UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2020

OR

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

Commission File Number 001-38613

Bionano Genomics, Inc.

(Exact name of Registrant as specified in its Charter)

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

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

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

Title of Each Class	Trading Symbol(s)	Name of Each Exchange on which Registered
Common Stock, $0.0001 par value	BNGO	The Nasdaq Stock Market, LLC
Warrants to purchase Common Stock	BNGOW	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 ☐

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

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

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

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

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

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

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

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

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant as of June 30, 2020 (the last business day of the registrant's most recently completed second fiscal quarter) was approximately $26.7 million based on the closing price of the registrant's common stock on June 30, 2020 of $0.51 per share, as reported by the Nasdaq Capital Market.

As of March 12, 2021, the Registrant had 278,661,545 shares of common stock, $0.0001 par value per share, outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the definitive proxy statement, or the Proxy Statement, for the Registrant's 2021 Annual Meeting of Stockholders are incorporated by reference into Part III of this Annual Report on Form 10-K. The Proxy Statement will be filed with the Securities and Exchange Commission within 120 days of the Registrant's fiscal year ended December 31, 2020.

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As used in this Form 10-K, "Bionano," the "Company," "we," "our," and "us" refer to Bionano Genomics, Inc. and its subsidiaries or, as the context may require, Bionano Genomics, Inc. only. "Lineagen" refers to our wholly owned subsidiary, Lineagen, Inc.

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;
- the impact of the COVID-19 pandemic on our business and operations;
- our ability to comply with the covenants and satisfy certain conditions of our debt facility;
- 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.

RISK FACTOR SUMMARY

Below is a summary of the principal factors that make an investment in our securities speculative or risky. This summary does not address *all of the risks that we face. Additional discussion of the risks and uncertainties summarized in this risk factor summary, and other risks and uncertainties that we face, are set forth below under the heading "Risk Factors" below and should be carefully considered, together with other information in this Annual Report on Form 10-K and our other filings with the SEC before making investment decisions regarding our securities.*

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

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

- Our business, and that of our customers, has been adversely affected by the effects of public health crises, including the COVID-19 pandemic; in particular, the COVID-19 pandemic has materially affected our operations globally, including at our headquarters in San Diego, California, as well as the business or operations of our research partners, customers and other third parties with whom we conduct business;

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

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

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

- 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;

- In the near term, sales of our Saphyr system, consumables and genome analysis services 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;

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

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

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

- The terms of our debt 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 debt 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; and

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

PART I

Item 1. Business.

Overview

We are a global leader in optical genome mapping, or OGM, solutions for genome analysis. We provide tools and services based primarily on our Saphyr® system to scientists and clinicians conducting genetic research and patient testing. We also provide diagnostic testing services for pediatric patients suspected of neurodevelopmental disabilities through our wholly owned subsidiary, Lineagen, Inc. Our Saphyr system is 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 identification of structural changes in chromosomes, known as cytogenetics. Our Saphyr system is comprised of an instrument, chip consumables, reagents and a suite of data analysis tools. We also offer genome analysis services with the Saphyr system for researchers who want to evaluate OGM data quickly and with a low up-front investment. Lineagen has been providing genetic testing services to families and their healthcare providers for over nine years and has performed over 65,000 tests for those with neurodevelopmental concerns.

Optical Genome Mapping

Optical genome mapping is a method of genome analysis that reveals structural variations, or SVs. 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 several hundred base pairs to as many as tens of millions of base pairs. Structural variations may be inherited or arise spontaneously. Structural variations are well known to cause diseases such as genetic disorders, cancer and others. We believe no other products exists that can detect structural variations more comprehensively or cost and time-efficiently than our Saphyr system does.

Our customers include researchers and clinicians who seek to identify and understand the biological or clinical implications of genome variation. OGM with the Saphyr system can be used to facilitate new research and to improve the treatment of patients through better testing and development of new medicines or treatment protocols. It can also be used as a single alternative to multiple traditional cytogenetic tests like karyotyping, microarrays and fluorescent *in-situ* hybridization (FISH), which are expensive, slow and labor-intense. OGM with the Saphyr system provides an advanced solution designed to simplify workflow, reduce cost, and increase diagnostic yield. Our customers also include researchers in non-human segments, such as agricultural genomics, seeking 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, including 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 Augusta University, Children's Hospital of Philadelphia, Children's National Health System, Boston Children's Hospital, PerkinElmer, GeneDx, Mayo Clinic, Columbia University, DuPont Pioneer, Garvan Institute of Medical Research, Genentech, McDonnell Genome Institute at Washington University, National Institutes of Health, Pennsylvania State University, Radboud University Medical Center and Salk Institute for Biological Studies.

We believe that Saphyr is the only genome analysis platform capable of comprehensive, cost effective & efficient detection of large structural variations, typically involving 500 base pairs and larger. Today, these structural variations cannot be reliably detected by gene sequencing. Research Use Only (RUO) high throughput sequencers, of which there are approximately 6,000 - 7,000 currently installed worldwide, cannot reliably detect the larger structural variations that our Saphyr is designed to detect. Therefore, Saphyr may be adopted alongside this installed base of sequencers as a complement that is designed to give users the ability to see a much wider scope of genome variation than ever before.

The Saphyr system, which is for RUO, is starting 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. We estimate that approximately 2,500 cytogenetics labs exist worldwide. These labs currently rely on legacy methods for clinical tests and research that look at chromosomal structure, location, and function in cells. Prominent guidelines for oncology and genetic disease clinical diagnostics recommend use of these existing methods for first-line structural variation testing. 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).

Over the past few years, several major medical institutions have conducted more than 20 human translational research and human clinical studies to assess Saphyr's ability to detect structural variations and diagnose patients and, in certain studies, to compare those results to those produced via existing cytogenetic methods. In 2020, the results of several of these studies were published by the institutions. We believe that these publications, as well as additional forthcoming publications and the results of large-scale clinical studies that are being conducted in 2021 will lead to further adoption of the Saphyr system.

Diagnostic Services

Through our wholly owned subsidiary, Lineagen, acquired in August 2020, we provide proprietary molecular genetic diagnostic services for individuals demonstrating clinical presentations consistent with neurodevelopmental disorders (NDDs), including Autism Spectrum Disorders (ASD) and other disorders of childhood development. Lineagen's comprehensive genetic testing services can detect a majority of known NDD-causing genome variations, including testing for proprietary variations, and combines testing with Lineagen's Proprietary Variant Index (PRISM) that uses a proprietary database of over 35,000 individuals with NDDs tested with over 60,000 tests that provides additional evidence for candidate genes associated with NDDs.

COVID-19 Overview

The COVID-19 pandemic, and the measures imposed to contain this pandemic in areas where we operate our business and elsewhere have disrupted and are expected to continue to impact our business. For example, to comply with applicable regulations and to safeguard the health and safety of our employees and customers, we temporarily reduced our on-site business operations, implemented work-from-home practices, and modified other business practices, including those related to employee travel and physical participation in meetings, events, and conferences. In addition, the quarantine of our personnel and the inability to access our facilities or customer sites adversely affected, and is expected to continue to adversely affect, our operations.

During the twelve months ended December 31, 2020, we experienced a $1.6 million decrease in revenue, as compared to the same period of the prior year, which we largely attribute to the COVID-19 pandemic due to labs shutting down and other measures restricting operation of facilities where our instruments are installed. While the COVID-19 pandemic did not prevent us from operating our business during the twelve months ended December 31, 2020, we took steps to reduce our cash used in operations in order to offset the decrease in cash generated from sales. For example, we implemented salary reductions for most of our salaried employees and reduced the number of working hours of most of our hourly employees by 25% from April through June of 2020.

Disruptions resulting from the COVID-19 pandemic may continue to impact our operations and overall business. The impact of COVID-19 is evolving rapidly and its future effects remain uncertain. As a result of such uncertainties, the duration of the disruption and the related impact on our business, operating results and financial condition cannot be reasonably estimated at this time. We are continuing to closely monitor the impact of the COVID-19 pandemic on our business and are taking proactive efforts designed to protect the health and safety of our workforce, continue our business operations and advance our corporate objectives.

Recent Saphyr System Highlights

Executed on Commercialization Offerings for Saphyr

The Company executed on its commercialization strategy, expanded the utilization of its Saphyr system and increased the amount of Bionano data generated across the globe, driving scientific momentum. The installed base of Saphyr systems was 97 at the end of the year, an increase of 24 from year-end 2019.

Validated System Utility with Benchmarking, Scientific Publication and Clinical Adoption

Rigorous and extensive benchmarking of Saphyr was conducted against traditional cytogenetic methods and long read sequencing and these results were published and validated in several key publications, presentations and announcements including:

- OGM concordant with traditional cytogenetics in landmark leukemia study;
- International consortium demonstrates that Bionano's Saphyr detects all 100 chromosomal aberrations in 85 Genetic Disease Patients;
- Large multi-center study on 100 AML samples shows that Saphyr outperforms standard-of-care and leads to the recommendation of Saphyr being a first line test.
- Publication reveals in side-by-side comparison that method using PacBio sequencing detects only 72% of the large structural variants detected by optical genome mapping with Saphyr; and
- University of Iowa Hospitals and Clinics (UIHC) switched their method of clinical molecular testing for patients with presumed Facioscapulohumeral Muscular Dystrophy (FSHD) to an assay based on OGM that they developed using Bionano's Saphyr and validated as a Laboratory Developed Test (LDT).

Expanded System Beyond Cytogenetics and Improved Diagnostics

Researchers and clinicians demonstrated the ability of OGM with Saphyr to go beyond the scope of detection of standard cytogenetics and traditional diagnostics as evidenced in several key publications including :

- UCSF & Children's Hospital Oakland study finds that Saphyr can diagnose an additional 18% of children with genetic disease who were undiagnosed after standard of care testing.

Revealed Genetic Drivers of Severe Covid-19 Susceptibility

OGM with Saphyr identified SVs that affect genes in pathways that control immune and inflammatory response, viral reproduction and mucosal function. These results became the foundation of multiple research efforts, including one international consortium and publication:

- COVID-19 Host Genome SV Consortium identifies structural variants with possible roles in pathogenesis and outcomes in severely ill COVID-19 patients using Bionano's Saphyr® system.

Expanded Applications of OGM in Human and Non-Human Research

Several other published studies illustrated key applications of OGM to areas of human and non-human research, including:

- Bionano Genomics data is essential part of the first ever complete assembly of a human X-Chromosome;
- Vertebrate Genome Project rules Bionano optical genome mapping technology as essential part of assembling reference quality genomes;
- Bionano's Saphyr plays essential role in identifying three previously unknown genetic mutation types in cancer in study from Weill Cornell.

Advanced and Optimized the Performance of the Saphyr System for Adoption in Labs that will Develop Clinical Assays and LDTs

The Company affected several enhancements to the system and made significant advancements in the system's capabilities including utility in identifying SVs in solid tumor oncology indications and DNA isolation:

- Bionano Genomics Releases Saphyr Updates for Industry-Leading Data Yields that Enable Analysis of Complex Cancer Samples at Unprecedented Depths;
- Bionano Genomics Solidifies its Entry into Solid Tumor Analysis with Launch of New Kit and Protocol that Significantly Simplify Tissue and Solid Tumor Analysis; and
- Bionano Genomics Achieves Key Milestone with Software Update for its Saphyr System that Increases Throughput to 96 Human Genomes Per Week and Adds Saphyr Assure for Monitoring System Health.

Recent Corporate Highlights

- In January 2021, Bionano raised approximately $350 million in gross proceeds from two underwritten public offerings of shares of its common stock. The underwriters exercised in full their options to purchase additional shares, which were priced at $3.05 per share and $6.00 per share, respectively;
- The Company successfully closed the acquisition of diagnostics services provider, Lineagen, to accelerate the clinical adoption of Saphyr for digital cytogenetics, expanded diagnostic testing menu with the launch of Lineagen's EpiPanelDx PLUS Gene Panel Test that identifies genetic conditions related to epilepsy; and
- The Company enhanced the senior management team with the appointments of Christopher Stewart as Chief Financial Officer and Dr. Alka Chaubey as Chief Medical Officer.

Industry Background

Optical Genome Mapping

Genome analysis is the process of extracting and interpreting 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.

Genome structure refers to the way in which the various functional elements of the genome such as genes, reading frames, promoters and others are ordered, oriented and organized across the 23 pairs of chromosomes. Variation in genome structure, or 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, cancer, metabolic disorders and other. Structural variations occur when large

groups of base pairs are deleted or change their 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. Many researchers and clinicians now agree that despite major advances in the speed and cost-effectiveness of DNA sequencing, it fails to reliably detect structural variations.

We believe the currently 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. For example, chromosomal microarray analysis (CMA) is a widely accepted, front-line test used in the diagnostic evaluation of children with developmental disabilities. CMA can detect most *unbalanced* structural variations, but cannot detect *balanced* structural variations which are identifiable by the Saphyr system. Balanced structural variations are known causes of cancer (ex: BRC-ABL and other fusion genes). CMA and similar methods therefore have very limited utility in population research studies that seek to discover new structural variations to explain a wide array of disease pathology. Without additional tools, researchers and clinicians cannot comprehensively study the genome, which we believe will ultimately result in the failure of genomics to deliver on its full promise of new therapies and diagnostics.

The Saphyr system is a proprietary, sample-to-result platform based on optical mapping of the genome, which is the process of assigning the chromosomal location, order and orientation of all 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.

Diagnostic Services

Through our Lineagen subsidiary, we offer tests that use chromosomal microarray analysis (CMA), which is recommended by the American College of Medical Genetics and Genomics (ACMGG), the American Academy of Pediatrics (AAP), and the American Academy of Neurology (AAN), among other renowned societies for evaluation of patients suspected of genetic disease. We are actively performing research to determine whether OGM with the Saphyr system can replace CMA as the front-line test for children with developmental disorders. As the scientific, peer-reviewed literature supports this claim, the coding entities such as CMS and the AMA would need to adopt the proper procedural codes to allow for insurance reimbursement of new testing methodologies before they become mainstream clinical diagnostic instruments. Importantly, OGM is expected to be able to detect full mutations consistent with fragile X syndrome, which is another front-line test for children, especially males, with autism spectrum disorder and intellectual disability. Studies are ongoing to determine the sensitivity and specificity for OGM as it relates to fragile X syndrome. We also employ Whole Exome Sequencing (WES), which aims to detect genome single nucleotide variations that are different from genome structural variations and are not detectable by OGM.

Market Opportunity

Optical Genome Mapping

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

The two areas 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 9,500 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 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 $60,000 to approximately $150,000 per year, suggesting a potential annual recurring revenue opportunity of approximately $0.6 billion to approximately $1.4 billion.

Therefore, we believe that our currently addressable portion of the genome analysis market is estimated to be between $2.7 billion and $3.5 billion. Further, we believe that if Saphyr is able to successfully penetrate the currently addressable market, this will spur additional basic and translational research creating new areas where Saphyr and OGM data can be used to improve medical care. These may include pre-conception and pre-natal genetic screening, uses to advance gene editing techniques and precision medicine.

Diagnostic Services

According to estimates from the Centers for Disease Control and Prevention (CDC), approximately one in six, or about 17%, of children have one or more developmental disabilities, including ADHD, ASD, and other NDDs. Excluding the approximate 5% to 6% subset of developmental disabilities that Lineagen does not provide genetic diagnostic genetic testing for, the total addressable market (TAM) for Lineagen's genetic diagnostic testing is estimated to be approximately 11% of children between the ages of 0 and 18 years old, or approximately 8,140,000 children.

We believe a portion of the TAM is not serviceable due to a number of factors, including suboptimal and/or inaccessible payors that include certain U.S. Medicaid plans, patients tested by in-house laboratories (i.e., at medical institutions) unavailable for testing by Lineagen, and patients previously tested/diagnosed. Given that CMA testing is recommended as first-line genetic diagnostic testing for all individuals with ASD and other forms of NDDs, we believe the serviceable addressable market (SAM) in the United States for Lineagen's first-line FirstStepDx PLUS testing is approximately is 1,971,069 children.

Therefore, based on reimbursement rates for CMA testing established by the Centers for Medicaid & Medicare Services (CMS) of between $900 - $1,160, we believe that our SAM of the first-line genetic testing market for ASD and other NDDs is estimated to be between $1.7 billion and $2.2 billion.

Our Commercial Offerings

Optical Genome Mapping

We develop and market the Saphyr system, a complete sample-to-result solution for structural variation analysis by OGM 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 detector of structural variations larger than 500 base pairs currently on the market.
- **Highly specific.** Saphyr has a very low false positive rate, typically less than 2%.
- **Cost effective.** We expect the end user cost of reagents and chip consumables per sample to continue to decline from less than $500 in 2020 to approximately $100 per sample in 2023.
- **Fast.** Saphyr generates over 4,400 giga base pairs of information per day, outpacing the fastest sequencers in the market. For highly sensitive structural variation detection, this performance allows Saphyr to process twelve human samples per day. We expect future generations of Saphyr to exhibit throughputs as high as 192 human samples per day by the end of 2023. Over this same period, we expect to continuously improve the automation of sample prep and bioinformatics to help drive efficiencies of workflow.

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 is currently capable of analyzing up to 5,000 human samples per year. A higher throughput version is currently in development that is expected to dramatically increase the throughput.

The Saphyr Chip

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

Saphyr Sample Prep and Labeling Kits

Our Bionano Prep Kits™ and DNA labeling kits provide the reagents and protocols needed to extract and label ultra-high molecular weight, or UHMW, 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 human or animal tissue and tumors, plant tissue, cell lines, bone marrow aspirates and human blood.

Our labeling reagents are optimized for applications on our genome mapping systems. Starting with 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 kit for DNA labeling, the Direct Label and Stain (DLS) kit, is a proprietary, nondestructive chemistry for sequence motif labeling of genomic DNA that improves every aspect of our genome mapping. DLS uses a single direct-labeling enzymatic reaction to attach a fluorophore to the DNA at a specific 6-base pair sequence motif, yielding approximately 16 labels per 100,000 base pairs in the human genome. After labeling, the molecules are linearized in the 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;
- detect variants with an allele fraction of 1%
- 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.

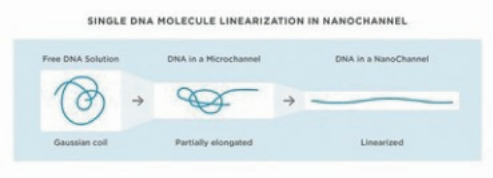
We have a suite of proprietary algorithms and databases that fully enable our proprietary bioinformatic and structural variation analysis pipelines. Using pairwise alignment of the single molecule images, consensus genome maps are constructed, refined, extended and merged. Molecules are then clustered 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 250 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 cluster-like performance in an affordable, compact solution and the Bionano Compute Server, which expands the analytical capacity of the suite of tools. With these solutions, our customers are capable of performing multiple simultaneous analyses and sustaining continuous throughput, which allows them to spend less time waiting for data, so they can focus on investigating results. We also offer a cloud-based solution for data analysis.

Our 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.

Diagnostic Services

- **Multiple LDTs focused on pediatric patients with ASD and other forms of NDDs**. All aspects of the testing services we offer were designed with a specific patient cohort in mind; namely, children with neurodevelopmental disabilities (NDDs). Based on the extreme hypersensitivities of children with NDDs, in many cases coupled with intellectual disability (ID), blood draws are incredibly challenging. We have developed and optimized all genetic testing solutions around DNA collected from a cheek swab, which also allows for operational simplicity and efficiency. In addition to the sample collection, we have sought technical and interpretive expertise specific to this disease group with customized genetic testing technology platforms and in-licensing of proprietary gene databases focused on NDDs.
- **Personalized, easy-to-understand results.** Because the number of children who qualify for clinical diagnostic testing for NDDs far exceed the number of genetic specialists, medical societies such as the American Academy of Pediatrics and the American Academy of Neurology recommend CMA testing be performed by other pediatric specialists. Without specific training in genetics, most test results are too complex to be meaningfully translated into actions that improve patient care. Our multi-disciplinary team of genetic counselors, laboratory directors, and variant analysts take care to write reports according to industry standard while also bringing the reading level down for non-genetic specialists and parents alike.
- **Genetic counseling and clinical education.** While medical societies support the use of diagnostic genetic testing, they also recommend (and some payors even require) genetic counseling prior to testing. Genetic counseling is a communication process for families provided by a licensed, nationally certified genetic counselor with a 2-year master's degree. The purpose is to ensure families understand the benefits and limitations of testing, as well as provide informed consent, to undergo testing that may reveal medical diagnoses or other challenging situations for the patient and possibly his/her relatives.
- **End-to-end customer support with reimbursement**. Although diagnostic genetic testing is a recommendation by several medical societies, it is not universally or equitably processed and reimbursed by insurance organizations. This has become a barrier that prevents physicians and medical clinics from employing standard of care genetic testing for children. Accordingly, we were the first in our class to develop an integrated process to streamline insurance submissions for diagnostic testing for NDDs.

Our Focus Areas

Optical Genome Mapping

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.

Genetic 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 definitive molecular diagnosis. In order to increase diagnostic yield, an increase in the understanding of the structure and structural variation of the genome is essential. 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 CMA and karyotyping techniques like metaphase chromosome spreads. More recently, whole exome sequencing or whole genome sequencing are increasingly being introduced.

A future workflow in which Saphyr is used as an alternative to karyotyping, the large majority of FISH, microarrays and MLPA tests would allow genetics clinics to 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.

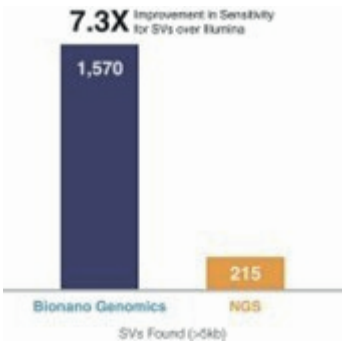
The Saphyr System's Industry-Leading Sensitivity and Specificity

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 by the Human Genome Structural Variation Consortium published in the journal *Science* allowed for a comparison between OGM with Saphyr and Pacific Biosciences' (PacBio) long-read sequencing technology's ability to detect structural variation. The consortium used a custom sequencing method based on high-coverage HiFi reads generated with PacBio's Sequel II system and the single-strand preparation and sequencing method StrandSeq to establish a comprehensive catalog of human SVs with base-pair and haplotype resolution. The PacBio-based method detected only 72% of the large SVs that OGM detected across 32 different human genomes. OGM uniquely made 5,590 large SV calls missed by PacBio, corresponding to 1,175 unique SV loci. Many of these large SVs consisted of more complex rearrangements or overlap with large repetitive areas called segmental duplications which are associated with developmental delay and adult neuropsychiatric disease, highlighting the importance of OGM in genome structure analysis. The publication did classify some large SVs as being uniquely detected by the sequencing-based method based on PacBio HiFi. Upon further analysis, however, most of these SVs were in fact identified by OGM but classified differently. Overall, less than 2% of the large SVs detected by PacBio were missed by OGM

In another 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.



Diagnostic Services

We offer a suite of multiple Laboratory Developed Tests (LDTs) specialized for providers focused on caring for pediatric patients with NDDs. Our LDT suite includes the following tests, several which are supported by multiple reimbursement codes, and all provide personalized, easy-to-understand result reports supported by a robust team of clinical genetic specialists, including genetic counselors, and cytogeneticists:

- **FirstStepDx (FSDx) PLUS.** Our FSDx PLUS is a Chromosomal Microarray (CMA) test designed to identify unbalanced structural variations in the genome (deletion and duplications) that are known to be underlying genetic causes of ASD, developmental delay, and intellectual disability. CMA is recommended as a first-tier genetic test for individuals with ASD and other forms of NDDs by a number of US-based medical organizations, including the American College of Medical Genetics and Genomics (ACMGG), American Academy of Neurology (AAN), and the American Academy of Pediatrics (AAP).
- **Fragile X Syndrome Testing.** Fragile X syndrome is a genetic condition caused by mutations in the FMR1 (fragile X mental retardation 1) gene. Fragile X is the most common heritable single gene cause of ASD. Fragile X also causes a range of developmental problems including other developmental disabilities and cognitive impairment as such, Fragile is also recommended as a first-tier genetic test for individuals with ASD and other forms of NDDs. Additionally, Fragile X can be inherited; a woman with Fragile X syndrome has a 50% chance of passing on the mutation to her children. Our Fragile X testing provides screening and diagnosis of triplet repeat expansions that cause this and related (FXTAS and FXPOI) conditions.
- **Pharmacogenetics (PGx) Testing.** Our PGx test analyzes genetic variations within genes known to play a role in the metabolism of medications that are commonly prescribed to individuals with ASD and other NDDs, including anti-epilepsy, anti-depression and anti-anxiety, and attention-deficit/hyperactivity disorder (ADHD) drugs. Our PGx test helps identify the risk of side effects from certain medications and provides healthcare professionals additional information on choice and dosage of most efficacious medications.
- **NextStepDx (NSDx) PLUS.** Our NSDx PLUS is a Whole Exome Sequencing (WES) test which aims to detect single nucleotide genome changes that are not detectable by the FSDx CMA test. The method of testing relies on technologies that allow rapid sequencing of large amounts of DNA in parallel, which are known as next-generation sequencing. As many known mutations that cause ASD and other forms of NDDs occur in gene-coding regions called exons (all exons in a genome make up a the “exome”), WES is an efficient method to identify additional disease-causing mutations.
- **EpiPanelDx PLUS.** EpiPanelDx PLUS is a genetic testing panel designed for patients who have experienced seizures, infantile spasms, encephalopathy, or febrile seizures. Much like CMA, WES, and Fragile X Syndrome testing, identification of the specific genetic etiology through panel testing can help confirm a clinical diagnosis or genetic syndrome, help

determine medical management, provide information about clinical course of disease, and assist family testing for at-risk relatives

- **Mitochondrial DNA Testing.** Mitochondrial DNA testing can help identify genetic variants associated with mitochondrial disorders, which comprise a large group of complex conditions with wide clinical variability. Mitochondrial disorders are caused by dysfunction of the mitochondrial respiratory chain, which is the process by which energy is made for the cell. Mitochondrial DNA, while largely controlled by genes in the nuclear DNA housed across the 23 chromosomes, is a distinct form of DNA that one inherits only from the mother. Because it is distinct, it is not included in most genetic testing assays unless specifically ordered.
- **Whole Genome Sequence (WGS) Testing.** Our WGS diagnostic test (WGDx) can detect the majority of genome mutations such as deletions, duplications, and single base changes, both within and outside of gene coding regions. In addition to diagnostic information for ASD and NDDs, understanding one's genome can give insights that lead to better physician or individual lifestyle, dietary, and disease prevention decisions.

Our Strategy

Optical Genome Mapping

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.

- ***Through our Lineagen subsidiary, develop novel LDT's and create reimbursement paths on the Saphyr System.*** With our recent acquisition of Lineagen, we are uniquely positioned to develop LDT's based on OGM with Saphyr that can improve upon the existing standards of care for diagnostic testing for neurodevelopmental disorders. We plan to work with payers to secure reimbursement alternatives for Saphyr based testing, which we would share with our customers to drive demand for the Saphyr system.

- ***Support the publication of findings with Saphyr by our customers beyond the more than 280 papers published to date.*** The annual number of publications featuring data generated by Saphyr and its predecessor system has steadily increased since 2010 when the first publication appeared. Recently, the overall number of these publications has grown significantly. For example, of the more than 280 papers published to date, approximately 80 were published in 2019 alone and 213 since 2017, the year Saphyr was launched. 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 significant majority of our total revenues to date. However, our instrument gross margin is significantly lower than our consumables gross margin. We expect our overall gross margin to expand in 2020 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 expect to continue developing and refining 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 of OGM 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

Optical Genome Mapping

As of December 31, 2020, our commercial team consisted of 72 individuals, including 29 salespeople, three marketing personnel, and 40 sales support personnel, including customer solutions personnel, field service engineers and field application specialists. This commercial staff is primarily located in North America, Europe, and China. Most of our sales support team is located at our headquarters in San Diego and some work remotely throughout the U.S., Europe, and China.

We sell our products through a direct sales force in based in North America, Europe. Our sales strategy involves the use of a combination of sales managers and sales representatives. Our direct sales force includes 18 salespeople located in the U.S. and 7 located in Europe, and 4 in China. 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. Three of our distributors are in China, one in Australia, one in Italy, one in Sweden, 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 seven with Ph.Ds., and generally have extensive experience in academic research and core sequencing lab experience.

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

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 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.

Diagnostic Services

We primarily sell our suite of LDTs to pediatric physicians through a physician-directed “in-person” sales model. As of December 31, 2020, our commercial team consisted of three salespeople, and one sales support personnel. This commercial staff is located in North America, and the sales personnel primarily work remotely in U.S. states where we have obtained insurance reimbursement.

Our sales and marketing efforts are targeted primarily on specialty pediatricians, including pediatric neurologists, medical geneticists, and developmental and behavioral pediatricians. We also target general pediatricians with large numbers of patients.

Our managed care efforts are directed to establishing contracts and/or credentialing with private and governmental insurance carriers that provide coverage for patients with ASD and other forms of NDDs. As of December 31, 2020, we had contracts or credentials with providers of insurance that cover approximately 90 million lives within the U.S.

Manufacturing and Supply

Optical Genome Mapping

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 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.

Diagnostic Services

We take advantage of outsourcing certain components of the genetic testing process. Instrumentation, chips, and reagents are developed by Illumina, a widely accepted manufacturer of CMA testing platforms. In fact, across all academic and commercial laboratories performing CMA, Illumina is one of the top three CMA manufacturers (in addition to Affymetrix/Thermo Fisher and Agilent). We have also historically contracted with third parties for kits, collection devices, and fulfillment. Finally, we maintain contracts with a network of laboratories to perform the wet work on our various LDT tests in order to conserve capital and maintain flexibility of adjusting contract lab based on the best-in-class/most updated technology and customer service. As of December 31, 2020, we have established contracts with two primary laboratories to perform wet lab services. All third-party laboratories have met stringent criteria, including passing a site visit from our management, and being CAP and CLIA-certified. We obtain raw data from laboratories for expert, optimized, and proprietary interpretation and reporting as previously described. In fact, we have our own CLIA license, for which regular site visits are held to ensure maintenance of compliance, under which this expert interpretation and reporting is carried out by the multidisciplinary team focused on clinical diagnostics for individuals with NDDs. Furthermore, we maintain all patient and provider touchpoints in all cases.

Key Agreements

Optical Genome Mapping

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.

Intellectual Property

Genome Analysis

Our core technology for nucleic acid research is related to methods and devices for non-sequencing based analysis of macromolecules such as nucleic acids. Using this technology, long (high-molecular weight) nucleic acids can be suitably labeled and elongated in order to ascertain structural information such as scaffold organization, copy number, and genomic repeats that is not readily obtained with current sequencing-based approaches. We 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 67 issued patents across 14 patent families and an exclusively licensed portfolio of patents and applications from Princeton University, which includes 29 patents across two families. The global patent portfolio owned and licensed by us has effective filing dates ranging from 2001 to 2018. The owned and licensed patent 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 focuses of these patent families are discussed below.

Commercial Focus	Number of Issued Patents and Pending Patent Applications
Nanochannel devices and systems	79
Methods of macromolecule analysis using nanochannel arrays	71
Methods of genetic detection and copy number analysis	31
Method of genomic sequence and epigenomic analysis.	53
Method of optimizing nanochannel analysis	6
Next-generation products	12

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

Diagnostic Services

Lineagen, Inc. has registered trademarks to certain of its genetic testing services and a patent portfolio of patent applications that relate to diagnostic tests and methods to diagnose or predict disease by detecting one or more of ASD-associated CNVs, methods for assessing the presence or absence of a chromosomal deletion or duplication syndrome and methods of selecting patients for treatment

based on such assessments, probe compositions, and related PCR-based methods of diagnosis by detecting ASD-associated SNPs and / or CNVs, methods for treating Wolf-Hirschhorn syndrome (4P- syndrome) seizures with cannabidiol or with vitamin B6 combination in patients with deletion of particular seizure susceptibility region, and has exclusively licensed a method of identifying a genome sequence mutation that is linked to causality of a disease using computer program product from The Hospital for Sick Children (SickKids) in in Toronto, Canada.

Government Regulation

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

Optical Genome Mapping

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 a marketed product.

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

510(k) Clearance Pathway

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

Premarket Approval Pathway

A PMA must be submitted if a new device cannot be cleared through the 510(k) process. The PMA process is generally more complex, costly and time consuming than the 510(k) process. A PMA must be supported by extensive data including, but not limited to, technical, preclinical, clinical trials, manufacturing and labeling to demonstrate to the FDA's satisfaction the safety and effectiveness of the device for its intended use. After a PMA is sufficiently complete, the FDA will accept the application for filing and begin an in-depth review of the submitted information. By statute, the FDA has 180 days to review the accepted application,

although, review of the application generally can take between one and three years. During this review period, the FDA may request additional information or clarification of information already provided. Also during the review period, an advisory panel of experts from outside the FDA may be convened to review and evaluate the application and provide recommendations to the FDA as to the approvability of the device. In addition, the FDA will conduct a preapproval inspection of the manufacturing facility to ensure compliance with its quality system regulations, or QSRs. New premarket approval applications or premarket approval application supplements are also required for product modifications that affect the safety and efficacy of the device.

Clinical Trials

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

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

- compliance with QSRs, which require manufacturers to follow stringent design, testing, control, documentation, record maintenance, including maintenance of complaint and related investigation files, and other quality assurance controls during the manufacturing process;
- reporting of device malfunctions, serious injuries or deaths;
- registration of the establishments where the devices are produced;
- 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, and its corresponding regulations, as well as additional federal and state laws that impose a variety of fraud and abuse prohibitions on healthcare providers, including clinical laboratories.

Laboratory Developed Tests (LDTs)

Federal agencies involved in the regulation of LDTs include CMS and the Food and Drug Administration (FDA). CMS regulates the quality of clinical laboratories and the clinical testing process pursuant to the Clinical Laboratory Improvement Amendments of 1988 (CLIA) and the FDA regulates the safety and effectiveness of the diagnostic test pursuant to authorities in the Federal, Food, Drug, and Cosmetic Act. 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
Federal Food, Drug, and Cosmetic Act and FDA regulations with respect to LDTs, which are a subset of in vitro diagnostic tests that are intended for clinical use and designed, manufactured and used entirely within a single laboratory. The FDA does not consider devices to be LDTs if they are designed or manufactured completely, or partly, outside of the laboratory that offers and uses them. We sell our Saphyr system on an RUO basis to CLIA certified cytogenetic 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 cytogenetics 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, including a risk-based classification system and increasing the requirements for conformity assessment. The conformity assessment process results in the receipt of a CE designation which has been sufficient to begin marketing many types of IVDs. That process will become more difficult and costly to complete.

Other Governmental Regulation

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

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 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 or services our customers try to commercialize.

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

Ultimately, coverage and reimbursement of new products and services is uncertain, and whether laboratories that use our instruments to develop their own products or services will attain coverage and adequate reimbursement is unknown. In the U.S., there is no uniform policy for determining coverage and reimbursement. Coverage can differ from payor to payor, and the process for determining whether a payor will provide coverage may be separate from the process for setting the reimbursement rate. In addition,

the U.S. government, state legislatures and foreign governments have shown significant interest in implementing cost containment programs to limit the growth of government-paid healthcare costs, including price controls and restrictions on reimbursement.

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. For example, the ACA contained a 2.3% excise tax on certain entities that manufacture or import medical devices offered for sale in the U.S., which has been permanently eliminated as part of the 2020 spending package.

There have been executive, judicial and Congressional challenges to certain aspects of the ACA. For example, President Trump signed several 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 considered legislation to 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 complying with the ACA's individual mandate to carry health insurance. 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. Additionally, on December 18, 2019, the U.S. Court of Appeals for the 5th Circuit upheld the District Court ruling that the individual mandate was unconstitutional and remanded the case back to the District Court to determine whether the remaining provisions of the ACA are invalid as well. The United States Supreme Court is currently reviewing this case, but it is unknown when a decision will be reached. Although the Supreme Court has not yet ruled on the constitutionality of the ACA, on January 28, 2021, President Biden issued an executive order to initiate a special enrollment period from February 15, 2021 through May 15, 2021 for purposes of obtaining health insurance coverage through the ACA marketplace. The executive order also instructs certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the ACA. It is unclear how the Supreme Court ruling, other such litigation, and the healthcare reform measures of the Biden administration will impact the ACA and our business.

Further, other legislative changes have been proposed and adopted since the ACA was enacted. For example, on 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, particularly in light of the new presidential administration, 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. Further, it is possible that additional governmental action is taken in response to the COVID-19 pandemic.

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 or services. 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.

Further, the Eliminating Kickbacks in Recovery Act of 2018, or EKRA, prohibits payments for referrals to recovery homes, clinical treatment facilities, and laboratories. EKRA's reach extends beyond federal health care programs to include private insurance (i.e., it is an "all payor" statute). For purposes of EKRA, the term "laboratory" is defined broadly and without reference to any connection to substance use disorder treatment. The law includes a limited number of exceptions, some of which closely align with corresponding federal Anti-Kickback Statute exceptions and safe harbors, and others that materially differ. Additionally, the Stark Law, which prohibits a physician from making a referral for certain designated health services covered by the Medicare or Medicaid program, including laboratory and pathology services, if the physician or an immediate family member of the physician has a financial relationship with the entity providing the designated health services and prohibits that entity from billing, presenting or causing to be presented a claim for the designated health services furnished pursuant to the prohibited referral, unless an exception applies.

There are also state and foreign law equivalents of each of the above federal laws, such as anti-kickback and false claims laws, that may impose similar or more prohibitive restrictions, and may apply to items or services reimbursed by any non-governmental third-party payors, including private insurers. 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.

Diagnostic Services

Clinical Laboratory Improvement Amendments of 1988 and State Regulation

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

CLIA provides that a state may adopt laboratory licensure requirements and regulations that are more stringent than those under federal law and requires compliance with such laws and regulations. The State of Utah follows all Clinical Laboratory Improvement Amendments (CLIA) regulations for laboratory facility and personnel requirements. Utah does not have any additional licensure and regulations.

Our laboratory in Salt Lake City, Utah has also been accredited by the College of American Pathologists, or CAP, which means that our laboratory has been certified as following CAP standards and guidelines in operating the laboratory facility and in performing tests that ensure the quality of our test results.

HIPAA and other Privacy Laws

The Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), established comprehensive federal standards for the privacy and security of health information. The HIPAA standards apply to three types of organizations: health plans, healthcare clearing houses, and healthcare providers that conduct certain healthcare transactions electronically ("Covered Entities"). Title II of HIPAA, the Administrative Simplification Act, contains provisions that address the privacy of health data, the security of health data, the standardization of identifying numbers used in the healthcare system and the standardization of certain healthcare transactions. The privacy regulations protect medical records and other protected health information by, among other things, limiting their use and release, giving patients the right to access their medical records and limiting most disclosures of health information to the minimum amount necessary to accomplish an intended purpose. The HIPAA security standards require the adoption of administrative, physical, and technical safeguards and the adoption of written security policies and procedures.

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

Under HITECH's breach notification requirements, Covered Entities must report breaches of protected health information that has not been encrypted or otherwise secured in accordance with guidance from the Secretary of the U.S. Department of Health and Human Services (the "Secretary"). Required breach notices must be made as soon as is reasonably practicable, but no later than 60 days following discovery of the breach. Reports must be made to affected individuals and to the Secretary and, in some cases depending on the size of the breach, they must be reported through local and national media. Breach reports can lead to investigation, enforcement and civil litigation, including class action lawsuits.

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

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

The General Data Protection Regulation ("GDPR"), which applies to all EU member states from May 25, 2018, also applies to some of our operations. The GDPR is discussed in more detail elsewhere in this report. The GDPR applies not only to organizations within the EU, but also applies to organizations outside of the EU that offer goods or services to EU data subjects or that process or hold personal data of EU data subjects. The regulation specifies higher potential liabilities for certain data protection violations, and we anticipate that it will result in a greater compliance burden for us as we conduct our business in the European Union. Fines for non-compliance can range from the greater of 2% of annual global revenues or €10 million, up to the greater of 4% of annual global revenues or €20 million. The GDPR is discussed in more detail under the heading "International Regulations" below.

Transparency Laws and Regulations

A federal law known as the Physician Payments Sunshine Act (the "Sunshine Act") requires certain medical device manufacturers to track and report to the federal government certain payments and other transfers of value made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals and ownership or investment interests held by physicians and their immediate family members. Manufacturers must report data for the previous calendar year by the 90th day of the then-current calendar year. CMS then publishes the data on a publicly available website no later than June 30th. Beginning in 2022, applicable manufacturers also will be required to report such information regarding its payments and other transfers of value to physician assistants, nurse practitioners, clinical nurse specialists, anesthesiologist assistants, certified registered nurse anesthetists and certified nurse midwives during the previous year. There are also state "sunshine" laws that require manufacturers to provide reports to state governments on pricing and marketing information. Several states have enacted legislation requiring medical device manufacturers to, among other things, establish marketing compliance programs, file periodic reports with the state, make periodic public disclosures on sales and marketing activities, and such laws may also prohibit or limit certain other sales and marketing practices. These laws may adversely affect our sales, marketing, and other activities by imposing administrative and compliance burdens on us. If we fail to track and report as required by these laws or to otherwise comply with these laws, we could be subject to the penalty provisions of the pertinent state and federal authorities.

Reimbursement and Billing

Reimbursement and billing for diagnostic services is highly complex. Laboratories must bill various payors, such as private third-party payors, including managed care organizations ("MCO"), and state and federal health care programs, such as Medicare and Medicaid, and each may have different billing requirements. Additionally, the audit requirements we must meet to ensure compliance

with applicable laws and regulations, as well as our internal compliance policies and procedures, add further complexity to the billing process. Other factors that complicate billing include:

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

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

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

Presently, approximately 90% of our diagnostic service revenue is paid by private third-party payors.

Federal and State Fraud and Abuse Laws

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

Anti-Kickback Laws

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

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

Further, the Eliminating Kickbacks in Recovery Act of 2018, or EKRA, prohibits payments for referrals to recovery homes, clinical treatment facilities, and laboratories. EKRA's reach extends beyond federal health care programs to include private insurance (i.e., it is an "all payor" statute). For purposes of EKRA, the term "laboratory" is defined broadly and without reference to any connection to substance use disorder treatment. The law includes a limited number of exceptions, some of which closely align with corresponding federal Anti-Kickback Statute exceptions and safe harbors, and others that materially differ.

Physician Self-Referral Bans

The federal ban on physician self-referrals, commonly known as the Stark Law, prohibits, subject to certain exceptions, physician referrals of Medicare patients to an entity providing certain designated health services, which include laboratory services, if the physician or an immediate family member of the physician has any financial relationship with the entity. Several Stark Law exceptions are relevant to arrangements involving clinical laboratories, including but not limited to: (1) fair market value

compensation for the provision of items or services; (2) payments by physicians to a laboratory for clinical laboratory services; (3) certain space and equipment rental arrangements that satisfy certain requirements; and (4) personal services arrangements. Penalties for violating the Stark Law include the return of funds received for all prohibited referrals, fines, civil monetary penalties and possible exclusion from federal health care programs. In addition to the Stark Law, many states have their own self-referral bans, which may extend to all self-referrals, regardless of the payor.

State and Federal Prohibitions on False Claims

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

Civil Monetary Penalties Law

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

International Regulations

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

Other Regulatory Requirements

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

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

Human Capital Management

As of December 31, 2020, we had 147 employees, of which 72 work in sales, sales support and marketing, 38 work in research and development, 24 work in operations and 13 work in general and administrative. As of December 31, 2020, of our 147 employees, 126 were located in the U.S. and 21 were employed outside the U.S. None of our employees are represented by a labor union or are subject to a collective bargaining agreement.

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

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.

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 $41.1 million and $29.8 million and used cash in operations of $38.3 million and $29.5 million for the years ended December 31, 2020 and 2019, respectively. As of December 31, 2020, we had an accumulated deficit of $143.7 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;
- our ability to successfully execute our sales and marketing strategy for our Lineagen products and diagnostic assays; 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 may not achieve substantial growth rates in future periods. Investors should not rely on our operating results for any prior periods as an indication of our future operating performance. To effectively manage our anticipated future growth, we must continue to maintain and enhance our financial, accounting, manufacturing, customer support and sales administration systems, processes and controls. 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 and services, as well as continue our research and development efforts. If we fail to obtain additional funding, we will be forced to delay, reduce or eliminate our commercialization and development efforts.

Our operations have consumed substantial amounts of cash since our inception. We expect to continue to spend substantial amounts in order to continue the commercialization of our products as well as our research and development programs. During October 2020 through January 2021, as described further under the heading Capital Resources included in Item 7 of this Annual Report, we raised an aggregate of $370.8 million in gross proceeds from an at-the-market facility and other public offerings, before deducting underwriting discounts and commissions and other offering costs and expenses. However, in the future, we may need to raise additional funding. For example, we may need to raise additional capital to:

- expand our sales and marketing efforts to further commercialize our products and services;
- expand our research and development efforts to improve our existing products and services and develop and launch new products and services, particularly if any of our products and services are deemed by the U.S. Food and Drug Administration, or FDA, to be medical devices or otherwise subject to additional regulation by the FDA;
- seek FDA approval to market our existing RUO 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
- cover increased costs incurred 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 and services;
- 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.

In addition, the COVID-19 pandemic may compromise our ability to comply with the terms of our loan agreement and could result in an event of default. If an event of default were to occur, our lender could accelerate our repayment obligations or enforce other rights under our loan agreements. Any such default may also require us to seek additional or alternative financing, which may not be available on commercially reasonable terms or at all. For example, for the three months ended September 30, 2020, we were not in compliance with the revenue covenant under the Innovatus LSA. Although we secured a waiver for such noncompliance in December 2020, there can be no assurance that we will be able to maintain compliance with our covenants in the Innovatus LSA in the future and securing such waivers in the future may require us to divert further cash towards the repayment of debt and subject us to fees incurred in connection with the negotiation of such waivers.

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.

Our business, and that of our customers, has been adversely affected by the effects of public health crises, including the COVID-19 pandemic. In particular, the COVID-19 pandemic has materially affected our operations globally, including at our headquarters in San Diego, California, as well as the business or operations of our research partners, customers and other third parties with whom we conduct business.

Our business could be adversely affected by health crises in regions where we have operations, concentrations of sales and marketing teams, distributors or other business operations. Such health crises could also affect the business or operations of our research partners, customers and other third parties with whom we conduct business. In particular, the COVID-19 pandemic and the measures imposed to contain this pandemic have disrupted and are expected to continue to impact our business.

In response to public health directives and orders implemented in response to the COVID-19 pandemic, we have implemented work-from-home policies for certain employees and temporarily scaled back our operations. We have also modified certain business practices, including those related to employee travel and cancellation of physical participation in meetings, events and conferences, and implemented new protocols to promote social distancing and enhance sanitary measures in our offices and facilities. The quarantine of our personnel and the inability to access our facilities or customer sites has adversely affected, and is expected to continue adversely affecting, our operations. For example, certain members of our workforce are now performing their duties remotely and these employees have not been able to maintain the same level of productivity and efficiency due a lack of resources that would otherwise be available to them in our offices and additional demands on their time, such as increased responsibilities resulting from school closures or the illness of family members.

The effects of these public health directives and orders and our related adjustments in our business have negatively impacted productivity, disrupted our business and delayed our timelines, the magnitude of which will depend, in part, on the length and severity of the restrictions and other limitations on our ability to conduct our business in the ordinary course. The spread of COVID-19 has resulted in a widespread health crisis that is also adversely affecting the economies and financial markets of many countries, including in the United States, Europe and Asia, which has resulted in an economic downturn that may negatively affect demand for our products and services and materially affect us financially. For example, customers who have committed to order minimum quantities of consumables or to purchase our Saphyr instrument could delay or default on these commitments. Further, restrictions on our ability to travel, stay-at-home orders and other similar restrictions on our business have limited our ability to support our global and domestic operations, including providing installation and training and customer service, resulting in disruptions in our sales and marketing efforts and negative impacts on our commercial strategy. In addition, disruption of global financial markets as a result of COVID-19 may limit our ability to access capital, which could negatively affect our liquidity. A recession or market correction resulting from the spread of COVID-19 could also materially affect our business and the value of our common stock even after the outbreak of COVID-19 has subsided, due to unforeseen adverse impacts on us or our third-party manufacturers, vendors and customers.

Also, in connection with our Diagnostic Services, COVID-19 poses the risk that we or our employees, contractors, suppliers, courier delivery services and other partners may be prevented from conducting business activities for an indefinite period of time, including due to spread of the disease within these groups or due to shutdowns that may be requested or mandated by governmental authorities. The continued spread of COVID-19 and the measures taken by the governments of countries affected could disrupt the supply chain of materials needed for our diagnostic tests, interrupt our ability to receive specimens, impair our ability to perform or deliver the results from our tests, impede patient movement or interrupt healthcare services causing a decrease in test volumes, delay coverage decisions from Medicare and third-party payors, delay ongoing and planned clinical trials involving our tests and have a material adverse effect on our business, financial condition and results of operations.

These and similar, and perhaps more severe, disruptions in our operations could negatively impact our business, operating results and financial condition. In addition, quarantines, stay-at-home, executive and similar government orders, or the perception that such orders, shutdowns or other restrictions on the conduct of business operations could occur, could disrupt our supply chain and affect customer decision-making. For example, any actual or perceived disruption in our product distribution channel could alter customer buying decisions, prompting customers to delay or cancel their orders, which would negatively impact our sales revenue and could harm our reputation. In addition, we anticipate that ongoing disruptions in our supply chain will cause shortages in the materials required to operate our instruments, therefore limiting our ability to process customer samples and the ability of users of our system to operate our system.

In addition, we are subject to various affirmative and negative covenants in our loan agreement with our lender. If the effects of COVID-19 cause us to fall out of compliance with one or more of such covenants and we are unable to secure a waiver or negotiate an amendment to our loan agreement on reasonable terms, or at all, an event of default could occur, which would allow our lender to accelerate our repayment obligations or enforce its other rights under our loan agreement. Any such default may also

require us to seek additional or alternative financing, which may not be available on commercially reasonable terms or at all. If we are unable to access funds to repay our lender, our lender could take control of our pledged assets. Any of the foregoing events would negatively impact our financial condition and liquidity.

The ultimate impact of the COVID-19 outbreak or a similar health epidemic is highly uncertain and subject to change. We do not yet know the full extent of potential delays or impacts on our business or the global economy as a whole, and such impacts may not be fully recoverable. In addition, the current and potential adverse impacts of the COVID-19 pandemic on our business, financial condition, results of operations and growth prospects, may also have the effect of heightening many of the other risks and uncertainties described in this Annual Report.

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

New income, sales, use or other tax laws, statutes, rules, regulations or ordinances could be enacted at any time, which could adversely affect our business operations and financial performance. Further, existing tax laws, statutes, rules, regulations or ordinances could be interpreted, changed, modified or applied adversely to us. For example, legislation enacted in 2017 informally titled the Tax Cuts and Jobs Ac, or the Tax Act, enacted many significant changes to the U.S. tax laws. Future guidance from the Internal Revenue Service and other tax authorities with respect to the Tax Act may affect us, and certain aspects of the Tax Act could be repealed or modified in future legislation. For example, the Coronavirus Aid, Relief and Economic Security Act, or the CARES Act, modified certain provisions of the Tax Act. In addition, it is uncertain if and to what extent various states will conform to the Tax Act, the CARES Act or any newly enacted federal tax legislation. Changes in corporate tax rates, the realization of net deferred tax assets relating to our operations, the taxation of foreign earnings, and the deductibility of expenses under the Tax Act or future reform legislation could have a material impact on the value of our deferred tax assets, could result in significant one-time charges, and could increase our future U.S. tax expense.

Our ability to use net operating losses and certain other tax attributes to offset future taxable income and taxes may be subject to limitations.

As of December 31, 2020, the Company has federal and state tax net operating loss carryforwards of $266.7 million and $114.0 million, respectively. The federal tax loss carryforwards include $102.5 million that do not expire but utilization is limited to 80% of the Company's taxable income in any given tax year based on current federal tax laws. The remaining federal tax loss carryforwards of $164.2 million and state tax loss carryforwards begin to expire in 2027 and 2023, respectively, unless previously utilized. As of December 31, 2020, the Company also has federal and California research credit carryforwards of $5.5 million and $5.0 million, respectively. The federal research credit carryforwards begin to expire in 2027 unless previously utilized. The California research credits carry forward indefinitely.

In addition, utilization of net operating losses and research and development credit carryforwards may be subject to limitations due to ownership changes that have occurred or that could occur in the future in accordance with applicable provisions of the Internal Revenue Code of 1986, as amended, or the Code, and corresponding provisions of state law. We may have experienced one or more ownership changes in the past and we may also experience additional ownership changes in the future as a result of subsequent changes in our stock ownership, some of which may be outside of our control. If an ownership change occurs and our ability to use our net operating loss or research and development credit carryforwards is materially limited, it would harm our future operating results by increasing our future tax obligations. In addition, at the state level, there may be periods during which the use of net operating loss carryforwards is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed.

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 debt 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 debt 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.

On March 14, 2019, we entered into a Loan and Security Agreement, or the Innovatus LSA, with Innovatus Life Sciences Lending Fund I, LP, or Innovatus, and certain lenders, which provides for borrowings up to $25.0 million pursuant to certain term loans and an additional $5.0 million under a revolving credit line. The Innovatus LSA is secured by a lien covering substantially all

of our assets, including our intellectual property. As of December 31, 2020, we owed approximately $16.0 million in principal amounts of term loans under the Innovatus LSA.

The Innovatus LSA 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. The Innovatus LSA also includes standard events of default, including a provision that Innovatus 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 Innovatus LSA or upon the collateral or the liens on the collateral under the agreement, thereby requiring us to repay the loan immediately, together with a prepayment fee and other applicable fees.

If we default under the Innovatus LSA, Innovatus may accelerate all of our repayment obligations and, if we are unable to access funds to meet those obligations or to renegotiate our agreement, Innovatus could take control of our pledged assets and we could immediately cease operations. For example, we were unable to maintain compliance with certain covenants under the Innovatus LSA as of September 30, 2019, December 31, 2019 and September 30, 2020. In order to secure waivers for the September 30, 2019, December 31, 2019, September 30, 2020 breaches, we have been required to pay consideration to Innovatus, including, with respect to our breach of our covenant as of December 31, 2019, our agreement to pay a waiver fee of $200,000 and a prepayment of $2.1 million of principal, as well as to prepay an additional $2.9 million of principal upon the earlier of April 30, 2020 or the closing of one or more equity financings during a specified period resulting in at least $15.0 million of gross proceeds to us in the aggregate, and a $100,000 prepayment fee in connection with such second repayment. In addition, to secure a waiver in December 2020 with respect to our breach of our covenant as of September 30, 2020, we agreed to close an equity financing during a specified period resulting in at least $20.0 million of gross proceeds to us in the aggregate, which we satisfied in January 2021.

We may not be able to maintain compliance with our covenants in the Innovatus LSA in the future and, although we have been able to secure waivers from Innovatus in the past, securing such waivers in the future may require us to divert further cash towards the repayment of debt and subject us to fees incurred in connection with the negotiation of such waivers. If we are unable to maintain compliance or obtain a waiver of any breach under the Innovatus LSA, Innovatus could declare an event of default or require us to renegotiate the Innovatus LSA on terms that may be significantly less favorable to us. If we were liquidated, Innovatus' right to repayment would be senior to the rights of our stockholders to receive any proceeds from the liquidation. Any declaration by Innovatus 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. In order to obtain waivers for any future breaches of covenants, we may be required to pay additional fees and penalties and issue shares of our common stock to Innovatus as consideration.

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 Innovatus LSA. 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 demonstrate to potential customers that our technology is an attractive alternative to existing technologies. Compared to some competing technologies, our technology is new and complex, and many potential customers have limited knowledge of, or experience with, our products. 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.

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

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

- disruption in our relationships with customers, distributors or suppliers as a result of such a transaction;
- unanticipated expenses and 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;
- possible write-offs or impairment charges relating to acquired businesses;
- difficulties developing and marketing new products and services;
- entering markets in which we have limited or no prior experience; and
- coordinating our efforts throughout various localities and time zones.

Foreign acquisitions involve unique risks in addition to those mentioned above, including those related to integration of operations across different cultures and languages, currency risks and the particular economic, political and regulatory risks associated with specific countries. In addition, in connection with any such transactions, we may also issue equity securities, incur additional debt, assume contractual obligations or liabilities or expend significant cash. Such transactions could harm our operating results and cash position, negatively affect the price of our stock and cause dilution to our current stockholders.

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.

For example, as previously disclosed, we recently completed the acquisition of Lineagen, Inc., or Lineagen, a U.S.-based provider of proprietary molecular diagnostics services for individuals presenting with certain neurodevelopmental disorders, for aggregate consideration consisting of approximately 6,167,510 shares of our common stock (subject to adjustment for cash, accounts receivable, unpaid indebtedness, unpaid transaction expenses and certain other liabilities of Lineagen), $1.9 million in cash, and the assumption of approximately $2.9 million in certain liabilities of Lineagen, pursuant to the terms of that certain Agreement and Plan of Merger, dated as of August 21, 2020, by and among us, Alta Merger Sub, Inc., Lineagen and Michael S. Paul, Ph.D., solely in his capacity as exclusive agent and attorney-in-fact of the securityholders of Lineagen, or the Lineagen Acquisition.

The issuance of shares as consideration in the Lineagen Acquisition resulted in dilution to our existing stockholders. In addition, pursuant to the Lineagen Acquisition, headcount of our consolidated operations increased by 33 employees, which has resulted in and will continue to result in increased selling, general and administrative expenses. Although we conducted extensive business, financial and legal due diligence in connection with our evaluation of the Lineagen Acquisition, our due diligence investigations may not have identified every matter that could adversely affect our business, operating results and financial condition. We may be unable to

adequately address the financial, legal and operational risks introduced by the Lineagen Acquisition and may have difficulty developing experience with the industry in which Lineagen operates. Accordingly, we cannot guarantee that the Lineagen Acquisition will yield the results we have anticipated and unforeseen complexities and expenses may arise. In addition, we may not achieve the revenues, growth prospects and synergies expected from this acquisition any such benefits we do achieve may not offset increased costs, resulting in a potential impairment of goodwill or other assets that were acquired. For future acquisitions, we may similarly be unable achieve revenue, growth prospects and synergies in a manner consistent with our expectations. Our failure to do so could adversely affect our business, operating results and financial condition.

Equity issuances in connection with strategic transactions or raising additional capital may cause dilution to our stockholders or restrict our operations.

From time to time, we expect to finance our strategic transactions or cash needs through a combination of equity and debt financings. To the extent that we finance our strategic transactions or raise additional capital through the sale of equity or convertible debt securities, your ownership interest could be diluted and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a common stockholder. Debt financing may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends and may be secured by all or a portion of our assets.

For example, on August 13, 2020, we entered into an At Market Issuance Sales Agreement, or the Sales Agreement, with Ladenburg Thalmann & Co. Inc., as sales agent, or Ladenburg, under which we were eligible to offer and sell up to $40.0 million of shares of our common stock from time to time through Ladenburg. During the fiscal year ended December 31, 2020, we sold 27,025,384 shares of common stock under the Sales Agreement for aggregate gross proceeds of approximately $22.1 million and from January 1, 2021 through January 11, 2021, we sold 6,298,152 shares of common stock under the Sales Agreement for aggregate gross proceeds of approximately $16.9 million. On January 12, 2021, we announced the completion of an underwritten public offering of 33,368,851 shares of our common stock for gross proceeds, before deducting underwriting discounts and commissions and offering expenses, of approximately $101.8 million. Moreover, on January 25, 2021, we announced the completion of an underwritten public offering of 38,333,352 shares of our common stock for gross proceeds, before deducting underwriting discounts and commissions and offering expenses, of approximately $230.0 million. In addition, we issued shares of our common stock in connection with the Lineagen Acquisition and to Innovatus in lieu of waiver fees. Any future significant sales of our capital stock would result in dilution to our current stockholders. As a result of these issuances, our investors experienced dilution of their ownership interests.

If we are unable to execute our sales and marketing strategy for our Lineagen products and services, including diagnostic assays, and are unable to gain acceptance in the market, we may be unable to generate sufficient revenue to sustain our Lineagen business.

Our Lineagen business provides molecular diagnostics services and has engaged in only limited sales and marketing activities for the diagnostic assays currently offered through our CLIA-certified laboratory. To date, the revenue generated by our Lineagen business has been insufficient to fund operations.

Although we believe that our current assays and our planned future assays represent a promising commercial opportunity, our products or assays may never gain significant acceptance in the marketplace and therefore may never generate substantial revenue or profits for us. We will need to establish a market for our products and diagnostic assays and build that market through physician education, awareness programs and the publication of clinical trial results. Gaining acceptance in medical communities requires, among other things, publications in leading peer-reviewed journals of results from studies using our current products, assays and services and/or our planned future products, assays and services. The process of publication in leading medical journals is subject to a peer review process and peer reviewers may not consider the results of our studies sufficiently novel or worthy of publication. Failure to have our studies published in peer-reviewed journals would limit the adoption of our current products, assays and services and our planned future products, assays and services.

Our ability to successfully market the products and diagnostic assays that we have developed, and may develop in the future, will depend on numerous factors, including:

- conducting clinical utility studies of such assays in collaboration with key thought leaders to demonstrate their use and value in important medical decisions such as treatment selection;
- whether our current or future partners, vigorously support our offerings;
- the success of our sales force;
- whether healthcare providers believe such diagnostic assays provide clinical utility;
- whether the medical community accepts that such diagnostic assays are sufficiently sensitive and specific to be meaningful in patient care and treatment decisions;
- our ability to continually source raw materials, shipping kits and other products that we sell or consume in our manufacturing process that are of sufficient quality and supply;

- our ability to continue to fund planned sales and marketing activities; and
- whether private health insurers, government health programs and other third-party payers will adopt our current and future assays in their guidelines, or cover such diagnostic assays and, if so, whether they will adequately reimburse us.

The COVID-19 pandemic may also increase the risk and uncertainty of the events described above and delay our development timelines. Failure to achieve widespread market acceptance of our current products, assays and services, as well as our planned future products, assays and services, would materially harm our business, financial condition and results of operations.

In the near term, sales of our Saphyr system, consumables and genome analysis services 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 from sales of our Saphyr system, consumables and OGM services will be derived primarily from sales 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
- customers' willingness to adopt new technologies.

In addition, if we fail to accurately predict future customer needs and preferences or fail to produce viable technologies, we may invest heavily in research and development of products 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.

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

Our current customer base for our RUO products is primarily composed of academic and governmental research institutions and biopharmaceutical and contract research companies and, for our Diagnostic Services, physicians and their patients. Our success will depend upon our ability to respond to the evolving needs of, and increase our market share among, existing customers and additional potential customers, marketing new products and services 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
- the fact that our sales, marketing and service force may be unable to execute successful commercial activities.

We have utilized third parties to assist with sales, distribution and customer support in certain regions of the world. 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 RUO products for any such diagnostic purposes would require that we obtain regulatory clearance or approval to market our products for those purposes and also that we acquire the materials and components used in such products from suppliers without an RUO restriction. There can be no assurance that we will be able to acquire these materials and components for use in diagnostic products on acceptable terms, if at all. If we are unable to do so, we would not be able to expand our non-Lineagen 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 RUO 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.

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 our Saphyr system 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 optical genome mapping systems and a single contract manufacturer for our chip consumables. If either of these manufacturers should fail or not perform satisfactorily, our ability to supply these products would be negatively and adversely affected.

We currently rely on a single contract manufacturer to manufacture and supply all of our non-Lineagen instruments. See "Business–Key Agreements" in this Annual Report. 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 non-Lineagen 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.

If our laboratory facilities become damaged or inoperable or we are required to vacate our existing facilities, our ability to conduct our laboratory analysis and pursue our research and development efforts may be jeopardized.

We currently perform all research and development activities and most of our OGM services at a single laboratory facility in San Diego, California with the remaining genome analysis services at a facility we occupy at a customer's lab in Clermont-Ferrand, France. All of our molecular diagnostics services are processed at a single laboratory facility in Salt Lake City, Utah.

Our facilities and equipment could be harmed or rendered inoperable by natural or man-made disasters, including war, fire, earthquake, power loss, communications failure, terrorism, burglary, public health crises (including restrictions that may be imposed on businesses by state and local governments under stay-at-home or similar orders and mandates, such as those implemented in response to the COVID-19 pandemic) or other events, which may make it difficult or impossible for us to perform our testing services for some period of time or to receive and store samples. The inability to perform tests or to reduce the backlog of sample analysis that could develop if one or both of our facilities become inoperable, for even a short period of time, may result in the loss of revenue, loss of customers or harm to our reputation, and we may be unable to regain that revenue, those customers or repair our reputation in the future. Furthermore, integral parties in our supply chain are operating from single sites, increasing their vulnerability to natural disasters and man-made disasters or other sudden, unforeseen and severe adverse events.

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

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

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

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

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

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

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

Undetected errors or defects in our products 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 reputations. If that occurs, we may incur significant costs, the attention of our key personnel could be diverted, or other significant customer relations problems may arise. We may also be subject to warranty and liability claims for damages related to errors or defects in our products. 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.

If our customers develop or use our products or assays for diagnostic purposes, someone could file a product liability claim alleging that one of our products contained a design or manufacturing defect that resulted in the failure to adequately perform, leading to death or injury. In addition, the marketing, sale and use of our current or future products and assays could lead to the filing of product liability claims against us if someone alleges that our products failed to perform as designed. We may also be subject to liability for errors in the results we provide or for a misunderstanding of, or inappropriate reliance upon, the information we provide.

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

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

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

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

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

During 2020 approximately 58% 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.

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.

We are increasingly dependent upon information technology systems, infrastructure and data to operate our business. In the ordinary course of our business, we collect, store and transmit sensitive data and confidential information, including but not limited to intellectual property, proprietary business information owned or controlled by ourselves or our customers, financial information and, where allowed, personal information.

The procedures and controls we use to monitor these threats and mitigate our exposure may not be sufficient to prevent cyber security incidents, and our internal information technology systems and those of our contractors and consultants are potentially vulnerable to breakdown or other damage or interruption from service interruptions, system malfunction, natural disasters, terrorism, war, public health crises and telecommunication and electrical failures, as well as security breaches from inadvertent or intentional actions by our employees, contractors, consultants, business partners, and/or other third parties, or from cyber-attacks by malicious third parties (including the deployment of harmful malware, ransomware, denial-of-service attacks, social engineering and other means to affect service reliability and threaten the confidentiality, integrity and availability of information), which may compromise our system infrastructure or lead to data leakage. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and reputational damage. In addition, these incidents could result in disrupted operations, lost opportunities, misstated financial data, increased costs arising from the implementation of additional security protective measures and litigation costs.

Any remedial costs or other liabilities related to cyber security incidents may not be fully insured or indemnified by other means. For example, any such event that leads to unauthorized access, use, or disclosure of personal information, including personal information related to our patient samples or employees, could harm our reputation directly, compel us to comply with federal and/or state breach notification laws and foreign law equivalents, subject us to mandatory corrective action, and otherwise subject us to liability under laws and regulations that protect the privacy and security of personal information, which could result in significant legal and financial exposure and reputational damages that could potentially have an adverse effect on our business.

While we have not experienced any such system failure, accident or material security breach to date, we cannot assure you that our data protection efforts and our investment in information technology will prevent significant breakdowns, data leakages, breaches

in our systems or other cyber incidents that could have a material adverse effect upon our reputation, business, operations or financial condition. For example, we maintain proprietary algorithms and databases that enable our proprietary bioinformatic and structural variation analysis pipelines and that contain certain information relating to patient or research samples. If we were to lose this information, our ability to further validate, improve and therefore maintain and grow sales could be significantly impaired.

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.

Our application for the Paycheck Protection Program Loan, or our application for forgiveness of the Paycheck Protection Program Loan, could in the future be determined to have been impermissible or could result in damage to our reputation.

On April 17, 2020, we received loan proceeds of approximately $1.8 million (the "PPP Loan") pursuant to the Paycheck Protection Program under the Coronavirus Aid, Relief, and Economic Security Act (the "CARES Act") administered by the U.S. Small Business Administration (the "SBA"). In February 2021, we applied for forgiveness of the PPP Loan, and in March 2021, the PPP Loan, including all accrued interest, was forgiven in full.

In order to apply for the PPP Loan, we were required to certify, among other things, that the current economic uncertainty made the PPP Loan request necessary to support our ongoing operations. We made this certification in good faith after analyzing, among other things, the maintenance of our workforce, our need for additional funding to continue operations, and our ability to access alternative forms of capital in the current market environment to offset the effects of the COVID-19 pandemic. Following this analysis, we believe that we satisfied all eligibility criteria for the PPP Loan, and that our receipt of the PPP Loan is consistent with the broad objectives of the CARES Act. The certification described above did not contain any objective criteria and is subject to interpretation.

On April 23, 2020, the SBA issued guidance stating that it is unlikely that a public company with substantial market value and access to capital markets will be able to make the required certification in good faith. The lack of clarity regarding loan eligibility under the Paycheck Protection Program has resulted in significant media coverage and controversy with respect to public companies applying for and receiving loans. If, despite our good-faith belief that given our circumstances we satisfied all eligibility requirements for the PPP Loan, we are later determined to have violated any applicable laws or regulations that may apply to us in connection with

the PPP Loan or it is otherwise determined that we were ineligible to receive the PPP Loan, we may be required to repay the PPP Loan in its entirety and/or be subject to additional penalties, which could also result in adverse publicity and damage to our reputation. Should we be audited or reviewed by federal or state regulatory authorities as a result of filing an application for forgiveness of the PPP Loan or otherwise, such audit or review could result in the diversion of management's time and attention and legal and reputational costs. If we were to be audited or reviewed and receive an adverse determination or finding in such audit or review, we could be required to return the full amount of the PPP Loan. Any of these events could have a material adverse effect on our business, results of operations and financial condition.

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.

Legal, political and economic uncertainty surrounding the exit of the U.K., from the European Union, or EU, may be a source of instability in international markets, create significant currency fluctuations, adversely affect our operations or intended operations in the U.K. and pose additional risks to our business, revenue, financial condition and results of operations.

Nearly 4% of our sales in fiscal year 2020 came from the United Kingdom. Following the result of a referendum in 2016, the U.K. left the EU on January 31, 2020, commonly referred to as Brexit. Pursuant to the formal withdrawal arrangements agreed between the U.K. and the EU, the U.K. will be subject to a transition period until December 31, 2020, or the Transition Period, during which EU rules will continue to apply. Negotiations between the U.K. and the EU are expected to continue in relation to the customs and trading relationship between the U.K. and the EU following the expiry of the Transition Period.

The uncertainty concerning the U.K's legal, political and economic relationship with the EU after the Transition Period may be a source of instability in the international markets, create significant currency fluctuations, and/or otherwise adversely affect trading agreements or similar cross-border co-operation arrangements (whether economic, tax, fiscal, legal, regulatory or otherwise).

These developments, or the perception that any of them could occur, have had, and may continue to have, a significant adverse effect on global economic conditions and the stability of global financial markets, and could significantly reduce global market liquidity and limit the ability of key market participants to operate in certain financial markets. In particular, it could also lead to a period of considerable uncertainty in relation to the U.K. financial and banking markets, as well as on the regulatory process in Europe. Asset valuations, currency exchange rates and credit ratings may also be subject to increased market volatility.

If the U.K. and the EU are unable to negotiate acceptable trading and customs terms or if other EU Member States pursue withdrawal, barrier-free access between the U.K. and other EU Member States or among the European Economic Area overall could be diminished or eliminated. The long-term effects of Brexit will depend on any agreements (or lack thereof) between the U.K. and the EU and, in particular, any arrangements for the U.K. to retain access to EU markets after the Transition Period.

Such a withdrawal from the EU is unprecedented, and it is unclear how the U.K's access to the European single market for goods, capital, services and labor within the EU, or single market, and the wider commercial, legal and regulatory environment, will impact our business. Any current or planned future operations in the U.K. as well as in other countries in the EU and European Economic Area, or EEA, could be disrupted by Brexit, particularly if there is a change in the U.K's relationship to the single market.

Brexit has caused, and may continue to create, volatility in global stock markets and regional and global economic uncertainty particularly in the United Kingdom financial and banking markets. Weakening of economic conditions or economic uncertainties tend to harm our business. There may continue to be economic uncertainty surrounding the consequences of Brexit which could adversely impact customer confidence resulting in customers reducing their spending budgets on our solutions, which could adversely affect our business, revenue, financial condition and results of operations.

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

Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware is the exclusive forum for the following types of actions or proceedings under Delaware statutory or common law:

- any derivative action or proceeding brought on our behalf;
- any action asserting a breach of fiduciary duty;
- any action asserting a claim against us arising under the Delaware General Corporation Law, our amended and restated certificate of incorporation, or our amended and restated bylaws; and
- any action asserting a claim against us that is governed by the internal-affairs doctrine.

This provision would not apply to suits brought to enforce a duty or liability created by the Exchange Act. Furthermore, Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all such Securities Act actions. Accordingly, both state and federal courts have jurisdiction to entertain such claims. To prevent having to litigate claims in multiple jurisdictions and the threat of inconsistent or contrary rulings by different courts, among other considerations, our amended and restated certificate of incorporation further provides that the federal district courts of the United States of America will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act. While the Delaware courts have determined that such choice of forum provisions are facially valid, a stockholder may nevertheless seek to bring a claim in a venue other than those designated in the exclusive forum provisions. In such instance, we would expect to vigorously assert the validity and enforceability of the exclusive forum provisions of our amended and restated certificate of incorporation. This may require significant additional costs associated with resolving such action in other jurisdictions and there can be no assurance that the provisions will be enforced by a court in those other jurisdictions.

These exclusive forum provisions may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees, which may discourage lawsuits against us and our directors, officers and other employees. If a court were to find either exclusive-forum provision contained in our amended and restated certificate of incorporation to be inapplicable or unenforceable in an action, we may incur further significant additional costs associated with resolving the dispute in other jurisdictions, all of which could adversely affect our results of operations and financial condition.

Risks related to government regulation and diagnostic product reimbursement

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

Our RUO products are focused on the life sciences research market. This includes laboratories associated with academic and governmental research institutions, as well as pharmaceutical, biotechnology and contract research companies. Accordingly, our products are labeled as "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. Our Lineagen diagnostic services are provided as LDTs. The FDA maintains that LDTs are medical devices and has for the most part exercised enforcement discretion for most LDTs. A significant change in the way that the FDA regulates any LDTs that we, our collaborators or our customers market or develop using our technology could affect our business. If the FDA requires laboratories to undergo premarket review and comply with other applicable FDA requirements in the future, the cost and time required to commercialize an LDT will increase substantially, and may reduce the financial incentive for us to continue to offer our Lineagen genetic diagnostic services or for our customer laboratories to develop LDTs, which could reduce demand for our RUO instruments and our other products. In addition, if the FDA were to change the way that it regulates LDTs to require that we undergo pre-market review or comply with other applicable FDA requirements before we can sell our RUO instruments or our other products to clinical cytogenetics laboratories, our ability to sell our RUO instruments and other products to this addressable market would be delayed, thereby impeding our ability to penetrate this market and generate revenue from sales of our instruments and our other products.

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

Foreign jurisdictions have laws and regulations similar to those described above, which may adversely affect our ability to market our products as planned in such countries. The number and scope of these requirements are increasing. As in the 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.

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

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

Several factors make the billing process complex, including:

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

- incorrect or missing billing information; and
- the resources required to manage the billing and claims appeals process.

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

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

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

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

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

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

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

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

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

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

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

Currently, our Saphyr 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.

Healthcare legislative or regulatory reform measures may have a negative impact on our business and results of operations.

In March 2010, the ACA became law. The ACA is a sweeping law intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add new transparency requirements for the healthcare and health insurance industries, impose new taxes and fees on the health industry and impose additional health policy reforms. For example, the ACA contained a 2.3% excise tax on certain entities that manufacture or import medical devices offered for sale in the U.S., with limited exceptions, which has been permanently eliminated as part of the 2020 spending package.

There have been executive, judicial and Congressional challenges to certain aspects of the ACA. While Congress has not passed comprehensive repeal legislation, it has enacted laws that modify certain provisions of the ACA such as removing penalties, starting January 1, 2019, for not complying with the ACA's individual mandate to carry health insurance. On 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. Additionally, on December 18, 2019, the U.S. Court of Appeals for the 5th Circuit upheld the District Court ruling that the individual mandate was unconstitutional and remanded the case back to the District Court to determine whether the remaining provisions of the ACA are invalid as well. The U.S. Supreme Court is currently reviewing the case, although it is unknown when a decision will be made. It is unclear how the Supreme Court ruling, other such litigation, and the healthcare reform measures of the Biden administration 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. Such reporting has been subject to numerous delays. Beginning on January 1, 2018, CMS has begun using reported private payor pricing to periodically revise payment rates under the CLFS.

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. Further, it is possible that additional governmental action is taken in response to the COVID-19 pandemic. Any reduction in payments from Medicare or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent our customers from successfully commercializing any tests for which they receive approval, which could prevent us from being able to generate revenue and attain profitability.

Complying with numerous regulations pertaining to our business is an expensive and time-consuming process, and any failure to comply could result in substantial penalties.

We are subject to the Clinical Laboratory Improvement Amendment of 1988, or CLIA, which is a federal law regulating clinical laboratories that perform testing on specimens derived from humans for the purpose of providing information for the diagnosis, prevention or treatment of disease. Our clinical laboratory is located in Utah and must be certified under CLIA in order for us to perform testing on human specimens. CLIA is intended to ensure the quality and reliability of clinical laboratories in the United States by mandating specific standards in the areas of personnel qualifications, administration, and participation in proficiency testing, patient test management, quality control, quality assurance and inspections. We have a current certificate of compliance under CLIA to perform cytogenetics. To renew this certificate, we are subject to survey and inspection every two years. Moreover, CLIA inspectors may make periodic inspections of our clinical laboratory outside of the renewal process. The failure to comply with CLIA requirements can result in enforcement actions, including the revocation, suspension, or limitation of our CLIA certificate of compliance, as well as a directed plan of correction, state on-site monitoring, civil money penalties, civil injunctive suit and/or criminal penalties. We must maintain CLIA compliance and certification to be eligible to bill for assays provided to Medicare beneficiaries. If we were to be found out of compliance with CLIA program requirements and subjected to sanctions, our business and reputation could be harmed. Even if it were possible for us to bring our laboratory back into compliance, we could incur significant expenses and potentially lose revenue in doing so.

We hold laboratory licenses from the states of California, Pennsylvania, and Maryland, to test specimens from patients in those states or received from ordering physicians in those states. Other states, such as Rhode Island and New York, may have similar requirements or may adopt similar requirements in the future. Finally, we may be subject to regulation in foreign jurisdictions if we seek to expand international distribution of our assays outside the United States.

If we were to lose our CLIA certification or state laboratory licenses, whether as a result of a revocation, suspension or limitation, we would no longer be able to offer our assays, which would limit our revenues and harm our business. If we were to lose, or fail to obtain, a license in any other state where we are required to hold a license, we would not be able to test specimens from those states. If we were to lose our CAP accreditation, our reputation for quality, as well as our business, financial condition and results of operations, could be significantly and adversely affected.

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

Our operations are subject to various federal and state fraud and abuse laws, including, without limitation, the federal and state anti-kickback statutes and false claims laws. These laws may impact, among other things, our sales and marketing and education programs, and our financial and business relationships with health care professionals. The laws that may affect our ability to operate include, but are not limited to:

- the federal Anti-Kickback Statute, or the AKS, which prohibits, among other things, any person or entity from knowingly and willfully soliciting, receiving, offering or paying any remuneration, directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, order or recommendation of an item or service reimbursable, in whole or in part, under a federal healthcare program, such as the Medicare and Medicaid programs. The term ‘‘remuneration’’ has been broadly interpreted to include anything of value. There are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution, however these are drawn narrowly. Additionally, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. In addition, the ACA codified case law that a claim including items or services resulting from a violation of the AKS constitutes a false or fraudulent claim for purposes of the federal False Claims Act, or the FCA;
- the Stark Law, which prohibits a physician from making a referral for certain designated health services covered by the Medicare or Medicaid program, including laboratory and pathology services, if the physician or an immediate family member of the physician has a financial relationship with the entity providing the designated health services and prohibits that entity from billing, presenting or causing to be presented a claim for the designated health services furnished pursuant to the prohibited referral, unless an exception applies;
- federal civil and criminal false claims laws and civil monetary penalty laws, such as the FCA, which can be enforced by private citizens through civil qui tam actions, prohibits individuals or entities from, among other things, knowingly presenting, or causing to be presented false, fictitious or fraudulent claims for payment or approval by the federal government, including federal health care programs, such as Medicare and Medicaid, and knowingly making, using or causing to be made or used a false record or statement material to a false or fraudulent claim, or knowingly making a false statement to improperly avoid, decrease or conceal an obligation to pay money to the federal government;
- the Eliminating Kickbacks in Recovery Act of 2018, or EKRA, prohibits payments for referrals to recovery homes, clinical treatment facilities, and laboratories. EKRA’s reach extends beyond federal health care programs to include private insurance (i.e., it is an “all payor” statute). For purposes of EKRA, the term “laboratory” is defined broadly and without reference to any connection to substance use disorder treatment. The law includes a limited number of exceptions, some of which closely align with corresponding federal Anti-Kickback Statute exceptions and safe harbors, and others that materially differ;

- HIPAA, which, among other things, imposes criminal liability for executing or attempting to execute a scheme to defraud any healthcare benefit program, including private third-party payors, knowingly and willfully embezzling or stealing from a healthcare benefit program, willfully obstructing a criminal investigation of a healthcare offense, and knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement or representation, in connection with the delivery of or payment for healthcare benefits, items or services. Like the AKS, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, and their implementing regulations, which imposes privacy, security and breach reporting obligations with respect to individually identifiable health information upon entities subject to the law, such as health plans, healthcare clearinghouses and certain healthcare providers, known as covered entities, and their respective business associates, individuals or entities that perform services for them that involve individually identifiable health information as well as their covered subcontractors;
- state laws that prohibit other specified practices, such as billing physicians for tests that they order or providing tests at no or discounted cost to induce physician or patient adoption; insurance fraud laws; waiving coinsurance, copayments, deductibles, and other amounts owed by patients; billing a state Medicaid program at a price that is higher than what is charged to one or more other third-party payors employing, exercising control over or splitting professional fees with licensed professionals in violation of state laws prohibiting fee splitting or the corporate practice of medicine and other professions; and
- federal and state consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers;
- the prohibition on reassignment of Medicare claims, which, subject to certain exceptions, precludes the reassignment of Medicare claims to any other part;
- state and foreign law equivalents of each of the above federal laws, such as anti-kickback and false claims laws, that may impose similar or more prohibitive restrictions, and may apply to items or services reimbursed by any non-governmental third-party payors, including private insurers; and
- federal, state and foreign laws that govern the privacy and security of health information or personally identifiable information in certain circumstances, including state health information privacy and data breach notification laws which govern the collection, use, disclosure, and protection of health-related and other personal information, many of which differ from each other in significant ways and often are not pre-empted by HIPAA, thus complicating compliance efforts.

As a clinical laboratory, our business practices may face additional scrutiny from government regulatory agencies such as the Department of Justice, the U.S. Department of Health and Human Services Office of Inspector General, or OIG, and CMS. Certain arrangements between clinical laboratories and referring physicians have been identified in fraud alerts issued by the OIG as implicating the AKS. The OIG has stated that it is particularly concerned about these types of arrangements because the choice of laboratory, as well as the decision to order laboratory tests, typically are made or strongly influenced by the physician, with little or no input from patients. Moreover, the provision of payments or other items of value by a clinical laboratory to a referral source could be prohibited under the Stark Law unless the arrangement meets all criteria of an applicable exception. The government has been active in enforcement of these laws as they apply to clinical laboratories.

We have entered into consulting and scientific advisory board arrangements, speaking arrangements and clinical research agreements with physicians and other healthcare providers, including some who could influence the use of our products. Although we believe that these have been structured in compliance with applicable laws, because of the complex and far-reaching nature of these laws, regulatory agencies may view these transactions as prohibited arrangements that must be restructured, or discontinued, or for which we could be subject to other significant penalties. We could be adversely affected if regulatory agencies interpret our financial relationships with providers who may influence the ordering of and use of our products to be in violation of applicable laws.

Ensuring that our business arrangements with third parties comply with applicable healthcare laws and regulations is costly. If our operations are found to be in violation of any of these laws, we may be subject to significant penalties, including, without limitation, civil, criminal, and administrative penalties, damages, fines, disgorgement, the curtailment or restructuring of our operations, exclusion from participation in federal and state healthcare programs, additional integrity oversight and reporting obligations, imprisonment, contractual damages, and reputational harm, any of which could adversely affect our ability to operate our business and our results of operations. If any of the physicians or other healthcare providers or entities with whom we do business is found to be not in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs.

Additionally, sales of our products outside of the 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 February 28, 2021, we (directly or through our wholly owned subsidiary Lineagen, Inc.) were the assignee or assignee-applicant of 17 granted U.S. patents and 15 pending U.S. patent applications. We also were the assignee-applicant of approximately 81 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 or services around our patented technologies. Further, we cannot assure investors that other parties will not challenge any patents granted to us, or that courts or regulatory agencies will hold our patents to be valid, enforceable, and/or infringed. We cannot guarantee investors that we will be successful in defending challenges made against our patents and patent applications. Any successful third-party challenge or challenges to our patents could result in the unenforceability or invalidity of such patents, or such patents being interpreted narrowly and/or in a manner adverse to our interests. Our ability to establish or maintain a technological or competitive advantage over our competitors and/or market entrants may be diminished because of these uncertainties. For these and other reasons, our intellectual property may not provide us with any competitive advantage. For example:

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

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

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

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

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

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

Some of the intellectual property rights assigned to us and/or in-licensed to us have been generated through the use of U.S. government funding and are therefore subject to certain federal regulations. For example, all of the intellectual property rights licensed to us under our license agreement with Princeton University have been generated using U.S. government funds. As a result, the U.S. government has certain rights to intellectual property embodied in our current or future products pursuant to the Bayh-Dole Act of 1980. These U.S. government rights in certain inventions developed under a government-funded program include a non-exclusive, non-transferable, irrevocable worldwide license to use inventions for any governmental purpose. In addition, the U.S. government has the right to require us to grant exclusive, partially exclusive, or non-exclusive licenses to any of these inventions to a third-party if the government determines that: (i) adequate steps have not been taken to commercialize the invention; (ii) government action is necessary to meet public health or safety needs; or (iii) government action is necessary to meet requirements for public use under federal regulations (also referred to as "march-in rights"). The U.S. government also has the right to take title to these inventions if we fail, or the applicable licensor fails, to disclose the invention to the government, elect title, and file an application to register the intellectual property within specified time limits. In addition, the U.S. government may acquire title to these inventions in any country in which a patent application is not filed within specified time limits. Intellectual property generated under a government funded program is also subject to certain reporting requirements, compliance with which may require us, or the applicable licensor, to expend substantial resources. In addition, the U.S. government requires that any products embodying the subject invention or produced through the use of the subject invention be manufactured substantially in the 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 or license inventions that result from such funding, intellectual property rights to such discoveries may be subject to the applicable provisions of the Bayh-Dole Act. To the extent any of our current or future intellectual property is generated through the use of U.S. government funding, the provisions of the Bayh-Dole Act may similarly apply. Any exercise by the government of certain of its rights could harm our competitive position, business, financial condition, results of operations and prospects.

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

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

- royalty payments;

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

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

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

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

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

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

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

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

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

Our success also depends on our ability to develop, manufacture, market and sell our products and perform our services without infringing the proprietary rights of third parties. Numerous U.S. and foreign-issued patents and pending patent applications owned by third parties exist in the fields in which we are developing manufacturing, marketing and selling products and performing 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, services or proprietary technologies may infringe. Moreover, we may fail to identify issued patents of relevance or incorrectly conclude that an issued patent is invalid or not infringed any of our products, services or proprietary technologies. There is a substantial amount of litigation involving patents and other intellectual property rights in our industry. If a third-party claims that we or any of our licensors, customers or collaboration partners infringe upon a third-party's intellectual property rights, we may have to:

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

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

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

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

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

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

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

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

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

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

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

Filing, prosecuting, maintaining, and defending patents on current and future products and services 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 or services, 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 or services may compete with our products or services and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing. Even if we pursue and obtain issued patents in particular jurisdictions, our patent claims or other intellectual property rights may not be effective or sufficient to prevent third parties from so competing. Patent protection must ultimately be sought on a country-by-country basis, which is an expensive and time-consuming process with uncertain outcomes. Accordingly, we may choose not to seek patent protection in certain countries, and we will not have the benefit of patent protection in such countries.

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

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

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

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 technologies, we may not be able to fully use or extract value from our intellectual property rights. For example:

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

- we may not develop or in-license additional proprietary technologies that are patentable; and
- the patents or other intellectual property of others may have an adverse effect on our business.

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

Risks Related to Ownership of our Securities

The price of our securities 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 genome analysis systems, including sales and revenue trends;
- changes in laws or regulations applicable to our systems;
- adverse developments related to our laboratory facilities;
- increased competition in the diagnostics services industry;
- the failure to obtain and/or maintain coverage and adequate reimbursement for our Lineagen products and diagnostic assays and patients' willingness to pay out-of-pocket in the absence of such coverage and adequate reimbursement;
- the failure of our customers to obtain and/or maintain coverage and adequate reimbursement for their services using our Saphyr systems;
- 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 proprietary rights in 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.

If we are not able to comply with the applicable continued listing requirements or standards of The Nasdaq Capital Market, Nasdaq could delist our common stock.

Our ability to publicly or privately sell equity securities and the liquidity of our common stock could be adversely affected if we are delisted from The Nasdaq Capital Market or if we are unable to transfer our listing to another stock market. In order to maintain this listing, we must satisfy minimum financial and other continued listing requirements and standards, including a requirement to maintain a minimum bid price of the Company's common stock of $1.00 per share.

For example, in a letter dated April 22, 2020, or the Notice, we were notified by the Nasdaq Stock Market LLC, or Nasdaq, that for 30 consecutive trading days preceding the date of the Notice, the bid price of our common stock had closed below the $1.00 per share minimum required for continued listing on The Nasdaq Capital Market pursuant to Nasdaq Listing Rule 5550(a)(2), or the Minimum Bid Price Requirement. Under Nasdaq Listing Rule 5810(c)(3)(A), we had 180 calendar days following the date of the Notice to regain compliance with the Minimum Bid Price Requirement, and due to extraordinary market conditions, Nasdaq determined to toll the compliance period for the Minimum Bid Price Requirement through September 30, 2020, or the Tolling Period. As a result, the compliance Period ended on December 28, 2020, or the Compliance Period, instead of October 20, 2020. Nasdaq subsequently granted us an extension until June 28, 2021 to regain compliance with the Minimum Bid Price Requirement.

On January 13, 2021, Nasdaq notified that Company that it had regained compliance with the Minimum Bid Price Requirement because the closing bid price of our common stock had been at least $1.00 per share or greater from December 29, 2020 to January 12, 2021. Although we have regained compliance with Nasdaq, if we fail to satisfy another Nasdaq requirement for continued listing, Nasdaq staff could provide notice that our common stock may become subject to delisting. In such event, Nasdaq rules permit us to appeal the decision to reject our proposed compliance plan or any delisting determination to a Nasdaq Hearings Panel. Accordingly, there can be no guarantee that we will be able to maintain our Nasdaq listing. If our common stock is delisted by Nasdaq, it could lead to a number of negative implications, including an adverse effect on the price of our common stock, increased volatility in our common stock, reduced liquidity in our common stock, the loss of federal preemption of state securities laws and greater difficulty in obtaining financing. In addition, delisting of our common stock could deter broker-dealers from making a market in or otherwise seeking or generating interest in our common stock, could result in a loss of current or future coverage by certain sell-side analysts and might deter certain institutions and persons from investing in our securities at all. Delisting could also cause a loss of confidence of our customers, collaborators, vendors, suppliers and employees, which could harm our business and future prospects.

If our common stock is delisted by Nasdaq, our common stock may be eligible to trade on the OTC Bulletin Board, OTC-QB or another over-the-counter market. Any such alternative would likely result in it being more difficult for us to raise additional capital through the public or private sale of equity securities and for investors to dispose of or obtain accurate quotations as to the market value of, our common stock. In addition, there can be no assurance that our common stock would be eligible for trading on any such alternative exchange or markets. Moreover, if our common stock is delisted, it may come within the definition of "penny stock" under the Exchange Act, which imposes additional sales practice requirements on broker-dealers who sell securities to persons other than established customers and accredited investors. For example, we and/or broker-dealers are required to make a special suitability determination for purchases of such securities and must receive a purchaser's written consent to the transaction prior to any purchase. Additionally, unless exempt, prior to a transaction involving a penny stock, the penny stock rules require the delivery of a disclosure schedule prescribed by the SEC relating to the penny stock market. The broker-dealer must also disclose the commissions payable to the broker-dealer, current quotations for the securities and, if the broker-dealer is the sole market-maker for the security, the fact that they are the sole market-maker and their presumed control over the market. Finally, monthly statements disclosing recent price information on the limited market in penny stocks must be sent to holders of such penny stocks. These requirements may reduce trading activity in the secondary market for our common stock and may impact the ability or willingness of broker-dealers to sell our securities which could limit the ability of stockholders to sell their securities in the public market and limit our ability to attract and retain qualified employees or raise additional capital in the future.

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, the Innovatus LSA contains a negative covenant which prohibits us from paying dividends without the prior written consent of Innovatus.

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.

We have identified material weaknesses in our internal control over financial reporting. If our internal control over financial reporting is not effective, we may not be able to accurately report our financial results or file our periodic reports in a timely manner, which may cause adverse effects on our business and may cause investors to lose confidence in our reported financial information and may lead to a decline in our stock price.

We are subject to the reporting requirements of the 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. Effective internal control over financial reporting is necessary for us to provide reliable financial reports in a timely manner.

For the year ended December 31, 2020, we concluded there was a material weakness in our internal control environment over financial reporting because we did not have a sufficient number of resources to support the growth and complexity of our financial reporting requirements. This material weakness contributed to a material weakness in our control activities based on the criteria set forth in the 2013 Framework. Specifically, the design of certain controls did not adequately provide appropriate segregation of duties. The failure to maintain appropriate segregation of duties had a pervasive impact and as such, this deficiency resulted in a risk that could have impacted all financial statement account balances and disclosures. The material weaknesses did not result in any identified material misstatements to our financial statements, and there were no changes to previously released financial results.

In an attempt to remediate the material weaknesses, we have (i) engaged an external consulting firm to assist with our internal accounting functions and further enhance our internal controls, which has increased the number of personnel involved in financial

reporting and (ii) we are in the process of hiring additional qualified individuals that will increase the number of personnel involved in financial reporting and the control environment. However, we cannot assure you that these efforts will remediate our material weakness in a timely manner, or at all.

If we are unable to remediate the material weaknesses described above, or if we or our independent registered public accounting firm are otherwise unable to conclude that our internal control over financial reporting is effective we could lose investor confidence in the accuracy and completeness of our financial reports, the market price of our securities could decline, and we could be subject to sanctions or investigations by Nasdaq, the 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.

Based on the evaluation of our disclosure controls and procedures as of December 31, 2020, we concluded that, as of such date, our disclosure controls and procedures were not effective at a reasonable assurance level as a result of the material weakness that existed in our internal control over financial reporting, as described above. Although we are implementing certain measures to address such material weakness, as described above, we cannot assure you that these efforts will successfully remediate our material weakness in a timely manner, or at all.

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, as of December 31, 2020, we have filed registration statements on Form S-8 under the Securities Act registering the issuance of an aggregate of 11,387,220 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 these registration statements on Form S-8 are available for sale in the public market subject to vesting arrangements and exercise of options, the lock-up agreements described above and the restrictions of Rule 144 in the case of our affiliates.

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

An active trading market for our common stock may not be sustained.

Our shares of common stock began trading on The Nasdaq Capital Market on September 21, 2018. Given the limited trading history of our common stock, there is a risk that an active trading market for our shares will not be sustained, which could put downward pressure on the market price of our common stock and thereby affect the ability of our stockholders to sell their shares.

General Risk Factors

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

The trading market for our securities will depend in part on the research and reports that securities or industry analysts publish about us or our business. As a 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.

Future sales of substantial amounts of our common stock, or the possibility that such sales could occur, could adversely affect the market price of our common stock.

Future sales in the public market of shares of our common stock, including shares issued upon exercise of our outstanding stock options, or the perception by the market that these sales could occur, could lower the market price of our common stock or make it difficult for us to raise additional capital.

Our business could be negatively affected as a result of actions of activist stockholders, and such activism could impact the trading value of our securities.

Stockholders may, from time to time, engage in proxy solicitations or advance stockholder proposals, or otherwise attempt to effect changes and assert influence on our board of directors and management. Activist campaigns that contest or conflict with our strategic direction or seek changes in the composition of our board of directors could have an adverse effect on our operating results and financial condition. A proxy contest would require us to incur significant legal and advisory fees, proxy solicitation expenses and administrative and associated costs and require significant time and attention by our board of directors and management, diverting their attention from the pursuit of our business strategy. Any perceived uncertainties as to our future direction and control, our ability to execute on our strategy, or changes to the composition of our board of directors or senior management team arising from a proxy contest could lead to the perception of a change in the direction of our business or instability which may result in the loss of potential business opportunities, make it more difficult to pursue our strategic initiatives, or limit our ability to attract and retain qualified personnel and business partners, any of which could adversely affect our business and operating results. If individuals are ultimately elected to our board of directors with a specific agenda, it may adversely affect our ability to effectively implement our business strategy and create additional value for our stockholders. We may choose to initiate, or may become subject to, litigation as a result of the proxy contest or matters arising from the proxy contest, which would serve as a further distraction to our board of directors and management and would require us to incur significant additional costs. In addition, actions such as those described above could cause significant fluctuations in our stock price based upon temporary or speculative market perceptions or other factors that do not necessarily reflect the underlying fundamentals and prospects of our business.

Securities class action litigation could divert our management's attention and harm our business and could subject us to significant liabilities.

The stock markets have from time to time experienced significant price and volume fluctuations that have affected the market prices for the equity securities of life sciences and biotechnology companies. These broad market fluctuations may cause the market price of our ordinary shares to decline. In the past, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for us because biotechnology and biopharma companies have experienced significant stock price volatility in recent years. Even if we are successful in defending claims that may be brought in the future, such litigation could result in substantial costs and may be a distraction to our management and may lead to an unfavorable outcome that could adversely impact our financial condition and prospects.

Item 1B. Unresolved Staff Comments.

None.

Item 2. Properties.

We lease approximately 35,823 square feet of office, laboratory, and manufacturing space at our headquarters in San Diego, California, with the lease expiring December 31, 2025. From November 2018 to December 31, 2020, sublet one of our two leased facilities in San Diego. In December 2019, we amended the lease of one our two San Diego facilities to add 2,695 square footage and extend the lease through December 2025. In February 2021, we amended the lease of our other San Diego facilities to extend the term from through December 2025. We also lease 9,710 square feet of office space in a Salt Lake City, Utah under a non-cancelable operation lease with a term ending September 30, 2021. The Company has the ability to enter into renewal negotiations, prior to the lease end date, with no specific terms. 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 12, 2021, there were approximately 90 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 12, 2021, 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.

Recent Sales of Unregistered Securities

Not applicable.

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 that provides tools and services based on its Saphyr system to scientists and clinicians conducting genetic research and patient testing, and provides diagnostic testing for those with autism spectrum disorder ("ASD") and other neurodevelopmental disabilities through our wholly owned subsidiary Lineagen. 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, and genome analysis services to provide access to data generated by the Saphyr system for researchers who want to evaluate Saphyr data quickly and with a low up-front investment. Lineagen has been providing genetic testing services to families and their healthcare providers for over nine years and has performed over 65,000 tests for those with neurodevelopmental concern.

We have incurred losses in each year since our inception. We have incurred losses in each year since our inception. Our net losses were $41.1 million and $29.8 million for the years ended December 31, 2020 and 2019, respectively. As of December 31, 2020, we had an accumulated deficit of $143.7 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.

COVID-19

We are subject to additional risks and uncertainties as a result of the continued spread of COVID-19 and uncertain market conditions, which could continue to have a material impact on our business and financial results. The Company closely monitors and complies with various applicable guidelines and legal requirements in the jurisdictions in which it operates, which may continue to result in reduced business operations in response to new or existing stay-at-home orders, travel restrictions and other social distancing measures. Our manufacturing partners, suppliers, and customers, have implemented similar operational reductions. This overall reduction in activity has contributed to a decrease in sales which has negatively impacted the Company's 2020 financial results. The future effects of COVID-19 are unknown and the Company's financial results may continue to be negatively affected in the future.

There may be long-term negative effects of the COVID-19 pandemic, even after it has subsided. Specifically, product demand may be reduced due to an economic recession, a decrease in corporate capital expenditures, prolonged unemployment, reduction in consumer confidence, or any similar negative economic condition. These negative effects could have a material impact on our operations, business, earnings, and liquidity.

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.

Follow-On Public Offerings

In October 2019, we completed an underwritten public offering of 10,014,000 shares of our common stock and, to certain investors, pre-funded warrants to purchase 10,924,000 shares of our common stock, and accompanying common warrants to purchase

up to an aggregate of 20,938,000 shares of our common stock. Each share of common stock and pre-funded warrant to purchase one share of common stock was sold together with a common warrant to purchase one share of common stock. The public offering price of each share of common stock and accompanying common warrant was $0.86 and $0.859, respectively. The pre-funded warrants are immediately exercisable at a price of $0.001 per share of common stock. The common warrants are immediately exercisable at a price of $0.86 per share of common stock and will expire five years from the date of issuance. The shares of common stock and pre-funded warrants, and the accompanying common warrants, were issued separately and were immediately separable upon issuance. We received gross proceeds, before deducting underwriting discounts and commissions and other offering expenses, of $18.0 million.

In April 2020, we completed an underwritten public offering of 16,896,000 shares of our common stock and, to certain investors, pre-funded warrants to purchase 37,650,000 shares of our common stock, and accompanying common warrants to purchase up to an aggregate of 54,546,000 shares of our common stock. Each share of common stock and pre-funded warrant to purchase one share of common stock was sold together with a common warrant to purchase one share of common stock. The public offering price of each share of common stock and accompanying common warrant was $0.33 and $0.329 for each pre-funded warrant. The pre-funded warrants are immediately exercisable at a price of $0.001 per share of common stock. The common warrants are immediately exercisable at a price of $0.33 per share of common stock and will expire five years from the date of issuance. The shares of common stock and pre-funded warrants, and the accompanying common warrants, were issued separately and were immediately separable upon issuance. We received gross proceeds, before deducting underwriting discounts and commissions and other offering expenses, of $18.0 million.

On January 12, 2021, we completed an underwritten public offering of 33,368,851 shares of our common stock, including 4,352,458 shares of our common stock sold pursuant to the underwriters' exercise in full of their option to purchase additional shares. The price to the public in the offering was $3.05 per share and the underwriters purchased the shares from us pursuant to the underwriting agreement at a price of $2.867 per share. The gross proceeds to us were approximately $101.8 million before deducting underwriting discounts and commissions and other offering expenses.

On January 25, 2021, we completed an underwritten public offering of 38,333,352 shares of our common stock, including 5,000,002 shares of our common stock sold pursuant to the underwriters' exercise in full of their option to purchase additional shares. The price to the public in the offering was $6.00 per share and the underwriters purchased the shares from us pursuant to the underwriting agreement at a price of $5.64 per share. The gross proceeds to us were approximately $230.0 million before deducting underwriting discounts and commissions and other offering expenses.

Shelf Registration Statement and At-the-Market Facility

In August 2020, the Company filed a shelf registration statement on Form S-3 with the SEC covering the offering, issuance and sale of up to $125.0 million of the Company's securities, including up to $40.0 million of common stock pursuant to an at-the-market facility ("ATM") with Ladenburg Thalmann & Co. Inc. acting as sales agent. During October through December 2020, the Company sold 27,025,384 shares of common stock under the ATM at an average share price of $0.82, and received gross proceeds of approximately $22.1 million before deducting offering costs of $573,263. In January 2021, the Company sold an additional 6,298,152 shares of common stock under the ATM at an average share price of $2.68, and received gross proceeds of approximately $16.9 million before deducting offering costs of $422,034.

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. In addition, the Company provides instruments to certain customers under its reagent rental program, under which the Company provides an instrument to customers at no cost and the customers agree to purchase minimum quantities of consumables. 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. We also generate service revenue from the sale of diagnostic testing services for those with autism spectrum disorder and other neurodevelopmental disabilities through our wholly owned subsidiary Lineagen. Other revenue consists of warranty and other service-based revenue.

The following table presents our revenue for the periods indicated:

	Year Ended December 31,	
	2020	2019
Product revenue	$ 6,229,611	$ 9,474,444
Service and other revenue[1]	2,273,373	655,064
Total	$ 8,502,984	$ 10,129,508

[1] Includes $1.5 million of revenue generated by Lineagen from the date of acquisition through December 31, 2020.

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,			
	2020		2019	
	$	%	$	%
North America	$ 4,489,359	53 %	$ 5,030,267	50 %
EMEIA	3,162,694	37 %	3,627,602	36 %
Asia Pacific	850,931	10 %	1,471,639	14 %
Total	$ 8,502,984	100 %	$ 10,129,508	100 %

Cost of Revenue

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

Research and Development Expenses

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

Selling, General and Administrative Expenses

Selling, general and administrative expenses consist primarily of salaries and other personnel costs, intangibles amortization, 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, 2020 and 2019

The following table sets forth our results of operations for the years ended December 31, 2020 and 2019:

	Year Ended December 31,		Period-to-Period Change	
	2020	2019	$	%
Product revenue	$ 6,229,611	9,474,444	$ (3,244,833)	(34)%
Service and other revenue	2,273,373	655,064	1,618,309	247%
Total revenue	8,502,984	10,129,508	(1,626,524)	(16)%
Cost of product revenue	4,810,408	6,495,693	(1,685,285)	(26)%
Cost of service and other revenue	919,729	272,454	647,275	238%
Total cost of revenue	5,730,137	6,768,147	(1,038,010)	(15)%
Research and development	10,256,109	9,080,891	1,175,218	13%
Selling, general and administrative	31,068,060	20,155,376	10,912,684	54%
Total operating expenses	41,324,169	29,236,267	12,087,902	41%
Loss from operations	(38,551,322)	(25,874,906)	(12,676,416)	49%
Interest expense	(2,518,893)	(2,286,196)	(232,697)	10%
Loss on debt extinguishment	—	(1,333,496)	1,333,496	(100)%
Other expense	(6,943)	(299,424)	292,481	(98)%
Loss before income taxes	(41,077,158)	(29,794,022)	(11,283,136)	38%
Provision for income taxes	(29,193)	(21,048)	(8,145)	39%
Net loss	$ (41,106,351)	$ (29,815,070)	$ (11,291,281)	38%

Revenue

	Year Ended December 31,		Period-to-Period Change	
	2020	2019	$	%
Instrument revenue	$ 3,084,869	$ 6,762,463	$ (3,677,594)	(54)%
Consumable revenue	3,144,742	2,711,981	432,761	16%
Product revenue	6,229,611	9,474,444	(3,244,833)	(34)%
Services and other revenue	2,273,373	655,064	1,618,309	247%
Total revenue	$ 8,502,984	$ 10,129,508	$ (1,626,524)	(16)%

Revenue decreased by $1.6 million, or 16% to $8.5 million for the year ended December 31, 2020, as compared to $10.1 million for the same period in 2019. The decrease was largely driven by customers limiting their lab operations in response to COVID-19 restrictions to address the pandemic. The decrease impacted all regions. Below is a summary of changes for the year ended December 31, 2020 as compared to the same period in 2019:

- North America revenue decreased by $0.5 million, or 11%;
- EMEIA revenue decreased by $0.5 million, or 13%; and
- Asia Pacific revenue decreased by $0.6 million, or 42%.

Revenue for the year ended December 31, 2020 includes service revenue of $2.3 million of which $1.5 million is from our recently acquired subsidiary, Lineagen, from the date of the acquisition of August 21, 2020 to December 31, 2020.

Cost of Revenue

Cost of revenue decreased by $1.0 million, or 15%, to $5.7 million for the year ended December 31, 2020, as compared to $6.8 million for the same period in 2019. The decrease was driven by the decrease in revenue as well as a change in the mix of revenue between instrument sales and our reagent rental program. This was partially offset by an increase in consumable units sold of 59% and cost of service revenue of $0.5 million from our recently acquired subsidiary, Lineagen, from the date of the acquisition of August 21, 2020 to December 31, 2020.

Research and Development Expenses

Research and development expenses increased by $1.2 million, or 13%, to $10.3 million for the year ended December 31, 2020 as compared to $9.1 million for the same period in 2019. This is due to headcount additions to our development teams, but slightly offset by the salary reductions implemented in April 2020. In addition, our materials and supply expense increased during the year ended December 31, 2020 due to continued efforts to innovate our product.

Selling, General and Administrative Expenses

Selling, general and administrative expenses increased $10.9 million, or 54%, to $31.1 million for the year ended December 31, 2020 as compared to $20.2 million for the same period in 2019. This is due to organic headcount additions to our global sales and back-office teams to support world-wide product distribution, as well as headcount additions attributed to the acquisition of Lineagen. Also, we incurred increased legal and accounting fees to support business operations both domestically and internationally. A total of $1.5 million in transaction-related expenses were recorded for the Lineagen acquisition. Lastly, we recognized bad debt expense of $1.8 million during the year ended December 31, 2020.

Interest Expense

Interest expense increased by $0.2 million, or 10%, to $2.5 million for the year ended December 31, 2020, as compared to $2.3 million for the same period in 2019, driven by changes in our long-term debt. In March 2019, the Company retired its $10.0 million Credit and Security Agreement with MidCap Financial (the "CSA") and replaced it with a $20.0 million facility under our Loan and Security Agreement with Innovatus Life Sciences Lending Fund I, LP.

Liquidity and Capital Resources

Since our inception, we have incurred net losses and negative cash flows from operations. We incurred net losses of $41.1 million, and $29.8 million, and used $38.3 million and $29.5 million of cash from our operating activities for the years ended December 31, 2020 and 2019, respectively. As of December 31, 2020, we had an accumulated deficit of $143.7 million and cash and cash equivalents of $38.4 million.

Sources of Liquidity

Since our IPO, we have generated cash flows from sales of common stock and other equity instruments. We anticipate that future sources of liquidity will principally come from sales of common stock and other equity instruments, borrowings from credit facilities and revenue from our commercial operations. See Note 9 to our consolidated financial statements for a discussion of our recent equity activity and Note 8 to our consolidated financial statements for a discussion of terms and provisions of our debt included in this Annual Report on Form 10-K for more information.

Cash Flows

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

	Year Ended December 31,	
	2020	2019
Net cash provided by (used in):		
Operating activities	$ (38,314,378)	(29,529,720)
Investing activities	(2,449,952)	(61,056)
Financing activities	61,901,667	30,379,420

Operating Activities

Net cash used in operating activities was $38.3 million during the year ended December 31, 2020 as compared to $29.5 million during the year ended December 31, 2019. The increase in cash used in operating activities of $8.8 million is attributed to increased headcount across the business, increased professional fees to support ongoing business operations and increase our international presence, increased spending on materials and supplies, as well as $1.5 million in acquisition-related costs.

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. During the year ended December 31, 2020, cash used in investing activities related to the acquisition of Lineagen, our new wholly owned subsidiary. We did not use a significant amount of cash in investing activities during the year ended December 31, 2019.

Financing Activities

Net cash provided by financing activities was $61.9 million during the year ended December 31, 2020 as compared to $30.4 million during the year ended December 31, 2019, an increase of $31.5 million. During the year ended December 31, 2020, we raised approximately $16.4 million in net proceeds from a follow-on offering, and $28.6 million from warrant exercises, and $21.6 million in ATM sales. In addition, we received approximately $1.8 million pursuant to the PPP Loan, as defined in Note 8 to our consolidated financial statements included in this Annual Report. Offsets included payments of $2.3 million on our revolving line of credit and $5.0 million in term-loan principal prepayments in accordance with the Second Amendment. During the year ended December 31, 2019, we had net proceeds of $11.0 million from the Innovatus LSA and Innovatus Purchase Agreement, $2.5 million from the Aspire Purchase Agreement, and net proceeds from our follow-on public offering of $16.0 million.

Capital Resources

As of December 31, 2020, we had approximately $38.4 million in cash and cash equivalents, and working capital of $37.8 million. In addition, we have a revolving line of credit with Innovatus Life Sciences Lending Fund I, LP (the "Innovatus LSA"), under which no borrowings were outstanding as of December 31, 2020. As of December 31, 2020, the amount available under the revolving line of credit was $5.0 million. This facility is scheduled to expire in March 2024. See Note 8 to our consolidated financial statements for a discussion of terms and provisions of our debt included in this Annual Report on Form 10-K for more information.

During October through December 2020, pursuant an effective registration statement on Form S-3, we sold 27,025,384 shares of our common stock under an at-the-market facility, or the Ladenburg ATM, at an average share price of $0.82, and received gross proceeds of approximately $22.1 million before deducting offering costs of $573,263. In January 2021, we sold an additional 6,298,152 shares of our common stock under the Ladenburg ATM at an average share price of $2.68, and received gross proceeds of approximately $16.9 million before deducting offering costs of $422,034.

On January 12, 2021, we completed an underwritten public offering of 33,368,851 shares of our common stock, including 4,352,458 shares of our common stock sold pursuant to the underwriters' exercise in full of their option to purchase additional shares. The price to the public in the offering was $3.05 per share and the underwriters purchased the shares from us pursuant to the underwriting agreement at a price of $2.867 per share. The gross proceeds to us were approximately $101.8 million before deducting underwriting discounts and commissions and other offering expenses.

On January 25, 2021, we completed an underwritten public offering of 38,333,352 shares of our common stock, including 5,000,002 shares of our common stock sold pursuant to the underwriters' exercise in full of their option to purchase additional shares. The price to the public in the offering was $6.00 per share and the underwriters purchased the shares from us pursuant to the underwriting agreement at a price of $5.64 per share. The gross proceeds to us were approximately $230.0 million before deducting underwriting discounts and commissions and other offering expenses.

Management believes the available cash balance will be sufficient to fund operations, obligations as they become due, and capital investments for at least the next twelve months.

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 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

We generate revenue from the sale of our OGM products, primarily our Saphyr system and related consumables, and related services, which are primarily support, repair and maintenance services on the instruments. These products are sold primarily through a direct sales force, and within international markets, there is more reliance on distributors. In addition, we provide the Saphyr system to certain customers under our reagent rental program, under which we provides Saphyr systems to customers at no cost and the customers agree to purchase minimum quantities of consumables. We also generate revenue by performing diagnostic testing services, sourced from our recently acquired subsidiary, Lineagen. Revenue is recorded net of sales tax. We provide assurance-type warranties on our instruments with a term of one year, which are not material performance obligations, and also offer separately-priced extended warranties for periods after the initial year.

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

Transfer of control for our products is generally at shipment or delivery, depending on contractual terms, but occurs when title and risk of loss transfers to the customer which represents the point in time when the customer obtains the use of and substantially all of the remaining benefit of the product. As such our performance obligation related to product sales is satisfied at a point in time.

Revenue from support and maintenance contracts and extended warranties are recognized over time based on the contract term, which represents a faithful depiction of the transfer of goods and services given the stand-ready nature of the performance obligations. Service revenue related to repairs and customer sample evaluations are recognized as the services are performed based on the specific nature of the service.

For transfers of instruments and consumables to customers under our rental reagent program, we allocate the total contract consideration between the instrument and the consumables based on estimates of stand-alone selling prices, and we recognize the instrument revenue evenly over the rental period, and the consumables revenue when the consumables are delivered.

Revenue from the completion of diagnostic testing services is recorded at the billed value less estimated contractual adjustments. We perform our obligation under a contract with a customer by processing diagnostic tests and communicating the test results, which we have determined is the point at which control is transferred to the customer for revenue recognition purposes.

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

Some of our contracts have multiple performance obligations. For contracts with multiple performance obligations, we allocate the transaction price to each performance obligation using our best estimate of the standalone selling price of each distinct good or service in the contract. If the product or service does not have a history of sales or if sales volume is not sufficient, including

instruments under reagent rental agreements, we have estimated the standalone selling price to be the incremental sales price generally charged for consumables to customers under the reagent rental agreements in relation to amounts charged to other customers.

Variable Consideration

We exercise judgment in estimating variable consideration, if any, which would be recorded as a reduction to revenue. To the extent the transaction price includes variable consideration, we apply judgment in constraining the estimated variable consideration due to factors that may cause reversal of revenue recognized. We evaluate constraints based on our historical and projected experience with similar customer contracts.

Our contracts typically do not provide for product returns or refunds. In general, estimates of variable consideration and constraints are not material to our financial statements.

Remaining Performance Obligations

As of December 31, 2020, the estimated revenue expected to be recognized in the future related to performance obligations that are unsatisfied was $513,379. These remaining performance obligations primarily relate to extended warranty and support and maintenance obligations. We expect to recognize approximately 81% of this amount as revenue in 2021, 16% in 2022 and 3% in 2023. Warranty revenue is included in service and other revenue.

Contract Assets and Liabilities

We disclose accounts receivable separately in the consolidated balance sheets at their net realizable value. Contract assets primarily relate to our conditional right to consideration for work completed but not billed at the reporting date. Contract assets at the beginning and end of the period, as well as the changes in the balance, were immaterial.

Contract liabilities primarily relate to payments received from customers in advance of performance under the contract. We record a contract liability, or deferred revenue, when we have an obligation to provide service, and to a much lesser extent product, to the customer and payment is received or due in advance of performance. Deferred revenue primarily relates to support and maintenance contracts and extended warranty obligations. Contract liabilities are classified as other current liabilities and other long-term liabilities on the consolidated balance sheets. We recognized revenue of $357,492 and $270,171 during the years ended December 31, 2020 and 2019, respectively, which was included in the contract liability balance at the end of the previous year.

Distributor Transactions

In certain markets, we sell products and provide 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 our services to install the instrument at the end customer or 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. 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.

Goodwill Impairment

We review goodwill annually at the reporting unit level at the same time every year or when an event occurs or circumstances change such that it is reasonably possible that an impairment may exist. We have established December 31 as the annual impairment test date. We first make a qualitative assessment as to whether goodwill is impaired and if it is more likely than not that goodwill is impaired, we perform a quantitative impairment analysis to determine if goodwill is impaired. We may also determine to skip the qualitative assessment in any year and move directly to the quantitative test. For the quantitative test, we determine the fair value of the reporting unit, then compare the fair value of the reporting unit to its carrying value. Goodwill impairment is recorded for any excess of a reporting unit's carrying amount over its fair value, not to exceed the total amount of goodwill allocated to the reporting unit. The determination of fair value requires a number of significant assumptions and judgments, including assumptions about future economic conditions, revenue growth, operating margins, and discount rates.

We have determined that the Company is a single reporting unit for purposes of goodwill impairment testing. As of December 31, 2020, we performed a qualitative assessment of goodwill impairment which included an evaluation of changes in industry, market and macroeconomic conditions as well as consideration of our financial performance and any significant trends. Our qualitative assessment indicated that it was not more likely that not that goodwill is impaired. No impairments of goodwill were reported during the years ended December 31, 2020 and 2019.

Business Combinations

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

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

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, or (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.

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Report of Independent Registered Public Accounting Firm

Stockholders and Board of Directors
Bionano Genomics, Inc.
San Diego, California

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheet of Bionano Genomics, Inc. (the "Company") as of December 31, 2020, the related consolidated statements of operations, stockholders' equity, and cash flows for the year then ended, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2020, and the results of its operations and its cash flows for the year then ended, in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

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

We conducted our audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audit 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 audit included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audit also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audit provide a reasonable basis for our opinion.

/s/ BDO USA, LLP

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

San Diego, California
March 23, 2021

Report of Independent Registered Public Accounting Firm

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

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheet of Bionano Genomics, Inc and subsidiaries (the "Company") as of December 31, 2019, the related consolidated statements of operations, convertible preferred stock and stockholders' equity (deficit), and cash flows for the year ended December 31, 2019, 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, 2019, and the results of its operations and its cash flows for the year ended December 31, 2019, 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 has suffered recurring losses from operations and has a net capital deficiency that raises substantial doubt about its ability to continue as a going concern. In addition, the Company is not in compliance with the covenants included in its loan agreement with its lender. 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 audit 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 audit, 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 audit 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 audit 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 audit provide a reasonable basis for our opinion.

/s/ Deloitte & Touche LLP
San Diego, California
March 10, 2020

We have served as the Company's auditor since 2017. In 2020 we became the predecessor auditor.

Bionano Genomics, Inc.

Consolidated Balance Sheets

	December 31,	
	2020	2019
Assets		
Current assets:		
Cash and cash equivalents	$ 38,448,710	$ 17,311,373
Accounts receivable, net of allowance for doubtful accounts of $2,119,042 and $554,867 as of December 31, 2020 and 2019, respectively	2,775,042	6,333,963
Inventory	3,315,708	3,443,559
Prepaid expenses and other current assets	2,249,696	1,169,346
Total current assets	46,789,156	28,258,241
Property and equipment, net	4,910,414	1,949,625
Intangible assets, net	1,474,667	—
Goodwill	7,172,649	—
Other long-term assets	102,640	—
Total assets	$ 60,449,526	$ 30,207,866
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 2,929,662	$ 2,699,153
Accrued expenses	5,598,810	3,225,431
Contract liabilities	415,504	357,492
Current portion of long-term debt	—	20,084,945
Total current liabilities	8,943,976	26,367,021
Long-term debt, net of current portion	16,325,501	—
Long-term contract liabilities	97,875	182,648
Other non-current liabilities	—	44,479
Total liabilities	25,367,352	26,594,148
Commitments and contingencies (Note 10)		
Stockholders' equity:		
Common stock, $0.0001 par value, 400,000,000 and 200,000,000 shares authorized at December 31, 2020 and 2019, respectively; 189,952,944 and 34,274,469 shares issued and outstanding at December 31, 2020 and 2019, respectively	18,995	3,427
Preferred stock, $0.0001 par value; 10,000,000 shares authorized and no shares issued or outstanding as of December 31, 2020 and 2019	—	—
Additional paid-in capital	178,747,028	106,187,789
Accumulated deficit	(143,683,849)	(102,577,498)
Total stockholders' equity	35,082,174	3,613,718
Total liabilities and stockholders' equity	$ 60,449,526	$ 30,207,866

See accompanying notes to the consolidated financial statements.

Bionano Genomics, Inc.

Consolidated Statements of Operations

	Year Ended December 31,	
	2020	**2019**
Revenue:		
Product revenue	$ 6,229,611	$ 9,474,444
Service and other revenue	2,273,373	655,064
Total revenue	8,502,984	10,129,508
Cost of revenue:		
Cost of product revenue	4,810,408	6,495,693
Cost of service and other revenue	919,729	272,454
Total cost of revenue	5,730,137	6,768,147
Operating expenses:		
Research and development	10,256,109	9,080,891
Selling, general and administrative	31,068,060	20,155,376
Total operating expenses	41,324,169	29,236,267
Loss from operations	(38,551,322)	(25,874,906)
Other expenses		
Interest expense	(2,518,893)	(2,286,196)
Loss on debt extinguishment	—	(1,333,496)
Other expenses	(6,943)	(299,424)
Total other expenses	(2,525,836)	(3,919,116)
Loss before income taxes	(41,077,158)	(29,794,022)
Provision for income taxes	(29,193)	(21,048)
Net loss	$ (41,106,351)	$ (29,815,070)
Net loss per share, basic and diluted	$ (0.39)	$ (1.99)
Weighted-average common shares outstanding, basic and diluted	104,251,327	14,977,901

See accompanying notes to the consolidated financial statements.

Bionano Genomics, Inc.
Consolidated Statements of Stockholders' Equity

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount			
Balance at January 1, 2019	10,055,072	$ 1,004	$ 82,898,775	$ (72,762,428)	$ 10,137,351
Net loss	—	—	—	(29,815,070)	(29,815,070)
Issue stock, net of issuance costs	11,829,388	1,183	10,958,352	—	10,959,535
Stock-based compensation expense	—	—	1,346,023	—	1,346,023
Stock option exercises	50,665	6	65,858	—	65,864
Issue stock for covenant waiver	572,917	57	504,110	—	504,167
Reduce warrant exercise price for covenant waiver	—	—	45,787	—	45,787
Issue stock for employee stock purchase plan	87,969	9	141,697	—	141,706
Issue stock for debt	—	—	201,789	—	201,789
Issue warrants for debt	—	—	629,830	—	629,830
Stock warrant exercises	11,678,458	1,168	9,395,568	—	9,396,736
Balance at December 31, 2019	34,274,469	$ 3,427	$106,187,789	$(102,577,498)	$ 3,613,718
Net loss	—	—	—	(41,106,351)	(41,106,351)
Issue stock, net of issuance costs	43,921,384	4,392	37,930,202	—	37,934,594
Stock-based compensation expense	—	—	1,554,069	—	1,554,069
Stock option exercises	1,354	—	1,359	—	1,359
Issue stock for covenant waiver	872,601	87	299,913	—	300,000
Issue stock for employee stock purchase plan	87,940	9	39,652	—	39,661
Issue stock for acquisition	6,167,510	617	4,099,282	—	4,099,899
Stock warrant exercises	104,627,686	10,463	28,634,762	—	28,645,225
Balance at December 31, 2020	189,952,944	$ 18,995	$178,747,028	$(143,683,849)	$ 35,082,174

See accompanying notes to the consolidated financial statements.

Bionano Genomics, Inc.
Consolidated Statements of Cash Flows

	Year Ended December 31,	
	2020	**2019**
Operating activities:		
Net loss	$ (41,106,351)	$ (29,815,070)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization expense	1,479,537	1,127,850
Non-cash interest expense	1,263,911	883,269
Stock-based compensation	1,554,069	1,346,023
Provision for bad debt expense	1,808,991	554,867
Inventory impairment	125,640	—
Loss on debt extinguishment	—	1,333,496
Loss on disposal of fixed assets	—	11,918
Changes in operating assets and liabilities (net of assets acquired and liabilities assumed in acquisition)		
Accounts receivable	2,086,927	(2,374,497)
Inventory	(4,201,281)	(3,641,017)
Prepaid expenses and other current assets	(999,194)	(245,046)
Accounts payable	(1,809,309)	1,362,397
Accrued expenses and contract liabilities	1,482,682	(73,910)
Net cash used in operating activities	(38,314,378)	(29,529,720)
Investing activities:		
Lineagen acquisition, net of cash acquired	(2,449,952)	—
Purchases of property and equipment	—	(61,056)
Net cash used in investing activities	(2,449,952)	(61,056)
Financing activities:		
Proceeds from issuance of debt, net of issuance costs	—	19,134,424
Repayment of term-loan debt	(5,000,000)	(10,812,000)
Proceeds from PPP Loan	1,774,600	—
Proceeds from borrowing from line of credit	760,527	5,113,072
Repayments of borrowing from line of credit	(2,258,482)	(3,615,117)
Proceeds from sale of common stock	39,933,977	19,556,464
Offering expenses on sale of common stock	(2,000,000)	—
Proceeds from sale of common stock under employee stock purchase plan	39,661	141,706
Proceeds from warrant and option exercises	28,651,384	860,871
Net cash provided by financing activities	61,901,667	30,379,420
Net increase in cash and cash equivalents	21,137,337	788,644
Cash and cash equivalents at beginning of period	17,311,373	16,522,729
Cash and cash equivalents at end of period	$ 38,448,710	$ 17,311,373
Supplemental disclosure of non-cash financing and investing activity		
Fair value of stock and warrants issued in conjunction with debt	$ —	$ 831,619
Transfer of instruments and servers from inventory into property and equipment	$ 4,656,432	$ 1,266,015
Transfer of instruments and servers from property and equipment into inventory	$ 432,109	$ —
Issue stock for acquisition	$ 4,099,899	$ —
Issue stock for covenant waiver	$ 300,000	$ 504,167
Reduce warrant exercise price for covenant waiver	$ —	$ 45,787
Supplemental disclosure of cash flow information		
Interest paid	$ 1,251,535	$ 1,277,184

See accompanying notes to the consolidated financial statements.

1. Organization and Operations

Description of Business

Bionano Genomics, Inc. (collectively, with its consolidated subsidiaries, the "Company") is a life sciences instrumentation company in the genome analysis space that provides tools and services based on its Saphyr system to scientists and clinicians conducting genetic research and patient testing, and provides diagnostic testing for those with autism spectrum disorder ("ASD") and other neurodevelopmental disabilities through newly acquired Lineagen, Inc., a wholly owned subsidiary of the Company ("Lineagen"). The Company currently develops and markets the Saphyr system, a platform for ultra-sensitive and ultra-specific structural variation detection that is designed to enable 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. The Saphyr system is comprised of an instrument, chip consumables, reagents and a suite of data analysis tools, and genome analysis services to provide access to data generated by the Saphyr system for researchers who want to evaluate Saphyr data quickly and with a low up-front investment.

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, financial covenant breaches, and significant accumulated deficit since its inception and expects to continue to incur net losses into the foreseeable future. The Company had an accumulated deficit of $102.6 million as of December 31, 2019. In 2019, the Company used $29.5 million cash in operations. As of December 31, 2019, the Company had cash and cash equivalents of $17.3 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 had prepared cash flows forecasts which indicated that based on the Company's expected operating losses and negative cash flows and current debt obligations, there was 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, 2019, were issued.

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.

Liquidity

As of December 31, 2020, the Company had approximately $38.4 million in cash and cash equivalents, and working capital of 37.8 million. In addition, the Company has a $5.0 million revolving line of credit with Innovatus Life Sciences Lending Fund I, LP (the "Innovatus LSA"), under which no borrowings were outstanding as of December 31, 2020. This facility is scheduled to expire in March 2024.

During October through December 2020, pursuant an effective registration statement on Form S-3, we sold 27,025,384 shares of our common stock under an at-the-market facility, or the Ladenburg ATM, at an average share price of $0.82, and received gross proceeds of approximately $22.1 million before deducting offering costs of $573,263. In January 2021, we sold an additional 6,298,152 shares of our common stock under the Ladenburg ATM at an average share price of $2.68, and received gross proceeds of approximately $16.9 million before deducting offering costs of $422,034.

On January 12, 2021, the Company completed an underwritten public offering of 33,368,851 shares of common stock, including 4,352,458 shares of common stock sold pursuant to the underwriters' exercise in full of their option to purchase additional shares. The price to the public in the offering was $3.05 per share and the underwriters purchased the shares from the Company

pursuant to the underwriting agreement at a price of $2.867 per share. The gross proceeds were approximately $101.8 million before deducting underwriting discounts and commissions and other offering expenses.

On January 25, 2021, the Company completed an underwritten public offering of 38,333,352 shares of common stock, including 5,000,002 shares of common stock sold pursuant to the underwriters' exercise in full of their option to purchase additional shares. The price to the public in the offering was $6.00 per share and the underwriters purchased the shares from the Company pursuant to the underwriting agreement at a price of $5.64 per share. The gross proceeds were approximately $230.0 million before deducting underwriting discounts and commissions and other offering expenses.

The Company expects to continue to incur net losses for the foreseeable future. The Company plans to continue to fund its losses from operations and capital funding needs through a combination of equity offerings, debt financings or other sources, including potential collaborations, licenses and other similar arrangements. If the Company is not able to secure adequate additional funding, the Company may be forced to make reductions in spending, potentially harming the Company's business.

COVID-19

The Company is subject to additional risks and uncertainties as a result of the continued spread of COVID-19 and uncertain market conditions, which could continue to have a material impact on the Company's business and financial results. The Company closely monitors and complies with various applicable guidelines and legal requirements in the jurisdictions in which it operates, which may continue to result in reduced business operations in response to new or existing stay-at-home orders, travel restrictions and other social distancing measures. The Company's manufacturing partners, suppliers, and customers, have implemented similar operational reductions. This overall reduction in activity has contributed to a decrease in sales which has negatively impacted the Company's 2020 financial results. The future effects of COVID-19 are unknown and the Company's financial results may continue to be negatively affected in the future.

There may be long-term negative effects of the COVID-19 pandemic, even after it has subsided. Specifically, product demand may be reduced due to an economic recession, a decrease in corporate capital expenditures, prolonged unemployment, reduction in consumer confidence, or any similar negative economic condition. These negative effects could have a material impact on the Company's operations, business, earnings, and liquidity.

2. Summary of Significant Accounting Policies

Use of Estimates

The preparation of financial statements in conformity with U.S. generally accepted accounting principles ("U.S. GAAP") requires management to make significant estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting periods. Significant estimates and assumptions used by management include estimates of selling prices for multiple performance obligation arrangements, expected future cash flows including growth rates, discount rates, terminal values and other assumptions and estimates used in purchase accounting and to evaluate the recoverability of long-lived assets and goodwill, warranty reserves, certain accrued expenses, contingent liabilities, tax reserves, deferred tax rates and recoverability of the Company's net deferred tax assets and related valuation allowances. Although the Company regularly assesses these estimates, actual results could differ materially from these estimates. Changes in estimates are recorded in the period in which they become known. The Company bases its estimates on historical experience and various other assumptions that it believes to be reasonable under the circumstances.

Basis of Presentation

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

Lineagen Acquisition

On August 21, 2020, Alta Merger Sub, Inc., a wholly owned subsidiary of the Company ("Merger Sub"), Lineagen, a Delaware corporation, and Michael S. Paul, Ph.D., solely in his capacity as exclusive agent and attorney-in-fact of the securityholders of Lineagen, entered into an Agreement and Plan of Merger (the "Merger Agreement"). Pursuant to the terms and conditions of the Merger Agreement, Merger Sub merged with and into Lineagen (the "Merger") whereupon the separate corporate existence of Merger Sub ceased, with Lineagen continuing as the surviving corporation of the Merger as a wholly owned subsidiary of the Company.

The Company accounted for its acquisition of Lineagen using the acquisition method of accounting pursuant to Accounting Standards Codification Topic 805, Business Combinations ("ASC 805"). Under ASC 805, the tangible and identifiable intangible

assets acquired and liabilities assumed in a business combination are recorded based on their estimated fair values as of the acquisition date. Any excess purchase price over the estimated fair value assigned to the tangible and identifiable intangible assets acquired and liabilities assumed is recorded to goodwill.

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

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

Cash and Cash Equivalents

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 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.

Concentrations

Credit Risks

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

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

Sources of Materials and Products

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

Accounts Receivable

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

For OGM products and services, credit is extended based upon an evaluation of each customer's credit history, financial condition, and other factors. Estimates of allowances for 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. During the years ended December 31, 2020 and 2019, the Company recorded bad debt expense of $1.8 million and $554,867, respectively, which is included in selling, general and administrative expenses. Amounts are charged to the allowance for doubtful accounts when collection efforts have been exhausted and are deemed uncollectible.

Accounts receivable is subject to concentration risk whenever a customer has a balance that meets or exceeds 10% of the Company's total accounts receivable balance. As of December 31, 2019, Gene Company Limited represented 10% of the Company's total accounts receivable balance. As of December 31, 2020, Illumina, and Quest Diagnostics represented 17.3%, and 10.1%, respectively, of the Company's total accounts receivable balance.

Inventory

Inventory is stated at the lower of cost or net realizable value, on a first-in, first-out basis. Inventory 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,	
	2020	2019
Raw materials	$ 2,282,673	$ 950,846
Finished goods	1,033,035	2,492,713
	$ 3,315,708	$ 3,443,559

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

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

Intangible assets acquired in a business combination are recognized separately from goodwill and are initially recognized at their fair value at the acquisition date. Intangible assets are amortized over the estimated useful life of the asset on a basis that approximates the pattern of economic benefit. Intangible assets are reviewed for impairment if indicators of potential impairment exist. There was no indication of impairment of intangible assets for any of the periods presented.

As a result of the Lineagen acquisition the Company recorded intangible assets, which consist of a trade name intangible and customer relationship intangible, which are both being amortized on a straight-line basis over their estimated useful lives of five years, Straight-line amortization was determined to be materially consistent with the pattern of expected use of the intangible assets.

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

During the years ended December 31, 2020 and 2019, the Company recognized no impairment losses on long-lived assets. Substantially all of the Company's long-lived assets are located in the U.S.

Goodwill

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

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

During the years ended December 31, 2020 and 2019, the Company recognized no impairment losses on goodwill.

Revenue Recognition

Revenue by Source

	Year Ended December 31,	
	2020	2019
Instruments	$ 3,084,869	$ 6,762,463
Consumables	3,144,742	2,711,981
Total product revenue	6,229,611	9,474,444
Services and other	2,273,373	655,064
Total revenue	$ 8,502,984	$ 10,129,508

Revenue by Geographic Location

	Year Ended December 31,			
	2020		2019	
	$	%	$	%
North America	$ 4,489,359	53%	$ 5,030,267	50%
EMEIA	3,162,694	37%	3,627,602	36%
Asia Pacific	850,931	10%	1,471,639	14%
Total	$ 8,502,984	100%	$ 10,129,508	100%

The Company generates revenue from the sale of its products, primarily its Saphyr system and related consumables, and related services, which are primarily support, repair and maintenance services on the instruments. These products are sold primarily through a direct sales force, and within international markets, there is more reliance on distributors. In addition, the Company provides the Saphyr system to certain customers under its reagent rental program, under which the Company provides Saphyr systems to customers at no cost and the customers agree to purchase minimum quantities of consumables. The Company also generates revenue by performing diagnostic testing services, sourced from our recently acquired subsidiary, Lineagen. Revenue is recorded net of sales tax. The Company provides assurance-type warranties on its Saphyr system with a term of one year, which are not material performance obligations, and also offers separately-priced extended warranties for periods after the initial year.

The tables above provide revenue from contracts with customers by source and geographic location on a disaggregated basis. 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. For the years ended December 31, 2020 and 2019, the United States represented 42% and 47%, and China represented 8% and 5%, respectively, of total revenue.

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

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

Revenue from support and maintenance contracts and extended warranties is recognized over time based on the contract term, which represents a faithful depiction of the transfer of goods and services given the stand-ready nature of the performance obligations. Service revenue related to repairs and customer sample evaluations is recognized as the services are performed based on the specific nature of the service.

For transfers of instruments and consumables to customers under the Company's rental reagent program, the Company allocates the total contract consideration between the instrument and the consumables based on estimates of stand-alone selling prices, and recognizes the instrument revenue evenly over the rental period, and the consumables revenue when the consumables are delivered.

Revenue from the completion of diagnostic testing services is recorded at the billed value less estimated contractual adjustments. The Company performs its obligation under a contract with a customer by processing diagnostic tests and communicating

the test results, which the Company has determined is the point at which control is transferred to the customer for revenue recognition purposes.

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

Some of the Company's contracts have multiple performance obligations. For contracts with multiple performance obligations, the Company allocates the transaction price to each performance obligation using its best estimate of the standalone selling price of each distinct good or service in the contract. If the product or service does not have a history of sales or if sales volume is not sufficient, including instruments under reagent rental agreements, the Company has estimated the standalone selling price to be the incremental sales price generally charged for consumables to customers under the reagent rental agreements in relation to amounts charged to other customers.

Variable Consideration

The Company exercises judgment in estimating variable consideration, if any, and would be recorded as a reduction to revenue. To the extent the transaction price includes variable consideration, the Company applies judgment in constraining the estimated variable consideration due to factors that may cause reversal of revenue recognized. The Company evaluates constraints based on its historical and projected experience with similar customer contracts.

The Company's contracts typically do not provide for product returns or refunds. In general, estimates of variable consideration and constraints are not material to the Company's financial statements.

Remaining Performance Obligations

As of December 31, 2020, the estimated revenue expected to be recognized in the future related to performance obligations that are unsatisfied was $513,379. These remaining performance obligations primarily relate to extended warranty and support and maintenance obligations. The Company expects to recognize approximately 81% of this amount as revenue in 2021, 16% in 2022 and 3% in 2023. Warranty revenue is included in service and other revenue.

Contract Assets and Liabilities

The Company discloses accounts receivable separately in the consolidated balance sheets at their net realizable value. Contract assets primarily relate to the Company's conditional right to consideration for work completed but not billed at the reporting date. Contract assets at the beginning and end of the period, as well as the changes in the balance, were immaterial.

Contract liabilities primarily relate to payments received from customers in advance of performance under the contract. The Company records a contract liability, or deferred revenue, when it has an obligation to provide service, and to a much lesser extent product, to the customer and payment is received or due in advance of performance. Deferred revenue primarily relates to support and maintenance contracts and extended warranty obligations. Contract liabilities are classified as other current liabilities and other long-term liabilities on the consolidated balance sheets. The Company recognized revenue of $357,492 and $270,171 during the years ended December 31, 2020 and 2019, respectively, which was included in the contract liability balance at the end of the previous year.

Distributor Transactions

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

Cost of Revenue

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

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

Research and Development Costs

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

Patent Costs

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

Stock-based Compensation

The Company issues stock-based awards as compensation to employees and directors. Stock-based awards may include stock options, stock appreciation rights, vesting stock awards and performance share awards. These awards are accounted for as equity awards. To-date, the Company has issued stock options and recognizes stock-based compensation expense net of actual forfeitures on a straight-line basis over the underlying award's requisite service period, which is generally the vesting period, as measured using the award's grant date fair value.

Income Taxes

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

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

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

Segment Reporting

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

Net Loss Per Share

Basic net loss per share is calculated by dividing the net loss by the weighted-average number of common shares outstanding for the period. Diluted net loss per share is computed by dividing the net loss by the weighted average number of common shares and common share equivalents outstanding for the period. Common share equivalents are only included when their effect is dilutive. Pre-funded warrants from the Company's follow-on offering have been treated as if they were common shares outstanding on the date of issuance. The Company's potentially dilutive securities which include outstanding warrants to purchase stock and outstanding stock options under the Company's equity incentive plans have been excluded from the computation of diluted net loss per share as they

would be anti-dilutive to the net loss per share. For all periods presented, there is no difference in the number of shares used to calculate basic and diluted shares outstanding due to the Company's net loss position.

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

	Year Ended December 31,	
	2020	2019
Common stock options	5,289,501	1,742,912
Common warrants	15,174,114	24,026,550
Total	20,463,615	25,769,462

Recently Issued But Not Yet Adopted Accounting Pronouncements

In April 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, unless the Company elects early adoption of any standards, will adopt the new or revised accounting standards on the relevant dates on which adoption of such standards is required for non-public companies, which are the dates included below.

In February 2015, the FASB issued Accounting Standards Update ("ASU") 2016-2, Leases (Topic 842), which amends the accounting guidance for 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. ASU 2016-2 initially mandated a modified retrospective transition method, however, in July 2018, the FASB issued ASU 2018-11, Leases (Topic 842): Targeted Improvements, which amends ASU 2016-2, permitting entities the option to adopt this standard prospectively with a cumulative-effect adjustment to opening equity in the year of adoption and include required disclosures for prior periods but will not restate prior periods. The Company anticipates implementing the accounting guidance for leases using the alternative method beginning with the annual reporting period ending December 31, 2022 and interim reporting periods in 2023. The Company is currently evaluating impact that adoption of this standard will have on its consolidated financial statements and related disclosures.

In June 2016, the FASB issued ASU No. 2016-13, Financial Instruments - Credit Losses: Measurement of credit Losses on Financial Instruments (ASU 2016-13), which amends the impairment model by requiring entities to use a forward looking approach based on expected losses to estimate credit losses on certain types of financial instruments, including trade receivables and available-for-sale debt securities. The standard is effective for the company beginning in the first quarter of 2023, with early adoption permitted. The Company is currently evaluating impact that adoption of this standard will have on its consolidated financial statements and related disclosures.

In August 2020, the FASB issued ASU No. 2020-06, Debt - Debt with Conversion and other Options (Subtopic 470-20) and Derivatives and Hedging - Contracts in Entity's Own Equity (Subtopic 815-40): Accounting for Convertible Instruments and Contracts in an Entity's Own Equity ("ASU 2020-06"), which simplifies accounting for convertible instruments by removing major separation models required under current U.S. GAAP. ASU 2020-06 removes certain settlement conditions that are required for equity contracts to qualify for the derivative scope exceptions and also simplifies the diluted earnings per share calculation in certain areas. The standard is effective for public business entities, excluding entities eligible to be smaller reporting companies as defined by the SEC, for fiscal years and interim periods within those fiscal years beginning after December 15, 2021. For all other entities, the standard will be effective for fiscal years beginning after December 15, 2023. Early adoption is permitted, but no earlier than fiscal years beginning after December 15, 2020, and adoption must be as of the beginning of the Company's annual fiscal year. The Company is currently evaluating the impact that adoption of this standard will have on its consolidated financial statements and related disclosures.

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).

Financial instruments that are not re-measured at fair value include cash equivalents, accounts receivable, prepaid expenses and other current assets, accounts payable and accrued liabilities, and debt. The carrying values of these financial instruments approximate their fair values. The Company estimates the fair value of any cash equivalents using level 1 inputs. The Company estimates the fair value of all other financial instruments using Level 2 inputs.

4. Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets consist of the following:

	December 31, 2020	December 31, 2019
Prepayment to supplier	$ 1,145,705	$ 409,851
Prepaid insurance	642,488	302,433
Other current assets	461,503	457,062
Total	$ 2,249,696	$ 1,169,346

5. Property and Equipment, Net

Property and equipment, net consist of the following:

	December 31, 2020	December 31, 2019
Computer and office equipment	$ 492,436	$ 476,402
Lab equipment	6,718,674	4,623,714
Service equipment placed at customer sites	3,266,559	1,247,328
Leasehold improvements	1,888,873	1,875,647
	12,366,542	8,223,091
Less accumulated depreciation and amortization	(7,456,128)	(6,273,466)
	$ 4,910,414	$ 1,949,625

For the years ended December 31, 2020 and 2019 the Company recorded depreciation expense of $1,369,433 and $1,127,850, respectively, which includes an allocation to cost of revenue of $544,176 and $41,118, respectively.

6. Intangible Assets, Net

Intangible assets, net, consist of the following:

December 31, 2020	Customer Relationships	Trade Name	Total
Gross balance	$ 950,000	$ 630,000	$ 1,580,000
Accumulated amortization	(63,333)	(42,000)	(105,333)
Intangibles, net	$ 886,667	$ 588,000	$ 1,474,667

The Company recorded amortization expense for intangible assets of $105,333 for the year ended December 31, 2020, in selling, general and administrative expenses. The customer relationships and trade name intangibles are both being amortized on a straight-line basis over their estimated useful lives of five years, and have remaining amortization periods of 4.7 years. Future amortization expense of intangible assets is as follows:

2021	316,000
2022	316,000
2023	316,000
2024	316,000
2025 and thereafter	210,667
Total	$ 1,474,667

7. Accrued Expenses

Accrued expenses consist of the following:

	December 31, 2020	December 31, 2019
Compensation expenses	$ 3,250,709	$ 1,805,357
Deferred rent	—	266,282
Goods received not invoiced	567,092	191,721
Taxes payable	562,149	268,129
Insurance	357,618	—
Professional fees and royalties	247,222	213,514
Interest	98,152	125,743
Other	515,868	354,685
Total	$ 5,598,810	$ 3,225,431

8. Long-Term Debt

Paycheck Protection Program

On April 17, 2020, the Company received loan proceeds of approximately $1.8 million (the "PPP Loan") pursuant to the Paycheck Protection Program ("the PPP") under the Coronavirus Aid, Relief, and Economic Security Act (the "CARES Act") administered by the U.S. Small Business Administration (the "SBA"). The PPP Loan accrued interest at a rate of 1.00% per annum, and was subject to the standard terms and conditions applicable to loans administered by the SBA under the CARES Act. In February 2021, the Company applied for forgiveness of the PPP Loan, and in March 2021, the PPP Loan, including all accrued interest, was forgiven in full.

Under the terms of the CARES Act, recipients of loans under the PPP can apply for and be granted forgiveness for all or a portion of such loan granted under the PPP. Such forgiveness will be determined, subject to limitations, based on the use of loan proceeds for payment of payroll costs and certain other eligible costs (the "Eligible Costs"). Pursuant to the Paycheck Protection Program Flexibility Act (the "PPPFA"), enacted on June 5, 2020, the Company was permitted to use loan proceeds on Eligible Costs through October 2, 2020, or the date that was 24 weeks from the PPP Loan origination date (the "Covered Period"). In order to apply for the PPP Loan, the Company was required to certify, among other things, that the current economic uncertainty made the PPP Loan request necessary to support the Company's ongoing operations. This certification further required the Company to take into account the maintenance of its workforce, the Company's need for additional funding to continue operations, and the Company's ability to access alternative forms of capital in the current market environment to offset the effects of the COVID-19 pandemic.

Innovatus LSA

In March 2019, the Company entered into a Loan and Security Agreement (the "LSA") by and among Innovatus Life Sciences Lending Fund I, LP, a Delaware limited partnership ("Innovatus"), as collateral agent and the lenders listed on Schedule 1.1 thereto, including East West Bank. The LSA provided a first term loan of $17.5 million, a second term loan of $2.5 million and a third term loan of $5.0 million (collectively, "Term Loans") if the Company satisfied certain funding conditions. Interest on the Term Loans is due on the first of each month at a rate of 10.25% per annum in cash or a discounted rate of 7.25% in cash with 3.0% of the 10.25%

per annum rate added to the principal of the loan and subject to accruing interest through the end of the interest only payment period, which ends March 1, 2022. At inception, the Company elected to pay interest in cash at a rate of 7.25% per annum and have 3.0% per annum of the interest added back to the outstanding principal. As of December 31, 2020, the effective interest rate, including debt issuance costs, for Term Loans was 16.7%. Beginning in April 2022, the Company must make 24 equal monthly payments of principal and interest with a final maturity date in March 2024, which may be earlier due to an event of default if not cured within time specified. The LSA provides for prepayment fees of 3.0% of the outstanding balance of the loan if the loan is repaid on or prior to March 14, 2020, 2.0% of the amount prepaid if the prepayment occurs after March 14, 2020 but prior to March 14, 2021, 1.0% of the amount prepaid after March 14, 2021 but prior to March 14, 2022 and 0% of the amount prepaid if the prepayment occurs thereafter. In addition, upon the final repayment of the total amounts borrowed, the Company is required to pay an end of term fee of $0.8 million. This end of term fee is being recognized as interest expense over the term of the LSA.

The LSA also provides for a revolving line of credit in an amount not to exceed $5.0 million (the "Revolver"). The Company may repay and reborrow amounts under the Revolver at any time prior to the March 1, 2024 maturity date without penalty or premium. The outstanding balance of amounts borrowed under the Revolver bears interest at a rate equal to 2.0% above the prime rate, per annum, as specified in the terms of the Revolver. The LSA allows the Company to borrow and repay amounts at any time prior to the maturity date in 2024.

The LSA is collateralized by substantially all of the Company's assets, including its intellectual property. The LSA requires the Company to comply with various affirmative and negative covenants, including: (1) a liquidity covenant requiring the Company to maintain a minimum cash balance at all times in a collateral account and (2) a revenue covenant requiring the Company to meet certain minimum revenue targets measured at the end of each calendar quarter. The LSA also includes certain standard events of default, and a provision that Innovatus could declare an event of default upon the occurrence of any event that it interprets as having a material adverse impact to the Company's business, operations, or condition, a material impairment on the Company's ability to pay the secured obligations under the LSA, or upon a material adverse effect on the collateral under the agreement, thereby requiring the Company to repay the loans immediately, together with a prepayment fee and other applicable fees. As of December 31, 2020, the Company believes there have been no events or changes in conditions that could require immediate repayment of amounts due to Innovatus.

In March 2019, in connection with the receipt of $20.0 million in proceeds from the Term Loans, the Company issued to Innovatus a warrant to purchase up to 161,987 shares of its common stock at an exercise price of $4.63 per share, which has a term of 10 years. The Company applied the Black-Scholes option pricing model to estimate the fair value of the warrants, with the following assumptions: a) risk-free rate of 2.43%; b) expected volatility of 66.93%; c) no dividend expected to be paid; and d) expected life of 10 years. Based on this model, the relative fair value of the warrant was determined to be $0.6 million, which was recorded as a debt discount and is being amortized as interest expense using the effective-interest method over the term of the LSA. Pursuant to the LSA, if the Company borrows the third term loan of $5.0 million, Innovatus will be entitled to purchase up to an additional 40,496 shares of the Company's common stock at an exercise price of $4.63 per share.

In addition, in connection with entry into the LSA, the Company paid fees to third parties of approximately $0.8 million which were recorded as a deduction of the debt liability and are being amortized as interest expense using the effective-interest method over the term of the LSA.

In June 2019, the LSA was amended to among other things: (i) extend the deadline for the Company to maintain its domestic depository and operating accounts with the Bank, subject to a control agreement in favor of Innovatus, to July 31, 2019 and (ii) permit the Company to incur credit card indebtedness in an amount not to exceed $150,000.

As of September 30, 2019, the Company did not achieve the revenue covenant under the Innovatus LSA. As a result, in October 2019, the Company obtained a waiver letter from Innovatus. Pursuant to the waiver letter, Innovatus agreed to allow the Company to cure its noncompliance with the revenue covenant as of September 30, 2019 so long as the Company (i) raised at least $10 million in gross proceeds from the sale of its securities in an underwritten public offering by October 31, 2019 and (ii) amended the warrant to purchase stock, issued by the Company to Innovatus in March 2019 to decrease the exercise price of the warrant from $4.63 per share to $0.48 per share. Also pursuant to the waiver letter, as consideration for the prospective breach of a liquidity covenant, the Company agreed to issue to Innovatus 572,917 shares of the Company's common stock. As a result of the amendment and shares issued, the Company recognized $549,955 as a debt discount, which is being amortized as interest expense over the remaining term of the LSA.

As of December 31, 2019, the Company did not achieve certain financial covenants under the Innovatus LSA. As a result, in March 2020, the Company and Innovatus entered into an amendment to the Innovatus LSA (the "Second Amendment") to, among other things: (i) waive the events of default from not achieving the specific financial covenants for the December 31, 2019 measurement date, (ii) require an immediate partial repayment of $2.1 million, (iii) require an additional partial repayment of $2.9 million on the earlier of completion of an Equity Event (as defined in the Second Amendment), or April 30, 2020, (iv) modify the liquidity covenant, such that the Company's minimum cash balance shall vary based on outstanding borrowing capacity under the Revolver (provided, however, that the Company shall maintain a minimum cash balance of $2 million at any given time), (v) reduce the dollar amount of certain minimum revenue covenants measured as of the end of each calendar quarter (each, a "Revenue Covenant") and (vi) modify the terms of certain events of default. For example, the Second Amendment provides for a cure

period in connection with the breach of certain minimum revenue financial covenants, as long as the Company submits an updated management plan and financial projections, which are subject to Innovatus approval, and completes a Qualified Financing Event (as defined in the Second Amendment) within 45 days of such breach.

In connection with the Second Amendment, the Company was obligated to pay Innovatus a waiver fee in the amount of $200,000 and a prepayment fee of $100,000, payable in cash or in shares of the Company's common stock at the Company's election, no later than following completion of the Equity Event, as defined in the Second Amendment. As described in Note 9 below, the Company completed a follow-on public offering in April 2020 that constituted an Equity Event under the Second Amendment. A portion of the proceeds from the follow-on offering were used to pay-down $2.9 million of principal balance outstanding under the Term Loans in accordance with the Second Amendment. In addition, the Company issued 872,601 shares of its common stock to Innovatus to satisfy the $200,000 waiver fee and the $100,000 prepayment fee due under the Second Amendment. As a result of the amendment and shares issued, the Company recognized $300,000 as a debt discount, which is being amortized as interest expense over the remaining term of the LSA. Also pursuant to the Second Amendment, the Company subsequently registered such shares for resale on a registration statement on Form S-3 (the "Registration Statement") filed with the Securities and Exchange Commission on June 22, 2020 and declared effective on July 7, 2020. The Company has not and will not receive any of the proceeds from the offering described in the Registration Statement.

In connection with the Merger, the Company and Lineagen entered into a Third Amendment (the "Third Amendment") to the Innovatus LSA. Among other things, the Third Amendment adds Lineagen as a "Borrower" under the Innovatus LSA and updates certain financial covenants in light of Lineagen becoming a wholly owned subsidiary of the Company.

On December 31, 2020, the Company obtained a waiver from Innovatus of its previously disclosed noncompliance, as of September 30, 2020, with the revenue covenant contained in the LSA.

As of December 31, 2020, the Company was in compliance with the covenants under the Innovatus LSA.

Summary of Debt Obligations

The carrying value of the Company's debt for the periods presented was as follows:

	December 31, 2020	December 31, 2019
Term Loans	15,980,814	$ 20,473,436
Revolver	—	1,497,955
PPP Loan	1,774,600	—
Total principal	17,755,414	21,971,391
Less: unamortized debt issuance costs	(1,429,913)	(1,886,446)
Total carrying value of debt	$ 16,325,501	$ 20,084,945

As of December 31, 2020, future minimum scheduled principal payments for the Term Loans are as follows:

2021	—
2022	7,811,845
2023	8,049,660
2024	1,893,909
2025 and thereafter	—
Total	$ 17,755,414

These future minimum scheduled principal payments include scheduled principal payments on the PPP Loan as of December 31, 2020. However, as discussed above, In March 2021, the Company received forgiveness of the full principal amount and accrued interest under PPP Loan.

9. Stockholders' Equity

Common Stock

Sale of Common Stock

In March 2019, the Company entered into a Common Stock Purchase Agreement (the "Aspire Purchase Agreement") with Aspire Capital Fund, LLC ("Aspire Capital") which provides that, upon the terms and subject to the conditions and limitations therein, Aspire Capital is committed to purchase up to an aggregate of $10.0 million of shares of the Company's common stock, subject to certain limitations, including that Aspire Capital is not required to purchase shares if such purchase would result in Aspire Capital (together with its affiliates) beneficially owning more than 19.99% of the Company's common stock outstanding.

Concurrently with entering into the Aspire Purchase Agreement, the Company also entered into a registration rights agreement with Aspire Capital, in which the Company agreed to file one or more registration statements, as permissible and necessary to register under the Securities Act of 1933, as amended, the sale of the shares of the Company's common stock that have been and may be issued to Aspire Capital under the Aspire Purchase Agreement.

Upon execution of the Aspire Purchase Agreement, the Company sold 272,479 shares of the Company's common stock to Aspire Capital at $3.67 per share for net proceeds of approximately $1.0 million. Aspire Capital was committed to purchase up to $9.0 million of additional shares of common stock, subject to beneficial ownership limitations, solely at the Company's request from time to time during a 30 month period beginning in April 2019 and at a per share purchase price equal to the lesser of:

- the lowest sale price of the Company's common stock on the purchase date; or
- the average of the three lowest closing sale prices for the Company's common stock during the ten consecutive trading days ending on the trading day immediately preceding the purchase date.

In consideration for entering into the Aspire Purchase Agreement and concurrently with the execution of the Aspire Purchase Agreement, the Company issued 69,444 shares of its common stock to Aspire Capital. The value of these shares was netted against the proceeds received as issuance costs.

In December 2019, pursuant to the terms of the Aspire Purchase Agreement, the Company sold 1,067,361 shares of its common stock to Aspire Capital, resulting in $1,116,067 in gross proceeds to the Company. As of December 31, 2020, due to beneficial ownership limitations, the Company cannot sell additional shares of its common stock to Aspire Capital.

Follow-on Public Offerings

In October 2019, the Company completed an underwritten public offering of 10,013,600 shares of its common stock and, to certain investors, pre-funded warrants to purchase 10,923,958 shares of its common stock, and accompanying common warrants to purchase up to an aggregate of 20,937,558 shares of its common stock. Each share of common stock and pre-funded warrant to purchase one share of common stock was sold together with a common warrant to purchase one share of common stock. The public offering price of each share of common stock and accompanying common warrant was $0.86 and $0.859 for each pre-funded warrant and accompanying common warrant. The pre-funded warrants are immediately exercisable at a price of $0.001 per share of common stock. The common warrants are immediately exercisable at a price of $0.86 per share of common stock and will expire five years from the date of issuance. The shares of common stock and pre-funded warrants, and the accompanying common warrants, were issued separately and were immediately separable upon issuance. The gross proceeds to the Company, before deducting offering costs of $2.0 million, were $18.0 million.

In April 2020, the Company completed an underwritten public offering of 16,896,000 shares of its common stock and, to certain investors, pre-funded warrants to purchase 37,650,000 shares of its common stock, and accompanying common warrants to purchase up to an aggregate of 54,546,000 shares of its common stock. Each share of common stock and pre-funded warrant to purchase one share of common stock was sold together with a common warrant to purchase one share of common stock. The public offering price of each share of common stock and accompanying common warrant was $0.33 and $0.329 for each pre-funded warrant. The pre-funded warrants are immediately exercisable at a price of $0.001 per share of common stock. The common warrants are immediately exercisable at a price of $0.33 per share of common stock and will expire five years from the date of issuance. The shares of common stock and pre-funded warrants, and the accompanying common warrants, were issued separately and were immediately separable upon issuance. The gross proceeds to the Company, before deducting offering costs of $1.6 million, were $18.0 million.

On January 12, 2021, the Company completed an underwritten public offering of 33,368,851 shares of common stock, including 4,352,458 shares of common stock sold pursuant to the underwriters' exercise in full of their option to purchase additional shares. The price to the public in the offering was $3.05 per share and the underwriters purchased the shares from the Company pursuant to the underwriting agreement at a price of $2.867 per share. The gross proceeds were approximately $101.8 million before deducting underwriting discounts and commissions and other offering expenses.

On January 25, 2021, the Company completed an underwritten public offering of 38,333,352 shares of common stock, including 5,000,002 shares of common stock sold pursuant to the underwriters' exercise in full of their option to purchase additional shares.. The price to the public in the offering was $6.00 per share and the underwriters purchased the shares from the Company

pursuant to the underwriting agreement at a price of $5.64 per share. The gross proceeds to us were approximately $230.0 million before deducting underwriting discounts and commissions and other offering expenses.

Shelf Registration Statement and Ladenburg At-the-Market Facility

In August 2020, the Company filed a shelf registration statement on Form S-3 with the SEC covering the offering, issuance and sale of up to $125.0 million of the Company's securities, including up to $40.0 million of common stock pursuant to an at-the-market facility, or the Ladenburg ATM, with Ladenburg Thalmann & Co. Inc. acting as sales agent. During October through December 2020, the Company sold 27,025,384 shares of common stock under the Ladenburg ATM at an average share price of $0.82, and received gross proceeds of approximately $22.1 million before deducting offering costs of $573,263. In January 2021, the Company sold an additional 6,298,152 shares of common stock under the ATM at an average share price of $2.68, and received gross proceeds of approximately $16.9 million before deducting offering costs of $422,034.

Common Stock Warrants

A summary of the Company's warrant activity for the year ended December 31, 2020 was as follows:

	Shares of Stock under Warrants	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term	Aggregate Intrinsic Value
Outstanding at January 1, 2019	4,062,507	$ 6.32	4.67	
Granted	32,023,503	$ 0.57	4.84	
Exercised	(11,678,458)	$ 0.07		$ 10,457,345
Canceled	(1,502)	$ 59.90		
Outstanding at December 31, 2019	24,406,050	$ 1.76	4.82	$ 7,932,689
Granted	95,396,000	$ 0.22	4.28	
Exercised	(104,627,695)	$ 0.28		$ 56,779,739
Canceled	(241)	$ 59.90		
Outstanding at December 31, 2020	15,174,114	$ 2.34	3.76	$ 26,840,636

During the year ended December 31, 2019, the Company recognized debt issuance costs of $675,617 for warrants issued in 2019.

In March 2020, the Company entered into a Warrants Amendment and Agreement with certain holders of warrants that were exercisable for 3,200,000 shares of common stock. The agreement reduced the exercise price of existing warrants from $.86 per share to $0.75 per share, which were exercised following the amendment, in addition to issuing 3,200,000 new warrants at an exercise price per share of $1.06 that were exercisable beginning six months from the date of issuance and have a contractual term of five years, six months.

2018 Equity Incentive Plan

In August 2018, the Company's board of directors (the "Board") and its stockholders adopted the 2018 Equity Incentive Plan (the "2018 Plan"), as a successor to and continuation of the Company's 2006 Equity Incentive Plan (the "2006 Plan"). Under the 2018 Plan, the Company may grant stock options, stock appreciation rights, restricted stock, restricted stock units and other awards to individuals who are then its employees, directors and consultants, including employees and consultants of its affiliates. The Company has initially reserved 1,499,454 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, 2020, 5,119,378 shares of common stock were authorized for future grants under the 2018 Plan.

Stock Options

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

	Shares of Stock under Stock Options	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term	Aggregate Intrinsic Value
Outstanding at January 1, 2019	1,282,847	$ 6.90	9.2	
Granted	716,960	$ 3.78		
Exercised	(50,665)	$ 1.30		$ 151,819
Canceled	(206,230)	$ 7.20		
Outstanding at December 31, 2019	1,742,912	$ 5.73	8.2	$ 4,356
Granted	4,385,666	$ 0.67		
Exercised	(3,290)	$ 1.10		$ 7,261
Canceled	(835,787)	$ 3.37		
Outstanding at December 31, 2020	5,289,501	$ 1.91	8.7	$ 10,177,942
Vested and expected to vest at December 31, 2020	5,261,148	$ 1.91	8.7	$ 10,127,495
Vested and exercisable at December 31, 2020	1,474,891	$ 4.02	8.0	$ 1,750,896

The weighted-average grant date fair value of stock option grants during the years ended December 31, 2020 and 2019 was $0.44 and $2.16, respectively. The contractual term of stock options granted to employees was 10 years, which is also the maximum contractual term permitted for stock options (and stock appreciation rights) issued under the 2018 Plan. Stock options generally vest or become exercisable monthly over a four-year period.

Stock-Based Compensation Expense

The Company recognized stock-based compensation expense for the years ended December 31, 2020 and 2019 was as follows:

	Year Ended December 31,	
	2020	2019
Research and development	$ 375,471	$ 240,692
General and administrative	1,178,598	1,105,331
Total stock-based compensation expense	$ 1,554,069	$ 1,346,023

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

	Year Ended December 31,	
	2020	2019
Risk-free interest rate	.6%	2.4%
Expected volatility	77.0%	66.7%
Expected term (in years)	5.8	5.1
Expected dividend yield	0.0%	0.0%

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

Expected volatility. 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, 2020, the unrecognized compensation cost related to outstanding stock options was $2,834,598 and is expected to be recognized as expense over a weighted-average period of 2.55 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 were initially reserved for issuance under the ESPP. In addition, the number shares of common stock reserved for issuance under the ESPP will automatically increase on January 1 of each calendar year, beginning on January 1, 2019, through January 1, 2028, by the lesser of (1) 1% of the total number of shares of the Company's common stock outstanding on the last day of the calendar month before the date of the automatic increase, (2) 220,000 shares, or (3) a lesser number of shares as determined by the Board. As of December 31, 2020, 297,462 shares of common stock were authorized for future grants under the ESPP.

10. Commitments and Contingencies

Leases

We lease approximately 35,823 square feet of office, laboratory, and manufacturing space at our headquarters in San Diego, California, with the lease expiring December 31, 2025. From November 2018 to December 31, 2020, sublet one of our two leased facilities in San Diego. In December 2019, we amended the lease of one our two San Diego facilities to add 2,695 square footage and extend the lease through December 2025. In February 2021, we amended the lease of our other San Diego facilities to extend the term from through December 2025. We also lease 9,710 square feet of office space in a Salt Lake City, Utah under a non-cancelable operation lease with a term ending September 30, 2021. The Company has the ability to enter into renewal negotiations, prior to the lease end date, with no specific terms.

Rent expense was $239,886 and $171,796 for the years ended December 31, 2020 and 2019, respectively, including the offsets for amortization of the leasehold incentive obligation of $225,052 for each of the years ended December 31, 2020 and 2019 and sublease rental income of $422,116 and $422,116 for the years ended December 31, 2020 and 2019, respectively.

The future minimum lease payments required under non-cancelable leases as of December 31, 2020, are summarized as follows:

Year Ending December 31,	**Total Payments**
2021	733,626
2022	638,740
2023	666,411
2024	696,388
2025 and thereafter	728,671
Total minimum lease payments	$ 3,463,836

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.

Certain royalty agreements require the Company to make minimum payments regardless of the level of sales achieved. As of December 31, 2020, annual future minimum royalty payments total $110,000 and are payable through November 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 in March 2019. The contract can be terminated with 90 days written notice by either party. As of February 28, 2021, the Company was negotiating with the supplier to extend the agreement.

Litigation

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

11. Income Taxes

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

	Years Ended December 31,	
	2020	2019
Domestic	$ (41,191,343)	$ (29,851,428)
Foreign	114,185	57,406
Loss before provision for income taxes	$ (41,077,158)	$ (29,794,022)

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

	Years Ended December 31,	
	2020	2019
Current:		
Foreign	$ 24,158	$ 19,492
State and local	5,035	1,556
Income tax provision	$ 29,193	$ 21,048

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

	December 31,	
	2020	2019
Income taxes at statutory rate	$ (8,626,202)	$ (6,256,953)
State income taxes, net of federal benefits	(521,863)	(529,351)
Change in valuation allowance	9,815,771	6,786,990
Other permanent differences	(66,647)	449,958
Research credits	(568,126)	(429,596)
Other	(3,740)	—
Income tax expense	$ 29,193	$ 21,048

Significant components of the Company's deferred tax assets at December 31, 2020 and 2019 are as follows:

	December 31,	
	2020	2019
Deferred tax assets:		
Net operating loss carryforwards	$ 62,353,368	$ 41,780,806
Research and development credits	5,670,225	5,007,178
Other	2,249,177	1,406,893
Total	70,272,770	48,194,877
Less: valuation allowance	(70,272,770)	(48,194,877)
Deferred tax assets, net of valuation allowance	$ —	$ —

As of December 31, 2020, the Company has federal and state tax net operating loss carryforwards of $266.7 million and $114.0 million, respectively. The federal tax loss carryforwards include $102.5 million that do not expire but utilization is limited to 80% of the Company's taxable income in any given tax year based on current federal tax laws. The remaining federal tax loss carryforwards of $164.2 million and state tax loss carryforwards begin to expire in 2027 and 2023, respectively, unless previously utilized. As of December 31, 2020, the Company also has federal and California research credit carryforwards of $5.5 million and $5.0 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 ("R&D") activities, the Company expects to continue to incur net losses into the foreseeable future. As such, the Company cannot conclude that it is more likely than not that its deferred tax assets will be realized. A valuation allowance of $70.3 million and $48.2 million as of December 31, 2020 and 2019, respectively, has been established to offset the deferred tax assets.

Utilization of the net operating losses and research and development ("R&D") credit carryforwards may be subject to annual limitations due to ownership changes that have occurred or that could occur in the future, as required by Sections 382 and 383 of the Internal Revenue Code of 1986, as amended (the "Code"), as well as similar state and foreign provisions. These ownership changes may limit the amount of net operating losses and R&D credit carryforwards that can be utilized annually to offset future taxable income and tax, respectively. In general, an "ownership change" as defined by Section 382 of the Code results from a transaction or series of transactions over a three-year period resulting in an ownership change of more than 50 percentage points of outstanding stock of a company by certain stockholders. Due to the existence of the valuation allowance, limitations created by past or future ownership changes, if any, will not impact its effective tax rate.

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.

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

	December 31,	
	2020	2019
Balance at beginning of the year	$ 3,708,162	$ 3,389,136
Additions/(reductions) for tax positions - prior year	52,268	—
Increase related to current year positions	440,121	319,026
Balance at the end of the year	$ 4,200,551	$ 3,708,162

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

The Company's practice is to recognize interest and penalties related to income tax matters in income tax expense. The Company had no accrual of interest and penalties on the Company's balance sheets and has not recognized any interest and penalties in the statements of operations for the years ended December 31, 2020 and 2019.

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.

On March 27, 2020, the United States enacted the Coronavirus Aid, Relief and Economic Security Act (CARES Act). The CARES Act is an emergency economic stimulus package that includes spending and tax breaks to strengthen the United States economy and fund a nationwide effort to curtail the effect of COVID-19. While the CARES Act provides sweeping tax changes in response to the COVID-19 pandemic, some of the more significant provisions are the extension of the carryback period of certain losses to five years, and the suspension of the 80 percent limitation imposed by the TCJA on utilization of NOLs generated in 2018, 2019 and 2020 to offset taxable income generated in tax years prior to 2021. The CARES Act also increased the ability to deduct interest expense from 30 percent, as imposed by the TCJA, to 50 percent of modified taxable income. The CARES Act also provides for a credit against employee wages, the opportunity to defer payment of a portion of federal payroll taxes to December 2021 and December 2022, and enhanced small business loans to assist businesses impacted by the pandemic. The Company's tax provision and financial position was not materially impacted by the CARES Act.

On December 27, 2020, the United States enacted the Consolidated Appropriations Act which extended and modified many of the tax related provisions of the CARES Act. The Company does not anticipate a material impact of the Consolidated Appropriations Act on its tax provision or financial position.

12. Employee Benefits

The Company has a defined contribution 401(k) plan available to eligible employees. Under the terms of the plan, employees may make voluntary contributions as a percent of compensation, limited to the maximum amount allowable under federal tax regulations. The Company, at its discretion, may make certain contributions to the 401(k) plan. The Company expensed matching contributions of $459,364 and $381,670 for the years ended December 31, 2020 and 2019, respectively.

13. Acquisition of Lineagen

In August 2020, the Company, Merger Sub, Lineagen, and Michael S. Paul, Ph.D., solely in his capacity as exclusive agent and attorney-in-fact of the security-holders of Lineagen, entered into the Merger Agreement. Pursuant to the terms and conditions of the Merger Agreement, Merger Sub merged with and into Lineagen whereupon the separate corporate existence of Merger Sub ceased, with Lineagen continuing as the surviving corporation of the Merger as a wholly owned subsidiary of the Company. Lineagen's expertise in development, commercialization and reimbursement of laboratory-developed tests provides a platform for accelerating sales growth for the Company's Saphyr system.

Pursuant to the terms of the Merger Agreement, at the effective time of the Merger (the "Effective Time"), the shares of capital stock of Lineagen and all options of Lineagen that were issued and outstanding immediately prior to the Effective Time were automatically cancelled and extinguished without any payment with respect thereto. Certain holders of convertible notes and other indebtedness of Lineagen at the closing of the Merger (the "Closing") received common stock of the Company. The total number of shares of the Company's common stock issued or reserved for issuance as consideration for the Merger is 6,167,510 shares, subject to adjustment for cash, accounts receivable, unpaid indebtedness, unpaid transaction expenses and certain other liabilities of Lineagen (the "Merger Shares"). 925,126 of the Merger Shares (the "Escrowed Shares") will be held in an escrow fund for purposes of satisfying any post-closing purchase price adjustments and indemnification claims under the Merger Agreement.

Also as consideration for the Merger, pursuant to the Merger Agreement, the Company paid approximately $1.9 million in cash to certain creditors and assumed certain liabilities of Lineagen totaling approximately $2.9 million, reflective of the Company's preliminary estimate of the post-closing purchase price adjustment (which adjustment is subject to finalization pursuant to the terms of the Merger Agreement). In addition, on August 21, 2020, concurrent with the Closing, the Company paid approximately $1.1 million to satisfy all outstanding principal and accrued interest amounts due pursuant to that certain Promissory Note, dated April 22, 2020, by and between Lineagen and Silicon Valley Bank (the "Lineagen PPP Loan"), issued pursuant to the CARES Act administered by the SBA. The Lineagen PPP Loan was repaid by the Company prior to maturity without penalty.

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

The purchase price allocation for the acquisition of Lineagen is preliminary and subject to revision as additional information about the fair value of assets and liabilities becomes available. As permitted under ASC 805, the Company is allowed a measurement period, which may not exceed one year, in which to complete its accounting for the acquisition. The Company has recognized provisional amounts for tax assets and liabilities, and subsequent adjustments during the measurement period to any of these items may affect the amount of goodwill recognized. During the fourth quarter of 2020, the Company recorded a $232,000 adjustment to the original purchase price allocation to reduce the estimated fair value of accounts receivable, with the offsetting amount recorded to goodwill.

As discussed above, the purchase price for the acquisition of Lineagen is subject to adjustment for cash, accounts receivable, unpaid indebtedness, unpaid transaction expenses and certain other liabilities of Lineagen. The following is the estimated purchase price for the acquisition of Lineagen:

Cash (a)	$	1,939,977
Cash transferred for repayment of Lineage PPP Loan (b)	$	1,104,508
Shares common stock issued as consideration (c)		6,167,510
Estimated shares of common stock to be returned to the Company (c)		(138,247)
Stock price per share on closing date	$	0.68
Value of estimated common stock consideration (c)	$	4,099,899
Total estimated purchase price (c)	$	7,144,384

(a) The Company paid approximately $1.9 million in cash to certain creditors of Lineagen.

(b) The Company paid approximately $1.1 million to satisfy all outstanding principal and accrued interest amounts due pursuant to the Lineagen PPP Loan.

(c) The total number of shares of the Company's common stock issued or reserved for issuance as consideration for the Merger was 6,167,510 shares. 925,126 of the Merger Shares will be held in an escrow fund for purposes of satisfying any post-closing purchase price adjustments and indemnification claims under the Merger Agreement. The total number of Merger Shares is subject to adjustment for cash, accounts receivable, unpaid indebtedness, unpaid transaction expenses and certain other liabilities of Lineagen. The value of the estimated common stock consideration and the total estimated purchase price incorporate the return of an estimated 138,247 Escrowed Shares to the Company based on a preliminary estimate of this adjustment.

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

Cash and cash equivalents	$	596,276
Accounts receivable		336,996
Other assets		209,429
Property and equipment		110,670
Intangible assets		1,580,000
Goodwill		7,172,649
Accounts payable and other accrued liabilities		(2,861,636)
Net assets acquired	$	7,144,384

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

Customer relationships	$	950,000
Trade name		630,000
Fair value of identifiable intangible assets	$	1,580,000

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

The Company recognized approximately $1.5 million of acquisition-related costs, including financial advisor fees, legal expenses and accounting fees during the year ended December 31, 2020. These costs are included in the consolidated statement of operations in selling, general and administrative expense. Also, the Company reported approximately $1.5 million of service revenue generated by Lineagen in its consolidated statement of operations from the date of acquisition through December 31, 2020.

The unaudited pro forma financial information in the table below summarizes the combined results of operations for the Company and Lineagen as if the companies had been combined as of January 1, 2019. The unaudited pro forma financial information is for informational purposes only and is not necessarily indicative of the results of operations that would have been achieved as if the acquisition had taken place as of January 1, 2019.

	Years Ended December 31, (Unaudited)	
	2020	2019
Revenue	$ 11,938,353	$ 17,664,410
Net loss	(42,317,665)	(36,655,467)
Basic and diluted net loss per share	$ (0.39)	$ (1.74)

These amounts have been calculated after applying the Company's accounting policies and adjusting the results of Lineagen to reflect (i) additional amortization that would have been charged based upon the fair value of the acquired intangible assets of $235,060 and $308,240 for the year ended December 31, 2020 and 2019, respectively; (ii) the removal of interest expense related to the historical debt of Lineagen which was not acquired of $742,135 and $3.8 million for the year ended December 31, 2020 and 2019, respectively, and (iii) the removal of acquisition costs incurred by the companies of $2.1 million for the year ended December 31, 2020.

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 principal executive and financial officer, evaluated the effectiveness of our disclosure controls and procedures as of December 31, 2020. 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, 2020, our principal executive and financial officer concluded that, as of such date, our disclosure controls and procedures were not effective at a reasonable assurance level as a result of the material weakness that existed in our internal control over financial reporting as described below.

Management's Annual Report on Internal Control over Financial Reporting

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

As the acquisition of Lineagen occurred in the third quarter of 2020, we excluded the internal control over financial reporting of Lineagen from the scope of our assessment of the effectiveness of the Company's internal controls. This exclusion is in accordance with the general guidance issued by the Staff of the SEC that an assessment of a recently-acquired business may be omitted from our scope in the year of acquisition, if specified conditions are satisfied. Goodwill and net intangibles assets acquired were not excluded from our assessment. Lineagen's total net assets excluded from our assessment constituted approximately 1% of the Company's total assets as of December 31, 2020, and Lineagen's revenues and net loss excluded from our assessment represented approximately 24% and 4%, respectively, of the Company's total revenue and net loss for the year ended December 31, 2020.

Material Weaknesses in Internal Control over Financial Reporting

A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that a reasonable possibility exists that a material misstatement of our annual or interim financial statements would not be prevented or detected on a timely basis.

For the year ended December 31, 2020, our management assessed the effectiveness of our internal control over financial reporting using the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission in Internal Control-Integrated Framework (2013 Framework). Based on this assessment, our management determined that, as of December 31, 2020, there was a material weakness in our internal control environment over financial reporting because we did not have a sufficient number of resources to support the growth and complexity of our financial reporting requirements. This material weakness contributed to a material weakness in our control activities based on the criteria set forth in the 2013 Framework. Specifically, the design of certain controls did not adequately provide appropriate segregation of duties. The failure to maintain appropriate segregation of duties had a pervasive impact and as such, this deficiency resulted in a risk that could have impacted all financial statement account balances and disclosures. The material weaknesses did not result in any identified material misstatements to our financial statements, and there were no changes to previously released financial results.

Remediation of Material Weaknesses

Management has been actively engaged in developing and implementing a remediation plan to address the material weaknesses described above. The remediation efforts that are in process or expected to be implemented include the following:

- Management has engaged external consultants to assist with our internal accounting functions and further enhance our internal controls which has increased the number of personnel involved in financial reporting.

- We recently hired a new Chief Financial Officer and are in the process of hiring additional qualified individuals that will increase the number of personnel involved in financial reporting and the control environment.

The additional resources and procedures described above are designed to enable us to broaden the scope and quality of our internal review of underlying information related to financial reporting and to formalize and enhance our internal control procedures. While the implementation of improved controls and procedures is ongoing, we have determined that as of December 31, 2020 that the material weaknesses described above have not been fully remediated.

Changes in Internal Control over Financial Reporting

Other than the continuation of the implementation of measures described above, there were no material changes in our internal control over financial reporting during the quarter ended December 31, 2020 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Attestation Report of the Registered Public Accounting Firm

This Annual Report on Form 10-K does not include an attestation report of our registered public accounting firm due to an exemption for "emerging growth companies."

Item 9B. Other Information.

Forgiveness of Paycheck Protection Program Loan

As previously reported, on April 17, 2020, we received loan proceeds of approximately $1.77 million, or the PPP Loan, pursuant to the Paycheck Protection Program under the Coronavirus Aid, Relief, and Economic Security Act administered by the U.S. Small Business Administration, or the SBA. The PPP Loan was evidenced by a promissory note, dated as of April 17, 2020, issued by East West Bank. We applied for forgiveness of the PPP Loan and on March 18, 2021, we received a notice from East West Bank confirming the SBA's forgiveness of the PPP Loan together with all accrued interest in full, effective as of March 15, 2021.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

The information required by this item and not set forth below will be set forth in our definitive proxy statement to be filed with the Securities and Exchange Commission in connection with our 2021 Annual Meeting of Stockholders, or the Proxy Statement, which is expected to be filed not later than 120 days after the end of our fiscal year ended December 31, 2020, and is incorporated in this Annual Report on Form 10-K by reference.

We have adopted a code of business conduct and ethics, or the Ethics Code, that applies to all our employees, officers and directors. This includes our principal executive officer, principal financial officer and principal accounting officer or controller, or persons performing similar functions. The full text of the Ethics Code is available on our website at www.bionanogenomics.com. If we make any substantive amendments to the Ethics Code or grant any waiver from a provision of the Ethics Code to any executive officer or director, we will promptly disclose the nature of the amendment or waiver on our website or in a Current Report on Form 8-K. Information contained in, or that can be accessed through, our website is not incorporated by reference herein, and you should not consider information on our website to be part of this Annual Report on Form 10-K.

Item 11. Executive Compensation.

The information required by this item will be set forth in the Proxy Statement and is incorporated in this Annual Report on Form 10-K by reference.

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

The information required by this item will be set forth in the Proxy Statement and is incorporated in this Annual Report on Form 10-K by reference.

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

The information required by this item will be set forth in the Proxy Statement and is incorporated in this Annual Report on Form 10-K by reference.

Item 14. Principal Accounting Fees and Services.

The information required by this item will be set forth in the Proxy Statement and is incorporated in this Annual Report on Form 10-K by reference.

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
2.1^[1]	Agreement and Plan of Merger, dated August 21, 2020, by and among the Company, Alta Merger Sub, Inc., Lineagen, Inc. and Michael S. Paul, Ph.D.
3.1	Amended and Restated Certificate of Incorporation.
3.2[2]	Amended and Restated Bylaws.
4.1[3]	Form of Common Stock Certificate.
4.2[3]	Form of Warrant to Purchase Series D-1 Preferred Stock issued to Midcap Financial Trust.
4.3[3]	Form of Warrant to Purchase Common Stock Issued to Underwriters.
4.4[3]	Form of Warrant Certificate (included in Exhibit 4.8).
4.5[3]	Form of Warrant Agent Agreement by and between the Registrant and American Stock Transfer & Trust Company LLC, as warrant agent.
4.6[4]	Form of Warrant to Purchase Common Stock for Service Providers.
4.7[5]	Registration Rights Agreement, dated March 14, 2019, between the Company and Aspire Capital Fund, LLC.
4.8[5]	Registration Rights Agreement, dated March 14, 2019, by and among the Company and the Innovatus Investors.
4.9[6]	Form of Warrant to Purchase Common Stock issued to Investors in October 2019 Public Offering.
4.10	Description of the Company's Securities.
10.1[3]	Fifth Amended and Restated Investors' Rights Agreement, dated August 5, 2016 as amended.
10.2+[3]	Bionano Genomics, Inc. Amended and Restated 2006 Equity Compensation Plan (the "2006 Plan").
10.3+[3]	Forms of grant notice, stock option agreement and notice of exercise under the 2006 Plan.
10.4+[7]	Bionano Genomics, Inc. 2018 Equity Incentive Plan (the "2018 Plan").
10.5+[3]	Forms of grant notice, stock option agreement and notice of exercise under the 2018 Plan.
10.6+[8]	Bionano Genomics, Inc. 2018 Employee Stock Purchase Plan.
10.7+[3]	Form of Indemnification Agreement by and between the Registrant and each director and executive officer.
10.8+[3]	Bionano Genomics, Inc. Non-Employee Director Compensation Policy.
10.9+[3]	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+[3]	Employment Agreement by and between the Registrant and R. Erik Holmlin, Ph.D., dated November 7, 2017, as amended.
10.11+[1]	Employment Agreement, effective as of September 1, 2020, by and between Christopher Stewart and the Company.
10.12+[1]	Employment Agreement, effective as of August 31, 2020, by and between Alka Chaubey and the Company.
10.13+[3]	Employment Agreement by and between the Registrant and Mark Oldakowski, dated November 7, 2017.
10.14[3]	Loan and Security Agreement by and between the Registrant and Western Alliance Bank, dated March 8, 2016.

Exhibit Number	Description
10.15[3]	First Amendment to the Loan and Security Agreement by and between the Registrant and Western Alliance Bank, dated December 9, 2016.
10.16[3]	Second Amendment to the Loan and Security Agreement by and between the Registrant and Western Alliance Bank, dated May 2, 2017.
10.17[3]	Third Amendment to the Loan and Security Agreement by and between the Registrant and Western Alliance Bank, dated November 20, 2017.
10.18[3]	Forbearance and Fourth Amendment to the Loan and Security Agreement by and between the Registrant and Western Alliance Bank, dated February 9, 2018.
10.19[3]	Lease by and between the Registrant and The Irvine Company LLC, dated January 16, 2012.
10.20[3]	First Amendment to the Lease by and between the Registrant and The Irvine Company LLC, dated September 10, 2013.
10.21[3]	Second Amendment to the Lease by and between the Registrant and The Irvine Company LLC, dated July 1, 2015.
10.22	Third Amendment to the Lease by and between the Registrant and The Irvine Company LLC, dated December 19, 2019.
10.23	Fourth Amendment to the Lease by and between the Registrant and The Irvine Company LLC, dated February 15, 2021.
10.24#[3]	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.
10.25#[3]	Manufacturing Services Agreement by and between the Registrant and Paramit Corporation, dated February 18, 2015.
10.26#[3]	License Agreement by and between Princeton University and the Registrant, dated January 7, 2004.
10.27#[3]	First Amendment to the License Agreement by and between Princeton University and the Registrant, dated December 17, 2004.
10.28#[3]	Second Amendment to the License Agreement by and between Princeton University and the Registrant, dated February 25, 2010.
10.29#[3]	Third Amendment to the License Agreement by and between Princeton University and the Registrant, dated October 17, 2011.
10.30#[3]	Fourth Amendment License Agreement by and between Princeton University and the Registrant, dated February 9, 2012.
10.31#[3]	Agreement by and between the Registrant and Berry Genomics Co., Ltd. dated August 2, 2016.
10.32#[3]	Sublicense Agreement by and between the Registrant and Industry 3200 dated December 27, 2013.
10.33#[3]	License Agreement by and between the Registrant and Q Biotechnology CV dated May 1, 2014.
10.34#[3]	Amendment to Non-Exclusive Patent License Agreement by and between the Registrant and Q Biotechnology CV dated May 1, 2014.
10.35#[3]	License Agreement by and between the Registrant and New York University dated November 4, 2013.
10.36#[3]	Option and Sublicense Agreement by and between the Registrant and Pacific Biosciences of California, Inc. dated February 2, 2016.
10.37[3]	Fifth Amendment to Loan and Security Agreement by and between the Registrant and Western Alliance Bank, dated June 13, 2018.
10.38#[3]	Amendment to Patent Sublicense Agreement by and between the Registrant and Industry 3200, dated June 28, 2018.
10.39[5]	Common Stock Purchase Agreement, dated March 14, 2019, by and among the Company and the Innovatus Investors.
10.40[5]	Loan and Security Agreement, dated March 14, 2019, by and among the Company, Innovatus Life Sciences Lending Fund I, LP and the Lenders listed on Schedule 1.1 thereto.
10.41[9]	Waiver and First Amendment to Loan and Security Agreement, dated June 25, 2019, by and among the Company, Innovatus Life Sciences Lending Fund I, LP and East West Bank.
10.42[10]	Second Amendment to Loan Agreement, dated March 6, 2020, by and among the Company, Innovatus Life Sciences Lending Fund I, LP and East West Bank.
10.43^[1]	Consent and Third Amendment to Loan and Security Agreement, dated August 21, 2020, by and among the Company, Lineagen, Inc., Innovatus Life Sciences Lending Fund I, LP and East West Bank.
10.44	Fourth Amendment to Loan and Security Agreement, dated December 30, 2020, by and among the Company, Lineagen, Inc., Innovatus Life Sciences Lending Fund I, LP and East West Bank.
10.45[5]	Common Stock Purchase Agreement, dated March 14, 2019, by and among the Company and the Innovatus Investors.
10.46[11]	At Market Issuance Sales Agreement, dated August 13, 2020, by and between the Company and Ladenburg Thalmann & Co. Inc.
10.47[12]	Bionano Genomics, Inc. 2020 Inducement Plan.
10.48[12]	Form of Stock Option Grant Notice and Stock Option Agreement under the Bionano Genomics, Inc. 2020 Inducement Plan.
22.1[2]	Subsidiaries of the Registrant.

Exhibit Number	Description
23.1	Consent of BDO USA LLP, independent registered public accounting firm.
23.2	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.
32.1*	Certification of Principal Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2*	Certification of Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS	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)	Incorporated by reference to the Registrant's Quarterly Report on Form 10-Q, filed with the SEC on November 13, 2020.
(2)	Incorporated by reference to the Registrant's Current Report on Form 8-K, filed with the SEC on August 24, 2018.
(3)	Incorporated by reference to the Registrant's Registration Statement on Form S-1 (File No. 333-225970), as amended.
3)	Incorporated by reference to the Registrant's Current Report on Form 8-K, filed with the SEC on November 21, 2018.
(5)	Incorporated by reference to the Registrant's Current Report on Form 8-K, filed with the SEC on March 14, 2019.
(6)	Incorporated by reference to the Registrant's Registration Statement on Form S-1 (File No. 333-233828), as amended.
(7)	Incorporated by reference to the Registrant's Registration Statement on Form S-8 (File No. 333-245764).
(8)	Incorporated by reference to the Registrant's Registration Statement on Form S-8 (File No. 333-227073).
(9)	Incorporated by reference to the Registrant's Quarterly Report on Form 10-Q, filed with the SEC on August 8, 2019.
(10)	Incorporated by reference to the Registrant's Annual Report on Form 10-K, filed with the SEC on March 10, 2020.
(11)	Incorporated by reference to the Registrant's Current Report on Form 8-K, filed with the SEC on August 14, 2020.
(12)	Incorporated by reference to the Registrant's Current Report on Form 8-K, filed with the SEC on August 24, 2020.
^	Certain exhibits and schedules have been omitted pursuant to Item 601(a)(5) of Regulation S-K. The Registrant hereby undertakes to furnish supplementally a copy of any omitted exhibit or schedule upon request by the SEC.
+	Indicates management contract or compensatory plan.
#	Confidential treatment has been granted with respect to certain portions of this exhibit. Omitted portions have been filed separately with the SEC.
*	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 23, 2021

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

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

Signature	Title	Date
/s/ R. Erik Holmlin, Ph.D. R. Erik Holmlin, Ph.D.	Chief Executive Officer and Director *(Principal Executive Officer)*	March 23, 2021
/s/ Christopher Stewart Christopher Stewart	Chief Financial Officer *(Principal Financial and Accounting Officer)*	March 23, 2021
/s/ David L. Barker, Ph.D. David L. Barker, Ph.D.	Director	March 23, 2021
/s/ Albert A. Luderer, Ph.D. Albert A. Luderer, Ph.D.	Director	March 23, 2021
/s/ Yvonne Linney, Ph.D. Yvonne Linney, Ph.D.	Director	March 23, 2021
/s/ Hannah Mamuszka Hannah Mamuszka	Director	March 23, 2021
/s/ Christopher Twomey Christopher Twomey	Director	March 23, 2021
/s/ Kristiina Vuori, M.D., Ph.D. Kristiina Vuori, M.D., Ph.D.	Director	March 23, 2021