in one period to be disproportionately higher or lower relative to the others. As a result, comparing our operating results on a period-to-period basis might not be meaningful. You should not rely on our past results as indicative of our future performance. Moreover, our stock price might be based on expectations of future performance that are unrealistic or that we might not meet and, if our revenue or operating results fall below the expectations of investors or securities analysts, the price of our securities could decline substantially.

Our operating results have varied in the past. In addition to other risk factors listed in this section, some of the important factors that may cause fluctuations in our quarterly and annual operating results include:

- adoption of our systems and related products;
- the timing of customer orders to purchase our systems;
- the rate of utilization of consumables by our customers;
- receipt and timing of revenue for services provided by out data solutions service;

- the timing of the introduction of new systems, products, system and product enhancements and services; and
- the receipt and timing of revenue from our distribution and marketing arrangements.

In addition, a significant portion of our operating expense is relatively fixed in nature, and planned expenditures are based in part on expectations regarding future revenue. Accordingly, unexpected revenue shortfalls could decrease our gross margins and cause significant changes in our operating results from quarter to quarter. If this occurs, the trading price of our securities could fall substantially.

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

We are an early, commercial-stage company and have a limited commercial history. Our limited commercial history may make it difficult to evaluate our current business and makes predictions about our future success or viability subject to significant uncertainty. We will continue to encounter risks and difficulties frequently experienced by early, commercial-stage companies, including scaling up our infrastructure and headcount. If we do not address these risks successfully, our business will suffer.

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

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

Our continued growth could require significant capital expenditures and might divert financial resources from other projects such as the development of new products and services. As additional products are commercialized, we may need to incorporate new equipment, implement new technology systems, or hire new personnel with different qualifications. Failure to manage this growth or transition could result in turnaround time delays, higher product costs, declining product quality, deteriorating customer service, and slower responses to competitive challenges. A failure in any one of these areas could make it difficult for us to meet market expectations for our products, and could damage our reputation and the prospects for our business.

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

Our future capital needs are uncertain and we will require additional funding in the future to advance the commercialization of Saphyr and our other products, as well as continue our research and development efforts. If we fail to obtain additional funding, we will be forced to delay, reduce or eliminate our commercialization and development efforts.

Our operations have consumed substantial amounts of cash since our inception. We expect to continue to spend substantial amounts to continue the commercialization of our products as well as our research and development programs. In connection with the preparation of our financial statements for the fiscal year ended December 31, 2018, we performed an analysis of our ability to continue as a going concern. We believe, based on our current business plan, that our existing cash and cash equivalents will be sufficient to fund our obligations through the fourth quarter of 2019. Our ability to execute our operating plan beyond the fourth quarter of 2019 depends on our ability to generate sales and obtain additional funding through equity offerings, debt financings or potential licensing and collaboration arrangements. For example, we will likely need to raise substantial additional capital to:

- expand our sales and marketing efforts to further commercialize our products;
- expand our research and development efforts to improve our existing products and develop and launch new products, particularly if any of our products are deemed by the U.S. Food and Drug Administration, or FDA, to be medical devices or otherwise subject to additional regulation by the FDA;
- seek FDA approval to market our existing products or new products utilized for diagnostic purposes;
- lease a larger facility or build out our existing facility as we continue to grow our employee headcount;
- hire additional personnel;
- enter into collaboration arrangements, if any, or in-license other products and technologies;

- add operational, financial and management information systems; and
- incur increased costs as a result of continued operation as a public company.

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

- market acceptance of our products;
- the cost and timing of establishing additional sales, marketing and distribution capabilities;
- the cost of our research and development activities;
- the success of our existing distribution and marketing arrangements and our ability to enter into additional arrangements in the future; and
- the effect of competing technological and market developments.

We cannot assure you that we will be able to obtain additional funds on acceptable terms, or at all. If we raise additional funds by issuing equity or equity-linked securities, our stockholders may experience dilution. Future debt financing, if available, may involve covenants restricting our operations or our ability to incur additional debt. Any debt or equity financing may contain terms that are not favorable to us or our stockholders. If we raise additional funds through collaboration and licensing arrangements with third parties, it may be necessary to relinquish some rights to our technologies or our products, or grant licenses on terms that are not favorable to us. If we do not have, or are not able to obtain, sufficient funds, we may have to delay development or commercialization of our products. We also may have to reduce marketing, customer support or other resources devoted to our products or cease operations. Any of these factors could have a material adverse effect on our financial condition, operating results and business. Any of the foregoing could significantly harm our business, prospects, financial condition and results of operation and could cause the price of our common stock to decline.

Comprehensive tax reform could adversely affect our business and financial condition.

On December 22, 2017, President Trump signed into law the Tax Cuts and Jobs Act which significantly revises the Internal Revenue Code of 1986, as amended. The Tax Cuts and Jobs Act, among other things, contains significant changes to corporate taxation, including reduction of the corporate tax rate from a top marginal rate of 35% to a flat rate of 21%, limitation of the tax deduction for interest expense to 30% of adjusted taxable income (except for certain small businesses), limitation of the deduction for net operating losses carried forward from taxable years beginning after December 31, 2017 to 80% of current year taxable income and elimination of net operating loss carrybacks, one-time taxation of offshore earnings at reduced rates regardless of whether they are repatriated, elimination of U.S. tax on foreign earnings (subject to certain important exceptions), immediate deductions for certain new investments instead of deductions for depreciation expense over time and modifying or repealing many business deductions and credits (including reducing the business tax credit for certain clinical testing expenses incurred in the testing of certain drugs for rare diseases or conditions). Notwithstanding the reduction in the corporate income tax rate, the overall impact of the Tax Cuts and Jobs Act is uncertain, and our business and financial condition could be adversely affected. In addition, it is unknown if and to what extent various states will conform to the Tax Cuts and Jobs Act. The impact of the Tax Cuts and Jobs Act on holders of our securities is likewise uncertain and could be adverse. We urge our stockholders to consult with their legal and tax advisors with respect to this legislation and the potential tax consequences of investing in or holding our securities.

Our ability to use net operating losses to offset future taxable income may be subject to limitations.

As of December 31, 2018, we had aggregate U.S. net operating loss carryforwards of approximately $147.6 million and aggregate U.S. research and development credits of approximately $4.5 million. These net operating loss carryforwards could expire unused and be unavailable to offset future income tax liabilities. Under the Tax Cuts and Jobs Act, federal net operating losses incurred in taxable years ending after December 31, 2017 may be carried forward indefinitely, but the deductibility of federal net operating losses generated in tax years beginning after December 31, 2017 is limited. It is uncertain if and to what extent various states will conform to the Tax Cuts and Jobs Act. In addition, under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, and corresponding provisions of state law, if a corporation undergoes an “ownership change” (which is generally defined as a greater than 50% change (by value) in its equity ownership over a three-year period), the corporation’s ability to use its pre-change net operating loss carryforwards and other pre-change tax attributes to offset its post-change income or taxes may be limited. We may have experienced one or more ownership changes in the past and we may also experience additional ownership changes in the future as a result of subsequent shifts in our stock ownership, some of which may be outside of our control. If an ownership change occurs and our ability to use our net operating loss carryforwards is materially limited, it would harm our future operating results by effectively increasing our future tax obligations.

U.S. taxation of international business activities or the adoption of tax reform policies could materially impact our future financial position and results of operations.

Limitations on the ability of taxpayers to claim and utilize foreign tax credits and the deferral of certain tax deductions until earnings outside of the U.S. are repatriated to the U.S., as well as changes to U.S. tax laws that may be enacted in the future, could impact the tax treatment of future foreign earnings. Should the scale of our international business activities expand, any changes in the U.S. taxation of such activities could increase our worldwide effective tax rate and harm our future financial position and results of operations.

The terms of our credit facility place restrictions on our operating and financial flexibility, and failure to comply with covenants or to satisfy certain conditions of the agreement governing the credit facility may result in acceleration of our repayment obligations and foreclosure on our pledged assets, which could significantly harm our liquidity, financial condition, operating results, business and prospects and cause the price of our securities to decline.

In June 2018, we entered into a credit and security agreement with Midcap Financial Trust, or Midcap, that is secured by a lien covering substantially all of our assets, including intellectual property. The credit and security agreement provides for a five year $15 million term loan facility, of which we drew $10 million at closing. Of the remaining $5 million, $2.5 million may be drawn upon satisfaction of certain conditions. The loan and security agreement governing the credit facility requires us to comply with a number of covenants (affirmative and negative), including restrictive covenants that limit our ability to: incur additional indebtedness; encumber the collateral securing the loan; acquire, own or make investments; repurchase or redeem any class of stock or other equity interest; declare or pay any cash dividend or make a cash distribution on any class of stock or other equity interest; transfer a material portion of our assets; acquire other businesses; and merge or consolidate with or into any other organization or otherwise suffer a change in control, in each case subject to exceptions. Our intellectual property is also subject to customary negative covenants. In addition, subject to limited exceptions, Midcap could declare an event of default upon the occurrence of any event that it interprets as having a material adverse effect upon our business, operations, properties, assets, or financial condition or upon our ability to perform or pay the secured obligations under the loan and security agreement or upon the collateral or Midcap's liens on the collateral under the agreement, thereby requiring us to repay the loan immediately, together with a prepayment charge of up to 4% of the then outstanding principal balance, together with other fees.

If we default under the credit facility, Midcap may accelerate all of our repayment obligations and, if we are unable to access funds to meet those obligations or to renegotiate our agreement, Midcap could take control of our pledged assets and we could immediately cease operations. If we were to renegotiate our agreement under such circumstances, the terms may be significantly less favorable to us. If we were liquidated, Midcap's right to repayment would be senior to the rights of our stockholders to receive any proceeds from the liquidation. Any declaration by Midcap of an event of default could significantly harm our liquidity, financial condition, operating results, business, and prospects and cause the price of our securities to decline.

We may incur additional indebtedness in the future. The debt instruments governing such indebtedness may contain provisions that are as, or more, restrictive than the provisions governing our existing indebtedness under the credit and security agreement with Midcap. If we are unable to repay, refinance or restructure our indebtedness when payment is due, the lenders could proceed against the collateral or force us into bankruptcy or liquidation.

Risks related to our business operations

If our products fail to achieve and sustain sufficient market acceptance, our revenue will be adversely affected.

Our success depends on our ability to develop and market products that are recognized and accepted as reliable, enabling and cost-effective. Most of the potential customers for our products already use expensive research systems in their laboratories that they have used for many years and may be reluctant to replace those systems with ours. Market acceptance of our systems will depend on many factors, including our ability to convince potential customers that our technology is an attractive alternative to existing technologies. Compared to some competing technologies, our technology is new and complex, and many potential customers have limited knowledge of, or experience with, our products. Prior to adopting our systems, some potential customers may need to devote time and effort to testing and validating our systems. Any failure of our systems to meet these customer benchmarks could result in potential customers choosing to retain their existing systems or to purchase systems other than ours. In addition, it is important that our gene mapping systems be perceived as accurate and reliable by the scientific and medical research community as a whole. Historically, a significant part of our sales and marketing efforts has been directed at demonstrating the advantages of our technology to industry leaders and encouraging such leaders to publish or present the results of their evaluation of our system. If we are unable to continue to motivate leading researchers to use our technology, or if such researchers are unable to achieve or unwilling to publish or present significant experimental results using our systems, acceptance and adoption of our systems will be slowed and our ability to increase our revenue would be adversely affected.

Our future success is dependent upon our ability to further penetrate our existing customer base and attract new customers.

Our current customer base is primarily composed of academic and governmental research institutions, as well as biopharmaceutical and contract research companies. Our success will depend upon our ability to respond to the evolving needs of, and increase our market share among, existing customers and additional potential customers, marketing new products as we develop them. Identifying, engaging and marketing to customers who are unfamiliar with our current products requires substantial time, expertise and expense and involves a number of risks, including:

- our ability to attract, retain and manage the sales, marketing and service personnel necessary to expand market acceptance for our technology;
- the time and cost of maintaining and growing a specialized sales, marketing and service force; and
- our sales, marketing and service force may be unable to execute successful commercial activities.

We have utilized third parties to assist with sales, distribution and customer support in certain regions of the world. There is no guarantee, when we enter into such arrangements, that we will be successful in attracting desirable sales and distribution partners. There is also no guarantee that we will be able to enter into such arrangements on favorable terms. Any failure of our sales and marketing efforts, or those of any third-party sales and distribution partners, would adversely affect our business.

We are currently limited to "research use only" with respect to many of the materials and components used in our consumable products including our assays.

Our instruments, consumable products and assays are purchased from suppliers with a restriction that they be used for research use only, or RUO. While we have focused initially on the life sciences research market and RUO products only, part of our business strategy is to expand our product line to encompass products that are intended to be used for the diagnosis of disease and precision healthcare, either alone or in collaboration with third parties. The use of our products for any such diagnostic purposes would require that we obtain regulatory clearance or approval to market our products for those purposes and also that we acquire the materials and components used in such products from suppliers without an RUO restriction. There can be no assurance that we will be able to acquire these materials and components for use in diagnostic products on acceptable terms, if at all. If we are unable to do so, we would not be able to expand our product offerings beyond RUO, and our business and prospects would suffer.

The FDA Guidance on "Distribution of In Vitro Diagnostic Products Labeled for Research Use Only or Investigational Use Only", or, the RUO/IUO Labeling Guidance, emphasizes that the FDA will review the totality of the circumstances when evaluating whether equipment and testing components are properly labeled as RUO. It further states that merely including a labeling statement that a product is intended for research use only will not necessarily render the device exempt from the FDA's 510(k) clearance, PMA, or other requirements, if the circumstances surrounding the distribution of the product indicate that the manufacturer intends for its product to be offered for clinical diagnostic use. These circumstances may include written or verbal marketing claims or links to articles regarding a product's performance in clinical applications, a manufacturer's provision of technical support for clinical validation or clinical applications, or solicitation of business from clinical laboratories, all of which could be considered evidence of intended uses that conflict with RUO labeling. If the FDA were to determine that our RUO products were intended for use in clinical investigation, diagnosis or treatment decisions, or that express or implied clinical or diagnostic claims were made for our RUO products, those products could be considered misbranded or adulterated under the Federal Food, Drug, and Cosmetic Act. If the FDA determines that our RUO products are being marketed for clinical diagnostic use without the required PMA or 510(k) clearance, we may be required to cease marketing our products as planned, recall the products from customers, revise our marketing plans, and/or suspend or delay the commercialization of our products until we obtain the required authorization. We also may be subject to a range of enforcement actions by the FDA, including warning or untitled letters, injunctions, civil monetary penalties, criminal prosecution, and recall and/or seizure of products, as well as significant adverse publicity.

If, in the future, we choose to commercialize our products for clinical diagnostic use, we will be required to comply with the FDA's premarket review and post-market control requirements for IVDs, as may be applicable. Complying with the FDA's PMA and/or 510(k) clearance requirements may be expensive, time-consuming, and subject us to significant and/or unanticipated delays. Our efforts may never result in an approved PMA or 510(k) clearance for our products. Even if we obtain a PMA or 510(k) clearance, where required, such authorization may not be for the use or uses we believe are commercially attractive and/or are critical to the commercial success of our products. As a result, being subject to the FDA's premarket review and/or post-market control requirements for our products could materially and adversely affect our business, financial condition and results of operations.

In the near term, our business will depend on levels of research and development spending by academic and governmental research institutions and biopharmaceutical companies, a reduction in which could limit demand for our products and adversely affect our business and operating results.

In the near term, we expect that our revenue will be derived primarily from sales of our instruments and consumables to academic and governmental research institutions, as well as biopharmaceutical and contract research companies worldwide for research applications. The demand for our products will depend in part upon the research and development budgets of these customers, which are impacted by factors beyond our control, such as:

- changes in government programs that provide funding to research institutions and companies;
- macroeconomic conditions and the political climate;
- changes in the regulatory environment;
- differences in budgetary cycles; and
- market acceptance of relatively new technologies, such as ours.

For example, in March 2017, the federal government announced the intent to cut federal biomedical research funding by as much as 18%. While there has been significant opposition to these funding cuts, the uncertainty regarding the availability of research funding for potential customers may adversely affect our operating results. Our operating results may fluctuate substantially due to reductions and delays in research and development expenditures by these customers. Any decrease in customers' budgets or expenditures, or in the size, scope or frequency of capital or operating expenditures, could materially and adversely affect our business, operating results and financial condition.

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

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

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

Our business is dependent on the continued improvement of our existing products and our development of new products utilizing our current or other potential future technology. As we introduce new products or refine, improve or upgrade versions of existing products, we cannot predict the level of market acceptance or the amount of market share these products will achieve, if any. We cannot assure you that we will not experience material delays in the introduction of new products in the future.

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

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

- correctly identify customer needs and preferences and predict future needs and preferences;
- allocate our research and development funding to products with higher growth prospects;
- anticipate and respond to our competitors' development of new products and technological innovations;
- innovate and develop new technologies and applications, and acquire or obtain rights to third-party technologies that may have valuable applications in the markets we serve;
- successfully commercialize new technologies in a timely manner, price them competitively and manufacture and deliver sufficient volumes of new products of appropriate quality on time; and

- convince customers to adopt new technologies.

In addition, if we fail to accurately predict future customer needs and preferences or fail to produce viable technologies, we may invest heavily in research and development of products that do not lead to significant revenue. Even if we successfully innovate and develop new products and product enhancements, we may incur substantial costs in doing so, and our profitability may suffer.

Our ability to develop new products based on innovation can affect our competitive position and often requires the investment of significant resources. Difficulties or delays in research, development or production of new products and services or failure to gain market acceptance of new products and technologies may reduce future revenues and adversely affect our competitive position.

If we do not successfully manage the development and launch of new products, our financial results could be adversely affected.

We face risks associated with launching new products. If we encounter development or manufacturing challenges or discover errors during our product development cycle, the product launch dates of new products may be delayed. The expenses or losses associated with unsuccessful product development or launch activities or lack of market acceptance of our new products could adversely affect our business or financial condition.

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

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

Although we do not, and cannot currently, promote the use of our products, or services based on our products, for diagnostic purposes, if our customers develop or use them for diagnostic purposes, someone could file a product liability claim alleging that one of our products contained a design or manufacturing defect that resulted in the failure to adequately perform, leading to death or injury. A product liability claim could result in substantial damages and be costly and time consuming to defend, either of which could materially harm our business or financial condition. We cannot assure investors that our product liability insurance would adequately protect our assets from the financial impact of defending a product liability claim. Any product liability claim brought against us, with or without merit, could increase our product liability insurance rates or prevent us from securing insurance coverage in the future.

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

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

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

During 2018 approximately 62% of our product revenue was generated from customers located outside of the U.S. We believe that a substantial percentage of our future revenue will come from international sources as we expand our overseas operations and develop opportunities in additional areas. We have limited experience operating internationally and engaging in international business involves a number of difficulties and risks, including:

- required compliance with existing and changing foreign regulatory requirements and laws;
- difficulties and costs of staffing and managing foreign operations;
- difficulties protecting or procuring intellectual property rights;

- required compliance with anti-bribery laws, such as the U.S. Foreign Corrupt Practices Act, data privacy requirements, labor laws and anti-competition regulations;
- export or import restrictions;
- laws and business practices favoring local companies;
- longer payment cycles and difficulties in enforcing agreements and collecting receivables through certain foreign legal systems;
- political and economic instability; and
- potentially adverse tax consequences, tariffs, customs charges, bureaucratic requirements and other trade barriers.

Historically, most of our revenue has been denominated in U.S. dollars. In the future, we may sell our products and services in local currency outside of the U.S. As our operations in countries outside of the U.S. grow, our results of operations and cash flows may be subject to fluctuations due to changes in foreign currency exchange rates, which could harm our business in the future. For example, if the value of the U.S. dollar increases relative to foreign currencies, in the absence of a corresponding change in local currency prices, our revenue could be adversely affected as we convert revenue from local currencies to U.S. dollars. If we dedicate significant resources to our international operations and are unable to manage these risks effectively, our business, operating results and financial condition will suffer.

We are subject to U.S. and foreign anti-corruption and anti-money laundering laws with respect to our operations and non-compliance with such laws can subject us to criminal and/or civil liability and harm our business.

We are subject to the U.S. Foreign Corrupt Practices Act, as amended, the U.S. domestic bribery statute contained in 18 U.S.C. § 201, the U.S. Travel Act, the USA PATRIOT Act, the United Kingdom Bribery Act 2010, and other state and national anti-bribery and anti-money laundering laws in countries in which we conduct activities. Anti-corruption laws are interpreted broadly and prohibit companies and their employees and third-party intermediaries from authorizing, promising, offering, providing, soliciting, or accepting, directly or indirectly, improper payments or benefits to or from any person whether in the public or private sector for the purpose of obtaining or retaining business or securing any other improper advantage. We rely on third-party representatives, distributors, and other business partners to support sales of our products and services and our efforts to ensure regulatory compliance. In addition, as we increase our international sales and business, we may engage with additional business partners. We can be held liable for the corrupt or other illegal activities of our employees, representatives, contractors, business partners, and agents, even if we do not explicitly authorize or have actual knowledge of such activities.

Any violations of anti-corruption and anti-money laundering laws, or allegations of such violations, could disrupt our operations, involve significant management distraction, involve significant costs and expenses, including legal fees, and could result in a material adverse effect on our business, prospects, financial condition, or results of operations. We could also incur severe penalties, including criminal and civil penalties, disgorgement, and other remedial measures.

We are subject to governmental export and import controls that could impair our ability to compete in international markets due to licensing requirements and subject us to liability if we are not in compliance with applicable laws.

Our products are subject to export control and import laws and regulations, including the U.S. Export Administration Regulations, U.S. Customs regulations, and various economic and trade sanctions regulations administered by the U.S. Treasury Department's Office of Foreign Assets Controls. Exports of our products must be made in compliance with these laws and regulations. If we fail to comply with these laws and regulations, we and certain of our employees could be subject to substantial civil or criminal penalties, including the possible loss of export or import privileges; fines, which may be imposed on us and responsible employees or managers; and, in extreme cases, the incarceration of responsible employees or managers.

In addition, changes in our products or changes in applicable export or import laws and regulations may create delays in the introduction and sale of our products in international markets, prevent our customers from deploying our products or, in some cases, prevent the export or import of our products to certain countries, governments or persons altogether. Any change in export or import laws and regulations, shift in the enforcement or scope of existing laws and regulations, or change in the countries, governments, persons or technologies targeted by such laws and regulations, could also result in decreased use of our products, or in our decreased ability to export or sell our products to existing or potential customers. Any decreased use of our products or limitation on our ability to export or sell our products would likely adversely affect our business, financial condition and results of operations.

If we are unable to recruit, train, retain, motivate and integrate key personnel, we may not achieve our goals.

Our future success depends on our ability to recruit, train, retain, motivate and integrate key personnel, including our recently expanded senior management team, as well as our research and development, manufacturing and sales and marketing personnel.

Competition for qualified personnel is intense. Our growth depends, in particular, on attracting and retaining highly-trained sales personnel with the necessary scientific background and ability to understand our systems at a technical level to effectively identify and sell to potential new customers and develop new products. Because of the complex and technical nature of our products and the dynamic market in which we compete, any failure to attract, train, retain, motivate and integrate qualified personnel could materially harm our operating results and growth prospects.

We have limited experience in marketing and selling our products, and if we are unable to successfully commercialize our products, our business and operating results will be adversely affected.

We have limited experience marketing and selling our products. We currently sell all our products for research use only, through our direct field sales and support organizations located in North America and Europe and through a combination of our own sales force and third-party distributors in additional major markets such as Australian, China, Japan and South Korea.

The future sales of our products will depend in large part on our ability to effectively market and sell our products, successfully manage and expand our sales force, and increase the scope of our marketing efforts. We may also enter into additional distribution arrangements in the future. Because we have limited experience in marketing and selling our products, our ability to forecast demand, the infrastructure required to support such demand and the sales cycle to customers is unproven. If we do not build an efficient and effective sales force, our business and operating results will be adversely affected.

We rely on a single contract manufacturer for our systems and rely on a single contract manufacturer for our chip consumables. If either of these manufacturers should fail or not perform satisfactorily, our ability to supply these instruments would be negatively and adversely affected.

We currently rely on a single contract manufacturer to manufacture and supply all of our instruments. See “Business–Key Agreements.” In addition, we rely on a single contract manufacturer to manufacture and supply all of our chip consumables. Since our contracts with these manufacturers do not commit them to supply quantities beyond the amounts included in our purchase orders, and do not commit them to carry inventory or make available any particular quantities, these contract manufacturers may give other customers’ needs higher priority than ours, and we may not be able to obtain adequate supplies in a timely manner or on commercially reasonable terms. If either of these manufacturers were to be unable to supply instruments, our business would be harmed.

In the event it becomes necessary to utilize different contract manufacturers for our instruments or chip consumables, we would experience additional costs, delays and difficulties in doing so as a result of identifying and entering into an agreement with a new supplier as well as preparing such new supplier to meet the logistical requirements associated with manufacturing our units, and our business would suffer. We may also experience additional costs and delays in the event we need access to or rights under any intellectual property of these current manufacturers.

We may experience manufacturing problems or delays that could limit the growth of our revenue or increase our losses.

We may encounter unforeseen situations that would result in delays or shortfalls in our production as well as delays or shortfalls caused by our outsourced manufacturing suppliers and by other third-party suppliers who manufacture components for our products. If we are unable to keep up with demand for our products, our revenue could be impaired, market acceptance for our products could be adversely affected and our customers might instead purchase our competitors’ products. Our inability to successfully manufacture our products would have a material adverse effect on our operating results.

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

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

In addition, certain of the components used in our instruments are sourced from limited or sole suppliers. If we were to lose such suppliers, there can be no assurance that we will be able to identify or enter into agreements with alternative suppliers on a timely basis on acceptable terms, if at all. An interruption in our ability to sell and deliver instruments to customers could occur if we encounter delays

or difficulties in securing these components, or if the quality of the components supplied do not meet specifications, or if we cannot then obtain an acceptable substitute. If any of these events occur, our business and operating results could be harmed.

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

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

Our business could be negatively impacted by cyber security threats.

In the ordinary course of our business, we collect and store sensitive data, intellectual property and proprietary business information owned or controlled by ourselves or our customers. We face various cyber security threats, including cyber security attacks to our information technology infrastructure and attempts by others to gain access to our proprietary or sensitive information. This information encompasses a wide variety of business-critical information including research and development information, commercial information, and business and financial information. The procedures and controls we use to monitor these threats and mitigate our exposure may not be sufficient to prevent cyber security incidents. The result of these incidents could include disrupted operations, lost opportunities, misstated financial data, liability for stolen assets or information, increased costs arising from the implementation of additional security protective measures, litigation and reputational damage. Any remedial costs or other liabilities related to cyber security incidents may not be fully insured or indemnified by other means.

The life sciences research and diagnostic markets are highly competitive. If we fail to effectively compete, our business, financial condition and operating results will suffer.

We face significant competition in the life sciences research and diagnostic markets. We currently compete with both established and early stage companies that design, manufacture and market systems and consumable supplies. We believe our principal competitors in the life sciences research and genome mapping markets include Pacific Biosciences of California, Oxford Nanopore Technologies, 10x Genomics, Genomic Vision and Dovetail Genomics. In addition, there are a number of new market entrants in the process of developing novel technologies for the life sciences research, diagnostic and screening markets.

Many of our current competitors are either publicly traded, or are divisions of publicly-traded companies, and may enjoy a number of competitive advantages over us, including:

- greater name and brand recognition;
- substantially greater financial and human resources;
- broader product lines;
- larger sales forces and more established distributor networks;
- substantial intellectual property portfolios;
- larger and more established customer bases and relationships; and
- better established, larger scale, and lower cost manufacturing capabilities.

We believe that the principal competitive factors in all of our target markets include:

- cost of instruments and consumables;
- accuracy, including sensitivity and specificity, and reproducibility of results;
- reputation among customers;
- innovation in product offerings;
- flexibility and ease of use; and
- compatibility with existing laboratory processes, tools and methods.

We cannot assure investors that our products will compete favorably or that we will be successful in the face of increasing competition from new products and technologies introduced by our existing competitors or new companies entering our markets. In addition, we cannot assure investors that our competitors do not have or will not develop products or technologies that currently or in the future will

enable them to produce competitive products with greater capabilities or at lower costs than ours. Any failure to compete effectively could materially and adversely affect our business, financial condition and operating results.

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

We may acquire other businesses, products or technologies as well as pursue strategic alliances, joint ventures, technology licenses or investments in complementary businesses. We have not made any acquisitions to date, and our ability to do so successfully is unproven. Any of these transactions could be material to our financial condition and operating results and expose us to many risks, including:

- disruption in our relationships with customers, distributors or suppliers as a result of such a transaction;
- unanticipated liabilities related to acquired companies;
- difficulties integrating acquired personnel, technologies and operations into our existing business;
- diversion of management time and focus from operating our business to acquisition integration challenges;
- increases in our expenses and reductions in our cash available for operations and other uses; and
- possible write-offs or impairment charges relating to acquired businesses.

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

Also, the anticipated benefit of any acquisition may not materialize. Future acquisitions or dispositions 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. We cannot predict the number, timing or size of future joint ventures or acquisitions, or the effect that any such transactions might have on our operating results.

Unfavorable global economic conditions could adversely affect our business, financial condition or results of operations.

Our results of operations could be adversely affected by general conditions in the global economy and in the global financial markets. A severe or prolonged global economic downturn could result in a variety of risks to our business, including our ability to raise additional capital when needed on acceptable terms, if at all. This is particularly true in Europe, which is undergoing a continued severe economic crisis. A weak or declining economy could also strain our suppliers, possibly resulting in supply disruption. Any of the foregoing could harm our business and we cannot anticipate all of the ways in which the current economic climate and financial market conditions could adversely impact our business.

The United Kingdom's referendum to leave the European Union or "Brexit," has and may continue to cause disruptions to capital and currency markets worldwide. The full impact of the Brexit decision, however, remains uncertain. A process of negotiation will determine the future terms of the United Kingdom's relationship with the European Union. During this period of negotiation, our results of operations and access to capital may be negatively affected by interest rate, exchange rate and other market and economic volatility, as well as regulatory and political uncertainty. Brexit may also have a detrimental effect on our suppliers and manufacturers, which would, in turn, adversely affect our financial condition.

Risks related to government regulation and diagnostic product reimbursement

If the FDA determines that our products are medical devices or if we seek to market our products for clinical diagnostic or health screening use, we will be required to obtain regulatory clearance(s) or approval(s), and may be required to cease or limit sales of our then marketed products, which could materially and adversely affect our business, financial condition and results of operations. Any such regulatory process would be expensive, time-consuming and uncertain both in timing and in outcome.

We have focused initially on the life sciences research market. This includes laboratories associated with academic and governmental research institutions, as well as pharmaceutical, biotechnology and contract research companies. Accordingly, our products are labeled as "Research Use Only," or RUO, and are not intended for diagnostic use. While we have focused initially on the life sciences research market and RUO products only, our strategy is to expand our product line to encompass products that are intended to be used for the diagnosis of disease, either alone or in collaboration with third parties (such as our collaboration with Berry Genomics). Such in-vitro diagnostic, or IVD, products will be subject to regulation by the FDA as medical devices, or comparable international agencies, including requirements for regulatory clearance or approval of such products before they can be marketed. If the FDA were to determine that our products are intended for clinical use or if we decided to market our products for such use, we would be required to obtain FDA 510(k) clearance or premarket approval in order to sell our products in a manner consistent with FDA laws and regulations. Such regulatory approval processes or clearances are expensive, time-consuming and uncertain; our efforts may never result in any approved premarket

approval application, or PMA, or 510(k) clearance for our products; and failure by us or a collaborator to obtain or comply with such approvals and clearances could have an adverse effect on our business, financial condition or operating results.

IVD products may be regulated as medical devices by the FDA and comparable international agencies and may require either clearance from the FDA following the 510(k) pre-market notification process or PMA from the FDA, in each case prior to marketing. If we or our collaborators are required to obtain a PMA or 510(k) clearance for products based on our technology, we or they would be subject to a substantial number of additional requirements for medical devices, including establishment registration, device listing, Quality Systems Regulations which cover the design, testing, production, control, quality assurance, labeling, packaging, servicing, sterilization (if required), and storage and shipping of medical devices (among other activities), product labeling, advertising, recordkeeping, post-market surveillance, post-approval studies, adverse event reporting, and correction and removal (recall) regulations. One or more of the products we or a collaborator may develop using our technology may also require clinical trials in order to generate the data required for PMA approval. Complying with these requirements may be time-consuming and expensive. We or our collaborators may be required to expend significant resources to ensure ongoing compliance with the FDA regulations and/or take satisfactory corrective action in response to enforcement action, which may have a material adverse effect on the ability to design, develop, and commercialize products using our technology as planned. Failure to comply with these requirements may subject us or a collaborator to a range of enforcement actions, such as warning letters, injunctions, civil monetary penalties, criminal prosecution, recall and/or seizure of products, and revocation of marketing authorization, as well as significant adverse publicity. If we or our collaborators fail to obtain, or experience significant delays in obtaining, regulatory approvals for IVD products, such products may not be able to be launched or successfully commercialized in a timely manner, or at all.

Laboratory developed tests, or LDTs, are a subset of IVD tests that are designed, manufactured and used within a single laboratory. The FDA maintains that LDTs are medical devices and has for the most part exercised enforcement discretion for most LDTs. A significant change in the way that the FDA regulates any LDTs that we, our collaborators or our customers develop using our technology could affect our business. If the FDA requires laboratories to undergo premarket review and comply with other applicable FDA requirements in the future, the cost and time required to commercialize an LDT will increase substantially, and may reduce the financial incentive for laboratories to develop LDTs, which could reduce demand for our instruments and our other products. In addition, if the FDA were to change the way that it regulates LDTs to require that we undergo pre-market review or comply with other applicable FDA requirements before we can sell our instruments or our other products to clinical cytogenics laboratories, our ability to sell our instruments and other products to this addressable market would be delayed, thereby impeding our ability to penetrate this market and generate revenue from sales of our instruments and our other products.

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

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

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

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

If diagnostic procedures that are enabled by our technology are subject to unfavorable pricing regulations or third-party payor coverage and reimbursement policies, our business could be harmed.

Currently, our product is for research use only, but clinical laboratories may acquire our instrumentation through a capital purchase or capital lease and use the Saphyr and direct label stain chemistry to create their own potentially reimbursable products, such as laboratory developed tests for in vitro diagnostics. Our customers may generate revenue for these testing services by seeking the necessary approval

of their product from the FDA or the Centers for Medicare & Medicaid Services, or CMS, along with coverage and reimbursement from third-party payors, including government health programs and private health plans. The ability of our customers to commercialize diagnostic tests based on our technology will depend in part on the extent to which coverage and reimbursement for these tests will be available from such third-party payors.

In the U.S., molecular testing laboratories have multiple options for reimbursement coding, but we expect that the primary codes used will be the genomic sequencing procedure codes, or GSPs. The American Medical Association, or AMA, added GSPs to its clinical laboratory fee schedule in 2015. In addition, CMS recently issued a coverage determination providing for the reimbursement of next-generation sequencing for certain cancer diagnostics using an FDA-approved in vitro diagnostic test. Private health plans often follow CMS coverage and reimbursement guidelines to a substantial degree, and it is difficult to predict what CMS will decide with respect to the coverage and reimbursement of any products our customers try to commercialize.

In Europe, coverage for molecular diagnostic testing is varied. Countries with statutory health insurance (e.g., Germany, France, The Netherlands) tend to be more progressive in technology adoption with favorable reimbursement for molecular diagnostic testing. In countries such as the United Kingdom with tax-based insurance, adoption and reimbursement for molecular diagnostic testing is not uniform and is influenced by local budgets.

Ultimately, coverage and reimbursement of new products is uncertain, and whether laboratories that use our instruments to develop their own products will attain coverage and adequate reimbursement is unknown. In the U.S., there is no uniform policy for determining coverage and reimbursement. Coverage can differ from payor to payor, and the process for determining whether a payor will provide coverage may be separate from the process for setting the reimbursement rate. In addition, the U.S. government, state legislatures and foreign governments have shown significant interest in implementing cost containment programs to limit the growth of government-paid healthcare costs, including price controls and restrictions on reimbursement. We cannot be sure that coverage will be available for any diagnostic tests based on our technology, and, if coverage is available, the level of payments. Reimbursement may impact the demand for those tests. If coverage and reimbursement is not available or is available only to limited levels, our customers may not be able to successfully commercialize any tests for which they receive marketing authorization.

Current and future legislation may increase the difficulty and cost to obtain marketing approval of and commercialize any products based on our technology and affect the prices that may be obtained.

In March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, collectively, the ACA, became law. The ACA is a sweeping law intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add new transparency requirements for the healthcare and health insurance industries, impose new taxes and fees on the health industry and impose additional health policy reforms. The ACA's provisions of importance to our business include, but are not limited to, a 2.3% excise tax on certain entities that manufacture or import medical devices offered for sale in the U.S., with limited exceptions, which has been suspended, but due to subsequent legislative amendments, will be automatically reinstated for medical device sales beginning January 1, 2020, unless Congress takes additional action to delay the implementation of the tax.

Some of the provisions of the ACA have yet to be implemented, and there have been judicial and Congressional challenges to certain aspects of the ACA, as well as efforts by the Trump administration to repeal or replace certain aspects of the ACA. Since January 2017, President Trump has signed two Executive Orders and other directives designed to delay the implementation of certain provisions of the ACA or otherwise circumvent some of the requirements for health insurance mandated by the ACA. Concurrently, Congress has considered legislation that would repeal or repeal and replace all or part of the ACA. While Congress has not passed comprehensive repeal legislation, it has enacted laws that modify certain provisions of the ACA such as removing penalties, starting January 1, 2019, for not complying with the ACA's individual mandate to carry health insurance and delaying the implementation of certain ACA-mandated fees including, without limitation, the medical device excise tax. On December 14, 2018, a Texas U.S. District Court Judge ruled that the ACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress as part of the Tax Cuts and Jobs Act. While the Texas U.S. District Court Judge, as well as the Trump administration and CMS, have stated that the ruling will have no immediate effect pending appeal of the decision, it is unclear how this decision, subsequent appeals, and other efforts to repeal and replace the ACA will impact the ACA and our business.

In addition, other legislative changes have been proposed and adopted since the ACA was enacted. For example, on April 1, 2014, the Protecting Access to Medicare Act of 2014, or PAMA, was signed into law, which, among other things, significantly altered the payment methodology under the Medicare Clinical Laboratory Fee Schedule, or CLFS. PAMA requires certain laboratories performing clinical diagnostic laboratory tests to report to CMS the amounts paid by private payors for laboratory tests. Beginning January 1, 2018, CMS will use reported private payor pricing to periodically revise payment rates under the CLFS.

We expect that the ACA, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and additional downward pressure on the price that we or our collaborators will receive for any cleared or approved

product. Any reduction in payments from Medicare or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent our customers from successfully commercializing any tests for which they receive approval, which could prevent us from being able to generate revenue and attain profitability.

We may be subject, directly or indirectly, to federal and state healthcare fraud and abuse laws and other federal and state laws applicable to our marketing practices. If we are unable to comply, or have not complied, with such laws, we could face substantial penalties.

Our operations are directly or indirectly, through our customers, subject to various federal and state fraud and abuse laws, including, without limitation, the federal and state anti-kickback statutes and false claims laws. These laws may impact, among other things, our sales and marketing and education programs, and our financial and business relationships with researchers who use our instruments to develop marketed products. By way of example: the federal Anti-Kickback Statute prohibits, among other things, any person or entity from, among other things, knowingly and willfully soliciting, receiving, offering or paying any remuneration, directly or indirectly, to induce, or in return for, purchasing, leasing, ordering, or arranging for or recommending the purchase, lease, or order of any good, facility, item, or service reimbursable, in whole or in part, under a federal healthcare program; and the federal false claims laws, including, without limitation the federal civil False Claims Act, prohibit, among other things, anyone from knowingly and willingly presenting, or causing to be presented for payment, to the federal government (including Medicare and Medicaid) claims for reimbursement for, among other things, drugs or services that are false or fraudulent, claims for items or services not provided as claimed, or claims for medically unnecessary items or services. The ACA, among other things, amended the intent requirement of the federal Anti-Kickback Statute to clarify that a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a crime. In addition, the ACA clarifies that the government may assert that a claim that includes items or service resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act.

In addition, we may be subject to the Health Insurance Portability and Accountability Act of 1996, or HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act and their implementing regulations, which imposes certain requirements relating to the privacy, security and transmission of individually identifiable health information without appropriate authorization by entities subject to the rule, such as health plans, health care clearinghouses and certain health care providers and their business associates who create, use or disclose individually identifiable health information on their behalf. We may also be subject to state and foreign laws, such as the General Data Protection Regulation (EU) 2016/679, that govern the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

If our operations are found to be in violation of any of these laws, we may be subject to significant penalties, including, without limitation, civil, criminal, and administrative penalties, damages, fines, disgorgement, the curtailment or restructuring of our operations, exclusion from participation in federal and state healthcare programs, additional integrity oversight and reporting obligations, imprisonment, contractual damages, and reputational harm, any of which could adversely affect our ability to operate our business and our results of operations.

Additionally, sales of our instruments outside of the U.S. will subject us to similar foreign regulatory requirements.

Risks Related to Intellectual Property

If we are unable to protect our intellectual property, it may reduce our ability to maintain any technological or competitive advantage over our competitors and potential competitors, and our business may be harmed.

We rely on patent protection as well as trademark, copyright, trade secret and other intellectual property rights protection and contractual restrictions to protect our proprietary technologies, all of which provide limited protection and may not adequately protect our rights or permit us to gain or keep any competitive advantage. As of March 8, 2019, we were the assignee or assignee-applicant of 12 granted U.S. patents and approximately 11 pending U.S. patent applications. We also were the assignee-applicant of approximately 89 pending patent applications and granted patents in particular jurisdictions outside the U.S. If we fail to protect and/or maintain our intellectual property, third parties may be able to compete more effectively against us, we may lose our technological or competitive advantage, and/or we may incur substantial litigation costs in our attempts to recover or restrict use of our intellectual property.

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

a technological or competitive advantage over our competitors and/or market entrants may be diminished because of these uncertainties. For these and other reasons, our intellectual property may not provide us with any competitive advantage. For example:

- we or our licensors might not have been the first to make the inventions claimed or disclosed by our pending patent applications or issued patents;
- we or our licensors might not have been the first to file patent applications for these inventions. To determine the priority of these inventions, we may have to participate in interference proceedings or derivation proceedings declared by the U.S. Patent and Trademark Office, or the USPTO, which could result in substantial cost to us, and could possibly result in a loss or narrowing of patent rights. No assurance can be given that our patent applications or granted patents (or those of our licensors) will have priority over any other patent or patent application involved in such a proceeding, or will be held valid as an outcome of the proceeding;
- other parties may independently develop similar or alternative products and technologies or duplicate any of our products and technologies, which can potentially impact our market share, revenue, and goodwill, regardless of whether intellectual property rights are successfully enforced against these other parties;
- it is possible that our owned or licensed pending patent applications will not result in granted patents, and even if such pending patent applications issue as patents, they may not provide intellectual property protection of commercially viable products or product features, may not provide us with any competitive advantages, or may be challenged and invalidated by third parties, patent offices, and/or the courts;
- we may be unaware of or unfamiliar with prior art and/or interpretations of prior art that could potentially impact the validity or scope of our patents or pending patent applications, or patent applications that we intend to file;
- we take efforts and enter into agreements with employees, consultants, collaborators, and advisors to confirm ownership and chain of title in intellectual property rights. However, an inventorship or ownership dispute could arise that may permit one or more third parties to practice or enforce our intellectual property rights, including possible efforts to enforce rights against us;
- we may elect not to maintain or pursue intellectual property rights that, at some point in time, may be considered relevant to or enforceable against a competitor;
- we may not develop additional proprietary products and technologies that are patentable, or we may develop additional proprietary products and technologies that are not patentable;
- the patents or other intellectual property rights of others may have an adverse effect on our business; and
- we apply for patents relating to our products and technologies and uses thereof, as we deem appropriate. However, we or our representatives or their agents may fail to apply for patents on important products and technologies in a timely fashion or at all, or we or our representatives or their agents may fail to apply for patents in potentially relevant jurisdictions.

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

Software is an important component of at least some of our products and services. To the extent such software is not protected by our patents, our dependence on trade secret protection may not provide adequate protection. In addition, the Supreme Court's ruling *Alice Corporation Pty. Ltd. v. CLS Bank International*, has narrowed the scope of patent protection available for software in certain circumstances.

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

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

had illegally obtained and was using our trade secrets, it would be expensive and time consuming, the outcome would be unpredictable, and any remedy may be inadequate. In addition, courts outside the U.S. may be less willing to protect trade secrets.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

We could incur substantial costs and divert the attention of our management and technical personnel in defending ourselves against claims of infringement made by third parties. Any adverse ruling by a court or administrative body, or perception of an adverse ruling, may have a material adverse impact on our ability to conduct our business and our finances. Moreover, third parties making claims against us may be able to obtain injunctive relief against us, which could block our ability to offer one or more products or services and could result in a substantial award of damages against us. In addition, since we sometimes indemnify customers, collaborators or licensees, we may have additional liability in connection with any infringement or alleged infringement of third-party intellectual property. Intellectual

property litigation can be very expensive, and we may not have the financial means to defend ourselves or our customers, collaborators and licensees.

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

- seek to obtain licenses that may not be available on commercially reasonable terms, if at all;
- abandon any product alleged or held to infringe, or redesign our products or processes to avoid potential assertion of infringement;
- pay substantial damages including, in exceptional cases, treble damages and attorneys' fees, which we may have to pay if a court decides that the product or proprietary technology at issue infringes upon or violates the third-party's rights;
- pay substantial royalties or fees or grant cross-licenses to our technology; or
- defend litigation or administrative proceedings that may be costly whether we win or lose, and which could result in a substantial diversion of our financial and management resources.

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

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

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

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

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

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

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

As is common in the life sciences industry, we engage the services of consultants and independent contractors to assist us in the development of our products. Many of these consultants and independent contractors were previously employed at, or may have previously or may be currently providing consulting or other services to, universities or other technology, biotechnology or pharmaceutical companies, including our competitors or potential competitors. We may become subject to claims that our company, a consultant or an independent contractor inadvertently or otherwise used or disclosed trade secrets or other information proprietary to their former employers or their former or current clients. We may similarly be subject to claims stemming from similar actions of an employee, such as one who was previously employed by another company, including a competitor or potential competitor. We may become subject to claims that one or more current or former employees, consultants, advisors, or independent contractors of ours owns rights in our intellectual property and/or has assigned or is under an obligation to assign rights in our intellectual property to another party. This may include a competitor of ours. If a competitor has rights in our patents, the competitor or a licensee or related entity may be able to make, use, sell, import, and/or export the patented technology without liability to us under our patents or the patents we license. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to our management team. If we were not successful, we could lose valuable intellectual property rights.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Our registered or unregistered trademarks or trade names may be challenged, infringed, circumvented or declared generic or determined to be infringing other marks. We may not be able to protect our rights to these trademarks and trade names, which we need to build name recognition by potential partners or customers in our markets of interest. At times, competitors may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. In addition,

there could be potential trade name or trademark infringement claims brought by owners of other registered trademarks. Over the long term, if we are unable to establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively and our business may be adversely affected.

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

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

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

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

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

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

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

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

- others may be able to develop and/or use technology that is similar to our technology or aspects of our technology but that does not cover the claims of any our patents or patents that may issue from our patent applications or those we license;
- we or the licensor of our licensed-in patents might not have been the first to make the inventions disclosed and/or claimed in a pending patent application that we own or license;
- we or the licensor of our licensed-in patents might not have been the first to file patent applications disclosing and/or claiming an invention;
- others may independently develop similar or alternative technologies without infringing our or our licensors' intellectual property rights;
- pending patent applications that we own or license may not lead to issued patents or may not result in the claims that we want (for example, as to the scope of issued claims, if any);

- patents, if issued, that we own or license may not provide us with any competitive advantages, or may be held invalid or unenforceable, as a result of legal challenges by our competitors or other third parties;
- third parties may compete with us in jurisdictions where we do not pursue and obtain patent protection;
- we may not be able to obtain and/or maintain necessary or useful licenses on reasonable terms or at all;
- third parties may assert an ownership interest in our intellectual property and, if successful, such disputes may preclude us from exercising exclusive rights over that intellectual property;
- we may not be able to maintain the confidentiality of our trade secrets or other proprietary information;
- we may not develop or in-license additional proprietary technologies that are patentable; and
- the patents or other intellectual property of others may have an adverse effect on our business.

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

Risks Related to Ownership of our Securities

The price of our securities may be volatile, and you could lose all or part of your investment.

The trading price of our securities is likely to be highly volatile and could be subject to wide fluctuations in response to various factors, some of which are beyond our control, including limited trading volume. In addition to the factors discussed in this Part I, Item 1A Risk Factors and elsewhere in this Annual Report, these factors include:

- our commercial progress in marketing and selling our systems, including sales and revenue trends;
- changes in laws or regulations applicable our systems;
- adverse developments related to our laboratory facilities;
- increased competition in the diagnostics services industry;
- the failure of our customers to obtain and/or maintain coverage and adequate reimbursement for their services using our systems;
- adverse developments concerning our manufacturers and suppliers;
- our inability to establish future collaborations;
- additions or departures of key scientific or management personnel;
- introduction of new testing services offered by us or our competitors;
- announcements of significant acquisitions, strategic partnerships, joint ventures or capital commitments by us or our competitors;
- our ability to effectively manage our growth;
- the size and growth, if any, of our targeted markets;
- actual or anticipated variations in quarterly operating results;
- our cash position;
- our failure to meet the estimates and projections of the investment community or that we may otherwise provide to the public;
- publication of research reports about us or our industry or positive or negative recommendations or withdrawal of research coverage by securities analysts;
- changes in the market valuations of similar companies;
- overall performance of the equity markets;
- issuances of debt or equity securities;
- sales of our securities by us or our stockholders in the future;
- trading volume of our securities;
- changes in accounting practices;

- ineffectiveness of our internal controls;
- disputes or other developments relating to proprietary rights, including our ability to adequately protect our technologies;
- significant lawsuits, including patent or stockholder litigation;
- general political and economic conditions; and
- other events or factors, many of which are beyond our control.

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

We have never paid dividends and we do not intend to pay dividends on our capital stock.

We have never declared or paid any cash dividend on our capital stock. We currently anticipate that we will retain future earnings for the development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. Any determination to pay dividends in the future will be at the discretion of our board of directors and will depend upon results of operations, financial condition, contractual restrictions, restrictions imposed by applicable law and other factors our board of directors deems relevant. Accordingly, realization of a gain on your investment will depend on the appreciation of the price of our securities, which may never occur. In addition, our loan and security agreement with Midcap contains a negative covenant which prohibits us from paying dividends without the prior written consent of Midcap.

Our principal stockholders and management own a significant percentage of our stock and will be able to exert significant control over matters subject to stockholder approval.

Our executive officers, directors and 5% stockholders and their affiliates currently beneficially own a significant percentage of our outstanding voting stock. These stockholders may be able to determine all matters requiring stockholder approval. For example, these stockholders may be able to control elections of directors, amendments of our organizational documents, or approval of any merger, sale of assets or other major corporate transaction. This may prevent or discourage unsolicited acquisition proposals or offers for our securities that you may feel are in your best interest as one of our stockholders.

We are an emerging growth company, and the reduced reporting requirements applicable to emerging growth companies could make our securities less attractive to investors.

We are an emerging growth company, as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act. For as long as we continue to be an emerging growth company, we may take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies, including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation in this Annual Report and our periodic reports and proxy statements and exemptions from the requirements of holding nonbinding advisory votes on executive compensation and stockholder approval of any golden parachute payments not previously approved. We can remain an emerging growth company until the earlier of (1) the last day of the fiscal year (a) ending December 31, 2023, which is the end of the fiscal year following the fifth anniversary of the closing of our initial public offering, (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 June 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 still qualify as a "smaller reporting company" which would allow us to take advantage of many of the same exemptions from disclosure requirements including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act and reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements. We cannot predict if investors will find our securities less attractive because we may rely on these exemptions, which could result in a less active trading market for our securities and increased volatility in the price of our securities.

Under the JOBS Act, emerging growth companies can also delay adopting new or revised accounting standards that have different effective dates for public and private companies until those standards apply to private companies. We have elected to use this extended transition period. As a result of this election, our timeline to comply with these standards will in many cases be delayed as compared to other public companies that are not eligible to take advantage of this election or have not made this election. Therefore, our financial statements may not be comparable to those of companies that comply with the public company effective dates for these standards.

In addition, if we cease to be an emerging growth company, we will no longer be able to use the extended transition period for complying with new or revised accounting standards. As a result, changes in rules of U.S. generally accepted accounting principles or their interpretation, the adoption of new guidance or the application of existing guidance to changes in our business could significantly affect our financial position and results of operations.

If we fail to maintain proper and effective internal controls, our ability to produce accurate financial statements on a timely basis could be impaired.

We are subject to the reporting requirements of the Securities Exchange Act of 1934, as amended, or the Exchange Act, the Sarbanes-Oxley Act and the rules and regulations of Nasdaq. The Sarbanes-Oxley Act requires, among other things, that we maintain effective disclosure controls and procedures and internal controls over financial reporting. Internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements in accordance with accounting principles generally accepted in the U.S. Commencing with our fiscal year ending December 31, 2019, we must perform system and process evaluation and testing 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 that year, as required by Section 404 of the Sarbanes-Oxley Act. 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 initial public offering, we were not 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.

During the evaluation and testing process of our internal controls, if we identify one or more material weaknesses in our internal control over financial reporting, we will be unable to assert that our internal control over financial reporting is effective. We cannot assure you that there will not be material weaknesses or significant deficiencies in our internal control over financial reporting in the future. Any failure to maintain internal control over financial reporting could severely inhibit our ability to accurately report our financial condition or results of operations. If we are unable to conclude that our internal control over financial reporting is effective, or if our independent registered public accounting firm determines we have a material weakness or significant deficiency in our internal control over financial reporting, we could lose investor confidence in the accuracy and completeness of our financial reports, the market price of our securities could decline, and we could be subject to sanctions or investigations by Nasdaq, the Securities and Exchange Commission, or the SEC, or other regulatory authorities. Failure to remedy any material weakness in our internal control over financial reporting, or to implement or maintain other effective control systems required of public companies, could also restrict our future access to the capital markets.

Our disclosure controls and procedures may not prevent or detect all errors or acts of fraud.

We have designed our disclosure controls and procedures to reasonably assure that information we must disclose in reports we file or submit under the Exchange Act is accumulated and communicated to management, and recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC. We believe that any disclosure controls and procedures or internal controls and procedures, no matter how well-conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met.

These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of simple errors or mistakes. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by an unauthorized override of the controls. Accordingly, because of the inherent limitations in our control system, misstatements due to error or fraud may occur and not be detected.

We have begun to incur significant increased costs as a result of operating as a public company, and our management will be required to devote substantial time to compliance initiatives.

As a newly public company, we have begun to incur significant legal, accounting and other expenses that we did not incur as a private company. We are subject to the reporting requirements of the Securities Exchange Act of 1934, as amended, which will require, among other things, that we file with the SEC annual, quarterly and current reports with respect to our business and financial condition. In addition, the Sarbanes-Oxley Act, as well as rules subsequently adopted by the SEC and Nasdaq to implement provisions of the Sarbanes-Oxley Act, impose significant requirements on public companies, including requiring establishment and maintenance of effective disclosure and financial controls and changes in corporate governance practices. Further, in July 2010, the Dodd-Frank Wall Street Reform and Consumer Protection Act, or the Dodd-Frank Act, was enacted. There are significant corporate governance and executive-compensation-related provisions in the Dodd-Frank Act that require the SEC to adopt additional rules and regulations in these areas. Recent legislation permits emerging growth companies to implement many of these requirements over a longer period and up to five years from the pricing of our initial public offering. We intend to take advantage of this new legislation, but cannot assure you that we will not be required to implement these requirements sooner than planned and thereby incur unexpected expenses. Stockholder activism,

the current political environment and the current high level of government intervention and regulatory reform may lead to substantial new regulations and disclosure obligations, which may lead to additional compliance costs and impact the manner in which we operate our business in ways we cannot currently anticipate.

We expect the rules and regulations applicable to public companies will continue to substantially increase our legal and financial compliance costs and to make some activities more time-consuming and costly. If these requirements divert the attention of our management and personnel from other business concerns, they could have a material adverse effect on our business, financial condition and results of operations. The increased costs will decrease our net income or increase our consolidated net loss, and may require us to reduce costs in other areas of our business or increase the prices of our products or services. For example, these rules and regulations to make it more difficult and more expensive for us to obtain director and officer liability insurance and we are required to incur substantial costs to maintain the same or similar coverage. We cannot predict or estimate the amount or timing of additional costs we may incur to respond to these requirements. The impact of these requirements also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, our board committees or as executive officers.

A significant portion of our total outstanding shares are restricted from immediate resale but may be sold into the market in the near future. This could cause the market price of our common stock to drop significantly, even if our business is doing well.

Sales of a substantial number of shares of our common stock in the public market could occur at any time, subject to the restrictions and limitations described below. If our stockholders sell, or the market perceives that our stockholders intend to sell, substantial amounts of our common stock in the public market, the market price of our common stock could decline significantly. All of our outstanding shares of common stock are available for sale in the public market, subject only to the restrictions of Rule 144 under the Securities Act in the case of our affiliates.

In addition, we have filed a registration statement on Form S-8 under the Securities Act registering the issuance of 2,091,391 shares of common stock subject to options or other equity awards issued or reserved for future issuance under our equity incentive plans. Shares registered under this registration statement on Form S-8 are available for sale in the public market subject to vesting arrangements and exercise of options, the lock-up agreements described above and the restrictions of Rule 144 in the case of our affiliates.

Additionally, the holders of approximately 2,906,915 shares of our common stock, or their transferees, have rights, subject to some conditions, to require us to file one or more registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or other stockholders. If we were to register the resale of these shares, they could be freely sold in the public market. If these additional shares are sold, or if it is perceived that they will be sold, in the public market, the trading price of our common stock could decline.

Anti-takeover provisions under our charter documents and Delaware law could delay or prevent a change of control which could limit the market price of our securities and may prevent or frustrate attempts by our securityholders to replace or remove our current management.

Our amended and restated certificate of incorporation and amended and restated bylaws, contain provisions that could delay or prevent a change of control of our company or changes in our board of directors that our stockholders might consider favorable. Some of these provisions include:

- a board of directors divided into three classes serving staggered three-year terms, such that not all members of the board will be elected at one time;
- a prohibition on stockholder action through written consent, which requires that all stockholder actions be taken at a meeting of our stockholders;
- a requirement that special meetings of stockholders be called only by the chairman of the board of directors, the chief executive officer, the president or by a majority of the total number of authorized directors;
- advance notice requirements for stockholder proposals and nominations for election to our board of directors;
- a requirement that no member of our board of directors may be removed from office by our stockholders except for cause and, in addition to any other vote required by law, upon the approval of not less than two-thirds of all outstanding shares of our voting stock then entitled to vote in the election of directors;
- a requirement of approval of not less than two-thirds of all outstanding shares of our voting stock to amend any bylaws by stockholder action or to amend specific provisions of our certificate of incorporation; and
- the authority of the board of directors to issue preferred stock on terms determined by the board of directors without stockholder approval and which preferred stock may include rights superior to the rights of the holders of common stock.

In addition, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporate Law, which may prohibit certain business combinations with stockholders owning 15% or more of our outstanding voting stock. These anti-takeover provisions and other provisions in our amended and restated certificate of incorporation and amended and restated bylaws could make it more difficult for stockholders or potential acquirers to obtain control of our board of directors or initiate actions that are opposed by the then-current board of directors and could also delay or impede a merger, tender offer or proxy contest involving our company. These provisions could also discourage proxy contests and make it more difficult for you and other stockholders to elect directors of your choosing or cause us to take other corporate actions you desire. Any delay or prevention of a change of control transaction or changes in our board of directors could cause the market price of our securities to decline.

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

The trading market for our securities will depend in part on the research and reports that securities or industry analysts publish about us or our business. As a newly public company, we have only limited research coverage on our company by equity research analysts. If securities or industry analysts elect not to initiate or continue to provide coverage of our company, the trading price for our securities would likely be negatively impacted. If one or more of the analysts who covers us downgrades our securities or publishes inaccurate or unfavorable research about our business, the price of our securities may decline. If one or more of these analysts ceases coverage of our company or fails to publish reports on us regularly, demand for our securities could decrease, which might cause the price of our securities and trading volume to decline.

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

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

Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware and, to the extent enforceable, the U.S. federal district courts will be the exclusive forums for substantially all disputes between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or other employees.

Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware is the sole and 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 under the Delaware General Corporation Law, our amended and restated certificate of incorporation or our amended and restated bylaws, or any action asserting a claim against us that is governed by the internal affairs doctrine. Our amended and restated 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, subject to and contingent upon a final adjudication in the State of Delaware of the enforceability of such exclusive forum provision. These choice of forum provisions may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees, which may discourage such lawsuits. If a court were to find either 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, which could adversely affect our results of operations and financial condition.

For example, the Court of Chancery of the State of Delaware recently determined that the exclusive forum provision of federal district courts of the United States of America for resolving any complaint asserting a cause of action arising under the Securities Act is not enforceable. However, this decision may be reviewed and ultimately overturned by the Delaware Supreme Court. If this ultimate adjudication were to occur, we would enforce the federal district court exclusive forum provision in our amended and restated certificate of incorporation.

Item 1B. Unresolved Staff Comments.

None.

Item 2. Properties.

We lease approximately 16,521 square feet of office, laboratory, and manufacturing space at our headquarters in San Diego, California, under a lease that expires on December 31, 2020. We believe that we will need additional space as we grow our operations, but believe that suitable additional or substitute space will be available to accommodate future growth of our business. We believe that our existing office, laboratory and manufacturing space will be sufficient to meet our needs in the interim.

Item 3. Legal Proceedings.

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

Item 4. Mine Safety Disclosures.

None.

PART II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities.

Market Information

Our common stock began trading on The Nasdaq Capital Market on September 21, 2018 under the symbol "BNGO." Prior to such time, there was no public market for our common stock.

Common Stock holders

As of March 8, 2019, there were approximately 106 holders of record of our common stock. Certain shares of our common stock are held in "street" name and thus the actual number of beneficial owners of such shares is not known or included in the foregoing number.

Warrant holders

As of March 8, 2019, there were no holders of record of our warrants issued in our initial public offering, which are listed on the Nasdaq Stock Market LLC under the symbol "BNGOW" ("Warrants"). The Warrants are held in "street" name and thus the actual number of beneficial owners of such Warrants is not known.

Dividend Policy

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

Securities Authorized for Issuance under Equity Compensation Plans

The information required by this Item regarding equity compensation plans is incorporated herein by reference to Item 12 of Part III of this Annual Report on Form 10-K.

Purchases of Equity Securities by the Issuer or Affiliated Purchasers

None.

Use of Proceeds from Initial Public Offering

On August 21, 2018, we completed our initial public offering, or our IPO, pursuant to a registration statement on Form S-1 (File No. 333-225970), which was declared effective by the SEC on August 20, 2018, in which we sold an aggregate of 3,864,000 units (each unit consisting of one share of our common stock and one warrant to purchase one share of our common stock) at a public offering price of $6.125 per unit, which included the sale of 504,000 units pursuant to the exercise of the underwriters' over-allotment option. Roth Capital Partners served as the sole book-running manager for the offering, Maxim Group acted as the lead manager, and LifeSci Capital acted as the co-manager. We received net cash proceeds of $19.4 million, after deducting underwriters' discounts and commissions of $2.2 million and other offering expenses of $2.1 million. None of these expenses consisted of payments made by us to directors, officers or persons owning 10% or more of our common stock or to their associates, or to our affiliates. There has been no material change in the planned use of proceeds from our IPO as described in our prospectus dated August 21, 2018 filed with the SEC on August 22, 2018 pursuant to Rule 424(b)(4). As of the commencement of trading on September 21, 2018, the units sold in the IPO separated in accordance with their terms and our common stock and warrants began trading separately on The Nasdaq Capital Market. Since the effective date of our registration statement through the date of these financial statements, we have used the proceeds from the IPO to fund our operating activities. The remainder is invested in cash and cash equivalent securities or highly-liquid investment securities.

Recent Sales of Unregistered Securities

On August 23, 2018, in connection with the underwriting agreement related to our IPO, we issued (i) to Roth Capital Partners, a warrant to purchase 68,040 shares of the our common stock, (ii) to Maxim Partners LLC, a warrant to purchase 22,680 shares of our common stock and (ii) to LifeSci Capital LLC, a warrant to purchase 10,080 shares of our common stock (together, the "Underwriter Warrants"), each having an exercise price of $9.1875 per share of our common stock and a term of five years. On August 30, 2018, pursuant to the exercise of the underwriters' over-allotment option, we issued (i) to Roth Capital Partners, a warrant to purchase

10,206 shares of the our common stock, (ii) to Maxim Partners LLC, a warrant to purchase 3,402 shares of our common stock and (ii) to LifeSci Capital LLC, a warrant to purchase 1,512 shares of our common stock (together, the "Over-Allotment Warrants"), each having an exercise price of $9.1875 per share of our common stock and a term of five years. The description of the Underwriter Warrants and the Over-Allotment Warrants is qualified in its entirety by the form of Warrant to Purchase Common Stock issued to the underwriters, filed as an exhibit hereto and incorporated herein by reference.

On November 19, 2018, we issued (i) to LifeSci Capital, LLC, a warrant to purchase 44,183 shares of the our common stock, and (ii) to Russell Creative Group, a warrant to purchase 3,311 shares of our common stock (together, the "Service Provider Warrants"), each having an exercise price of $8.25 per share of our common stock and a term of five years. The Service Provider Warrants were issued in full satisfaction of our obligations to pay (i) to LifeSci Capital, LLC an aggregate of $150,000 for capital advisory and investor relations services and (ii) to Russell Creative Group an aggregate of $15,000 for branding and marketing services. LifeSci Capital, LLC and Russell Creative Group are accredited investors and the issuance of the Service Provider Warrants was exempt from registration under the Securities Act in reliance on an exemption provided by Section 4(a)(2) of the Securities Act. The description of the Service Provider Warrants is qualified in its entirety by the form of Warrant to Purchase Common Stock filed as an exhibit hereto and incorporated herein by reference.

On November 19, 2018, we entered into an Amendment Agreement (the "Amendment Agreement") with Western Alliance Bank, an Arizona corporation (the "Holder"), in order to amend (i) that certain Warrant to Purchase Stock, dated March 8, 2016, (ii) that certain Warrant to Purchase Stock, dated December 9, 2016 ((i) and (ii) collectively, the "Bank Warrants") and (iii) that certain Loan and Security Agreement, dated as of March 8, 2016, as amended (the "Loan Agreement"). Pursuant to the Amendment Agreement, the exercise price of the Bank Warrants was decreased from $20.56 per share to $6.99 per share. All other terms of the Bank Warrants remain in full force and effect. The foregoing description is subject to, and qualified in its entirety by, the Amendment Agreement filed as an exhibit hereto and incorporated herein by reference.

Item 6. Selected Financial Data.

As a smaller reporting company, we are not required to provide information typically disclosed under this item.

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

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

Overview

We are a life sciences instrumentation company in the genome analysis space. We develop and market the Saphyr system, a platform for ultra-sensitive and ultra-specific structural variation detection that enables researchers and clinicians to accelerate the search for new diagnostics and therapeutic targets and to streamline the study of changes in chromosomes, which is known as cytogenetics. Our Saphyr system comprises an instrument, chip consumables, reagents and a suite of data analysis tools.

Structural variation refers to large-scale structural differences in the genomic DNA of one individual compared to another. Each structural variation involves the rearrangement or repetition of as few as hundreds to as many as tens of millions of DNA base pairs. Those rearrangements may be insertions, deletions, duplications, inversions or translocations of segments of one or more chromosomes. Structural variations may be inherited or arise spontaneously and many cause genetic disorders and diseases. Until our commercial launch of the Saphyr system in February 2017, and since, we believe no products existed or exist that could more comprehensively and cost and time-efficiently detect structural variation.

Our Saphyr system comprises an instrument, chip consumables, reagents and a suite of data analysis tools. Our customers include researchers and clinicians who seek to uncover and understand the biological or clinical impact of genome variation to improve the diagnosis and treatment of patients with better clinical tests and new medicines or to replace existing cytogenetic tests that are expensive, slow and labor-intense, with a modern solution that simplifies workflow and reduces costs and that has the potential to significantly increase diagnostic yields across the industry. Our customers also include researchers in non-human segments such as agricultural genomics where they seek to advance their understanding of how structural variation impacts industrial applications of plants and animals.

Since our inception, we have raised net proceeds of $148.7 million to fund our operations from the issuance of equity and convertible promissory notes. We have incurred losses in each year since our inception. Our net losses were $18.5 million and $23.4 million for the years ended December 31, 2018 and 2017, respectively. As of December 31, 2018, we had an accumulated deficit of $72.8 million.

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

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

Initial Public Offering

In August 2018, we completed our initial public offering of our common stock, or the IPO, in which we sold an aggregate of 3,864,000 units (each unit consisting of one share of our common stock and one warrant to purchase one share of our common stock) at a public offering price of $6.125 per unit for net proceeds of $19.4 million, after deducting underwriters' discounts and commissions of $2.2 million and other offering expenses of $2.1 million.

Financial Overview

Revenue

We generate product revenue from sales of our instruments and consumables. We currently sell our products for research use only applications and our customers are primarily laboratories associated with academic and governmental research institutions, as well as pharmaceutical, biotechnology and contract research companies. Sales of our consumables have consistently increased due to an increasing number of our instruments being installed in the field, all of which require certain of our consumables to run customers' specific tests. Consumable revenue consists of sales of complete assays which are developed internally by us, plus sales of kits which contain all the elements necessary to run tests. Other revenue consists of warranty and other service-based revenue.

The following table presents our revenue for the periods indicated:

	Year Ended December 31,	
	2018	2017
Product revenue	$ 11,463,173	$ 8,769,704
Other revenue	537,562	735,339
Total	$ 12,000,735	$ 9,505,043

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

	Year Ended December 31,			
	2018		2017	
	$	%	$	%
North America	$ 4,594,814	38%	$ 3,801,481	40%
EMEIA	3,954,693	33%	1,282,897	13%
Asia Pacific	3,451,228	29%	4,420,665	47%
Total	$ 12,000,735	100%	$ 9,505,043	100%

Cost of Revenue

Cost of revenue for our instruments and consumables includes cost from the manufacturer, raw material parts costs and associated freight, shipping and handling costs, contract manufacturer costs, salaries and other personnel costs, overhead and other direct costs related to those sales recognized as product revenue in the period.

Cost of other revenue consists of salaries and other personnel costs and costs related to warranties and other costs of servicing equipment at customer sites.

Research and Development Expenses

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

Selling, General and Administrative Expenses

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

Results of Operations

Comparison of the Years Ended December 31, 2018 and 2017

The following table sets forth our results of operations for the years ended December 31, 2018 and 2017:

	Year Ended December 31,		Period-to-Period Change	
	2018	2017	$	%
Product revenue	$ 11,463,173	$ 8,769,704	$ 2,693,469	31 %
Other revenue	537,562	735,339	(197,777)	(27)%
Total revenue	12,000,735	9,505,043	2,495,692	26 %
Cost of product revenue	8,562,042	5,958,537	2,603,505	44 %
Cost of other revenue	149,284	71,975	77,309	107 %
Total cost of revenue	8,711,326	6,030,512	2,680,814	44 %
Research and development	9,484,163	12,009,170	(2,525,007)	(21)%
Selling, general and administrative	14,220,331	14,079,658	140,673	1 %
Impairment of property and equipment	—	604,511	(604,511)	(100)%
Total operating expenses	23,704,494	26,693,339	(2,988,845)	(11)%
Loss from operations	(20,415,085)	(23,218,808)	2,803,723	(12)%
Interest expense	(1,381,024)	(590,927)	(790,097)	134 %
Change in fair value of preferred stock warrants and expirations	3,991,081	751,933	3,239,148	431 %
Other expense	(675,853)	(289,010)	(386,843)	134 %
Loss before income taxes	(18,480,881)	(23,346,812)	4,865,931	(21)%
Provision for income taxes	(15,511)	(18,552)	3,041	(16)%
Net loss	$ (18,496,392)	$ (23,365,364)	$ 4,868,972	(21)%

Revenue

Revenue increased by $2.5 million, or 26% to $12.0 million for the year ended December 31, 2018, as compared to $9.5 million for the same period in 2017. The increase in product revenue of $2.7 million was mostly due to a 29% increase in instrument unit sales. Consumable unit sales increased 63% in 2018 as compared to 2017. The increase is attributed to the cumulative growth of the Saphyr install base and the introduction of bundled orders to customers which offer purchase discounts in exchange for larger unit orders.

Cost of Revenue

Cost of product revenue increased by $2.7 million, or 44%, to $8.7 million for the year ended December 31, 2018, as compared to $6.0 million for the same period in 2017. The increase was primarily due to increased unit sales of instruments and consumables year over year. In addition, the Company recorded losses of $1.3 million and $0.4 million in 2018 and 2017, respectively, to write-down inventory to net realizable value of our Irys instrument (the predecessor to our Saphyr instrument). The write-downs were driven by the introduction of the Saphyr instrument during the first quarter of 2017. We expect the cost of product revenue per instrument to decrease in future periods as we benefit from economies of scale and modifications to the components and assembly over time.

Research and Development Expenses

Research and development expenses decreased by $2.5 million, or 21%, to $9.5 million for the year ended December 31, 2018 as compared to $12.0 million for the same period in 2017. The year over year decrease was mostly impacted by a 30% headcount reduction in the second half of 2017. In addition, at the beginning of 2018 a small group of employees transferred from supporting our development team to our customer support team in order to support a change in the Company's business development strategies. We expect our research and development expenses to increase in future periods as we expand on our instrument's throughput capabilities and our improve our cloud-based suite used for data analysis.

Selling, General and Administrative Expenses

Selling, general and administrative expenses increased $0.1 million, or 1%, to $14.2 million for the year ended December 31, 2018 as compared to $14.1 million for the same period in 2017. The 2017 reduction in force generated cost savings across both our general and administrative and sales and marketing teams for the second half of 2017 through the first half of 2018. However, these costs savings were offset by the cost of headcount additions hired through the second half of 2018 in order to expand our teams responsible for managing our public company responsibilities and increase our sales and marketing efforts. Furthermore, we experienced an increase in costs associated with being a public company including expenses relating to compliance with the rules and regulations of the SEC, Nasdaq, insurance, investor relations activities, and other administrative and professional services. We expect our selling, general and administrative expenses to increase in future periods as the number of sales, technical support and marketing and administrative personnel grows and we continue to broaden our customer base and grow our business.

Impairment of Property and Equipment

During the year ended December 31, 2017, we recognized an impairment loss of $0.6 million related to our Irys instruments located at customer sites as the carrying amount of the assets were determined to be in excess of the assets fair value. There were no impairments of property and equipment in 2018.

Interest Expense

Interest expense was $1.4 million and $0.6 million for the years ended December 31, 2018 and 2017, respectively. The increase is attributed to incremental interest on the MidCap CSA, a $10M Credit Facility, versus the Western Allicance CSA, a $7M Credit Facility. In addition, we incurred interest on the convertible notes. Our first convertible note was entered into in February 2018.

Change in Fair Value of Preferred Stock Warrants

Change in fair value of preferred stock warrants increased $3.2 million to $4.0 million for the year ended December 31, 2018 compared to $0.8 million for the same period in 2017. There were no warrants exercisable for the Company’s convertible preferred stock following the closing of the IPO in August 2018. Of the 37.2 million warrants previously exercisable for preferred stock, 35.7 million warrants expired on the effective date of the IPO. The remaining 1.5 million warrants previously exercisable for preferred stock were adjusted to become exercisable for common stock. Prior to the IPO, the Company estimated fair value of the convertible preferred stock warrants at the time of issuance and subsequent remeasurement using the Black-Scholes-Merton model at each reporting date. On the date of the IPO and going forward, all outstanding warrants are accounted for as equity and are not subject to remeasurement.

Other Expense

Other expense was $0.7 million and $0.3 million for the year ended December 31, 2018 and 2017, respectively. The increase is attributed to additional debt discount accretion costs on the MidCap FSA, amendment fees on restructuring the Western Alliance CSA, and losses incurred when terminating the Western Alliance CSA early.

Liquidity and Capital Resources

Since our inception, we have incurred net losses and negative cash flows from operations. We incurred net losses of $18.5 million, and $23.4 million, and used $19.9 million and $20.8 million of cash from our operating activities for the years ended December 31, 2018 and 2017, respectively. As of December 31, 2018, we had an accumulated deficit of $72.8 million and cash and cash equivalents of $16.5 million.

Sources of Liquidity

Prior to August 2018, we financed our operations principally through private placements of our convertible preferred stock, borrowings from credit facilities, and revenue from our commercial operations.

In August 2018, we completed the IPO, in which we sold 3,864,000 units (each unit consisting of one share of common stock and one warrant to purchase one share of its common stock) at a public offering price of $6.125 per unit for net cash proceeds of $19.4 million after deducting underwriters' discounts and commissions of $2.2 million and other offering expenses of $2.1 million.

Preferred stock financings

To date, we have raised approximately $129.3 million in net equity proceeds through sales of our preferred stock.

Loan facility

On March 8, 2016, we entered into a new term Loan and Security Agreement with Western Alliance Bank, or the Western Alliance LSA, for $7.0 million. The loan proceeds were used to repay the outstanding $5.0 million loan with Square 1 Bank, as required by the amended Loan and Security agreement between Square 1 Bank and us.

In February 2018, the Western Alliance LSA was amended requiring the Company to secure $21.0 million in funding prior to June 30, 2018. As part of the amendment, Western Alliance Bank agreed to forbear from exercising any of its default remedies set forth in the LSA as a result of our loan default.

On June 13, 2018, the Western Alliance LSA was amended, replacing previously amended funding requirements and requiring the Company to secure $5.0 million in funding prior to August 3, 2018. Additionally, the amendment restricted the Company's use of all cash collected from customers, received on and after the amendment date, until a total of $2.5 million of collections. As part of the amendment, Western Alliance Bank waived the existing default.

On June 29, 2018, we entered into a new Credit and Security Agreement with Midcap Financial Trust which provides for a five year $15 million term loan facility. The Credit and Security Agreement is secured by a lien covering substantially all of our assets, including intellectual property. Upon executing the agreement, we drew down a $10.0 million term loan from the credit facility. The loan proceeds were used to repay the outstanding $7.0 million balance on the Western Alliance LSA.

On November 19, 2018, the Western Alliance LSA was amended. Pursuant to Section 2.6(g) of the Western Alliance LSA, we were obligated to pay Western Alliance Bank a success fee of $210,000 in connection with our IPO. As part of the amendment, this success fee was decreased from $210,000 to $160,000.

See Note 7 to our financial statements for a discussion of terms and provisions to the Western Alliance LSA and Midcap Financial CSA.

Note purchase agreement

On February 9, 2018, we entered into a Note Purchase Agreement with various investors, or the Investors, pursuant to which we agreed to sell the Investors 8% Convertible Promissory Notes, or the Convertible Notes, in the original principal amount up to approximately $16.0 million. On April 2, 2018, we amended the Note Purchase Agreement to, among other things, increase the principal amount available for issuance under the Note Purchase Agreement to approximately $18.4 million. In addition, in connection with the Midcap Financial CSA, we again amended the Note Purchase Agreement to increase the amount available for issuance under the Note Purchase Agreement to approximately $19.4 million. The Convertible Notes had a maturity date of September 30, 2018 and were convertible either into our common stock or preferred stock, dependent on the conversion events as described in Note 12 to our consolidated financial statements.

In August 2018 the outstanding convertible promissory notes of $14,329,843 and accrued interest was converted into 3,239,294 shares of common stock upon completion of the IPO.

Cash Flows

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

	Year Ended December 31,	
	2018	2017
Net cash provided by (used in):		
Operating activities	$ (19,943,847)	$ (20,817,798)
Investing activities	(331,716)	(1,017,830)
Financing activities	35,776,395	17,607,905

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

Net cash used in operating activities was $19.9 million during the year ended December 31, 2018 as compared to $20.8 million during the year ended December 31, 2017. The decrease in cash used in operating activities of $0.9 million was mostly the result of lower compensation and benefits paid due to the second half 2017 reduction in force for the year ended December 31, 2018 compared to the same period 2017.

Investing Activities

Historically, our primary investing activities have consisted of capital expenditures for the purchase of capital equipment to support our expanding infrastructure. We expect to continue to incur additional costs for capital expenditures related to these efforts in future periods.

Net cash used in investing activities was $0.3 million during the year ended December 31, 2018 as compared to $1.0 million during the year ended December 31, 2017.

Financing Activities

Historically, we have financed our operations principally through private placements of our convertible preferred stock and promissory notes and borrowings from credit facilities, as well as gross profits from our commercial operations. In August 2018, we completed the IPO.

Net cash provided by financing activities was $35.8 million during the year ended December 31, 2018 as compared to $17.6 million during the year ended December 31, 2017, an increase of $18.2 million. During the year ended December 31, 2018 we had net proceeds from the issuance of convertible notes of $14.3 million, IPO net proceeds of $19.4 million, and net debt proceeds (net of payments outstanding loan) of $2.0 million. During the same period of 2017, we had net proceeds from the issuance preferred stock and warrants of $17.6 million.

Capital Resources

We performed an analysis of our ability to continue as a going concern. We believe, based on our current business plan, that our existing cash and cash equivalents will be sufficient to fund our obligations through the fourth quarter of 2019, but will not be sufficient to fund our obligations after the fourth quarter of 2019. We plan to continue to fund our losses from operations through cash and cash equivalents on hand, as well as through through public or private equity or debt financings, strategic collaborations, licensing arrangements, asset sales, or other arrangements. There can be no assurance that additional funds will be available when needed from any source or, if available, will be available on terms that are acceptable to us. Even if we raise additional capital, we may also be required to modify, delay or abandon some of our plans which could have a material adverse effect on our business, operating results and financial condition and our ability to achieve our intended business objectives. Any of these actions could materially harm our business, results of operations and future prospects.

Off-Balance Sheet Arrangements

We did not have during the periods presented, and we do not currently have, any off-balance sheet arrangements, as defined under SEC rules, and similarly did not and do not have any holdings in variable interest entities.

Recent Accounting Pronouncements

See Note 2 to our condensed consolidated financial statements included elsewhere in this Annual Report on for information concerning recent accounting pronouncements.

Critical Accounting Policies and Estimates

Our management’s discussion and analysis of our financial condition and results of operations is based on our consolidated financial statements, which have been prepared in accordance with generally accepted accounting principles in the United States. The preparation of our consolidated financial statements requires us to make estimates and assumptions that affect the reported amounts of assets, liabilities and expenses and the disclosure of contingent assets and liabilities in our consolidated financial statements and accompanying notes. We evaluate these estimates and judgments on an ongoing basis. We base our estimates on historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

While our significant accounting policies are more fully described in Note 2 to our consolidated financial statements appearing elsewhere in this Annual Report, we believe that the following accounting policies are the most critical for fully understanding and evaluating our financial condition and results of operations.

Revenue Recognition

Product Revenue

Product revenue represents the sale of our instruments and consumables to third parties. Timing of revenue recognition on instrument sales is based upon when delivery has occurred, the price is fixed or determinable, and collectability is reasonably assured.

The majority of our instruments contain embedded operating systems and other software which is included in the purchase price of the instrument. The software is deemed incidental to the system as a whole as it is not sold or marketed separately and its production costs are minor compared to those of the hardware system. Hardware and software elements are both delivered when ownership is transferred to the customer.

Installation services for direct sale customers are performed at the same time or shortly after the product is delivered and require only a minimal effort to complete. We believe installation is a perfunctory service and is not material to our obligations in the contract.

Other Revenue

Other revenue includes revenue from extended service contracts and other services that may be performed. Revenue for extended warranty contracts is recognized ratably over the service period. Revenue for other services is generally recognized based on proportional performance of the contract, when the Company's ability to complete project requirements is reasonably assured. Deferred revenue represents amounts received in advance for on-going service arrangements. Most of these services are completed in a short period of time from the receipt of the customer's order. When significant risk exists in the Company's ability to fulfill project requirements, revenue is recognized upon completion of the contract.

Multiple Element Arrangements

We regularly enter into contracts where revenue is derived from multiple deliverables, including products or services. These contracts typically include an instrument, consumables, and extended service contracts. Revenue recognition for contracts with multiple deliverables is based on the individual units of accounting determined to exist in the contract. A delivered item is considered a separate unit of accounting when the delivered item has value to the customer on a stand-alone basis. Items are considered to have stand-alone value when they are sold separately by any vendor or when the customer could resell the item on a stand-alone basis.

For transactions with multiple deliverables, consideration is allocated at the inception of the contract to all deliverables based on their relative selling price. The relative selling price for each deliverable is determined using vendor-specific objective evidence, or VSOE, of selling price or third-party evidence of selling price if VSOE does not exist. If neither VSOE nor third-party evidence exists, we use our best estimate of the selling price using average selling prices over an appropriate period coupled with an assessment of current market conditions. If the product or service has no history of sales or if the sales volume is not sufficient, we consider our approved standard prices adjusted for applicable discounts.

In order to establish VSOE of selling price, we must regularly sell the product or service on a standalone basis with a substantial majority priced within a relatively narrow range. In cases where there is not a sufficient number of standalone sales and VSOE of selling price cannot be determined, then we utilize third-party evidence to establish selling price.

Distributor Transactions

In certain markets, we sell products and provides services to customers through distributors that specialize in life sciences products. In cases where the product is delivered to a distributor, revenue recognition generally occurs when title transfers to the distributor. The terms of sales transactions through distributors are generally consistent with the terms of direct sales to customers, except the distributors do not require our services to install the instrument at the end customer and perform the services for the customer that are beyond our standard warranty in the first year following the sale. These transactions are accounted for in accordance with our revenue recognition policy described herein.

Stock-Based Compensation Expense

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

The inputs for the Black-Scholes valuation model require management's significant assumptions. Prior to our IPO, the common share price was determined by our board based on recent prices of common shares sold in private offerings prior to the IPO. Subsequent to the IPO, the common share price was determined by using the quoted price on the grant date. The risk-free interest rates were based on the rate for U.S. Treasury securities at the date of grant with maturity dates approximately equal to the expected life at

the grant date. The expected life was based on the simplified method in accordance with the SEC Staff Accounting Bulletin Nos. 107 and 110. The expected volatility was estimated based on historical volatility information of peer companies that are publicly available.

JOBS Act

We are an "emerging growth company," as defined in the Jumpstart Our Business Startups Act, or JOBS Act. Under the JOBS Act, an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards. This provision allows an emerging growth company to delay the adoption of new or revised accounting standards that have different transition dates for public and private companies until those standards would otherwise apply to private companies. We have elected to use this extended transition period. As a result of this election, our timeline to comply with these standards will in many cases be delayed as compared to other public companies that are not eligible to take advantage of this election or have not made this election. Therefore, our financial statements may not be comparable to those of companies that comply with the public company effective dates for these standards.

For so long as we are an emerging growth company we expect that:

- we will present only two years of audited consolidated financial statements, plus unaudited consolidated condensed financial statements for any interim period, and related management's discussion and analysis of financial condition and results of operations in our initial registration statement;
- we will avail ourselves of the exemption from the requirement to obtain an attestation and report from our auditors on the assessment of our internal control over financial reporting pursuant to the Sarbanes-Oxley Act;
- we will avail ourselves of the extended transition periods available to emerging growth companies under the JOBS Act for complying with new or revised accounting standards; and
- we will provide less extensive disclosure about our executive compensation arrangements.

We will remain an emerging growth company for up to five years, although we will cease to be an "emerging growth company" upon the earliest of: (1) December 31, 2023, which is the end of the fiscal year following the fifth anniversary of the closing of our IPO, (2) the last day of the first fiscal year in which our annual revenues are $1.07 billion or more, (3) the date on which we have, during the previous rolling three-year period, issued more than $1.0 billion in non-convertible debt securities, and (4) the date on which we are deemed to be a "large accelerated filer" as defined in the Exchange Act.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk.

As a smaller reporting company, we are not required to provide information typically disclosed under this item.

Item 8. Financial Statements and Supplementary Data.

Index to Consolidated Financial Statements

To the Stockholders and Board of Directors of Bionano Genomics, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Bionano Genomics, Inc. and its subsidiaries (the “Company”), as of December 31, 2018 and 2017 and the related consolidated statements of operations, consolidated statements of convertible preferred stock and stockholders’ equity (deficit), and consolidated statements of cash flows for each of the two years in the period ended December 31, 2018 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 as of December 31, 2018 and 2017, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2018, in conformity with accounting principles generally accepted in the United States of America.

Going Concern

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the financial statements, the Company's recurring net losses from operations, negative cash flows from operating activities, and significant accumulated deficit raise substantial doubt about its ability to continue as a going concern. Management’s plans in regard to these matters are also described in Note 1. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

These 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/ Deloitte & Touche, LLP

San Diego, California
March 14, 2019

We have served as the Company’s auditor since 2017.

Bionano Genomics, Inc.

Consolidated Balance Sheets

	December 31,	
	2018	**2017**
Assets		
Current assets:		
Cash and cash equivalents	$ 16,522,729	$ 1,021,897
Accounts receivable, net	4,514,333	3,352,214
Inventory	1,068,557	1,693,742
Prepaid expenses and other current assets	919,500	1,071,512
Total current assets	23,025,119	7,139,365
Property and equipment, net	1,777,302	3,005,788
Total assets	$ 24,802,421	$ 10,145,153
Liabilities, convertible preferred stock, and stockholders' equity (deficit)		
Current liabilities:		
Accounts payable	$ 1,351,736	$ 2,302,964
Accrued expenses	2,900,129	3,508,894
Deferred revenue	270,998	211,697
Preferred stock warrant liability	—	3,898,944
Current portion of long-term debt	—	6,729,752
Total current liabilities	4,522,863	16,652,251
Long-term debt, net of current portion	9,029,374	—
Long-term deferred revenue	304,467	142,929
Other non-current liabilities	808,366	567,047
Total liabilities	14,665,070	17,362,227
Commitments and contingencies (Note 9)		
Series A convertible preferred stock, $0.0001 par value; no shares and 418,767 shares authorized as of December 31, 2018 and 2017, respectively; no shares and 345,587 shares issued and outstanding as of December 31, 2018 and 2017, respectively	—	61,847
Series B convertible preferred stock, $0.0001 par value; no shares and 8,101,042 shares authorized as of December 31, 2018 and 2017, respectively; no shares and 8,058,170 shares issued and outstanding as of December 31, 2018 and 2017, respectively	—	842,845
Series B-1 convertible preferred stock, $0.0001 par value; no shares and 7,523,734 shares authorized as of December 31, 2018 and 2017, respectively; no shares and 3,437,950 shares issued and outstanding as of December 31, 2018 and 2017, respectively	—	359,593
Series C convertible preferred stock, $0.0001 par value; no shares and 23,357,047 shares authorized as of December 31, 2018 and 2017, respectively; no shares and 23,357,047 shares issued and outstanding as of December 31, 2018 and 2017, respectively	—	5,547,841
Series D convertible preferred stock, $0.0001 par value; no shares and 52,835,720 shares authorized as of December 31, 2018 and 2017, respectively; no shares and 20,652,486 shares issued and outstanding as of December 31, 2018 and 2017	—	4,838,379
Series D-1 convertible preferred stock, $0.0001 par value; no shares and 125,808,667 shares authorized as of December 31, 2018 and 2017, respectively; no shares and 66,141,257 shares issued and outstanding as of December 31, 2018 and 2017, respectively	—	31,359,632
Stockholders' equity (deficit):		
Preferred stock, $0.0001 par value; 10,000,000 shares authorized; no shares issued and outstanding as of December 31, 2018 and 2017	—	—
Common stock, $0.0001 par value; 200,000,000 and 243,160,120 shares authorized at December 31, 2018 and 2017, respectively; 10,055,072 and 77,257 shares issued and outstanding as of December 31, 2018 and 2017, respectively	1,004	8
Additional paid-in capital	82,898,775	4,038,817
Accumulated deficit	(72,762,428)	(54,266,036)
Total stockholders' equity (deficit)	10,137,351	(50,227,211)
Total liabilities, convertible preferred stock, and stockholders' equity (deficit)	$ 24,802,421	$ 10,145,153

See accompanying notes to the consolidated financial statements.

Bionano Genomics, Inc.

Consolidated Statements of Operations

	Year Ended December 31,	
	2018	**2017**
Revenue:		
Product revenue	$ 11,463,173	$ 8,769,704
Other revenue	537,562	735,339
Total revenue	12,000,735	9,505,043
Cost of revenue:		
Cost of product revenue	8,562,042	5,958,537
Cost of other revenue	149,284	71,975
Total cost of revenue	8,711,326	6,030,512
Operating expense:		
Research and development	9,484,163	12,009,170
Selling, general and administrative	14,220,331	14,079,658
Impairment of property and equipment	—	604,511
Total operating expenses	23,704,494	26,693,339
Loss from operations	(20,415,085)	(23,218,808)
Other income (expense)		
Interest expense	(1,381,024)	(590,927)
Change in fair value of preferred stock warrants and expirations	3,991,081	751,933
Other expense	(675,853)	(289,010)
Total other income (expenses)	1,934,204	(128,004)
Loss before income taxes	(18,480,881)	(23,346,812)
Benefit (provision) for income taxes	(15,511)	(18,552)
Net loss	$ (18,496,392)	$ (23,365,364)
Net loss per share, basic and diluted:	$ (2.61)	$ (8.65)
Weighted-average common shares outstanding, basic and diluted	7,077,126	2,701,065

See accompanying notes to the consolidated financial statements.

Bionano Genomics, Inc.

Consolidated Statements of Convertible Preferred Stock and Stockholders' Equity (Deficit)

	Series A Convertible Preferred Stock		Series B Convertible Preferred Stock		Series B-1 Convertible Preferred Stock		Series C Convertible Preferred Stock		Series D Convertible Preferred Stock		Series D-1 Convertible Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount			
Balance at January 1, 2017	345,587	$61,847	8,058,170	$842,845	3,437,950	$359,593	23,357,047	$5,547,841	20,652,486	$4,838,379	29,166,671	$13,766,022	70,178	$ 7	$ 3,641,693	$(30,900,672)	$(27,258,972)
Issuance of Series D-1 convertible preferred stock, net of issuance cost of $154,191	—	—	—	—	—	—	—	—	—	—	36,974,586	17,593,610	—	—	—	—	—
Stock option exercises	—	—	—	—	—	—	—	—	—	—	—	—	7,079	1	14,294	—	14,295
Stock-based compensation expense	—	—	—	—	—	—	—	—	—	—	—	—	—	—	382,830	—	382,830
Net loss	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	(23,365,364)	(23,365,364)
Balance at December 31, 2017	345,587	$61,847	8,058,170	$842,845	3,437,950	$359,593	23,357,047	$5,547,841	20,652,486	$4,838,379	66,141,257	$31,359,632	77,257	$ 8	$ 4,038,817	$(54,266,036)	$(50,227,211)
Stock option Exercises	—	—	—	—	—	—	—	—	—	—	—	—	2,062	—	3,499	—	3,499
IPO Units	—	—	—	—	—	—	—	—	—	—	—	—	3,864,000	386	19,389,592	—	19,389,978
Conversion of preferred stock upon IPO	(345,587)	(61,847)	(8,058,170)	(842,845)	(3,437,950)	(359,593)	(23,357,047)	(5,547,841)	(20,652,486)	(4,838,379)	(66,141,257)	(31,359,632)	2,850,280	285	43,009,852	—	43,010,137
Conversion of convertible note upon IPO	—	—	—	—	—	—	—	—	—	—	—	—	3,239,294	323	14,898,004	—	14,898,327
Conversion of preferred stock warrants into common stock warrants	—	—	—	—	—	—	—	—	—	—	—	—	—	—	84,676	—	84,676
Stock-based compensation expense	—	—	—	—	—	—	—	—	—	—	—	—	—	—	1,193,873	—	1,193,873
Issue Warrants for services	—	—	—	—	—	—	—	—	—	—	—	—	—	—	165,000	—	165,000
Issuance of common stock for Employee Stock Purchase Plan	—	—	—	—	—	—	—	—	—	—	—	—	22,179	2	115,462	—	115,464
Net loss	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	(18,496,392)	(18,496,392)
Balance at December 31, 2018	—	$ —	—	$ —	—	$ —	—	$ —	—	$ —	—	$ —	10,055,072	$1,004	$82,898,775	$(72,762,428)	$ 10,137,351

See accompanying notes to the consolidated financial statements.

Bionano Genomics, Inc.
Consolidated Statements of Cash Flows

	Year Ended December 31,	
	2018	**2017**
Operating activities:		
Net loss	$ (18,496,392)	$ (23,365,364)
Adjustments to reconcile net loss to cash used in operating activities:		
Depreciation expense	1,320,521	1,504,042
Accrued interest on convertible note	568,483	—
Change in fair value of preferred stock warrants and expirations	(3,991,081)	(751,933)
Stock-based compensation	1,193,873	382,830
Provision for bad debt expense	(262,000)	262,000
Inventory write-off	1,287,000	364,437
Impairment of property and equipment	—	604,511
Accretion of debt discount	181,991	96,576
Loss on debt extinguishment	342,164	—
Fair value of warrants issued for services	165,000	—
Employee stock purchase plan compensation	115,464	—
Changes in operating assets and liabilities:		
Accounts receivable	(900,119)	(1,767,647)
Inventory	(418,984)	(336,046)
Prepaid expenses and other current assets	152,012	770,553
Accounts payable	(954,377)	1,541,472
Accrued expenses and other liabilities	(247,402)	(123,229)
Net cash used in operating activities	(19,943,847)	(20,817,798)
Investing activities:		
Purchases of property and equipment	(331,716)	(1,017,830)
Net cash used in investing activities	(331,716)	(1,017,830)
Financing activities:		
Repayment of notes payable	(7,447,571)	—
Proceeds from issuance of long-term debt, net of offering costs	9,500,646	—
Proceeds from issuance of convertible note, net of offering costs	14,329,843	—
Proceeds from issuance of preferred stock and warrants, net of offering costs	—	17,593,610
Proceeds from Initial Public Offering, net of offering costs	19,389,978	—
Proceeds from option exercises	3,499	14,295
Net cash provided by financing activities	35,776,395	17,607,905
Net increase (decrease) in cash and cash equivalents	15,500,832	(4,227,723)
Cash and cash equivalents at beginning of period	1,021,897	5,249,620
Cash and cash equivalents at end of period	$ 16,522,729	$ 1,021,897
Supplementary schedule of non-cash transactions:		
Conversion of convertible note into common stock	$ 14,898,327	$ —
Conversion of preferred stock warrants into common stock and common stock warrants	$ 84,676	$ —
Property and equipment costs incurred but not paid included in accounts payable and accrued expenses	$ 3,150	$ 11,830
Transfer of instruments from property and equipment into inventory	$ 242,831	$ 75,268
Fair value of warrants issued with debt classified as a liability	$ 176,813	$ —
Final payment fee due in connection with the repayment of debt classified within other long-term liabilities	$ 400,000	$ —
Warrants issued for services	$ 165,000	$ —
Supplementary disclosure of cash flow information		
Interest paid	$ 700,353	$ 534,858

See accompanying notes to the consolidated financial statements.

1. Organization and Operations

Description of Business

Bionano Genomics, Inc. (the "Company") was formed in January 2003 as BioNanomatrix LLC, a Delaware limited liability company. In August 2007, the Company became BioNanomatrix Inc., a Delaware corporation. In October 2011, the Company changed its name to BioNano Genomics, Inc., and in July 2018, it changed its name to Bionano Genomics, Inc.

The Company is a life sciences instrumentation company in the genome analysis space. The Company currently develops and markets the Saphyr system, a platform for ultra-sensitive and ultra-specific structural variation detection that enables researchers and clinicians to accelerate the search for new diagnostics and therapeutic targets and to streamline the study of changes in chromosomes, which is known as cytogenetics.

Initial Public Offering

In August 2018, the Company completed its initial public offering (the "IPO"), in which it sold an aggregate of 3,864,000 units (each unit consisting of one share of the Company's common stock and one warrant to purchase one share of the Company's common stock) at a public offering price of $6.125 per unit, which included the sale of 504,000 units pursuant to the exercise of the underwriters' over-allotment option. The Company received net cash proceeds of $19.4 million, after deducting underwriters' discounts and commissions of $2.2 million and other offering expenses of $2.1 million.

In addition, each of the following occurred in connection with the completion of the IPO in August 2018:

- The conversion of all outstanding shares of convertible preferred stock into an aggregate 2,850,280 shares of common stock.
- The expiration of preferred stock warrants issued in connection with previous preferred stock offerings.
- The automatic adjustment of certain preferred stock warrants into common stock warrants; the entire $84,676 balance of preferred stock warrant liability was reclassified as additional paid-in-capital. In addition, the Company issued warrants to the IPO underwriters to purchase up to 115,920 shares of its common stock at fair value of $0.4 million.
- The conversion of an aggregate of $14.9 million of outstanding convertible promissory notes and accrued interest into an aggregate of 3,239,294 shares of common stock.

Each unit offered in the IPO consisted of one share of common stock and one warrant to purchase one share common stock. Each warrant to purchase common stock contained in the unit entitled the holder to purchase one share of common stock at an initial exercise price of $6.125 per share (100% of the offering price per unit), subject to adjustment. The warrants and shares of common stock traded together as units for 30 days following the IPO. After 30 days of trading, the units automatically separated and the common stock and warrants began trading separately.

The units, common stock, and warrants are listed on the Nasdaq Stock Market LLC under the symbols "BNGOU," "BNGO" and "BNGOW," respectively.

Reverse Stock Splits

On July 16, 2018, the Company effected a one-for-21.4 reverse stock split of its issued and outstanding shares of common stock and a proportional adjustment to the existing conversion ratios for each series of the Company's redeemable convertible preferred stock, and on August 15, 2018, the Company effected an additional one-for-two reverse stock split of its issued and outstanding shares of common stock and a proportional adjustment to the existing conversion ratios for each series of the Company's redeemable convertible preferred stock. Accordingly, all share and per share amounts for all periods presented in the accompanying financial statements and notes thereto have been adjusted retroactively, where applicable, to reflect these reverse stock splits and adjustments of the preferred stock conversion ratios.

Going Concern

In accordance with ASU 2014-15, *Presentation of Financial Statements – Going Concern (Subtopic 205-40): Disclosure of Uncertainties About an Entity's Ability to Continue as a Going Concern*, management is required to perform a two-step analysis over

its ability to continue as a going concern. Management must first evaluate whether there are conditions and events that raise substantial doubt about the Company's ability to continue as a going concern and to meet its obligations as they become due within one year after the date that the financial statements are issued (step 1). If management concludes that substantial doubt is raised, management is also required to consider whether its plans alleviate that doubt (step 2).

The Company has experienced recurring net losses from operations, negative cash flows from operating activities, and significant accumulated deficit since its inception and expects to continue to incur net losses into the foreseeable future. The Company has an accumulated deficit of $72.8 million as of December 31, 2018. In 2018, the Company used $19.9 million cash in operations. As of December 31, 2018, the Company had cash and cash equivalents of $16.5 million. Management expects operating losses and negative cash flows to continue for at least the next year as the Company continues to incur costs related to research and commercialization efforts. Management has prepared cash flows forecasts which indicate that based on the Company's expected operating losses and negative cash flows, there is substantial doubt about the Company's ability to continue as a going concern within twelve months after the date that the financial statements for the year ended December 31, 2018, are issued.

Management's ability to continue as a going concern is dependent upon its ability to raise additional funding. Management's plans to raise additional capital through equity offerings or debt financings to fulfill its operating and capital requirements for at least 12 months include public or private equity or debt financings, strategic collaborations, licensing arrangements, asset sales, or other arrangements. However, the Company may not be able to secure such financing in a timely manner or on favorable terms, if at all. Furthermore, if the Company issues equity securities to raise additional funds, its existing stockholders may experience dilution, and the new equity securities may have rights, preferences and privileges senior to those of the Company's existing stockholders. If the Company raises additional funds through collaboration, licensing or other similar arrangements, it may be necessary to relinquish valuable rights to its products or proprietary technologies or grant licenses on terms that are not favorable to the Company.

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

2. Summary of Significant Accounting Policies

Use of Estimates

The preparation of the Company's financial statements requires the Company 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 financial statements and accompanying notes. Management evaluates its estimates on an ongoing basis. Although estimates are based on the Company's historical experience, knowledge of current events and actions it may undertake in the future, actual results may ultimately materially differ from these estimates and assumptions.

Basis of Presentation

The financial statements are prepared in accordance with accounting principles generally accepted in the United States ("GAAP") and all intercompany transactions and balances have been eliminated in consolidation.

Cash and Cash Equivalents

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. Cash equivalents primarily represent funds invested in readily available checking and money market accounts.

The Company has not experienced any losses in such accounts. The Company believes that it is not exposed to any significant credit risk on cash and cash equivalents. Included in cash and cash equivalents is $252,594 in restricted cash as of December 31, 2018 and 2017, related to amounts held for leases and credit cards.

Fair Value of Financial Instruments

The carrying amounts of all cash equivalents, accounts receivable, prepaid expenses and other current assets, accounts payable and accrued liabilities are reasonable estimates of their fair value because of the short-term nature of these items. Company issued convertible preferred stock warrants were recorded at fair value on a recurring basis.

Concentration of Credit Risk

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

The Company's customers are located throughout the world. The Company generally does not require collateral from its customers, but it performs credit evaluations of their financial condition. More information on accounts receivable is contained in the paragraph titled "Accounts Receivable" below.

Accounts Receivable

The Company extends credit to its customers in the normal course of business based upon an evaluation of each customer's credit history, financial condition, and other factors. Estimates of allowances for doubtful accounts are determined by evaluating individual customer circumstances, historical payment patterns, length of time past due, and economic and other factors. Bad debt expense is recorded as necessary to maintain an appropriate level of allowance for doubtful accounts in selling, general and administrative expense.

The following table reflects the activity related to the Company's allowance for doubtful accounts:

	December 31,	
	2018	2017
Accounts receivable	$ 4,514,333	$ 3,614,214
Provision	—	(262,000)
Accounts receivable, net	$ 4,514,333	$ 3,352,214

For the years ended December 31, 2018 and 2017, Ultravision Technology Ltd. represented 13% and 21%, BioStar Company represented 12% and 15%, and HistoGenetics represented 10% and 1%, respectively, of the Company's accounts receivable balance.

Inventory

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

The components of inventories are as follows:

	December 31,	
	2018	2017
Materials and supplies	$ 161,468	$ 203,085
Finished Goods	907,089	1,490,657
	$ 1,068,557	$ 1,693,742

During the year ended December 31, 2017, in connection with the market launch of the Company's next generation product, the Saphyr system, the Company determined that its first generation Irys instruments on hand had net realizable values below carrying value. Accordingly, the Company recorded a charge of $0.4 million included in cost of product revenue to write-down these instruments to net realizable value of $1.3 million.

After considering the weight of evidence that accumulated during the year ended December 31, 2018, including the strategic shift towards minimal selling efforts of the Irys instruments, the Company determined that the Irys instruments on hand had net realizable values below their carrying value. Accordingly, the Company recorded a charge of $1.3 million included in cost of product revenue to write-down these instruments to $0 net realizable value.

Property and Equipment

Property and equipment are recorded at cost and depreciated or amortized using the straight-line method over the estimated useful lives of the assets (generally three to five years, or the remaining term of the lease for leasehold improvements, whichever is shorter) and

generally consist of laboratory equipment, computer and office equipment, furniture and fixtures, and leasehold improvements. Repairs and maintenance costs are charged to expense as incurred.

Long-Lived Assets

The Company regularly reviews the carrying value and estimated lives of all of its long-lived assets, including property and equipment, to determine whether indicators of impairment may exist which warrant adjustments to carrying values or estimated useful lives. Should an impairment exist, the impairment loss would be measured based on the excess over the carrying amount of the asset's fair value. During the year ended December 31, 2017, the Company recognized an impairment loss of $0.6 million related to equipment at customer sites. During the year ended December 31, 2018, the Company recognized $0 of impairment loss on long-lived assets.

Deferred Rent

Deferred rent consists of the difference between cash payments and the recognition of rent expense on a straight-line basis for the facilities the Company leases. The Company's leases for its facilities provide for fixed increases in minimum annual rental payments. The total amount of rental payments due over the lease terms are being charged to rent expense ratably over the life of the leases. The current portion of deferred rent is included in accrued expenses and the non-current portion in other non-current liabilities on the consolidated balance sheets.

Revenue Recognition

Product Revenue

Product revenue represents the sale of the Company's instruments and consumables to third parties. Timing of revenue recognition on instrument sales is based upon when delivery has occurred, the price is fixed or determinable, and collectability is reasonably assured.

The majority of our instruments contain embedded operating systems and other software which is included in the purchase price of the instrument. The software is deemed incidental to the system as a whole as it is not sold or marketed separately and its production costs are minor compared to those of the hardware system. Hardware and software elements are both delivered when ownership is transferred to the customer. Hardware upgrades, which are made available to customers for purchase, are recognized as revenue when delivered and all revenue recognition criteria noted above have been met.

Installation services for direct sale customers are performed at the same time or shortly after the product is delivered and require only a minimal effort to complete. We believe installation is a perfunctory service and is not material to our obligations in the contract.

Other Revenue

Other revenue includes revenue from extended service contracts and other services that may be performed. Revenue for extended warranty contracts is recognized ratably over the service period. Revenue for other services is generally recognized based on proportional performance of the contract, when the Company's ability to complete project requirements is reasonably assured. Deferred revenue represents amounts received in advance for on-going service arrangements. Most of these services are completed within two years from receipt of the customer's order. When significant risk exists in the Company's ability to fulfill project requirements, revenue is recognized upon completion of the contract.

Multiple Element Arrangements

The Company regularly enters into contracts where revenue is derived from multiple deliverables, including products or services. These contracts typically include an instrument, consumables, and extended service contracts. Revenue recognition for contracts with multiple deliverables is based on the individual units of accounting determined to exist in the contract. A delivered item is considered a separate unit of accounting when the delivered item has value to the customer on a stand-alone basis. Items are considered to have stand-alone value when they are sold separately by any vendor or when the customer could resell the item on a stand-alone basis.

For transactions with multiple deliverables, consideration is allocated at the inception of the contract to all deliverables based on their relative selling price. The relative selling price for each deliverable is determined using vendor-specific objective evidence ("VSOE") of selling price or third-party evidence of selling price if VSOE does not exist. If neither VSOE nor third-party evidence exists, the Company uses its best estimate of the selling price using average selling prices over an appropriate period coupled with an assessment of current market conditions. If the product or service has no history of sales or if the sales volume is not sufficient, the Company considers its approved standard prices adjusted for applicable discounts.

In order to establish VSOE of selling price, the Company must regularly sell the product or service on a standalone basis with a substantial majority priced within a relatively narrow range. In cases where there is not a sufficient number of standalone sales and VSOE of selling price cannot be determined, then the Company utilizes third-party evidence to establish selling price.

Distributor Transactions

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

The Company derives a significant portion of product revenue from a limited distributor base. For the years ended December 31, 2018 and 2017, Berry Genomics Corp. represented 5% and 4%, Ultravision Technology Ltd. represented 6% and 15%, Gene Company Ltd. represented 7% and 6% and BioStar Company represented 5% and 6%, respectively, of the Company's total revenues. No other distributor represented more than 10% of total Company revenues during these periods.

Cost of Revenue

Cost of revenue for products consists of the Company's instrument cost from the manufacturer, raw material parts costs and associated freight, shipping and handling costs, contract manufacturer costs, royalties due to third parties, salaries and other personnel costs, overhead and other direct costs related to those sales recognized as product revenue in the period.

Cost of other revenue consists of salaries and other personnel costs, and facility costs associated with costs related to warranties and other costs of servicing equipment at customer sites.

Research and Development Costs

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

Patent Costs

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

Offering Costs

The offering costs associated with the IPO consisted of legal, accounting and filing fees. The Company had $4.7 million of IPO costs as of the offering date. These costs have been recorded as a reduction of the gross proceeds from the IPO in stockholder's equity. Included in these costs is the fair value, valued at $0.4 million as of the date of the IPO, of warrants to purchase 115,920 shares of common stock issued to the underwriters as partial compensation for services rendered in connection with the IPO. The warrants are exercisable for common stock at a price of $9.1875 per share at any time beginning on August 20, 2019 through and including August 20, 2023, the expiration date.

Convertible Preferred Stock Warrants

The Company previously accounted for outstanding warrants to purchase shares of convertible preferred stock as liabilities in the balance sheets under preferred stock warrant liability. Until the IPO, holders of convertible preferred stock controlled the Board of Directors. Accordingly, upon certain change in control events that were outside of the Company's control, including liquidation, sale, or transfer of control of the Company, holders of the convertible preferred stock could cause its redemption. As such, the then outstanding warrants to purchase shares of any series of convertible preferred stock were classified as a liability at fair value. The convertible preferred stock warrants were subject to remeasurement at each reporting period, with changes in fair value recorded as change in fair value of warrants and expirations in the consolidated statements of operations. In connection with the IPO, all outstanding warrants previously exercisable for shares of preferred stock either expired or were adjusted to exercisable for shares of common stock. As of December 31, 2018, there are no outstanding warrants to purchase shares of convertible preferred stock due to this adjustment.

Income Taxes

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

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

As of December 31, 2018, and 2017, the Company maintained valuation allowances against its deferred tax assets as the Company concluded it had not met the "more likely than not" to be realized threshold. Changes in the valuation allowance when they are recognized in the provision for income taxes may result in a change in the estimated annual effective tax rate.

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

Comprehensive Loss

Net loss and comprehensive loss were the same for all periods presented; therefore, a separate statement of comprehensive loss is not included in the financial statements.

Segment Reporting

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

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

	Year Ended December 31,			
	2018		2017	
	$	%	$	%
North America	$ 4,594,814	38%	$ 3,801,481	40%
EMEIA	3,954,693	33%	1,282,897	13%
Asia Pacific	3,451,228	29%	4,420,665	47%
Total	$ 12,000,735	100%	$ 9,505,043	100%

For the years ended December 31, 2018 and 2017, the United States represented 38% and 37%, and China represented 17% and 28%, respectively of total revenue.

Net Loss Per Share

Basic net loss per share is calculated by dividing the net loss by the weighted-average number of common shares outstanding for the period. Diluted net loss per share is computed by dividing the net loss by the weighted average number of common shares and common share equivalents outstanding for the period. Common stock equivalents are only included when their effect is dilutive. The Company's potentially dilutive securities which include convertible preferred stock and outstanding stock options under the Company's equity incentive plan have been excluded from the computation of diluted net loss per share as they would be anti-dilutive to the net loss per share. For all periods presented, there is no difference in the number of shares used to calculate basic and diluted shares outstanding due to the Company's net loss position.

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

	Year Ended December 31,	
	2018	2017
Convertible preferred stock	—	2,850,280
Common stock options	1,282,847	436,341
Preferred warrants	—	855,212
Common warrants	4,062,507	—
Total	5,345,354	4,141,833

Recent Accounting Pronouncements

On April 5, 2012, the Jump-Start Our Business Startups Act (the "JOBS Act") was signed into law. The JOBS Act contains provisions that, among other things, reduce certain reporting requirements for an emerging growth company. As an emerging growth company, the Company may elect to adopt new or revised accounting standards when they become effective for non-public companies, which typically is later than when public companies must adopt the standards. The Company has elected to take advantage of the extended transition period afforded by the JOBS Act and, as a result, will comply with new or revised accounting standards on the relevant dates on which adoption of such standards is required for emerging growth companies, which are the dates included below.

In May 2014, the FASB issued ASU 2014-09, *Revenue from Contracts with Customers (Topic 606)*. ASU 2014-09 completes the joint effort by the FASB and International Accounting Standards Board to improve financial reporting by creating common revenue recognition guidance for GAAP and International Financial Reporting Standards. ASU 2014-09 applies to all companies that enter into contracts with customers to transfer goods or services. Under the standard, revenue is recognized when a customer obtains control of promised goods or services in an amount that reflects the consideration the entity expects to receive in exchange for those goods or services. In addition, the standard requires disclosure of the nature, amount, timing, and uncertainty of revenue and cash flows arising from contracts with customers. The guidance permits two methods of adoption: retrospectively to each prior reporting period presented (full retrospective method), or retrospectively with the cumulative effect of initially applying the guidance recognized at the date of initial application (modified retrospective method). The guidance is effective for reporting periods beginning after December 15, 2018, and interim periods beginning after December 15, 2019. The Company has evaluated this new guidance and does not expect the adoption to have a material impact on the financial statements or disclosures.

In February 2015, the FASB issued ASU 2016-02, *Leases (Topic 842)*, which amends the FASB Accounting Standards Codification and creates Topic 842, "Leases." The new topic supersedes Topic 840, "Leases," and increases transparency and comparability among organizations by recognizing lease assets and lease liabilities on the balance sheet and requires disclosures of key information about leasing arrangements. The guidance is effective for reporting periods beginning after December 15, 2019, and interim periods within fiscal years beginning after December 15, 2020. ASU 2016-02 mandates a modified retrospective transition method. In July 2018, the FASB issued ASU 2018-11, *Leases (Topic 842): Targeted Improvements* which allows entities the option to adopt this standard prospectively with a cumulative-effect adjustment to opening equity and include required disclosures for prior period. The Company anticipates implementing the standard by taking advantage of the alternative transition method and will apply the transition approach as of the beginning of the period of adoption and will not be restating comparative periods. The Company is in the process of evaluating the impact of adoption of the ASU on the financial statements.

In January 2016, the FASB issued ASU No. 2016-01, *Financial Instruments—Overall (Subtopic 825-10): Recognition and Measurement of Financial Assets and Financial Liabilities (ASU 2016-01)*. This guidance changes how entities measure equity investments that do not result in consolidation and are not accounted for under the equity method. Entities will be required to measure these investments at fair value at the end of each reporting period and recognize changes in fair value in net income. A practicability exception will be available for equity investments that do not have readily determinable fair values, however; the exception requires the Company to consider relevant transactions that can be reasonably known to identify any observable price changes that would impact the fair value. This guidance also changes certain disclosure requirements and other aspects of current GAAP. This guidance is effective for the Company for the year ending December 31, 2019 and for interim periods effective the three months ending March 31, 2020. Early adoption is permitted. The Company is currently evaluating the requirements of ASU 2016-01 and has not yet determined whether the adoption of the standard will have a material impact on the financial statements.

In August 2016, the FASB issued ASU 2016-15, *Classification of Certain Cash Receipts and Cash Payments (Topic 230)*. ASU 2016-15 addresses eight specific cash flow issues with the objective of reducing the existing diversity in practice for certain cash receipts and cash payments. The standard is effective for annual reporting periods beginning after December 15, 2018 and interim periods reporting within fiscal years beginning after December 15, 2019, with early adoption permitted. The Company does not believe the adoption of this guidance will have a material impact on the financial statements.

3. Fair Value Measurements

The accounting guidance defines fair value, establishes a consistent framework for measuring fair value and expands disclosure for each major asset and liability category measured at fair value on either a recurring or nonrecurring basis. 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: Unadjusted quoted prices in active markets that are accessible at the measurement date for identical, unrestricted assets or liabilities.

Level 2: Quoted prices for similar assets and liabilities in active markets, quoted prices in markets that are not active, or inputs which are observable, either directly or indirectly, for substantially the full term of the asset or liability.

Level 3: Prices or valuation techniques that require inputs that are both significant to the fair value measurement and unobservable (i.e. supported by little or no market activity).

		Fair Value Measurement Using		
	December 31, 2018	Quoted Prices in Active Markets for Identical Assets Level 1	Significant Other Observable Inputs Level 2	Significant Unobservable Inputs Level 3
Assets				
Cash and cash equivalents	$ 16,522,729	$ 16,522,729	$ —	$ —
Total assets	$ 16,522,729	$ 16,522,729	$ —	$ —

		Fair Value Measurement Using		
	December 31, 2017	Quoted Prices in Active Markets for Identical Assets Level 1	Significant Other Observable Inputs Level 2	Significant Unobservable Inputs Level 3
Assets				
Cash and cash equivalents	$ 1,021,897	$ 1,021,897	$ —	$ —
Total assets	$ 1,021,897	$ 1,021,897	$ —	$ —
Liabilities				
Preferred stock warrant liability	$ 3,898,944	$ —	$ —	$ 3,898,944
Total liabilities	$ 3,898,944	$ —	$ —	$ 3,898,944

As discussed in Note 2 above, there were no warrants exercisable for the Company's convertible preferred stock following the closing of the IPO. Of the 37.2 million warrants previously exercisable for preferred stock, 35.7 million warrants expired on the effective date of the IPO. The remaining 1.5 million warrants previously exercisable for preferred stock were adjusted to become exercisable for common stock. Prior to the IPO, the Company estimated fair value of the convertible preferred stock warrants at the time of issuance and subsequent remeasurement using the Black-Scholes-Merton model at each reporting date. On the date of the IPO and going forward, all outstanding warrants are accounted for as equity and are not subject to remeasurement.

Estimating fair values of derivative financial instruments, including Level 3 instruments, require the use of significant and subjective inputs that may, and are likely to, change over the duration of the instrument with related changes in internal and external market factors, including changes in the estimated fair value of the Company's equity securities.

The following table summarizes the changes in fair value of the Company's Level 3 liabilities for the years ended December 31, 2018 and 2017:

	Warrant Liability
Balance at January 1, 2017	$ 4,650,877
Expiration of Series A warrants	(1,424)
Change in fair value of preferred stock warrants	(750,509)
Balance at December 31, 2017	3,898,944
Issuance of warrants in connection with debt	176,813
Change in fair value of preferred stock warrants	(3,991,081)
Conversion of preferred stock warrants to common stock warrants due to IPO	(84,676)
Balance at December 31, 2018	$ —

The warrants to purchase convertible preferred stock were valued at each reporting period using the Black-Scholes-Merton model. This valuation includes observable inputs such as risk-free rate, as well as unobservable inputs for assumed volatility, the expected life of the warrants, and the fair value of the underlying convertible preferred stock. Quantitative information relating to unobservable inputs is disclosed below:

	December 31,	
	2018	2017
Risk-free interest rate	—%	1.75%
Volatility	—%	54.60%
Expected life (in years)	0.0	0.6
Dividend Yield	—	—
Fair value of Series A preferred stock	$ —	$ 0.66
Fair value of Series B-1 preferred stock	$ —	$ 0.36
Fair value of Series D preferred stock	$ —	$ 0.48
Fair value of Series D-1 preferred stock	$ —	$ 0.48

At December 31, 2017, the fair value of the underlying convertible preferred stock was determined using an Option Pricing Method ("OPM"). Under the OPM, once the fair market value of the enterprise is established, shares are valued by creating a series of call options with exercise prices based on the liquidation preference and conversion behavior of the different classes of equity. Accordingly, the aggregate equity value is allocated to each of the classes of equity shares outstanding. The Company utilized both the market and income approach to establish the fair market value of the enterprise.

Significant increases or decreases in any of these inputs in isolation (including those inputs utilized in the OPM) would result in a significantly different fair value measurement. An increase in the risk-free interest rate, and/or an increase in the remaining contractual term or expected volatility, and/or an increase in the fair value of the convertible preferred stock would result in an increase in the fair value of the warrants.

4. Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets consist of the following:

	December 31, 2018	December 31, 2017
Prepayment to supplier	$ 74,685	$ 492,330
Prepaid insurance	460,684	29,119
Other current assets	384,131	550,063
Total	$ 919,500	$ 1,071,512

5. Property and Equipment, net

Property and equipment, net consist of the following:

	December 31, 2018	December 31, 2017
Computer and office equipment	$ 476,402	$ 476,402
Lab equipment	4,437,794	3,995,731
Service equipment placed at customer sites	149,823	594,553
Leasehold improvements	1,875,647	1,860,667
	6,939,666	6,927,353
Less accumulated depreciation	(5,162,364)	(3,921,565)
	$ 1,777,302	$ 3,005,788

The Company recorded depreciation expense of $1,320,521 and $1,504,042 for the years ended December 31, 2018 and 2017, respectively in operating expenses.

6. Accrued Expenses

Accrued expenses consist of the following:

	December 31, 2018	December 31, 2017
Accrued expenses	$ 2,134,981	$ 2,596,137
Accrued bonus	765,148	912,757
Total	$ 2,900,129	$ 3,508,894

7. Long-Term Debt

Western Alliance LSA

On March 8, 2016, the Company entered into a new term Loan and Security Agreement with Western Alliance Bank (the “Western Alliance LSA”) for $7.0 million. The loan proceeds were used to repay the outstanding $5.0 million loan with Square 1 Bank, as required by the twelfth amendment to the Loan and Security Agreement with Square 1 Bank.

The Company paid debt issuance costs and a facility fee totaling $113,542 at the inception of the loan, which was recorded as a debt discount and was being recognized as additional interest expense over the term of the loan. In addition, upon repayment of the total amounts borrowed, the Company was required to pay an end of term charge equal to 3.25% of the total amount borrowed. Accordingly, an end of term charge of $227,500 was recorded as debt discount and was included on the balance sheet under current liabilities as December 31, 2017. The end of term charge was being recognized as additional interest expense over the term of the loan.

Additionally, in conjunction with the entry into Western Alliance LSA, the Company issued to Western Alliance Bank a warrant to purchase 510,417 shares of Series D convertible preferred stock at an exercise price of $0.48 per share. The Company valued the warrant to purchase Series D convertible preferred stock using the Black-Scholes-Merton model, and the initial fair value of the warrant to purchase Series D convertible preferred stock of $65,384 was recorded as a debt discount and was being amortized to interest expense over the term of the loan. Upon the closing of the IPO in August 2018, the warrants exercisable for shares of Series D convertible preferred stock were adjusted to warrants exercisable for 11,925 shares of common stock for $20.56 per share. The warrants expire on March 8, 2026.

On December 9, 2016, the Western Alliance LSA was amended, in conjunction with this amendment, the Company issued to Western Alliance Bank a warrant to purchase 291,667 shares of Series D-1 convertible preferred stock. The Company valued the warrant to purchase Series D-1 convertible preferred stock using the Black-Scholes-Merton model, and the initial fair value of the warrant to purchase Series D-1 convertible preferred stock of $34,300 was recorded as a debt discount and was being amortized to interest expense over the term of the loan. Upon the closing of the IPO in August 2018, the warrants exercisable for shares of Series D convertible preferred stock were adjusted to warrants exercisable for 6,814 shares of common stock for $20.56 per share. The warrants expire on Dec 9, 2026.

On November 20, 2017, the Western Alliance LSA was amended, in conjunction with this amendment, the Company agreed to pay an amendment fee of $17,500, which was payable on the earliest to occur of the loan maturity date or the prepayment date. The amount

was recorded as a debt discount on the balance sheet and was being recognized as additional interest expense over the remaining term of the loan.

The Company received a notice of default from Western Alliance Bank notifying the Company that as of December 31, 2017 it was in default, as it had failed to secure at least $15.0 million from the sale or issuance of its equity securities or subordinated debt as set forth in the amended Western Alliance LSA. Based on the notice of default the Company reclassified the total loan balance of $6.7 million to current liabilities on the consolidated balance sheet as of December 31, 2017, as the loan could be called at any time by Western Alliance Bank.

In February 2018, the Western Alliance LSA was amended requiring the Company to secure $21.0 million in funding prior to June 30, 2018. As part of the amendment, Western Alliance Bank agreed to forbear from exercising any of its default remedies set forth in the Western Alliance LSA as a result of the Company's loan default.

On June 13, 2018, the Western Alliance LSA was amended, replacing previously amended funding requirements and requiring the Company to secure $5.0 million in funding prior to August 3, 2018. Additionally, the amendment restricted Company use of all cash collected from customers, received on and after amendment date, until collecting a total of $2.5 million. As part of the amendment, Western Alliance Back waived the existing default.

One June 29, 2018, the Company repaid the Western Alliance LSA as part of the MidCap Financial Credit and Security Agreement discussed below.

On November 19, 2018, the Company entered into an Amendment Agreement with Western Alliance Bank to amend (i) that certain Warrant to Purchase Stock, dated March 8, 2016, (ii) that certain Warrant to Purchase Stock, dated December 9, 2016 ((i) and (ii) collectively, the "Bank Warrants") and (iii) the Western Alliance LSA. Pursuant to Section 2.6(g) of the Western Alliance LSA, the Company was obligated to pay Western Alliance Bank a success fee of $210,000 in connection with the IPO. As part of the Amendment Agreement, this success fee was decreased from $210,000 to $160,000 and the exercise price of the Bank Warrants was decreased from $20.56 per share to $6.99 per share.

MidCap Financial CSA

On June 29, 2018, the Company entered into a Credit and Security Agreement (CSA) with MidCap Financial Trust which provides a $15.0 million term loan facility available in three tranches, Tranche 1: $10.0 million, Tranche 2: $2.5 million, and Tranche 3: $2.5 million. The Company borrowed $10.0 million from Tranche 1 immediately upon closing the agreement, Tranche 2 is no longer available, and Tranche 3 is available to draw from if the Company achieves $16.0 million in trailing twelve month revenue by June 2019. Proceeds from the loan were used to repay the outstanding $7.0 million due to Western Alliance LSA.

The MidCap Financial CSA bears interest at an annual rate of one month LIBOR plus 7.5%, subject to a LIBOR floor of 1.5%. The loan has a 60-month term, with interest only for the first 18 months and straight-line amortization of principal and interest for the remaining 42 months. The CSA is secured by substantially all of the assets of the Company and matures on July 1, 2023.

The Company paid issuance fees of approximately $0.3 million at the inception of the loan, which was recorded as a debt discount and is being recognized as additional interest expense over the term of the loan. Subject to certain limited exceptions, amounts prepaid in relation to the MidCap Financial CSA are subject to a prepayment fee determined by multiplying the amount being prepaid by 4% in the first year of the term, 3% in year two, and 2% thereafter. In addition, upon repayment of the total amounts borrowed, the Company will be required to pay an end of term charge equal to 4% of the total amount borrowed. Accordingly, an end of term charge of $0.4 million was recorded as debt discount and is included in other long-term liabilities on the balance sheet as of December 31, 2018. The end of term charge is being recognized as additional interest expense over the term of the loan.

In conjunction with entering into the MidCap Financial CSA, the Company issued to MidCap a warrant to purchase 625,000 shares of Series D-1 convertible preferred stock at an exercise price of $0.48 per share that was immediately exercisable and expires June 29, 2028. The Company valued the warrant to purchase Series D convertible preferred stock using the Black-Scholes-Merton model, and the initial fair value of the warrant to purchase Series D-1 convertible preferred stock of $0.2 million was recorded as a debt discount and is being amortized to interest expense over the term of the loan. The assumptions used in the model were: the fair value of the Series D-1 convertible preferred stock, which was determined using an OPM analysis (see Note 3), an expected life of 10 years, a risk-free interest rate of 2.83% and an expected volatility of 59%. Upon the closing of the IPO in August 2018, the warrants exercisable for shares of Series D convertible preferred stock were adjusted to warrants exercisable for 14,602 shares of common stock for $20.56. The warrants expire on June 29, 2028.

In addition, MidCap invested $1.0 million in the convertible note offering at terms identical to other investors described in the Convertible Notes section below.

Convertible Notes

On February 9, 2018, the Company entered into a Note Purchase Agreement (the "Note Purchase Agreement") with various investors, which included related parties (the "Investors"), pursuant to which the Company agreed to sell to the Investors convertible promissory notes (the "Convertible Notes") in the original principal amount of up to $16.0 million. On April 2, 2018, the Company amended the Note Purchase Agreement to, among other things, increase the principal amount available for issuance under the Note Purchase Agreement to $18.4 million. The Convertible Notes had a maturity date of September 30, 2018 and were convertible either into the Company's common stock or convertible preferred stock, dependent on the conversion events.

On June 29, 2018, the Note Purchase Agreement was amended to increase the principal amount available for issuance from $18.4 million to $19.4 million.

In August 2018, the outstanding convertible promissory notes of $14.9 million of principal and interest were converted into 3,239,294 shares of common stock upon completion of the IPO. As of December 31, 2018, there are no convertible notes outstanding.

Debt and unamortized discount balances relating to the Western Alliance LSA are as follows:

	December 31, 2017
Term loan face value	$ 7,000,000
Fair value of warrant	(99,684)
End of term charge	(227,500)
Capitalized debt issuance costs	(131,042)
Accretion of debt issuance costs and end of term charge	148,225
Accretion of warrant fair value	39,753
Balance	6,729,752
Less current portion	6,729,752
Long-term debt	$ —

Debt and unamortized discount balances relating to the MidCap Financial CSA are as follows:

	December 31, 2018
Term loan face value	$ 10,000,000
Fair value of warrant	(176,813)
End of term charge	(400,000)
Capitalized debt issuance costs	(499,354)
Accretion of debt issuance costs and end of term charge	87,859
Accretion of warrant fair value	17,682
Balance	9,029,374
Less current portion	—
Long-term debt	$ 9,029,374

Non-cash interest expense related to debt discount amortization and accretion of end of term fees was $181,991 and $96,576 for the years ended December 31, 2018 and 2017, respectively.

Future minimum payments including interest under the MidCap Financial CSA are as follows as of December 31, 2018:

Year Ended December 31,	
2019	1,002,000
2020	3,727,929
2021	3,441,643
2022	3,155,357
2023	1,870,321
Total minimum loan payments	13,197,250
Unamortized interest	(2,797,250)
End of term charge	(400,000)
Warrant fair value	(159,132)
Capitalized debt issuance costs and end of term charge	(811,494)
Term loan	9,029,374
Less current portion	—
Long-term debt	9,029,374

8. Convertible Preferred Stock and Stockholders' Equity (Deficit)

Common Stock and Preferred Stock

On August 23, 2018, the Company amended and restated its Certificate of Incorporation in connection with the IPO. The Company's Amended and Restated Certificate of Incorporation authorizes 200,000,000 shares of common stock, $0.0001 par value per share, and 10,000,000 shares of preferred stock, $0.0001 par value per share, all of which shares of preferred stock are undesignated. Of the 200,000,000 authorized shares of common stock, 10,055,072 shares were issued as of December 31, 2018.

During the years ended December 31, 2018 and 2017, the company issued 2,062 and 7,079 shares of common stock in connection with the exercise of stock options for net proceeds of $3,499 and $14,294, respectively.

Convertible Preferred Stock

Prior to the August 2018 offering, there were 121,992,497 shares of convertible preferred stock outstanding. The Company's convertible preferred stock had been classified as temporary equity on the accompanying balance sheets in accordance with authoritative guidance for the classification and measurement of redeemable securities. Upon certain change in control events that were outside of the Company's control, including liquidation, sale or transfer of control of the Company, holders of the convertible preferred stock could cause its redemption

Conversion of all outstanding Preferred Stock to Common Stock

In August 2018, due to completion of a public offering meeting certain requires (as defined below), each 42.8 shares of Series Preferred was converted into one share of common stock at a Conversion Price of $1.3995 for each share of Series A, B and B-1 convertible preferred stock, $1.4043 for each share of Series C convertible preferred stock and $0.48 for each share of Series D and D-1 convertible preferred stock. As of December 31, 2018, there are no shares of convertible preferred stock outstanding.

The following sets forth information regarding all convertible preferred stock securities sold since January 1, 2017:

Series D-1 Convertible Preferred Stock Financing

From February through November 2017, the Company sold and issued 36,974,586 shares of Series D-1 convertible preferred stock at $0.48 per share, raising approximately $17,590,000, net of issuance costs of $154,191. At any time after December 31, 2021, holders of a majority of the then outstanding Series D-1 convertible preferred stock may redeem any unconverted or unredeemed Series D-1 convertible preferred stock in cash at the greater of the original convertible preferred stock purchase price plus all declared but unpaid dividends or the fair market value. The Company had determined not to adjust the carrying values of the Series D-1 convertible preferred stock to the liquidation preferences of such shares because of the uncertainty over whether or when such an event would occur. The Company had determined that it was not probable that such redemption would occur as a mandatory conversion event, the close of the public offering, was expected in advance of the redemption triggers.

Convertible Preferred Stock

The Series A, B, B-1, C, D and D-1 convertible preferred stock (collectively, the "Series Preferred") had the following rights and privileges immediately prior to conversion to common stock in connection with the public offering:

Voting rights

Series Preferred stockholders were entitled to cast the number of votes equal to the number of whole shares of common stock into which the convertible preferred stock was convertible.

Conversion

Each 42.8 shares of Series Preferred was convertible, at any time, into one share of common stock at the then-applicable Conversion Price (as defined below). The Series Preferred was automatically converted into common stock, at the then-applicable Conversion Price, upon (a) the vote or consent of 66-2/3% of the outstanding shares of Series Preferred or (b) upon the closing of the sale to the public of either shares of common stock or units comprised of shares of common stock and warrants to purchase shares of common stock (i) in which the price per share paid by the public (prior to the deduction of underwriting discounts and registration expenses) was no less than $6.00 per share, or to the extent units are sold in such offering, no less than $6.00 per unit (in each case as adjusted for any stock dividends, combinations, splits, recapitalizations and the like with respect to shares of common stock effectuated after August 15, 2018), in each case in the initial closing of the such offering, and (ii) resulting in at least $15,000,000 in gross proceeds to the company (prior to the deduction of underwriting discounts and registration expenses), in a firm-commitment underwritten public offering pursuant to an effective registration statement under the Securities Act of 1933, as amended. The Conversion Price was initially $1.3995 for each share of Series A, B and B-1 convertible preferred stock, $1.4043 for each share of Series C convertible preferred stock and $0.48 for each share of Series D and D-1 convertible preferred stock. The Conversion Price was subject to adjustment in certain circumstances.

Dividends

Holders of the Series Preferred were entitled to receive cash dividends at the rate of 8% of the applicable Original Issue Price (as defined below) per annum, on a non-cumulative basis, on each outstanding share of Series Preferred. The Company could not declare any dividends on any shares of Series Preferred other than shares of Series D-1 convertible preferred stock unless the holders of the Series D-1 convertible preferred stock then outstanding first receive, or simultaneously receive, full payment of a dividend. The Original Issue Price was $2.733 per share for the Series A convertible preferred stock, $1.3995 per share for the Series B convertible preferred stock, $1.3995 per share for the Series B-1 convertible preferred stock, $1.4043 per share for the Series C convertible preferred stock, $0.48 per share for the Series D convertible preferred stock and $0.48 per share for the Series D-1 convertible preferred stock, each subject to adjustment in the event of any reorganization, stock split, recapitalization or other similar event involving or affecting a change in the Company's capital structure.

Liquidation Preferences

In the event of liquidation or winding up of the Company, (i) the holders of the Series D and D-1 convertible preferred stock, on a pari passu basis, were entitled to receive, prior to and in preference to any payment or distribution to the holders of, Series C convertible preferred stock, Series B and B-1 convertible preferred stock, Series A convertible preferred stock and common stock, a per-share amount equal to the applicable Liquidation Preference (as defined below); (ii) the holders of the Series C convertible preferred stock, on a pari passu basis, were entitled to receive, prior to and in preference to any payment or distribution to the holders of Series B and B-1 convertible preferred stock, Series A convertible preferred stock, and common stock, a per-share amount equal to the applicable Liquidation Preference; and (iii) the holders of Series B and B-1 convertible preferred stock and the holders of Series A convertible preferred stock, on a pari passu basis, were entitled to receive, prior to and in preference to any payment or distribution to the holders of common stock, a per-share amount equal to the applicable Liquidation Preference. The Liquidation Preference was calculated as follows: (i) when the Company was valued at $91 million or below, the Liquidation Preference was equal to the applicable Original Issue Price for such shares plus the amount of any declared but unpaid dividends and (ii) when the company was valued greater than $91 million, the Liquidation Preference was equal to the applicable Original Issue Price for such shares plus the amount of any declared but unpaid dividends, with the first $10 million of proceeds above $91 million distributed to the holders of the Series D and D-1 convertible preferred stock on a pro rata basis ((i) and (ii) together, "Liquidation Preference").

The authorized shares, purchase price, outstanding shares and Liquidation Preference for each series of convertible preferred stock as of December 31, 2017, were as follows:

	Shares Authorized	Purchase Price Per Share	Shares Outstanding	Liquidation Preference
Convertible preferred stock:				
Series A	418,767	$ 1.39950	345,587	$ 483,649
Series B	8,101,042	$ 1.39950	8,058,170	$ 11,277,409
Series B-1	7,523,734	$ 1.39950	3,437,950	$ 4,811,411
Series C	23,357,047	$ 1.40430	23,357,047	$ 32,800,301
Series D	52,835,720	$ 0.48000	20,652,486	$ 9,913,193
Series D-1	125,808,667	$ 0.48000	66,141,257	$ 31,747,803
Total	218,044,977		121,992,497	$ 91,033,766

Convertible Preferred Stock Warrants

On July 3, 2012, in conjunction with the Square 1 LSA, the Company issued a warrant to purchase 64,309 shares of Series B-1 convertible preferred stock to Square 1 Bank at an exercise price of $1.3995 per-share. This warrant expires in July 2019.

On December 11, 2013, in conjunction with an amendment to the Square 1 LSA, the Company issued a warrant to purchase 10,718 shares of Series B-1 convertible preferred stock to Square 1 Bank at an exercise price of $1.3995 per-share. This warrant expires in December 2020.

On September 17, 2013, in conjunction with the subordinated convertible promissory notes that were issued in connection with the September 2013 Note and Warrant Purchase Agreement, the Company issued warrants to purchase 1,480,988 shares of Series B-1 convertible preferred stock. Per the terms of the September 2013 Note and Warrant Purchase Agreement, the number of shares of Series B-1 convertible preferred stock purchasable under these warrants was increased to 2,123,528 shares as the Company did not complete a qualified financing prior to January 1, 2014. The warrants allow the investors to purchase Series B-1 convertible preferred stock at an exercise price of $1.3995 per-share. These warrants were originally scheduled to expire in 2023.

On June 12, 2014, in conjunction with the subordinated convertible promissory notes that were issued in connection with the June 2014 Note and Warrant Purchase Agreement, the Company issued warrants to purchase 715,766 shares of Series B-1 convertible preferred stock at an exercise price of $1.3995 per- share. These warrants were originally scheduled to expire in 2024.

On September 9, 2014 and November 11, 2014, in conjunction with the issuance of Series C convertible preferred stock, the Company issued warrants to purchase 4,450,616 shares and 6,527,568 shares of Series C convertible preferred stock, respectively, at an exercise price of $1.4043 per-share. On March 31, 2016, all warrants to purchase Series C convertible preferred stock issued in conjunction with the Series C convertible preferred stock offering expired under the terms of their issue with no investors electing to exercise their warrants. As such, these warrants have been retired by the Company.

On March 4, 2016, in conjunction with the Series D convertible preferred stock offering, the Company issued warrants to purchase 31,672,817 shares of Series D convertible preferred stock at an exercise price of $0.41 per-share. These warrants expire in 2026.

On March 8, 2016, in conjunction with the Western Alliance LSA, the Company issued a warrant to purchase 510,417 shares of Series D convertible preferred stock to Western Alliance Bank at an exercise price of $0.48 per-share. Additionally, in conjunction with the first amendment to the Western Alliance LSA, on December 9 2016, the Company issued a warrant to purchase 291,667 shares of Series D-1 convertible preferred stock to Western Alliance Bank at an exercise price of $0.48 per-share. Both of these warrants expire in 2026.

On June 29, 2018, in conjunction with the MidCap Financial CSA, the Company issued a warrant to purchase 625,000 shares of Series D-1 convertible preferred stock to MidCap Financial at an exercise price of $0.48 per-share. This warrant expires in 2028.

All the outstanding warrants to purchase convertible preferred stock were classified as liabilities in the financial statements and were valued at each reporting period using the Black-Scholes-Merton model as discussed in Note 3, “Fair Value Measurements”. In connection with the IPO, outstanding convertible preferred stock warrants either expired or were adjusted to exercisable for shares of common stock.

Common Stock Warrants

On November 19, 2018, we issued to LifeSci Capital, LLC, a warrant to purchase 44,183 shares of the our common stock, and to Russell Creative Group, a warrant to purchase 3,311 shares of our common stock (together, the "Service Provider Warrants"), each having an exercise price of $8.25 per share of our common stock and a term of five years. The Service Provider Warrants were issued in full satisfaction of our obligations to pay to LifeSci Capital, LLC an aggregate of $150,000 for capital advisory and investor relations services and to Russell Creative Group an aggregate of $15,000 for branding and marketing services. The Company valued these warrants using the Black-Scholes-Merton model. The assumptions used in the model were: the fair value of the Company's common stock, an expected life of 10 years, a risk-free interest rate of 2.93%, and an expected volatility of 62.28%.

On November 19, 2018, we entered into an amendment agreement with Western Alliance Bank in order to amend the previously issued warrants to purchase preferred stock, dated March 8, 2016 and December 9, 2016, respectively, which, in connection with the IPO, were adjusted to warrants exercisable for shares of common stock. Pursuant to the Amendment Agreement, the exercise price of the Bank Warrants was decreased from $20.56 per share to $6.99 per share. All other terms of the Bank Warrants remain in full force and effect.

Stock Options

In August 2018, the Company's board of directors (the "Board") and its stockholders adopted the 2018 Equity Incentive Plan (the "2018 Plan"), as a successor to and continuation of the Company's 2006 Equity Incentive Plan (the "2006 Plan"). Under the 2018 Plan the Company may grant stock options, stock appreciation rights, restricted stock, restricted stock units and other awards to individuals who are then its employees, directors and consultants, including employees and consultants of its affiliates. The Company has initially reserved 1,499,454 shares of common stock for issuance under the 2018 Plan, which is the sum of (1) 1,000,000 new shares, plus (2) the number of shares that remained available for issuance under the 2006 Plan at the time the 2018 Plan became effective, and (3) any shares subject to outstanding stock options or other stock awards that were granted under the 2006 Plan that would have otherwise returned to the 2006 Plan. In addition, the number of shares of common stock reserved for issuance under the 2018 Plan will automatically increase on January 1 of each calendar year, starting on January 1, 2019 through January 1, 2028, in an amount equal to 5% of the total number of shares of the Company's capital stock outstanding on the last day of the calendar month before the date of each automatic increase, or a lesser number of shares determined by the Board.

As of December 31, 2018, there were 1,282,847 shares of common stock subject to outstanding options and 369,234 shares of common stock reserved for future stock awards under the 2018 Plan.

A summary of the Company's stock option activity under the 2018 Plan and 2006 Plan is as follows:

	Shares	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term	Aggregate Intrinsic Value
Outstanding at January 1, 2017	43,596	$ 42.80	8.0	—
Granted	461,978	1.28		—
Exercised	(7,077)	2.14		$80,959
Cancelled	(62,156)	3.42		—
Outstanding at December 31, 2017	436,341	$ 5.14	9.0	—
Granted	886,023	7.69		—
Exercised	(2,062)	1.70		$6,046
Cancelled	(37,455)	5.20		—
Outstanding at December 31, 2018	1,282,847	6.90	9.2	$1,461,567
Vested and expected to vest at December 31, 2018	1,273,745	6.85	9.2	$1,426,092
Vested and exercisable at December 31, 2018	494,968	6.99	8.7	$1,029,435

For the years ended December 31, 2018 and 2017, the Company granted to its employees options to purchase 886,023 shares and 461,978 shares of its common stock with an exercise price of $7.69 per share and $1.28 per share, respectively.

For the years ended December 31, 2018 and 2017, the total grant date fair value of vested options was $957,387 and $365,154, respectively. The weighted-average grant date fair value of employee option grants during the years ended December 31, 2018 and 2017 was $6.99 and $1.28, respectively.

Stock-Based Compensation Expense

The Company recognized stock-based compensation expense for the years ended December 31, 2018 and 2017 as follows:

	Year Ended December 31,	
	2018	2017
Research and development	$ 260,840	$ 128,210
General and administrative	933,033	254,620
Total stock-based compensation expense	$ 1,193,873	$ 382,830

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

	Year Ended December 31,	
	2018	2017
Risk-free interest rate	2.5 - 3.0%	1.8 - 2.0%
Expected volatility	62 - 64%	58 - 67%
Expected term (in years)	4.0 - 5.4	5.1 - 5.3
Expected dividend yield	0%	0%

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

Expected volatility. Due to the Company's limited operating history and lack of company-specific historical or implied volatility as a private company, the expected volatility assumption was determined by examining the historical volatilities of a group of industry peers whose share prices are publicly available.

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

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

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

As of December 31, 2018 the unrecognized compensation cost related to outstanding employee options was $2,888,363 and is expected to be recognized as expense over approximately 2.9 years.

Employee Stock Purchase Plan

In August 2018, the Board and the Company's stockholders adopted the 2018 Employee Stock Purchase Plan (the "ESPP"). A total of 175,000 shares of common stock are initially reserved for issuance under the ESPP. In addition, the number shares of common stock reserved for issuance under the ESPP will automatically increase each on January 1 of each calendar year, beginning on January 1, 2019, through January 1, 2028, by the lesser of (1) 1% of the total number of shares of the Company's common stock outstanding on the last day of the calendar month before the date of the automatic increase, (2) 220,000 shares, or (3) a lesser number of shares as determined by the Board. As of December 31, 2018, there 22,179 shares of common stock have been purchased under the ESPP.

Common Stock Reserved for Future Issuance

Common stock reserved for future issuance consist of the following:

	Year Ended December 31,	
	2018	2017
Convertible preferred stock	—	2,850,276
Stock options issued and outstanding	1,282,847	436,341
Authorized for future stock awards, option grants, or employee stock purchase program	369,234	57,904
Preferred warrants	—	855,212
Common warrants	4,062,507	—
Total	5,714,588	4,199,733

9. Commitments and Contingencies

Leases

The Company leases certain office and lab space in San Diego, California under a non-cancelable operating lease, which was amended July 1, 2015 to add laboratory space and office space and extend its terms through December 2020. Rent expense was $556,321 and $590,089 for the years ended December 31, 2018 and 2017, respectively, including the offset for amortization of the leasehold incentive obligation of $225,052 for the years ended December 31, 2018 and 2017.

In November, 2018 , the Company entered into a sublease agreement (the "Sublease") whereby a subtenant agreed to lease 16,607 square feet of office and lab space from the Company. The Sublease terminates on December 31, 2020. Rental income of $26,278 received from the subtenant has been classified by the Company as reduction of rent expense for the year ended December 31, 2018.

The future minimum lease payments required under non-cancelable leases as of December 31, 2018, are summarized as follows:

Year Ending December 31,	Gross Payments	Scheduled Sublease Payments	Net Payments
2019	$ 844,812	$ (388,797)	$ 456,015
2020	902,412	(464,334)	438,078
Total minimum lease payments	$ 1,747,224	$ (853,131)	$ 894,093

Royalty Agreements

The Company has entered into agreements to market and distribute chips and kits used in its instruments. The Company is obligated to pay royalties based on sales during each annual license period. Such royalty agreements extend through the life of underlying intellectual property which is affected by the patent filing date and jurisdiction. The Company paid total royalties of $377,437 and $233,128 for the years ended December 31, 2018 and 2017, respectively.

Certain royalty agreements require the Company to make minimum payments regardless of the level of sales achieved. As of December 31, 2018, annual future minimum royalty payments total $90,000 through December 31, 2019 and total $110,000, thereafter, on a continuing basis, and extend through November 29, 2026.

Purchase Commitments

The Company has a contractual commitment with a supplier to purchase $165,000 of products every three months for an initial term of two years beginning March 1, 2019. The contract can be terminated on 90 days written notice by either party.

Litigation

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

10. Income Taxes

Significant components of the Company's net deferred tax assets at December 31, 2018 and 2017 are shown below. A valuation allowance has been recorded to offset the net deferred tax asset as of December 31, 2018 and 2017, as the realization of such assets does not meet the more-likely-than-not threshold.

	December 31,	
	2018	2017
Deferred tax assets:		
Net operating loss carryforwards	$ 35,104,728	$ 30,528,420
Research and development credits	4,577,582	4,078,522
Other	1,725,577	1,163,659
Total gross	41,407,887	35,770,601
Valuation allowance	(41,407,887)	(35,770,601)
Net deferred tax assets	$ —	$ —

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

	Years Ended December 31,	
	2018	2017
Current:		
Foreign	$ 13,955	$ 16,996
State and local	1,556	1,556
Income tax provision	$ 15,511	$ 18,552

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

	Years Ended December 31,	
	2018	2017
Domestic	$ (18,515,638)	$ (23,455,215)
Foreign	34,757	108,403
Loss before provision for income taxes	$ (18,480,881)	$ (23,346,812)

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

	December 31,	
	2018	2017
Income taxes at statutory rate	$ (3,880,985)	$ (7,939,076)
State income taxes, net of federal benefits	(476,179)	(376,232)
Change in valuation allowance	5,617,471	(7,523,665)
Tax Cuts and Jobs Act	—	16,552,989
Other permanent differences	95,852	426,903
Research Credits	(502,511)	(866,710)
Change in Fair value of Warrants	(838,137)	(255,657)
Income tax expense	$ 15,511	$ 18,552

On December 22, 2017, the President of the United States signed into law the Tax Cuts and Jobs Act which, among a broad range of tax reform measures, reduced the U.S. corporate tax rate from 35% to a flat 21% effective January 1, 2018. The reduction in the U.S. corporate tax rate required the Company to remeasure the federal portion of deferred tax assets and liabilities at December 31, 2017 to the enacted tax rate expected to apply when the temporary differences are to be realized. The Company provisionally recorded $16.6 million of expense related, offset by a full valuation allowance, for the remeasurement of its deferred tax assets and liabilities. As of December 31, 2018, the Company completed its accounting for the tax effects of the enactment of the 2017 Act which resulted in immaterial adjustments to provisional estimates, offset by a full valuation allowance.

As of December 31, 2018, the Company has federal and state tax net operating loss carryforwards of $147.6 million and $58.0 million, respectively. The federal tax loss carryforwards of $19.3 million do not expire and are subject to 80% limitation due to the tax

law change of 2017. The remaining federal tax loss carryforwards of $128.3 million and state tax loss carryforwards begin to expire in 2027 and 2023, respectively, unless previously utilized. The Company also has federal and California research credit carryforwards of $4.5 million and $4.0 million, respectively. The federal research credit carryforwards begin to expire in 2027 unless previously utilized. The California research credits carry forward indefinitely.

Management assesses all available evidence to estimate if sufficient future taxable income will be generated to use the existing deferred tax assets. The Company has experienced net losses since inception, and the revenue and income potential of the Company's business and market are unproven. Due to the Company's continuing research and development activities, the Company expects to continue to incur net losses into the foreseeable future. As such, the Company cannot conclude that it is more likely than not that its deferred tax assets will be realized. A valuation allowance of $41.4 million and $35.8 million as of December 31, 2018 and 2017, respectively, has been established to offset the deferred tax assets, as realization of such assets is uncertain.

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

During 2013, the Company completed a Section 382/383 analysis, from inception through December 31, 2012, regarding the limitation of the net operating losses and R&D credits. Based upon the analysis, the Company determined that no ownership changes occurred during that period. However, there may have been ownership changes subsequent to December 31, 2012, that could limit the Company's ability to utilize the net operating loss and R&D credit carryforwards. The Company plans to complete an analysis prior to using any of the net operating losses and R&D credits.

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

	December 31,	
	2018	2017
Balance at beginning of the year	$ 3,018,563	$ 2,451,121
Additions/(reductions) for tax positions - prior year	—	—
Increase related to current year positions	370,573	567,442
Balance at the end of the year	$ 3,389,136	$ 3,018,563

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

The Company's practice is to recognize interest and penalties related to income tax matters in income tax expense. The Company had no accrual of interest and penalties on the Company's balance sheets and has not recognized interest and penalties in the statements of operations for the years ended December 31, 2018 and 2017.

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

11. Employee Benefits

The Company has a defined contribution 401(k) plan available to eligible employees. Under the terms of the plan, employees may make voluntary contributions as a percent of compensation, limited to the maximum amount allowable under federal tax regulations. The Company, at its discretion, may make certain contributions to the 401(k) plan. The Company made matching contributions of $272,507 and $395,360 for the years ended December 31, 2018 and 2017, respectively.

12. Quarterly Financial Data (unaudited)

The unaudited quarterly financial information should be read in conjunction with the our financial statements and related notes included elsewhere in this report. We believe that the following unaudited information reflects all normal recurring adjustments necessary

for a fair presentation of the information for the periods presented. The operating results for any quarter are not necessarily indicative of results for any future period. The following table contains selected unaudited financial data for each of the indicated periods:

	Three months ended			
	March 31,	**June 30,**	**September 30,**	**December 31,**
		2018		
Revenue	$ 1,768,485	$ 3,390,009	$ 2,828,704	$ 4,013,537
Cost of Revenue	$ 841,449	$ 1,813,430	$ 3,068,332	$ 2,988,115
Operating Expenses	$ 5,262,497	$ 5,588,800	$ 5,729,212	$ 7,123,985
Net Loss	$ 3,847,362	$ 3,311,476	$ 4,926,097	$ 6,411,457
		2017		
Revenue	$ 1,720,754	$ 2,196,110	$ 2,743,056	$ 2,845,123
Cost of Revenue	$ 1,205,264	$ 1,638,853	$ 1,690,223	$ 1,496,172
Operating Expenses	$ 6,703,475	$ 7,317,565	$ 6,083,995	$ 6,588,304
Net Loss	$ 5,685,530	$ 6,674,458	$ 5,085,452	$ 5,919,924

13. Subsequent Events

For the purposes of the financial statements as of December 31, 2018 and the years then ended, the Company identified subsequent events through March 14, 2019, the date on which the financial statements were issued.

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

None.

Item 9A. Controls and Procedures.
Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures as of December 31, 2018. The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (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 is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company's management, including its principal executive and principal financial officers, 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 management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of December 31, 2018, our Chief Executive Officer and Chief Financial Officer concluded that, as of such date, our disclosure controls and procedures were effective.

Changes in Internal Control over Financial Reporting

There were no material changes in our internal control over financial reporting during the quarter ended December 31, 2018 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Management Report on Internal Control over Financial Reporting

This annual report does not include a report of management's assessment regarding internal control over financial reporting or an attestation report of our registered independent public accounting firm due to a transition period established by rules of the SEC for newly public companies.

Item 9B. Other Information.

None.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

The following table sets forth information regarding our directors and executive officers as of December 31, 2018.

Name	Age	Position
Executive Officers:		
R. Erik Holmlin, Ph.D.	50	President, Chief Executive Officer and Director
Mike Ward	47	Chief Financial Officer
Warren Robinson	49	Chief Commercial Officer
Mark Borodkin	44	Chief Operating Officer
Non-Employee Directors:		
David L. Barker, Ph.D.[(1)(2)]	77	Chairman, Director
Darren Cai, Ph.D.[(1)]	53	Director
Albert Luderer, Ph.D.[(2)(3)]	70	Director
Junfeng Wang[(1)(3)]	44	Director
Christopher Twomey[(2)]	59	Director
Quan Zhou[(3)]	43	Director

(1) Member of the compensation committee.
(2) Member of the audit committee.
(3) Member of the nominating and corporate governance committee.

Executive Officers

R. Erik Holmlin, Ph.D. Dr. Holmlin has served as our President and Chief Executive Officer and as a member of our board of directors since January 2011. From June 2010 to February 2011, Dr. Holmlin served as president and Chief Executive Officer of GenVault Corporation, a private biosample management solutions company. Previously, Dr. Holmlin held positions as an entrepreneur in residence at Domain Associates, a dedicated life sciences venture capital firm; Chief Commercial Officer of Exiqon A/S, a publicly traded RNA research solutions company; founder and executive at GeneOhm Sciences, which was acquired by Becton Dickinson and Company; and a National Institutes of Health postdoctoral fellow at Harvard University. Until June 2016, Dr. Holmlin served as a director of Nanosphere, Inc., a publicly traded molecular diagnostic company, which was subsequently acquired by Luminex Corporation, a publicly traded biological testing company. Dr. Holmlin received his bachelor's degree in chemistry from Occidental College, his Ph.D. in chemistry from the California Institute of Technology and MBAs from University of California, Berkeley and Columbia University. Our board of directors believes that Dr. Holmlin's over 17 years of experience in the life sciences and healthcare industries, which includes the areas of technology development, product commercialization and venture financing, qualifies him to serve on our board of directors.

Mike Ward. Mr. Ward has served as our Chief Financial Officer since May 2018, and previously served as our Chief Business Officer from July 2017 and as our Vice President, Corporate Development since April 2014. From September 2009 to September 2013, Mr. Ward served as a Director and Vice President of the Private Equity and Venture Capital Investment team of Lurie Investment Fund. In addition, Mr. Ward previously served in investment banking positions at Leerink Partners, BMO Capital Markets, Dresdner Kleinwort Wasserstein, Prudential Securities and Credit Suisse. Mr. Ward has previously served on the boards of directors of public and private companies, including Nanosphere, Inc., CytoPherx, Inc., Aperion Biologics, Inc. and Impact Health, Inc. Mr. Ward has over 20 years of experience in the areas of investment banking, private equity and venture capital in the life sciences industry. Mr. Ward received his bachelor's degree in finance from the University of Illinois.

Warren Robinson. Mr. Robinson has served as our Chief Commercial Officer since November 2017 and previously served as a Vice President with us in various sales and marketing functions from October 2015 to November 2017, including most recently as our Vice President of Global Sales and Marketing. From June 2013 to October 2015, Mr. Robinson served as Division Vice President of Aegis Chemical Solutions, LLC, a private oil production services company. Previously, Mr. Robinson held various leadership roles in sales-focused positions with Life Technologies Corporation, a publicly traded research tools development company acquired by Thermo Fisher Scientific Inc. in February 2014, and Invitrogen Corporation, a publicly traded research tools development company acquired by Life Technologies in January 2008. Mr. Robinson received his bachelor's degree in biochemistry from The University of Lethbridge, a research university located in Canada.

Mark Borodkin. Mr. Borodkin has served as our Chief Operating Officer since November 2017 and previously served as our Vice President, Product Development and Operations since October 2014. From December 2011 to August 2014, Mr. Borodkin served as the

Senior Director of Engineering and Chief Product Officer at Brooks Life Science Systems, a provider of automation and cryogenic solutions for the life science industry, and from April 2009 to October 2011 as a Director of Engineering at Affymetrix, Inc., a private life science systems company that was acquired by Thermo Fisher Scientific in March 2016. From December 2007 to April 2009, Mr. Borodkin served as a Senior Manager and Core Team Leader of R&D for Siemens Healthcare Diagnostics, and for the prior 13 years, he developed sequencing and real-time PCR systems at Applied Biosystems, now a part of Thermo Fisher Scientific. Mr. Borodkin received both his bachelor's degree in electrical engineering and his master's degree in computer and systems engineering from Rensselaer Polytechnic Institute.

Non-Employee Directors

David L. Barker, Ph.D. Dr. Barker has served on our board of directors since May 2010, and as Chairman of our board of directors since August 2016. Dr. Barker also serves as a member of the board of directors of AmideBio, Singular Genomics Systems, and Aspen Neuroscience. He is also a scientific advisor to MiNDERA Corp. and Luna DNA. He served as Vice President and Chief Scientific Officer at Illumina, Inc., from 2000 to 2007, and on the Illumina scientific advisory board until May 2016. He was previously on the Boards of NextBio, which was acquired by Illumina in 2013, ProteinSimple, which was acquired by Bio-Techne in 2014, Zephyrus Biosciences, Inc., acquired by Bio-Techne in 2016, IntegenX, acquired by Thermo Fisher Scientific in 2018, and Integrated Diagnostics, acquired by Biodesix in 2018. Dr. Barker served from 1998 to 2000 as Vice President and Chief Science Advisor at Amersham Biosciences, now part of General Electric. From 1988 to 1998, Dr. Barker held senior positions, including Vice President of Research and Business Development, at Molecular Dynamics, Inc., until the acquisition of Molecular Dynamics by Amersham. In his academic career, Dr. Barker conducted interdisciplinary research in neurobiology as a postdoctoral fellow at Harvard Medical School, Assistant Professor at the University of Oregon and Associate Professor at Oregon State University. Dr. Barker holds a BS with honors in Chemistry from the California Institute of Technology and a PhD in Biochemistry from Brandeis University. Our board of directors believes Dr. Barker's extensive experience in managing and leading early stage and established companies within the clinical diagnostic and biotechnology industries qualifies him to serve on our board of directors.

Darren Cai, Ph.D. Dr. Cai has served on our board of directors since September 2014. From April 2015 to April 2018, Dr. Cai served as a Managing Director of Legend Capital, a Chinese early stage and expansion stage venture capital firm, and held a previous position as a Director of Legend Capital from October 2012. Dr. Cai also served as Chief Financial Officer of Beijing Genomics Institute, a genome sequencing company, from 2014 to 2016. During his tenure at Legend Capital, Dr. Cai focused on investment opportunities in the healthcare sector and led investment in more than 20 companies located in the U.S. and China. In addition, Dr. Cai previously served on the board of directors of Beijing Genomics Institute. Dr. Cai received his bachelor's degree in biophysics from the University of Science and Technology of China, MBA from Yale University and Ph.D. in vision science from the University of California, Berkeley. Our board of directors believes Dr. Cai's extensive experience in managing and developing investment and business opportunities within the healthcare sector qualifies him to serve on our board of directors.

Albert Luderer, Ph.D. Dr. Luderer has served on our board of directors since October 2011. Dr. Luderer currently serves as the Chief Executive Officer and a member of the board of directors of Indi Molecular, Inc., a synthetic antibody technology company, and as the Executive Chairman of the board of directors of Prostate Management Diagnostics Inc. Dr. Luderer has over 30 years of experience in executive leadership roles in the areas of technology development, operations and business development. Dr. Luderer received his bachelor's degree in zoology from Drew University and his MS in immunochemistry and Ph.D. in immunogenics from Rutgers University. Our board of directors believes Dr. Luderer's experience in the biotechnology sector, with special focuses on technology, business development and commercialization, qualifies him to serve on our board of directors.

Junfeng Wang. Mr. Wang has served on our board of directors since February 2018. Since October 2009, Mr. Wang has served as a Managing Director of Legend Capital, and held previous positions with Legend Capital as Executive Director from October 2007, Senior Vice President from October 2006 and Vice President from October 2005. Through his tenure at Legend Capital, Mr. Wang has worked in the healthcare and chemical industries, developing research and investment expertise in growth capital investment. Mr. Wang received his bachelor's degree in polymer chemistry from Lanzhou University, a research university located in China, and his MBA from McMaster University, a research university located in Canada. Our board of directors believes Mr. Wang's extensive experience as a venture capital investor in the healthcare and chemical industries qualifies him to serve on our board of directors.

Christopher J. Twomey has served on our board of directors since July 2018. Since August 2013, Mr. Twomey has served as a director and Chairman of the Audit Committee of Tandem Diabetes Care, Inc., a medical device company. From March 1990 to June 2007, Mr. Twomey served in various roles, including as Senior Vice President, Finance and Chief Financial Officer, at Biosite Incorporated, a medical diagnostics company. From October 1981 to March 1990, Mr. Twomey served as an audit manager for Ernst & Young, LLP. From March 2006 to November 2018, Mr. Twomey served as a director of Senomyx, Inc., a taste technologies company that was acquired by Firmenich in November 2018. From July 2006 to March 2014, Mr. Twomey also served as a director and Chairman of the Audit Committee of Cadence Pharmaceuticals, Inc., a specialty pharmaceutical company that was acquired by Mallinckrodt plc in 2014. Mr. Twomey received his bachelors degree in Business Economics from the University of California at Santa Barbara. Mr. Twomey

contributes substantial leadership skills and expertise in accounting and financial reporting that are especially valuable in his role as Chairman of our Audit Committee.

Quan Zhou. Mr. Zhou has served on our board of directors since February 2018. Since April 2016, Mr. Zhou has served as an Executive Director at Legend Capital, and held previous positions as Director from April 2015 and Vice President from October 2012. During his tenure at Legend Capital, Mr. Zhou has focused on the Medtech and diagnostics industries. Mr. Zhou received his bachelor's degree in Biology from the University of Science and Technology in China, his Masters in Neuroscience from the National University of Singapore, and his MBA from the China Europe International Business School. Our board of directors believes Mr. Zhou's extensive experience in investment in the healthcare sector qualifies him to serve on our board of directors.

Family Relationships

There are no family relationships among our directors, executive officers or persons nominated to become executive officers or directors.

Section 16(A) Beneficial Ownership Reporting Compliance

Section 16(a) of the Exchange Act requires our directors and executive officers, and persons who own more than 10% of a registered class of our equity securities, to file with the SEC initial reports of ownership and reports of changes in ownership of our common stock and other equity securities. Officers, directors and greater than 10% stockholders are required by SEC regulation to furnish us with copies of all Section 16(a) forms they file.

To our knowledge, based solely on a review of the copies of such reports furnished to us and written representations that no other reports were required, during the fiscal year ended December 31, 2018, all Section 16(a) filing requirements applicable to our officers, directors and greater than 10% beneficial owners of our capital stock were complied with except that David L. Barker failed to timely file a Form 4 during our fiscal year ended December 31, 2018 to report the purchase of common stock warrants on August 21, 2018 and the grant to Dr. Barker by the Company of stock options on October 1, 2018.

Board Leadership Structure

Our board of directors is currently chaired by Dr. Barker, who has authority, among other things, to call and preside over board of directors meetings, to set meeting agendas and to determine materials to be distributed to the board of directors. Accordingly, the chairperson of our board of directors has substantial ability to shape the work of the board of directors. We believe that separation of the positions of chairperson and chief executive officer reinforces the independence of our board of directors in its oversight of our business and affairs. In addition, we have a separate chair for each committee of our board of directors. The chair of each committee is expected to report annually to our board of directors on the activities of their committee in fulfilling their responsibilities as detailed in their respective charters or specify any shortcomings should that be the case.

Role of the Board in Risk Oversight

The audit committee of our board of directors is primarily responsible for overseeing our risk management processes on behalf of our board of directors. Going forward, we expect that the audit committee will receive reports from management at least quarterly regarding our assessment of risks. In addition, the audit committee reports regularly to our board of directors, which also considers our risk profile. The audit committee and our board of directors focus on the most significant risks we face and our general risk management strategies. While our board of directors oversees our risk management, management is responsible for day-to-day risk management processes. Our board of directors expects management to consider risk and risk management in each business decision, to proactively develop and monitor risk management strategies and processes for day-to-day activities and to effectively implement risk management strategies adopted by the audit committee and our board of directors. We believe this division of responsibilities is the most effective approach for addressing the risks we face and that our board of directors' leadership structure, which also emphasizes the independence of our board of directors in its oversight of its business and affairs, supports this approach.

Director Independence

Under the listing requirements and rules of Nasdaq, independent directors must comprise a majority of our board of directors as a listed company within one year of the listing date. Our board of directors has undertaken a review of the independence of each director. Based on information provided by each director concerning her or his background, employment and affiliations, our board of directors has determined that all of our directors, except Dr. Holmlin, are independent directors, as defined by Rule 5605(a)(2) of the Nasdaq Listing Rules.

Committees of Our Board of Directors

Our board of directors has established an Audit Committee, a Compensation Committee, and a Nominating and Corporate Governance Committee. The composition and responsibilities of each of the committees of our board of directors are described below. Members serve on these committees until their resignation or until otherwise determined by our board of directors. Our board of directors may establish other committees as it deems necessary or appropriate from time to time.

Audit Committee

Our audit committee consists of Mr. Twomey, Dr. Luderer and Dr. Barker, each of whom our board of directors has determined satisfies the independence requirements under the Nasdaq listing standards and Rule 10A-3(b)(1) of the Exchange Act. The chair of our audit committee is Mr. Twomey, who our board of directors has determined is an "audit committee financial expert" within the meaning of SEC regulations. Each member of our audit committee can read and understand fundamental financial statements in accordance with applicable requirements. In arriving at these determinations, the board of directors has examined each audit committee member's scope of experience and the nature of their employment in the corporate finance sector.

The primary purpose of the audit committee is to discharge the responsibilities of our board of directors with respect to our corporate accounting and financial reporting processes, systems of internal control and financial-statement audits, and to oversee our independent registered accounting firm. Specific responsibilities of our audit committee include:

- helping our board of directors oversee our corporate accounting and financial reporting processes;
- managing the selection, engagement, qualifications, independence and performance of a qualified firm to serve as the independent registered public accounting firm to audit our financial statements;
- discussing the scope and results of the audit with the independent registered public accounting firm, and reviewing, with management and the independent accountants, our interim and year-end operating results;
- developing procedures for employees to submit concerns anonymously about questionable accounting or audit matters;
- reviewing related person transactions;
- obtaining and reviewing a report by the independent registered public accounting firm at least annually, that describes our internal quality control procedures, any material issues with such procedures, and any steps taken to deal with such issues when required by applicable law; and
- approving, or, as permitted, pre-approving, audit and permissible non-audit services to be performed by the independent registered public accounting firm.

Compensation Committee

Our compensation committee consists of Dr. Barker, Dr. Cai and Mr. Wang. The chair of our compensation committee is Dr. Barker. Our board of directors has determined that each member of the compensation committee is independent under the Nasdaq listing standards, a "non-employee director" as defined in Rule 16b-3 promulgated under the Exchange Act and an "outside director" as that term is defined in Section 162(m) of the Code.

The primary purpose of our compensation committee is to discharge the responsibilities of our board of directors in overseeing our compensation policies, plans and programs and to review and determine the compensation to be paid to our executive officers, directors and other senior management, as appropriate. Specific responsibilities of our compensation committee include:

- reviewing and approving the compensation of our chief executive officer, other executive officers and senior management;
- reviewing and recommending to our board of directors the compensation paid to our directors;
- reviewing and approving the compensation arrangements with our executive officers and other senior management;
- administering our equity incentive plans and other benefit programs;
- reviewing, adopting, amending and terminating, incentive compensation and equity plans, severance agreements, profit sharing plans, bonus plans, change-of-control protections and any other compensatory arrangements for our executive officers and other senior management;
- reviewing, evaluating and recommending to our board of directors succession plans for our executive officers; and
- reviewing and establishing general policies relating to compensation and benefits of our employees, including our overall compensation philosophy.

Nominating and Corporate Governance Committee

Our nominating and corporate governance committee consists of Dr. Luderer, Mr. Wang and Mr. Zhou. The chair of our nominating and corporate governance committee is Dr. Luderer. Our board of directors has determined that each member of the nominating and corporate governance committee is independent under the Nasdaq listing standards, a non-employee director, and free from any relationship that would interfere with the exercise of his or her independent judgment.

Specific responsibilities of our nominating and corporate governance committee include:

- identifying and evaluating candidates, including the nomination of incumbent directors for reelection and nominees recommended by stockholders, to serve on our board of directors;
- considering and making recommendations to our board of directors regarding the composition and chairmanship of the committees of our board of directors;
- instituting plans or programs for the continuing education of our board of directors and orientation of new directors;
- developing and making recommendations to our board of directors regarding corporate governance guidelines and matters; and
- overseeing periodic evaluations of the board of directors' performance, including committees of the board of directors and management.

Code of Business Conduct and Ethics

We have adopted a code of business conduct and ethics that applies to all our employees, officers and directors. This includes our principal executive officer, principal financial officer and principal accounting officer or controller, or persons performing similar functions. The full text of our code of business conduct and ethics will be posted on our website at www.bionanogenomics.com. If we make any substantive amendments to the code of business conduct and ethics or grant any waiver from a provision of the code of business conduct and ethics to any executive officer or director, we will promptly disclose the nature of the amendment or waiver on our website. Information contained in, or that can be accessed through, our website is not incorporated by reference into this Annual Report, and you should not consider information on our website to be part of this Annual Report.

Item 11. Executive Compensation.

Our named executive officers for the year ended December 31, 2018, consisting of our principal executive officer and the next two most highly compensated executive officers, were:

- R. Erik Holmlin, Ph.D., our Chief Executive Officer;
- Mike Ward, our Chief Financial Officer;
- Warren Robinson, our Chief Commercial Officer; and
- Han Cao, Ph.D., our Chief Scientific Officer. [(1)]

[(1)] Dr. Cao, Ph.D. ceased serving as our Chief Scientific Officer effective November 5, 2018 and terminated service with us on December 7, 2018.

Summary Compensation Table

The following table presents all of the compensation awarded to or earned by or paid to our named executive officers during the fiscal year ended December 31, 2018.

Name and Principal Position	Year	Salary ($)	Bonus ($)	Option Awards[1] ($)	Non-Equity Incentive Plan Compensation[2] ($)	All Other Compensation[3] ($)	Total ($)
R. Erik Holmlin, Ph.D.	2018	389,986	—	1,993,316	132,595	11,360	2,527,257
Chief Executive Officer	2017	378,628	—	93,786	118,132	14,784	605,330
Mike Ward	2018	298,061	—	463,014	78,241	11,360	850,676
Chief Financial Officer	2017	289,380	—	20,841	72,056	14,198	396,475
Warren Robinson	2018	295,000		502,253	88,795	11,360	897,408
Chief Commercial Officer							
Han Cao, Ph.D.[4]	2018	309,451	—	180,497	—	11,360	501,578
Former Chief Scientific Officer	2017	300,451	—	31,262	45,518	14,468	391,699

(1) In accordance with SEC rules, this column reflects the aggregate grant date fair value of stock options granted to our named executive officers during fiscal year ended December 31, 2017 under our 2006 Plan and during fiscal year ended December 31, 2018 under our 2018 Plan, computed in accordance with ASC 718. The valuation assumptions used in calculating the fair value of the stock options are included in Note 8 to our financial statements included elsewhere in this Annual Report. These amounts do not reflect the actual economic value that may be realized by the named executive officer upon the vesting of the stock options, the exercise of the stock options, or the sale of the common stock underlying such stock options.

(2) Amounts reported represent bonuses earned for 2017 and paid in 2018 and earned in 2018 and paid in 2019 at the discretion of our board of directors.

(3) Amounts for 2018 reflect the following: $11,000 for 401(k) matching contributions and $360 for life insurance premiums.

(4) Dr. Cao ceased serving as our Chief Scientific Officer effective November 5, 2018 and terminated services with us on December 7, 2018.

Annual Base Salary

The compensation of our named executive officers is generally determined and approved by our board of directors, based on the recommendation of the compensation committee of our board of directors. The 2018 base salaries that became effective as of January 1, 2018 were as follows:

NAME	2018 BASE SALARY ($)
R. Erik Holmlin, Ph.D.	389,986
Mike Ward	298,091
Han Cao, Ph.D.	309,465
Warren Robinson	295,000

Bonus Opportunity

In addition to base salaries, our named executive officers are eligible to receive annual performance-based cash bonuses, which are designed to provide appropriate incentives to our executives to achieve defined annual performance goals and to reward our executives for individual achievement towards these goals. The annual performance-based bonus each named executive officer is eligible to receive is generally based on the extent to which we achieve the corporate goals that our compensation committee establishes each year and, for all except Dr. Holmlin, the individual's contributions to such achievements. Dr. Holmlin's payout is based entirely on Company performance, Dr. Cao's payout is based on Company performance (25% weighting) and his individual performance (75% weighting), and Mr. Ward's and Robinson's payouts are based on Company performance (50% weighting) and his individual performance (50% weighting). At the end of the year, our board of directors reviews each executive's performance and determines the actual bonus payout to be awarded to each of our named executive officers.

For 2018, the target bonus for Dr. Holmlin was 40% of base salary, for Mr. Ward was 30% of base salary, for Mr. Robinson was 35% of base salary and for Dr. Cao was 20% of base salary. Our corporate performance objectives for 2018, as established by our compensation committee, included achievement of our 2018 operating plan, launch of our Saphyr instrument, accomplishment of product

development milestones, entry into product development and marketing arrangements and securing additional financing. In March 2018, our board of directors approved a 85% overall achievement level of our corporate goals and awarded bonuses to our named executive officers, except for Dr. Cao who terminated service prior to year-end, based on Company achievements and, except for Dr. Holmlin, on individual performance in 2018.

Equity-Based Incentive Awards

We believe that our ability to grant equity-based awards is a valuable and necessary compensation tool that aligns the long-term financial interests of our employees, consultants and directors with the financial interests of our stockholders. In addition, we believe that our ability to grant equity-based awards helps us to attract, retain and motivate employees, consultants and directors, and encourages them to devote their best efforts to our business and financial success. Our board of directors is responsible for approving equity grants. Vesting of equity awards is generally tied to continuous service with us and serves as an additional retention measure. Our executives generally are awarded an initial new hire grant upon commencement of employment. Additional grants may occur periodically in order to specifically incentivize executives with respect to achieving certain corporate goals or to reward executives for exceptional performance.

Prior to our IPO, we granted all equity awards pursuant to the 2006 Plan. All options are granted with a per share exercise price equal to no less than the fair market value of a share of our common stock on the date of the grant of such award. Generally our stock option awards vest over a three-year period subject to the holder's continuous service to us.

In August 2018, our board of directors amended all outstanding options held as of such date by Dr. Holmlin and Mr. Ward such that, contingent upon and following the date of the underwriting agreement related to our IPO, the vesting of all such awards will be suspended until such time as the closing price of our common stock is at least $12.00 per share for 90 consecutive trading days, at which point the suspension will automatically and immediately lapse and the awards will vest to the extent they otherwise would have vested pursuant to their terms and notwithstanding the suspension and will continue to vest thereafter under their original vesting schedules. In addition, the suspension will lapse as to the awards held by Dr. Holmlin or Mr. Ward upon Dr. Holmlin's or Mr. Ward's respective death, disability or upon a change in control of the Company, as such terms are defined in the 2018 Plan.

In October 2018, our board of directors granted options to purchase 256,540 shares to Dr. Holmlin, 23,230 shares to Dr. Cao, 64,640 shares to Mr. Robinson and 59,590 shares to Mr. Ward. Each option has an exercise price of $7.77 per share and vests as follows: 25% of the shares vest immediately on the grant date and the balance of the shares vest in a series of 36 successive equal monthly installments thereafter, provided in each case that the holder is then providing services to us in accordance with the terms of the 2018 Plan. For additional information, please see below under"Outstanding Equity Awards at Fiscal Year-End."

Agreements with Our Named Executive Officers

Below are descriptions of our employment agreements with our named executive officers. For a discussion of the severance pay and other benefits to be provided in connection with a termination of employment and/or a change in control under the arrangements with our named executive officers, please see "—Potential Payments upon Termination or Change in Control" below.

Dr. Holmlin. We entered into an employment agreement with Dr. Holmlin in January 2011, as amended in March 2011 and in November 2017, which governs the current terms of his employment with us. Pursuant to the agreement, as amended, Dr. Holmlin was entitled to an initial annual base salary of $315,000 and is eligible to receive an annual performance bonus with a target of 40% of his base salary, with a higher amount possible if goals exceeding target are achieved, as determined by our compensation committee and subject to approval by our board of directors. In addition, Dr. Holmlin was eligible to receive an option to purchase shares of the Company's common stock representing 5.0% of the fully-diluted equity shares immediately subsequent to the closing of a Series B transaction, which were equal to 2,992 shares of our common stock and were granted in 2011. In addition, Dr. Holmlin's agreement provided for additional options to be granted in connection with specified events in order to maintain Dr. Holmlin's ownership percentage, pursuant to which Dr. Holmlin was granted additional options to purchase 1,115 shares in 2012 and 2,546 shares in 2015. No obligations to make additional grants to maintain Dr. Holmlin's ownership percentage remain under his employment agreement. Dr. Holmlin's employment is at will.

Mr. Ward. We entered into an employment agreement with Mr. Ward in July 2016, which governs the current terms of his employment with us. Pursuant to the agreement, Mr. Ward was entitled to an initial annual base salary of $278,250 and is eligible to receive an annual performance bonus with a target amount of up to 30% of his base salary, as determined by our board of directors. Mr. Ward's employment is at will.

Mr. Robinson. We entered into an employment agreement with Mr. Robinson in November 7, 2017, which governs the current terms of his employment with us. Pursuant to the agreement, Mr. Robinson was entitled to an initial annual base salary of $275,392 and is eligible to receive an annual performance bonus with a target amount of up to 30% of his base salary (subsequently increased to 35%), as determined by our board of directors. Mr. Robinson's employment is at will.

Dr. Cao. We entered into an employment agreement with Dr. Cao in July 2011, as amended in November 2017, which governed the terms of his employment with us. Pursuant to the agreement, Dr. Cao was entitled to an initial annual base salary of $250,000 and a one-time signing bonus of $40,000 in cash. Dr. Cao received certain benefits in connection with his relocation, which were paid in 2012. Dr. Cao was eligible to receive an annual performance bonus with a target amount of 20% of his base salary based on the Company's performance (25% weighting) and Dr. Cao's individual performance (75% weighting), as determined by our board of directors. In addition, Dr. Cao was eligible to receive an option to purchase a number of shares of the Company's common stock that, together with shares and/or options then owned by Dr. Cao and the shares of Series B preferred stock of the Company that was to be issued to Dr. Cao as described in his employment agreement, represented no less than 7.5% of the total outstanding shares of the common stock of the Company on a fully diluted basis, which was equal to 2,344 shares of our common stock and was granted in 2011. No obligations to make additional grants to maintain Dr. Cao's ownership percentage remain under his employment agreement. Dr. Cao was also entitled to a bonus consisting of 240,800 shares of Series B preferred stock of the Company pursuant to the terms of a restricted stock purchase agreement entered into in August 2011. Dr. Cao's employment ceased December 7, 2018.

Potential Payments upon Termination or Change in Control

Regardless of the manner in which a named executive officer's service terminates, each named executive officer is entitled to receive amounts earned during his term of service, including unpaid salary and unused vacation. In addition, each of our named executive officers is eligible to receive certain benefits pursuant to his employment agreement with us, as described below. For the definitions of "cause," "good reason" and "disability" referenced below, please refer to the individual employment agreements with each of our named executive officers.

Dr. Holmlin. Upon Dr. Holmlin's termination for any reason other than death, disability, cause or resignation without good reason, and subject to Dr. Holmlin's execution of a release, Dr. Holmlin shall be eligible to receive (i) a lump sum amount equal to nine months of base salary, (ii) accelerated vesting of any options or restricted shares that would have vested within 18 months after the date of termination and (iii) premiums for continued health coverage for nine months following the date of termination, or until Dr. Holmlin is no longer eligible for continuation coverage, whichever is earlier. In the event of termination due to disability, and subject to Dr. Holmlin's execution of a release, Dr. Holmlin shall be eligible to receive accelerated vesting in full for any unvested portion of the options granted pursuant to his agreement. In the event of a deemed liquidation event (as defined in Dr. Holmlin's employment agreement), the options granted to Dr. Holmlin pursuant to his agreement shall vest in full.

Mr. Ward. Upon termination without cause, and subject to Mr. Ward's execution of a release, Mr. Ward will be eligible to receive (i) six months of continued base salary payments at the rate in effect at the time of termination and (ii) premiums for continued health coverage for six months following the date of termination or until Mr. Ward is no longer eligible for continuation coverage or he becomes eligible for new healthcare eligibility available through new employment, whichever is earlier.

Mr. Robinson. Upon termination without cause, and subject to Mr. Robinson's execution of a release, Mr. Robinson will be eligible to receive (i) six months of continued base salary payments at the rate in effect at the time of termination and (ii) premiums for continued health coverage for six months following the date of termination or until Mr. Robinson is no longer eligible for continuation coverage or he becomes eligible for new healthcare eligibility available through new employment, whichever is earlier.

Dr. Cao. Prior to his termination, Dr. Cao was entitled to the following benefits under his employment agreement with us. Upon Dr. Cao's termination without cause or resignation for good reason, and subject to Dr. Cao's execution of a release, Dr. Cao was eligible to receive (i) six months of continued base salary, to be paid on the Company's normal pay days commencing with the first regular payroll date of the Company following the effective date of the release, and (ii) premiums for continued health coverage for a period of six months following the date of termination or until Dr. Cao was no longer eligible for such coverage, whichever is earlier. In addition, Dr. Cao's unvested options would immediately vest as if Dr. Cao had been employed for an additional six months from the date of termination, since more than two years has passed from start of Dr. Cao's employment. Upon Dr. Cao's termination by death or disability, Dr. Cao's unvested options would immediately vest as if Dr. Cao had been employed for an additional six months from the date of termination, since more than two years has passed from the start of Dr. Cao's employment. Under the terms of Dr. Cao's employment agreement, he received only his final regular salary payment and payment of unused vacation time when terminated service with us on December 7, 2018.

Each of our named executive officers holds stock options under the 2006 Plan that were granted subject to the general terms of the 2006 Plan and the form of stock option agreement. The specific vesting terms of each named executive officer's stock options are described below under "—Outstanding Equity Awards at Fiscal Year-End."

Outstanding Equity Awards at Fiscal Year-End

The following table presents information regarding outstanding equity awards held by our named executive officers as of December 31, 2018.

		Option Awards[1]			
Name	Grant Date	Number of Securities Underlying Unexercised Options Exercisable	Number of Securities Underlying Unexercised Options Unexercisable	Option Exercise Price Per Share[2]	Option Expiration Date
R. Erik Holmlin, Ph.D[6]	10/1/2018[3]	74,824	153,605	$ 7.77	10/1/2028
	2/7/2017[4]	96,243	57,744	$ 1.28	2/6/2027
	1/29/2015	4,146	592	$ 64.20	1/28/2025
	1/29/2015	2,546	—	$ 64.20	1/28/2025
	6/20/2012	1,115	—	$ 68.48	6/19/2022
	5/16/2011	2,992	—	$ 42.80	5/15/2021
Mike Ward[6]	10/1/2018[3]	17,379	42,211	$ 7.77	10/1/2028
	2/7/2017[4]	14,971	19,248	$ 1.28	2/6/2027
	1/29/2015[5]	697	317	$ 64.20	1/28/2025
	4/21/2014[5]	535	76	$ 81.32	4/20/2024
Warren Robinson	10/1/2018[3]	18,853	45,787	$ 7.77	10/1/2028
	2/7/2017	19,997	9,089	$ 1.28	2/6/2027
	11/9/2015	876	292	$ 64.20	11/9/2025
Han Cao, Ph.D.	10/1/2018[3]	5,441	—	$ 7.77	3/7/2019
	10/1/2018[3]	1,333	—	$ 7.77	3/7/2019
	2/7/2017[4]	22,456	—	$ 1.28	3/7/2019
	1/29/2015[5]	2,398	—	$ 64.20	3/7/2019
	1/29/2015	1,599	—	$ 64.20	3/7/2019
	8/10/2011	2,344	—	$ 42.80	3/7/2019
	4/2/2010	46	—	$ 38.52	3/7/2019
	1/15/2009	46	—	$ 291.04	1/15/2019

(1) Option awards were granted under the 2006 Plan and 2018 Plan.

(2) All of the option awards were granted with a per share exercise price equal to the fair market value of one share of our common stock on the date of grant, as determined in good faith by our board of directors.

(3) Each option award vests as follows: 25% of the shares subject to the option vest on the date of grant and the balance of the shares vest in a series of 36 successive equal monthly installments thereafter, provided in each case that the holder is then providing services to us in accordance with the terms of the 2018 Plan.

(4) Each option award vests as follows: 25% of the shares subject to the option are fully vested and 6.25% of the shares subject to the option vest at the end of each three month anniversary of the vesting commencement date, subject to single trigger acceleration of vesting in connection with a change of control, provided in each case that the holder is then providing services to us in accordance with the terms of the 2006 Plan.

(5) Each option award vests as follows: 25% of the shares subject to the option shall vest at the end of the first anniversary of the vesting commencement date, and 6.25% of the shares subject to the option vest at the end of each three month anniversary of the vesting commencement date, subject to single trigger acceleration of vesting in connection with a change of control, provided in each case that the holder is then providing services to us in accordance with the terms of the 2006 Plan.

(6) All outstanding options, other than the 2018 grant, held by Dr. Holmlin and Mr. Ward were amended by our board of directors in August 2018 to suspend the vesting until the achievement of certain milestones, as further described above under "—Equity-Based Incentive Awards."

Perquisites, Health, Welfare and Retirement Benefits

All of our current named executive officers are eligible to participate in our employee benefit plans, including our medical, dental, vision, life, disability and accidental death and dismemberment insurance plans, in each case on the same basis as all of our other employees.

We pay the premiums for the life, disability, accidental death and dismemberment insurance for all of our employees, including our named executive officers. In addition, we provide a 401(k) plan to our employees, including our named executive officers, as discussed in the section below entitled "—401(k) Plan." We generally do not provide perquisites or personal benefits to our named executive officers.

Nonqualified Deferred Compensation

Our named executive officers did not participate in, or earn any benefits under, a nonqualified deferred compensation plan sponsored by us during the fiscal year ended December 31, 2018. Our board of directors may elect to provide our officers and other employees with nonqualified defined contribution or other nonqualified deferred compensation benefits in the future if it determines that doing so is in our best interests.

Equity Benefit Plans

The principal features of our equity plans are summarized below. These summaries are qualified in their entirety by reference to the actual text of the plans, which are filed as exhibits hereto and incorporated herein by reference.

2018 Equity Incentive Plan

Our 2018 Plan became effective upon our IPO following approval by our board of directors and our stockholders. Our 2018 Plan provides for the grant of incentive stock options, or ISOs, within the meaning of Section 422 of the Code, to employees, including employees of any parent or subsidiary, and for the grant of nonstatutory stock options, or NSOs, stock appreciation rights, restricted stock awards, restricted stock unit awards, performance stock awards, performance cash awards and other forms of stock awards to employees, directors and consultants, including employees and consultants of our affiliates. Our 2018 Plan is a successor to and continuation of our 2006 Plan. Our compensation committee has the authority, concurrent with our board of directors, to administer our 2018 Plan, and may also delegate to one or more of our officers certain authority under the terms of the 2018 Plan.

Stock options under the 2018 Plan are generally granted with an exercise price equal to the fair market value of our common stock on the date of grant. Options granted under the 2018 Plan vest at the rate specified in the stock option agreement as determined by the plan administrator. Options may have a term up to a maximum of 10 years. Unless the terms of an optionee's stock option agreement provides otherwise, if an optionee's service relationship with us, or any of our affiliates, ceases for any reason other than disability, death or cause, the optionee may generally exercise any vested options for a period of three months following the cessation of service. If an optionee's service relationship with us, or any of our affiliates, ceases due to disability or death, or an optionee dies within a certain period following cessation of service, the optionee or a beneficiary may generally exercise any vested options for a period of 12 months in the event of disability and 18 months in the event of death. In the event of a termination for cause, options generally terminate immediately upon the termination of the individual. In no event may an option be exercised beyond the expiration of its term.

Our 2018 Plan provides that in the event of certain specified significant corporate transactions (or a change in control, as defined below), unless otherwise provided in an award agreement or other written agreement between us and the award holder, the administrator may take one or more of the following actions with respect to such stock awards:

- arrange for the assumption, continuation, or substitution of a stock award by a successor corporation;
- arrange for the assignment of any reacquisition or repurchase rights held by us to a successor corporation;
- accelerate the vesting, in whole or in part, of the stock award and provide for its termination if not exercised (if applicable) at or before the effective time of the transaction;
- arrange for the lapse, in whole or in part, of any reacquisition or repurchase rights held by us;
- cancel or arrange for the cancellation of the stock award, to the extent not vested or not exercised before the effective time of the transaction, in exchange for a cash payment, if any, as determined by the board; or
- make a payment, in the form determined by our board of directors, equal to the excess, if any, of (A) the value of the property the participant would have received on exercise of the award immediately before the effective time of the transaction, over (B) any exercise price payable by the participant in connection with the exercise.

The plan administrator is not obligated to treat all stock awards or portions of stock awards, even those that are of the same type, in the same manner and is not obligated to treat all participants in the same manner.

Under the 2018 Plan, a corporate transaction is generally the consummation of: (1) a sale of all or substantially all of our assets, (2) the sale or disposition of more than 50% of our outstanding securities, (3) a merger or consolidation where we do not survive the transaction, or (4) a merger or consolidation where we do survive the transaction but the shares of our common stock outstanding immediately before such transaction are converted or exchanged into other property by virtue of the transaction.

In the event of a change in control, the board of directors may take any of the above-mentioned actions. Awards granted under the 2018 Plan will not receive automatic acceleration of vesting and exercisability in the event of a change in control, although this treatment may be provided for in an award agreement or other written agreement between the Company and the participant. Under the 2018 Plan, a change in control is generally (1) the acquisition by any person or company of more than 50% of the combined voting power of our then outstanding stock, (2) a merger, consolidation or similar transaction in which our stockholders immediately before the transaction do not own, directly or indirectly, more than 50% of the combined voting power of the surviving entity (or the parent of the surviving entity), (3) a sale, lease, exclusive license or other disposition of all or substantially all of our assets other than to an entity more than 50% of the combined voting power of which is owned by our stockholders, (4) a complete dissolution or liquidation of the Company, or (5) when a majority of our board of directors becomes comprised of individuals who were not serving on our board of directors on the date of the underwriting agreement related to our IPO, or the incumbent board, or whose nomination, appointment, or election was not approved by a majority of the incumbent board still in office.

Amended and Restated 2006 Equity Compensation Plan

Our board of directors adopted and our stockholders originally approved our 2006 Plan in September 2006, and it was subsequently amended and restated in September 2008 and most recently amended in March 2016. No further grants may be made under our 2006 Plan following our IPO, however outstanding awards granted under our 2006 Plan remain subject to the terms of our 2006 Plan and applicable award agreements.

Our 2006 Plan allowed for the grant of ISOs to employees, including employees of any subsidiary, and for the grant of NSOs, stock appreciation rights, restricted stock awards and restricted stock units and other equity awards to employees, directors and consultants, including employees and consultants of our subsidiaries. Our compensation committee has the authority, concurrent with our board of directors, to administer our 2006 Plan. Unless the terms of an optionee's stock option agreement provides otherwise, if an optionee's service relationship with us, or any of our affiliates, ceases for any reason other than disability, death or cause, the optionee may generally exercise any vested options for a period of three months following the cessation of service. If an optionee's service relationship with us, or any of our affiliates, ceases due to disability or death, or an optionee dies within a certain period following cessation of service, the optionee or a beneficiary may generally exercise any vested options for a period of 12 months in the event of disability or death. In the event of a termination for cause, options generally terminate immediately upon the termination of the individual. In no event may an option be exercised beyond the expiration of its term.

Our 2006 Plan provides that in the event of a change of control, all awards granted under the 2006 Plan shall become fully vested and exercisable (as applicable), unless the board of directors determines otherwise. In the event of a change of control, the administrator may take any of the following actions with respect to any or all outstanding awards: (i) determine that all outstanding options and stock appreciation rights that are not exercised shall be assumed by, or replaced with comparable options by the surviving corporation (or a parent or subsidiary of the surviving corporation), and other outstanding grants that remain in effect after the change of control shall be converted to similar grants of the surviving corporation (or a parent or subsidiary of the surviving corporation), (ii) require that grantees surrender their outstanding options and stock appreciation rights in exchange for one or more payments, in cash or Company stock as determined by the board of directors, in an amount, if any, equal to the amount by which the then fair market value of the shares of Company stock subject to the grantee's unexercised options and stock appreciation rights exceeds the exercise price or base amount of the options and stock appreciation rights, on such terms as the board of directors determines, or (iii) after giving grantees an opportunity to exercise their outstanding options and stock appreciation rights, terminate any or all unexercised options and stock appreciation rights at such time as the board of directors deems appropriate.

Such assumption, surrender or termination shall take place as of the date of the change of control or such other date as the board of directors may specify.

Under the 2006 Plan, a change of control is generally (1) the acquisition by any person or company of more than 50% of the combined voting power of our then outstanding stock, (2) the consummation of a merger or consolidation with another corporation where our stockholders, immediately prior to the merger or consolidation, will not beneficially own, immediately after the merger or consolidation, shares entitling such stockholders to more than 50% of all votes to which all stockholders of the surviving corporation would be entitled in the election of directors, (3) the consummation of a sale or other disposition of all or substantially all of our assets, or (4) the consummation of a liquidation or dissolution.

2018 Employee Stock Purchase Plan

Additional long-term equity incentives are provided through the 2018 Employee Stock Purchase Plan, or the ESPP, which became effective in connection with our IPO. The ESPP is intended to qualify as an "employee stock purchase plan" within the meaning of Section 423 of the Code. Our compensation committee has the authority, concurrent with our board of directors, to administer the ESPP. Under the ESPP, generally all of our regular employees (including our Named Executive Officers during their employment with us) may participate and may contribute, normally through payroll deductions, up to 15% of their earnings for the purchase of our common stock.

The ESPP is implemented through a series of offerings of purchase rights to eligible employees. Under the ESPP, we may specify offerings with a duration of not more than 27 months, and may specify shorter purchase periods within each offering. Each offering will have one or more purchase dates on which our common stock will be purchased for employees participating in the offering. Unless otherwise determined by our compensation committee, shares are purchased for accounts of employees participating in the ESPP at a price per share equal to the lower of (a) 85% of the fair market value of our common stock on the first date of an offering or (b) 85% of the fair market value of our common stock on the date of purchase.

401(k) Plan

We maintain a defined contribution employee retirement plan, or 401(k) plan, for our employees. Our named executive officers are eligible to participate in the 401(k) plan on the same basis as our other employees. The 401(k) plan is intended to qualify as a tax-qualified plan under Section 401(k) of the Code. The plan permits us to make discretionary contributions, including matching contributions and discretionary profit sharing contributions. The 401(k) plan currently does not offer the ability to invest in our securities.

Director Compensation

Our board of directors adopted a non-employee director compensation policy in July 2018 that became effective upon our IPO and that is applicable to each member of our board of directors who is not also serving as an employee or consultant to the Company. This compensation policy provides that each such non-employee director will receive the following compensation for service on our board of directors:

- an annual cash retainer of $30,000;
- an additional annual cash retainer of $20,000 for service as chairman of the board of directors;
- an additional annual cash retainer of $15,000, $10,000 and $10,000 for service as chair of the audit committee, compensation committee and the nominating and corporate governance committee, respectively;
- an additional annual cash retainer of $7,500, $5,000 and $5,000 for service as a member of the audit committee, compensation committee and the nominating and corporate governance committee, respectively (not applicable to committee chairs);
- an initial option grant to purchase common stock with an aggregate Black-Scholes option value of $50,000 on the date of each such non-employee director’s appointment to our board of directors; and
- an annual option grant to purchase common stock with an aggregate Black-Scholes option value of $35,000 on the date of each of our annual stockholder meetings.

Each of the option grants described above will be granted under our 2018 Plan, the terms of which are described in more detail above under "Equity Benefit Plans." Each such option grant will vest and become exercisable subject to the director’s continuous service to us, provided that each option will vest in full upon a change in control (as defined in the 2018 Plan). The term of each option will be 10 years, subject to earlier termination as provided in the 2018 Plan, provided that upon a termination of service other than for death, disability or cause, the post-termination exercise period will be 12 months from the date of termination. An eligible director may decline all or any portion of his or her compensation by giving notice to the Company prior to the date cash may be paid or equity awards are to be granted, as the case may be. Our board of directors determined that each of our non-employee directors would receive the grant of an initial option under the non-employee director compensation policy in connection with our initial public offering and such grants were effective on October 1, 2018.

We have reimbursed and will continue to reimburse all of our non-employee directors for their reasonable out-of-pocket expenses incurred in attending board of directors and committee meetings. Dr. Holmlin, our President and Chief Executive Officer, is also a director but did not receive any additional compensation for his service as a director.

The following table sets forth in summary form information concerning the compensation that was earned by each of our non-employee directors during the year ended December 31, 2018:

NAME	FEES EARNED OR PAID IN CASH	OPTION AWARDS ($)[1]	TOTAL ($)
David L. Barker, Ph.D.	$ 24,395	$ 50,000	$ 74,395
Darren Cai, Ph.D.	$ 12,649	$ 50,000	$ 62,649
Brian K. Halak, Ph.D.[2]	$ —		
Albert Luderer, Ph.D.	$ 17,167	$ 50,000	$ 67,167
Junfeng Wang	$ 14,457	$ 50,000	$ 64,457
Christopher Twomey[3]	$ 16,254	$ 50,000	$ 66,254
Quan Zhou[4]	$ 12,649	$ 50,000	$ 62,649

(1) The amounts reported reflect the aggregate grant date fair value of each equity award granted to our non-employee directors during the fiscal year ended December 31, 2018, as computed in accordance with Financial Accounting Standard Board Accounting Standards Codification Topic 718 for stock-based compensation transactions (ASC 718). Assumptions used in the calculation of these amounts are included in Note 2 to our financial statements for the fiscal year ended December 31, 2018. As required by SEC rules, the amounts shown exclude the impact of estimated forfeitures related to service-based vesting conditions. These amounts do not reflect the actual economic value that will be realized by our non-employee directors upon the vesting of the stock options, the exercise of the stock options, or the sale of the common stock underlying such stock options. As of December 31, 2018, the aggregate number of shares outstanding under all options to purchase our common stock held by our non-employee directors were: Dr. Barker, 23,906; Dr. Cai, 10,516; Dr. Halak, 5,155; Dr. Luderer 19,697; Mr. Wang, 10,516; Mr. Towmey, 10,516, and Mr. Zhou, 10,516.

(2) Dr. Halak resigned from our Board of Directors in May 2018.

(3) Mr. Twomey was appointed to our Board of Directors in July 2018.

(4) Mr. Zhou was appointed to our Board of Directors in July 2018.

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

PRINCIPAL STOCKHOLDERS

The following table sets forth information regarding beneficial ownership of our capital stock by:

- each person, or group of affiliated persons, known by us to beneficially own more than 5% of our common stock;
- each of our directors;
- each of our named executive officers; and
- all of our current executive officers and directors as a group.

The following table is based upon information supplied by officers, directors and principal stockholders and Schedules 13D and 13G filed with the SEC. Unless otherwise indicated in the footnotes to this table and subject to community property laws where applicable, the Company believes that each of the stockholders named in this table has sole voting and investment power with respect to the shares indicated as beneficially owned. Applicable percentages are based on 10,096,407 shares of our common stock outstanding on March 11, 2019, adjusted as required by rules promulgated by the SEC. Unless otherwise indicated, the address for the following stockholders is care of: Bionano Genomics, Inc., 9640 Towne Centre Drive, Suite 100, San Diego, CA 92121.

Unless otherwise indicated, the address for each beneficial owner listed in the table below is c/o Bionano Genomics, Inc., 9640 Towne Centre Drive, Suite 100, San Diego, California 92121.

Name of Beneficial Owner	Shares Owned Directly	Options Exercisable within 60 Days of 3/11/2019	Warrants	Number of Shares Beneficially Owned[1]	%[2]
Greater than 5% Stockholders					
LC Fund VI, L.P. and Affiliates[3]	2,906,915		—	2,906,915	28.8%
Wealth Strategy Holding Limited [4]	975,000		975,000	1,950,000	17.6%
AIGH Capital Management, LLC and Affiliates[5]	651,802			651,802	6.5%
Entities affiliated with Domain Partners VIII, L.P.[6]	950,769		15,000	965,769	9.6%
Sio Capital Management, LLC[7]	714,842		675,000	1,389,842	12.9%
ETP Global Fund, LP[8]	680,400		325,000	1,005,400	9.6%
Directors and Named Executive Officers	**	**	**	**	
David L. Barker, Ph.D.	3,894	13,025	3,894	20,813	0.2%
Darren Cai, Ph.D.	—	2,044	—	2,044	—%
Han Cao, Ph.D.	138,287	—	—	138,287	1.4%
R. Erik Holmlin, Ph.D.	1,848	238,053	1,630	241,531	2.3%
Albert Luderer, Ph.D.	—	9,584	—	9,584	0.1%
Warren Robinson	826	52,741	—	53,567	0.5%
Christopher Twomey	10,000	2,044	10,000	22,044	0.2%
Junfeng Wang[3]	2,906,915	2,044	—	2,908,959	28.8%
Mike Ward	—	53,019	—	53,019	0.5%
Quan Zhou[3]	2,906,915	2,044	—	2,908,959	28.8%
All directors and executive officers as a group (11 persons)[9]	**5,975,995**	**424,117**	**16,339**	**6,416,451**	**60.9%**
Shares outstanding as of 3/11/2019	**9,948,808**	**—**	**2,006,339**	**10,096,407**	

* Represents beneficial ownership of less than 1%.

(1) Beneficial ownership is determined in accordance with SEC rules. In computing the beneficial ownership we have included shares for which the named person has sole or shared power over voting or investment decisions. The number of shares of common stock beneficially owned includes common stock which the named person has the right to acquire, through option exercise or otherwise, within 60 days after March 11, 2019.

(2) For each named person, the percentage ownership includes common stock that the person has the right to acquire within 60 days after March 11, 2019, as described in Footnote 1. However, such shares are not deemed outstanding with respect to the calculation of ownership percentage for any other person. In some cases, beneficial ownership calculations for five percent or greater stockholders are based solely on publicly-filed Schedules 13D or 13G, which five percent or greater stockholders are required to file with the SEC, and which generally set forth ownership interests as of December 31, 2018 unless otherwise provided.

(3) Consists of (i) 426,900 shares of common stock held by LC Fund VI, L.P., (ii) 20,656 shares of common stock held by LC Parallel Fund VI, L.P., (iii) 325,359 shares of common stock held by LC Healthcare Fund I, L.P., and (iv) 1,134,000 shares of common stock held by Rosy Shine Limited, (v) 2,044 shares of common stock subject to options exercisable as of May 11, 2019 held by Junfeng Wang and (vi) 2,044 shares of common stock subject to options exercisable as of May 11, 2019 held by Quan Zhou. Each of LC Fund VI, L.P., LC Parallel Fund VI, L.P., and LC Healthcare Fund I, L.P., collectively referred to as the LC Funds, are ultimately controlled and managed by Legend Capital, a limited liability Chinese company. Legend Capital is ultimately controlled by a management team consisting of three key individuals, Linan Zhu, Hao Chen, and Nengguang Wang. In addition, Junfeng Wang is a Managing Director of Legend Capital. Each of these individual managers of Legend Capital shares voting and investment power over the shares held by the LC Funds and each disclaims beneficial ownership of all shares held by Legend Capital, except to the extent of each such member's actual pecuniary interest therein. Rosy Shine Limited is ultimately controlled and managed by Legend Holdings, a limited liability Chinese joint stock company listed on a Stock Exchange of Hong Kong (3396), which is controlled by its board of directors. The board of directors of Legend Holdings has sole voting and investment power over the shares held by Rosy Shine Limited. None of the members of the board of directors has individual voting or investment power with respect to such shares and each disclaims beneficial ownership of such shares. The address of the each of the above entities is

Legend Capital, 10F, Tower A, Raycom Infotech Park, No.2, Kexueyuan South Road, Zhongguancun, Haidian District, Beijing 100190 PRC.

(4) Based solely on a Schedule 13G filed with the SEC by the reporting person on December 14, 2018, the indicated ownership consists of 975,000 shares of common stock and 975,000 shares of common stock issuable upon the exercise of warrants held by Wealth Strategy Holding Limited. According to the Schedule 13G, Mr. Kung Hung Ka may be deemed to have sole voting and dispositive power with respect to the shares held by Wealth Strategy Holding Limited. The Schedule 13G/A filed by the reporting person provides information as of August 21, 2018 and, consequently, the beneficial ownership of the reporting person may have changed between August 21, 2018 and March 11, 2019. The address for Wealth Strategy Holding Limited listed in the Schedule 13G is Level 12, International Commerce Centre, 1 Austin Road West, Kowloon, Hong Kong.

(5) Based solely on a Schedule 13G filed with the SEC by the reporting person on February 15, 2019, the indicated ownership consists of (1) 651,802 shares of common stock held by AIGH Capital Management, LLC and (ii) 651,802 shares of common stock held by Orin Hirschman. According to the Schedule 13G, Mr. Hirschman is the Managing Member of AIGH Capital Management, LLC and may be deemed to have sole voting and dispositive power with respect to the shares held by AIGH Capital Management, LLC and himself. The Schedule 13G/A filed by the reporting person provides information as of December 31, 2018 and, consequently, the beneficial ownership of the reporting person may have changed between December 31, 2018 and March 11, 2019. The address of both AIGH Capital Management, LLC and Mr. Hirschman is 6006 Berkeley Avenue, Baltimore, MD 21209.

(6) Based solely on a Schedule 13G filed with the SEC by the reporting person on January 11, 2019, the indicated ownership consists of (i) 958,878 shares of common stock and 15,000 shares of common stock issuable upon the exercise of warrants held by Domain Partners VIII, L.P. and (ii) 6,891 shares of common stock held by DP VIII Associates, L.P.. James C. Blair, Brian H. Dovey, Brian K. Halak, Jesse I. Treu and Nicole Vitullo, the managing members of One Palmer Square VIII, L.L.C., share voting and investment power over the shares held by Domain Partners VIII, L.P. and DP VIII Associates, L.P. The Schedule 13G/A filed by the reporting person provides information as of December 31, 2018 and, consequently, the beneficial ownership of the reporting person may have changed between December 31, 2018 and March 11, 2019. The address for the Domain Entities is One Palmer Square, Suite 515, Princeton, NJ 08542.

(7) Based solely on a Schedule 13G filed with the SEC by the reporting person on February 14, 2019, the indicated ownership consists of 714,842 shares of common stock held by Sio Capital Management, LLC. According to the Schedule 13G, Sio Capital Management, LLC, or Sio, and Sio GP, LLC, or GP, act as investment advisor and general partner, respectively, to various clients that are the record owners of the common stock held by Sio. Because Sio's investment discretion with respect to such clients is subject to oversight by the GP, the GP may be deemed to be the beneficial owner of the common stock owned by such clients. Both Sio and the GP are controlled by Michael Castor, who may be deemed to control the voting and dispositive decisions with respect to the shares of common stock held by Sio. The Schedule 13G/A filed by the reporting person provides information as of December 31, 2018 and, consequently, the beneficial ownership of the reporting person may have changed between December 31, 2018 and March 11, 2019. The address for Sio is 535 Fifth Avenue, Suite 910, New York, New York 10017.

(8) ETP Global Fund, LP, or ETP Global, is a limited partnership organized under the laws of the State of Delaware. Emerging Technology Partners LLC is the general partner of ETP Global, and Wei-Wu He is its managing member, who exercises sole voting and investment power over the shares held by ETP Global. Wei-Wu He disclaims beneficial ownership of the shares held by ETP Global, except to the extent of his pecuniary interest therein. The registered address of ETP Global and Emerging Technology Partners LLC is 4919 Rebel Ridge Dr., Sugarland, TX 77478.

(9) Consists of shares identified in the list of Directors and Named Executive Officers above plus (i) 7,310 shares of common stock, (ii) 49,519 options exercisable within 60 days of 3/11/2019, and (iii) 815 warrants.

Equity Compensation Plan Information

The following table provides information as of December 31, 2018 with respect to equity compensation plans (including individual compensation arrangements) under which the Company's common stock is authorized for issuance.

Plan Category	Number of securities to be issued upon exercise of outstanding options and rights	Weighted average exercise price of outstanding options and rights	Number of securities remaining available for future issuance under equity compensation plans
Equity compensation plans approved by stockholders			
Amended and Restated 2006 Equity Compensation Plan	—	$ 5.14	—
2018 Equity Incentive Plan	1,499,454	$ 7.69	216,413
2018 Employee Stock Purchase Plan	175,000	$ 5.08	152,821
Equity compensation plans not approved by stockholders			
None			
Total	1,674,454	$ 6.87	369,234

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

Other than compensation arrangements for our directors and executive officers, which are described elsewhere in this Annual Report, below we describe transactions since January 1, 2017 to which we were a party or will be a party, in which:

- the amounts involved exceeded or will exceed the lesser of (a) $120,000 or (b) 1% of our total assets at December 31, 2017 or 2018; and
- any of our directors, executive officers or holders of more than 5% of our capital stock, or any member of the immediate family of, or person sharing the household with, the foregoing persons, had or will have a direct or indirect material interest.

Series D-1 Convertible Preferred Stock Financing

In August 2016, as well as January, February, March, April, May, July, August and November 2017, we issued and sold, in a series of closings, an aggregate of 66,141,257 shares of our Series D-1 convertible preferred stock at a purchase price of $0.48 per share for an aggregate gross proceeds of approximately $31.7 million. All purchasers of our Series D-1 convertible preferred stock are entitled to certain registration rights. See the section titled "Description of Securities—Registration Rights" for more information regarding these registration rights. The following table summarizes the Series D-1 convertible preferred stock purchased by affiliates of our executive officers and of members of our board of directors and holders of more than 5% of our outstanding capital stock:

Name of Participant	Shares of Series D-1 Convertible Preferred Stock		Aggregate Purchase Price
Entities affiliated with LC Fund VI, L.P.(1)	27,305,708	$	13,106,740
Praise Alliance International Limited	12,500,000	$	6,000,000
Full Succeed International Limited	10,416,667	$	5,000,000
Entities affiliated with Domain Partners VIII, L.P.(2)	3,710,247	$	1,780,918
Novartis Bioventures Ltd.	1,070,373	$	513,779
Han Cao, Ph.D.	104,167	$	50,000

(1) Includes (i) $1,883,867 in cash from LC Fund VI, L.P.; (ii) $11,106,738 in cash from LC Healthcare Fund I, L.P.; and (iii) $116,135 in cash from LC Parallel Fund VI, L.P.
(2) Includes (i) $1,767,801 in cash from Domain Partners VIII, L.P., and (ii) $13,117 in cash from DP VIII Associates, L.P.

Convertible Promissory Note Financing

In February 2018, we issued convertible promissory notes in the aggregate principal amount of approximately $13.4 million with an interest rate of 8% per annum. These convertible promissory notes provide for conversion under the following three circumstances:

Conversion at Qualifying financing – Upon the closing of an equity financing involving the sale by us of convertible preferred stock in which we receive an aggregate of at least $15.0 million in cumulative gross proceeds, the conversion price will equal 75% of the lowest per share cash purchase price of the convertible preferred stock sold by us in such qualified financing. The original principal amount and accrued interest under each convertible promissory note shall automatically convert into convertible preferred stock.

Conversion at Initial Public Offering – Prior to the maturity date of the convertible promissory notes, if we complete our initial public offering, the convertible promissory notes will automatically convert into shares of our common stock at an amount equal to the original principal amount and accrued interest under each convertible promissory note divided by 75% of either the per share cash purchase price of the common stock offered to the public in the initial public offering or the per unit cash purchase price of the units offered to the public in the initial public offering, as applicable.

Optional Conversion at Maturity – Upon maturity, and at the election of the holder, the convertible promissory notes will convert into shares of Series D-2 convertible preferred stock as is equal to the original principal amount and accrued interest under each convertible promissory note divided by the price per share. The price per share is defined as $60,000,000 divided by the aggregate number of outstanding shares of our common stock as of the maturity date.

In August 2018, the outstanding convertible promissory notes of $14.9 million of principal and interest were converted into 3,239,294 shares of common stock upon completion of the IPO. As of December 31, 2018, there are no convertible notes outstanding.

The participants in this note financing included the following members of our board of directors and holders of more than 5% of our outstanding capital stock:

Name of Participant	Total Principal Amount
Entities affiliated with LC Fund VI, L.P. (1)	$ 8,460,000
Entities affiliated with Domain Partners VIII, L.P.(2)	$ 1,500,000

(1) Includes (i) $3,460,000 in cash from LC Healthcare Fund I, L.P.; and (ii) $5,000,000 cash from Rosy Shine Limited.
(2) Includes (i) $1,488,952 in cash from Domain Partners VIII, L.P., and (ii) $11,048 in cash from DP VIII Associates, L.P.

One of our directors, Junfeng Wang, is affiliated with LC Fund VI, L.P. (and its affiliated entities that participated in the financings described above).

Investors' Rights Agreement

In August 2016, we entered into a fifth amended and restated investors' rights agreement, or the IRA, with certain holders of our preferred stock and common stock, including entities affiliated with LC Fund VI, L.P. and Domain Partners VIII, L.P. and including certain members of, and affiliates of, our directors and certain of our executive officers. The agreement was amended in July and August 2018. The IRA provides the holders of our preferred stock with certain registration rights, including the right to demand that we file a registration statement or request that their shares be covered by a registration statement that we are otherwise filing. After 12 months following the date of our initial public offering, the holders of 4,948,360 shares of our common stock issuable upon conversion of outstanding preferred stock will be entitled to rights with respect to the registration of their shares of common stock under the Securities Act under this agreement.

Indemnification Agreements

Our amended and restated certificate of incorporation contains provisions limiting the liability of directors, and our amended and restated bylaws provides that we will indemnify each of our directors and officers to the fullest extent permitted under Delaware law. Our amended and restated certificate of incorporation and amended and restated bylaws also provide our board of directors with discretion to indemnify our employees and other agents when determined appropriate by the board. In addition, we have entered into an indemnification agreement with each of our directors and executive officers, which requires us to indemnify them.

Policies and Procedures for Transactions with Related Persons

In 2018 we adopted a written policy that our executive officers, directors, nominees for election as a director, beneficial owners of more than 5% of any class of our common stock and any members of the immediate family of any of the foregoing persons are not permitted to enter into a related person transaction with us without the approval or ratification of our board of directors or our audit committee. Any request for us to enter into a transaction with an executive officer, director, nominee for election as a director, beneficial owner of more than 5% of any class of our common stock, or any member of the immediate family of any of the foregoing persons, in which the amount involved exceeds $120,000 and such person would have a direct or indirect interest, must be presented to our board of directors or our audit committee for review, consideration and approval. In approving or rejecting any such proposal, our board of directors or our audit committee is to consider the material facts of the transaction, including whether the transaction is on terms no less favorable than terms generally available to an unaffiliated third party under the same or similar circumstances and the extent of the related person's interest in the transaction.

Board Independence

The board has determined that, except for Mr. Holmlin, all of its members are independent directors as defined in the Nasdaq Stock Market listing standards. Mr. Holmlin is not considered independent because he is employed by us as our CEO. In addition to the board-level standards for director independence, all members of the audit committee, compensation committee and nominating and corporate governance committee are independent directors.

Item 14. Principal Accounting Fees and Services.

The following table summarizes the aggregate fees billed to the Company by its independent registered public accounting firm, Deloitte & Touche, LLP, for the fiscal years ended December 31, 2018 and 2017:

	2018	2017
Audit fees [1]	$ 1,020,000	$ 45,000
Audit-related fees [2]	49,000	—
Tax fees [3]	20,000	16,700
All other fees [4]	2,000	1,900
Total	$ 1,091,000	$ 63,600

(1) Audit fees consist of fees billed for professional services rendered for the audit of the consolidated annual financial statements of the Company, review of the interim condensed consolidated financial statements included in quarterly reports, review of the SEC-filings associated with the Company's IPO, and services that are normally provided by Deloitte & Touche, LLP in connection with statutory and regulatory filings or engagements.

(2) Audit-related fees consist of fees billed for assurance and related services that are reasonably related to the performance of the audit or review of the consolidated financial statements of the Company and are not reported under "Audit fees." For the fiscal years ended December 31, 2018 and 2017, these fees primarily related to miscellaneous professional services.

(3) Tax fees consist of fees billed for professional services rendered for tax compliance, advice and planning. For the fiscal years ended December 31, 2018 and 2017, these services included assistance regarding federal and state tax compliance and consultations regarding various income tax issues.

(4) All other fees for the fiscal year ended December 31, 2018 and 2017 related to software subscription services.

In considering the nature of the services provided by Deloitte & Touche, LLP, the audit committee determined that such services were compatible with the provision of independent audit services. The audit committee discussed these services with Deloitte & Touche, LLP and Management to determine that they were permitted under the rules and regulations concerning auditor independence promulgated by the SEC to implement the Sarbanes-Oxley Act of 2002, as well as the Public Company Accounting Oversight Board. The audit committee requires that all services performed by Deloitte & Touche, LLP be pre-approved prior to the services being performed. During the fiscal years ended December 31, 2018 and 2017, all services were pre-approved in accordance with these procedures.

PART IV

Item 15. Exhibits, Financial Statement Schedules.

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

(1) Financial statements

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

(2) Financial statement schedule.

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

(3) Exhibits

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

Exhibit Index

Exhibit Number	Description
3.1[(1)]	Amended and Restated Certificate of Incorporation.
3.2[(2)]	Amended and Restated Bylaws.
4.1[(3)]	Form of Common Stock Certificate
4.2[(4)]	Form of Warrant to Purchase Series B-1 Preferred Stock issued to Square 1 Bank.
4.3[(5)]	Form of Warrant to Purchase Series D Preferred Stock issued to Western Alliance Bank.
4.4[(6)]	Warrant to Purchase Series D-1 Preferred Stock issued to Western Alliance Bank.
4.5[(7)]	Form of Warrant to Purchase Series D-1 Preferred Stock issued to Midcap Financial Trust.
4.6[(8)]	Form of Warrant to Purchase Common Stock Issued to Underwriters.
4.7[(9)]	Form of Warrant to Purchase Common Stock for Service Providers.
10.1[(10)]	Fifth Amended and Restated Investors' Rights Agreement, dated August 5, 2016 as amended.
10.2+[(11)]	Bionano Genomics, Inc. Amended and Restated 2006 Equity Compensation Plan (the "2006 Plan").
10.3+[(12)]	Forms of grant notice, stock option agreement and notice of exercise under the 2006 Plan.
10.4+[(13)]	Bionano Genomics, Inc. 2018 Equity Incentive Plan (the "2018 Plan").
10.5+[(14)]	Forms of grant notice, stock option agreement and notice of exercise under the 2018 Plan.
10.6+[(15)]	Bionano Genomics, Inc. 2018 Employee Stock Purchase Plan.
10.7+[(16)]	Form of Indemnification Agreement by and between the Registrant and each director and executive officer.
10.8+[(17)]	Bionano Genomics, Inc. Non-Employee Director Compensation Policy.
10.9+[(18)]	Credit and Security Agreement by and between the Registrant, Midcap Financial Trust and the Lenders listed on the Schedule of Lenders attached thereto, dated June 29, 2018.
10.10+[(19)]	Employment Agreement by and between the Registrant and R. Erik Holmlin, Ph.D., dated November 7, 2017, as amended.
10.11+[(20)]	Employment Agreement by and between the Registrant and Han Cao, Ph.D., dated November 7, 2017, as amended.
10.12+[(21)]	Employment Agreement by and between the Registrant and Mike Ward, dated July 1, 2016.
10.13+[(22)]	Employment Agreement by and between the Registrant and Warren Robinson, dated November 7, 2017.
10.14+[(23)]	Employment Agreement by and between the Registrant and Mark Borodkin, dated November 7, 2017.
10.15[(24)]	Loan and Security Agreement by and between the Registrant and Western Alliance Bank, dated March 8, 2016.
10.16[(25)]	First Amendment to the Loan and Security Agreement by and between the Registrant and Western Alliance Bank, dated December 9, 2016.
10.17[(26)]	Second Amendment to the Loan and Security Agreement by and between the Registrant and Western Alliance Bank, dated May 2, 2017.

Exhibit Number	Description
10.18[27]	Third Amendment to the Loan and Security Agreement by and between the Registrant and Western Alliance Bank, dated November 20, 2017.
10.19[28]	Forbearance and Fourth Amendment to the Loan and Security Agreement by and between the Registrant and Western Alliance Bank, dated February 9, 2018.
10.20[29]	Lease by and between the Registrant and The Irvine Company LLC, dated January 16, 2012.
10.21[30]	First Amendment to the Lease by and between the Registrant and The Irvine Company LLC, dated September 10, 2013.
10.22[31]	Second Amendment to the Lease by and between the Registrant and The Irvine Company LLC, dated July 1, 2015.
10.23#[32]	Master Services Agreement by and between the Registrant and Skorpios Technologies, Inc. (f/k/a Novati Technologies, Inc. and f/k/a SVTC Technologies, LLC), dated March 2, 2009, as amended.
10.24#[33]	Manufacturing Services Agreement by and between the Registrant and Paramit Corporation, dated February 18, 2015.
10.25#[34]	License Agreement by and between Princeton University and the Registrant, dated January 7, 2004.
10.26#[35]	First Amendment to the License Agreement by and between Princeton University and the Registrant, dated December 17, 2004.
10.27#[36]	Second Amendment to the License Agreement by and between Princeton University and the Registrant, dated February 25, 2010.
10.28#[37]	Third Amendment to the License Agreement by and between Princeton University and the Registrant, dated October 17, 2011.
10.29#[38]	Fourth Amendment License Agreement by and between Princeton University and the Registrant, dated February 9, 2012.
10.30#[39]	Agreement by and between the Registrant and Berry Genomics Co., Ltd. dated August 2, 2016.
10.31#[40]	Sublicense Agreement by and between the Registrant and Industry 3200 dated December 27, 2013.
10.32#[41]	License Agreement by and between the Registrant and Q Biotechnology CV dated May 1, 2014.
10.33#[42]	Amendment to Non-Exclusive Patent License Agreement by and between the Registrant and Q Biotechnology CV dated May 1, 2014.
10.34#[43]	License Agreement by and between the Registrant and New York University dated November 4, 2013.
10.35#[44]	Option and Sublicense Agreement by and between the Registrant and Pacific Biosciences of California, Inc. dated February 2, 2016.
10.36[45]	Note Purchase Agreement by and among the Registrant and the Investors listed on Exhibit A thereto, dated February 9, 2018.
10.37[46]	First Amendment to Note Purchase Agreement by and among the Registrant and the Investors listed on the Schedule of Investors attached thereto, dated April 2, 2018.
10.38[47]	Fifth Amendment to Loan and Security Agreement by and between the Registrant and Western Alliance Bank, dated June 13, 2018.
10.39#[48]	Amendment to Patent Sublicense Agreement by and between the Registrant and Industry 3200, dated June 28, 2018.
10.40[49]	Second Amendment to Note Purchase Agreement by and between the Registrant and the Investors listed on the Schedule of Investors attached thereto, dated June 29, 2018.
10.41[50]	Omnibus Amendment to Convertible Promissory Notes by and among the Registrant and the Holders identified in the signature pages thereto, dated June 29, 2018.
10.42[51]	Omnibus Amendment to Convertible Promissory Notes by and among the Registrant and the Holders identified in the signature pages thereto, dated August 14, 2018.
10.43[52]	Omnibus Amendment to Warrants to Purchase Series B-1 Preferred Stock by and among the Registrant and the Holders identified in the signature pages thereto, dated August 14, 2018.
10.44[53]	Omnibus Amendment to Warrants to Purchase Series D Preferred Stock by and among the Registrant and the Holders identified in the signature pages thereto, dated August 14, 2018.
10.45[54]	Amendment Agreement, by and between the Registrant and Western Alliance Bank, dated November 19, 2018.
22.1[55]	Subsidiaries of the Registrant.
23.1	Consent of Deloitte & Touche LLP, independent registered public accounting firm.
24.1	Power of Attorney (included on signature page)
31.1*	Certification of Principal Executive Officer pursuant to Rules 13a-14(a) and 15d-14(a) promulgated under the Securities Exchange Act of 1934, as amended.
31.2*	Certification of Principal Financial Officer pursuant to Rules 13a-14(a) and 15d-14(a) promulgated under the Securities Exchange Act of 1934, as amended.

Exhibit Number	Description
32.1*	Certification of Principal Executive Officer and Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS	XBRL Instance Document.
101.SCH	XBRL Taxonomy Extension Schema Document.
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document.
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document.
101.LAB	XBRL Taxonomy Extension Label Linkbase Document.
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document.
(1)	Previously filed as Exhibit 3.1 to the Company's Current Report on Form 8-K, filed with the Securities and Exchange Commission on August 24, 2018, and incorporated herein by reference.
(2)	Previously filed as Exhibit 3.2 to the Company's Current Report on Form 8-K, filed with the Securities and Exchange Commission on August 24, 2018, and incorporated herein by reference.
(3)	Previously filed as Exhibit 4.1 to Amendment No. 2 to the Company's Registration Statement on Form S-1 (File No. 333-225970), filed with the Securities and Exchange Commission on July 17, 2018, and incorporated herein by reference.
(4)	Previously filed as Exhibit 4.3 to the Company's Registration Statement on Form S-1 (File No. 333-225970), filed with the Securities and Exchange Commission on June 28, 2018, and incorporated herein by reference.
(5)	Previously filed as Exhibit 4.5 to the Company's Registration Statement on Form S-1 (File No. 333-225970), filed with the Securities and Exchange Commission on June 28, 2018, and incorporated herein by reference.
(6)	Previously filed as Exhibit 4.7 to the Company's Registration Statement on Form S-1 (File No. 333-225970), filed with the Securities and Exchange Commission on June 28, 2018, and incorporated herein by reference.
(7)	Previously filed as Exhibit 4.8 to Amendment No. 1 to the Company's Registration Statement on Form S-1 (File No. 333-225970), filed with the Securities and Exchange Commission on July 13, 2018, and incorporated herein by reference.
(8)	Previously filed as Exhibit 1.1 to Amendment No. 5 to the Company's Registration Statement on Form S-1 (File No. 333-225970), filed with the Securities and Exchange Commission on August 15, 2018, and incorporated herein by reference.
(9)	Previously filed as Exhibit 4.1 to the Company's Current Report on Form 8-K, filed with the Securities and Exchange Commission on November 21, 2018, and incorporated herein by reference.
(10)	Previously filed as Exhibit 10.1 to the Company's Registration Statement on Form S-1 (File No. 333-225970), filed with the Securities and Exchange Commission on June 28, 2018, and incorporated herein by reference.
(11)	Previously filed as Exhibit 10.2 to the Company's Registration Statement on Form S-1 (File No. 333-225970), filed with the Securities and Exchange Commission on June 28, 2018, and incorporated herein by reference.
(12)	Previously filed as Exhibit 10.3 to the Company's Registration Statement on Form S-1 (File No. 333-225970), filed with the Securities and Exchange Commission on June 28, 2018, and incorporated herein by reference.
(13)	Previously filed as Exhibit 10.4 to Amendment No. 2 to the Company's Registration Statement on Form S-1 (File No. 333-225970), filed with the Securities and Exchange Commission on July 17, 2018, and incorporated herein by reference.
(14)	Previously filed as Exhibit 10.5 to Amendment No. 2 to the Company's Registration Statement on Form S-1 (File No. 333-225970), filed with the Securities and Exchange Commission on July 17, 2018, and incorporated herein by reference.
(15)	Previously filed as Exhibit 10.6 to Amendment No. 2 to the Company's Registration Statement on Form S-1 (File No. 333-225970), filed with the Securities and Exchange Commission on July 17, 2018, and incorporated herein by reference.
(16)	Previously filed as Exhibit 10.7 to Amendment No. 2 to the Company's Registration Statement on Form S-1 (File No. 333-225970), filed with the Securities and Exchange Commission on July 17, 2018, and incorporated herein by reference.
(17)	Previously filed as Exhibit 10.8 to Amendment No. 2 to the Company's Registration Statement on Form S-1 (File No. 333-225970), filed with the Securities and Exchange Commission on July 17, 2018, and incorporated herein by reference.
(18)	Previously filed as Exhibit 10.40 to Amendment No. 1 to the Company's Registration Statement on Form S-1 (File No. 333-225970), filed with the Securities and Exchange Commission on July 13, 2018, and incorporated herein by reference.
(19)	Previously filed as Exhibit 10.10 to the Company's Registration Statement on Form S-1 (File No. 333-225970), filed with the Securities and Exchange Commission on June 28, 2018, and incorporated herein by reference.

Exhibit Number	Description
(20)	Previously filed as Exhibit 10.11 to the Company's Registration Statement on Form S-1 (File No. 333-225970), filed with the Securities and Exchange Commission on June 28, 2018, and incorporated herein by reference.
(21)	Previously filed as Exhibit 10.12 to the Company's Registration Statement on Form S-1 (File No. 333-225970), filed with the Securities and Exchange Commission on June 28, 2018, and incorporated herein by reference.
(22)	Previously filed as Exhibit 10.13 to the Company's Registration Statement on Form S-1 (File No. 333-225970), filed with the Securities and Exchange Commission on June 28, 2018, and incorporated herein by reference.
(23)	Previously filed as Exhibit 10.14 to the Company's Registration Statement on Form S-1 (File No. 333-225970), filed with the Securities and Exchange Commission on June 28, 2018, and incorporated herein by reference.
(24)	Previously filed as Exhibit 10.15 to the Company's Registration Statement on Form S-1 (File No. 333-225970), filed with the Securities and Exchange Commission on June 28, 2018, and incorporated herein by reference.
(25)	Previously filed as Exhibit 10.16 to the Company's Registration Statement on Form S-1 (File No. 333-225970), filed with the Securities and Exchange Commission on June 28, 2018, and incorporated herein by reference.
(26)	Previously filed as Exhibit 10.17 to the Company's Registration Statement on Form S-1 (File No. 333-225970), filed with the Securities and Exchange Commission on June 28, 2018, and incorporated herein by reference.
(27)	Previously filed as Exhibit 10.18 to the Company's Registration Statement on Form S-1 (File No. 333-225970), filed with the Securities and Exchange Commission on June 28, 2018, and incorporated herein by reference.
(28)	Previously filed as Exhibit 10.19 to the Company's Registration Statement on Form S-1 (File No. 333-225970), filed with the Securities and Exchange Commission on June 28, 2018, and incorporated herein by reference.
(29)	Previously filed as Exhibit 10.20 to the Company's Registration Statement on Form S-1 (File No. 333-225970), filed with the Securities and Exchange Commission on June 28, 2018, and incorporated herein by reference.
(30)	Previously filed as Exhibit 10.21 to the Company's Registration Statement on Form S-1 (File No. 333-225970), filed with the Securities and Exchange Commission on June 28, 2018, and incorporated herein by reference.
(31)	Previously filed as Exhibit 10.22 to the Company's Registration Statement on Form S-1 (File No. 333-225970), filed with the Securities and Exchange Commission on June 28, 2018, and incorporated herein by reference.
(32)	Previously filed as Exhibit 10.23 to the Company's Registration Statement on Form S-1 (File No. 333-225970), filed with the Securities and Exchange Commission on June 28, 2018, and incorporated herein by reference.
(33)	Previously filed as Exhibit 10.24 to the Company's Registration Statement on Form S-1 (File No. 333-225970), filed with the Securities and Exchange Commission on June 28, 2018, and incorporated herein by reference.
(34)	Previously filed as Exhibit 10.25 to the Company's Registration Statement on Form S-1 (File No. 333-225970), filed with the Securities and Exchange Commission on June 28, 2018, and incorporated herein by reference.
(35)	Previously filed as Exhibit 10.26 to the Company's Registration Statement on Form S-1 (File No. 333-225970), filed with the Securities and Exchange Commission on June 28, 2018, and incorporated herein by reference.
(36)	Previously filed as Exhibit 10.27 to the Company's Registration Statement on Form S-1 (File No. 333-225970), filed with the Securities and Exchange Commission on June 28, 2018, and incorporated herein by reference.
(37)	Previously filed as Exhibit 10.28 to the Company's Registration Statement on Form S-1 (File No. 333-225970), filed with the Securities and Exchange Commission on June 28, 2018, and incorporated herein by reference.
(38)	Previously filed as Exhibit 10.29 to the Company's Registration Statement on Form S-1 (File No. 333-225970), filed with the Securities and Exchange Commission on June 28, 2018, and incorporated herein by reference.
(39)	Previously filed as Exhibit 10.30 to the Company's Registration Statement on Form S-1 (File No. 333-225970), filed with the Securities and Exchange Commission on June 28, 2018, and incorporated herein by reference.
(40)	Previously filed as Exhibit 10.31 to the Company's Registration Statement on Form S-1 (File No. 333-225970), filed with the Securities and Exchange Commission on June 28, 2018, and incorporated herein by reference.
(41)	Previously filed as Exhibit 10.32 to the Company's Registration Statement on Form S-1 (File No. 333-225970), filed with the Securities and Exchange Commission on June 28, 2018, and incorporated herein by reference.
(42)	Previously filed as Exhibit 10.33 to the Company's Registration Statement on Form S-1 (File No. 333-225970), filed with the Securities and Exchange Commission on June 28, 2018, and incorporated herein by reference.
(43)	Previously filed as Exhibit 10.34 to the Company's Registration Statement on Form S-1 (File No. 333-225970), filed with the Securities and Exchange Commission on June 28, 2018, and incorporated herein by reference.
(44)	Previously filed as Exhibit 10.35 to the Company's Registration Statement on Form S-1 (File No. 333-225970), filed with the Securities and Exchange Commission on June 28, 2018, and incorporated herein by reference.
(45)	Previously filed as Exhibit 10.36 to the Company's Registration Statement on Form S-1 (File No. 333-225970), filed with the Securities and Exchange Commission on June 28, 2018, and incorporated herein by reference.
(46)	Previously filed as Exhibit 10.37 to the Company's Registration Statement on Form S-1 (File No. 333-225970), filed with the Securities and Exchange Commission on June 28, 2018, and incorporated herein by reference.

Exhibit Number	Description
(47)	Previously filed as Exhibit 10.38 to the Company's Registration Statement on Form S-1 (File No. 333-225970), filed with the Securities and Exchange Commission on June 28, 2018, and incorporated herein by reference.
(48)	Previously filed as Exhibit 10.39 to Amendment No. 1 to the Company's Registration Statement on Form S-1 (File No. 333-225970), filed with the Securities and Exchange Commission on July 13, 2018, and incorporated herein by reference.
(49)	Previously filed as Exhibit 10.41 to Amendment No. 1 to the Company's Registration Statement on Form S-1 (File No. 333-225970), filed with the Securities and Exchange Commission on July 13, 2018, and incorporated herein by reference.
(50)	Previously filed as Exhibit 10.42 to Amendment No. 1 to the Company's Registration Statement on Form S-1 (File No. 333-225970), filed with the Securities and Exchange Commission on July 13, 2018, and incorporated herein by reference.
(51)	Previously filed as Exhibit 10.42 to Amendment No. 5 to the Company's Registration Statement on Form S-1 (File No. 333-225970), filed with the Securities and Exchange Commission on August 15, 2018, and incorporated herein by reference.
(52)	Previously filed as Exhibit 10.43 to Amendment No. 5 to the Company's Registration Statement on Form S-1 (File No. 333-225970), filed with the Securities and Exchange Commission on August 15, 2018, and incorporated herein by reference.
(53)	Previously filed as Exhibit 10.44 to Amendment No. 5 to the Company's Registration Statement on Form S-1 (File No. 333-225970), filed with the Securities and Exchange Commission on August 15, 2018, and incorporated herein by reference.
(54)	Previously filed as Exhibit 10.1 to the Company's Current Report on Form 8-K, filed with the Securities and Exchange Commission on November 21, 2018, and incorporated herein by reference.
(55)	Previously filed as Exhibit 21.1 to the Company's Registration Statement on Form S-1 (File No. 333-225970), filed with the Securities and Exchange Commission on June 28, 2018, and incorporated herein by reference.
+	Indicates management contract or compensatory plan.
#	Confidential treatment has been granted with respect to certain portions of this exhibit. Omitted portions have been filed separately with the SEC.
*	This certification is deemed not filed for purpose of section 18 of the Exchange Act or otherwise subject to the liability of that section, nor shall it be deemed incorporated by reference into any filing under the Securities Act or the Exchange Act.

Item 16. Form 10-K Summary

None

SIGNATURES

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

Company Name

Date: March 14, 2019 By: /s/ R. Erik Holmlin, Ph.D.

R. Erik Holmlin, Ph.D.

President and Chief Executive Officer

POWER OF ATTORNEY

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

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

Signature	Title	Date
/s/ R. Erik Holmlin, Ph.D. R. Erik Holmlin, Ph.D.	Chief Executive Officer and Director *(Principal Executive Officer)*	March 14, 2019
/s/ Mike Ward Mike Ward	Chief Financial Officer *(Principal Financial and Accounting Officer)*	March 14, 2019
/s/ David L. Barker, Ph.D. David L. Barker, Ph.D.	Director	March 14, 2019
/s/ Darren Cai, Ph.D. Darren Cai, Ph.D.	Director	March 14, 2019
/s/ Albert A. Luderer, Ph.D. Albert A. Luderer, Ph.D.	Director	March 14, 2019
/s/ Junfeng Wang Junfeng Wang	Director	March 14, 2019
/s/ Christopher Twomey Christopher Twomey	Director	March 14, 2019
/s/ Quan Zhou Quan Zhou	Director	March 14, 2019

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in the Registration Statement on Form S-8 (No. 333-227073) of our report dated March 14, 2019, relating to the consolidated financial statements of Bionano Genomics, Inc., (which report expresses an unqualified opinion and includes an explanatory paragraph relating to substantial doubt about Bionano Genomics, Inc.'s ability to continue as a going concern) appearing in this Annual Report on Form 10-K of Bionano Genomics, Inc. for the year ended December 31, 2018.

San Diego, CA

March 14, 2019

Exhibit 31.1

CERTIFICATION

I, R. Erik Holmlin, certify that:

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

Date: March 14, 2019

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

R. Erik Holmlin, Ph.D.

President and Chief Executive Officer
(Principal Executive Officer)

Exhibit 32.1

CERTIFICATION

Pursuant to the requirement set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, (the "Exchange Act") and 18 U.S.C. Section 1350 as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, R. Erik Holmlin, Chief Executive Officer of Bionano Genomics, Inc., a Delaware corporation (the "Company"), and Mike Ward, Chief Financial Officer of the Company, each hereby certifies that, to the best of his knowledge:

1. The Company's Quarterly Report on Form 10-K for the period ended December 31, 2018, as filed with the Securities and Exchange Commission on the date hereof (the "Periodic Report"), and to which this Certification is attached as Exhibit 32.1, fully complies with the requirements of Section 13(a) or Section 15(d) of the Exchange Act; and

2. The information contained in the Periodic Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: March 14, 2019

/s/ R. Erik Holmlin, Ph.D.	/s/ Mike Ward
R. Erik Holmlin, Ph.D.	Mike Ward
President and Chief Executive Officer	Chief Financial Officer
(Principal Executive Officer)	*(Principal Financial and Accounting Officer*

This certification accompanies and is being "furnished" with this Periodic Report, shall not be deemed "filed" by the Company for purposes of Section 18 of the Exchange Act, or otherwise subject to liability under that Section and shall not be deemed to be incorporated by reference into any filing of the Company under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, whether made before or after the date of this Periodic Report, irrespective of any general incorporation language contained in such filing.

Exhibit 31.2

CERTIFICATION

I, Mike Ward, certify that:

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

Date: March 14, 2019

/s/ Mike Ward

Mike Ward

Chief Financial Officer
(Principal Financial and Accounting Officer)