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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 September 30, 2021

OR

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

For the transition period from _____ to _____

Commission File Number: 001-38720

Twist Bioscience Corporation
(Exact Name of Registrant as Specified in its Charter)

Delaware		**46-205888**
(State or other jurisdiction of incorporation or organization)		**(I.R.S. Employer Identification No.)**

681 Gateway Blvd, South San Francisco, CA 94080
(Address of principal executive offices and zip code)

(800) 719-0671
(Registrant's telephone number, including area code)

Title of each class	**Trading Symbol(s)**	**Name of each exchange on which registered**
Common Stock	**TWST**	**The Nasdaq Global Select Market**

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. (Check one):

Large accelerated filer	☒	Accelerated filer	☐
Non-accelerated filer	☐	Small 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 ☒

As of March 31, 2021, the last business day of the registrant's most recently completed second fiscal quarter, the aggregate market value of shares of common stock held by non-affiliates of the registrant was approximately $4.885 billion based upon the closing sale price on the Nasdaq Global Select Market reported for such date. Shares of Common Stock held by each officer and director and by each person who owns 10% or more of the outstanding Common Stock have been excluded in that such persons may be deemed to be affiliates. This determination of affiliate status is not necessarily a conclusive determination for other purposes.

The number of shares of the Registrant's common stock outstanding as of November 18, 2021, was 49,632,483.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Registrant's definitive proxy statement to be filed in connection with its 2022 Annual Meeting of Stockholders are incorporated by reference into Part III of this Form 10-K.

TWIST BIOSCIENCE CORPORATION

ANNUAL REPORT ON FORM 10-K
FOR THE FISCAL YEAR ENDED SEPTEMBER 30, 2021

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Forward-looking statements

This Annual Report on Form 10-K for the fiscal year ended September 30, 2021, or Form 10-K, contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, or the Securities Act, and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act. These statements relate to, among other matters, plans for product development and licensing to third parties, plans and timeframe for the commercial development of DNA data storage capabilities, expectations regarding market penetration, anticipated customer conversions to our products, plans to expand in the international markets, identification and development of potential antibody candidates for the treatment of COVID-19 and other diseases, and the anticipated timeframe for remediating the material weakness in internal control over financial reporting. Forward-looking statements are also identified by the words “believe,” “will,” “may,” “estimate,” “continue,” “anticipate,” “intend,” “should,” “plan,” “expect,” “predict,” “could,” “potentially” and variations of such words and similar expressions. You should not rely upon forward-looking statements as predictions of future events. Such statements are based on management’s expectations as of the date of this filing and involve many risks and uncertainties that could cause our actual results, events or circumstances to differ materially from those expressed or implied in our forward-looking statements. Such risks and uncertainties include:

- our ability to increase our revenue and our revenue growth rate;
- our ability to accurately estimate capital requirements and our needs for additional financing; our estimates of the size of our market opportunities;
- our ability to increase DNA production, reduce turnaround times and drive cost reductions for our customers;
- our ability to effectively manage our growth;
- our ability to successfully enter new markets and manage our international expansion;
- our ability to protect our intellectual property, including our proprietary DNA synthesis platform;
- costs associated with defending intellectual property infringement and other claims;
- the effects of increased competition in our business;
- our ability to keep pace with changes in technology and our competitors;
- our ability to successfully identify, evaluate and manage any future acquisitions of businesses, solutions or technologies;
- the success of our marketing efforts;
- a significant disruption in, or breach in security of our information technology systems and resultant interruptions in service and any related impact on our reputation;
- our ability to attract and retain qualified employees and key personnel;
- the effects of natural or man-made catastrophic events, including those resulting from the novel strain of coronavirus that causes coronavirus disease 2019, or COVID-19, that was first identified in Wuhan, China;
- the effectiveness of our internal controls;
- changes in government regulation affecting our business;
- uncertainty as to economic and market conditions and the impact of adverse economic conditions; and
- other risk factors included under the section titled “Risk Factors.”

You should not rely upon forward-looking statements as predictions of future events. Such statements are based on management's expectations as of the date of this filing and involve many risks and uncertainties that could cause our actual results, events or circumstances to differ materially from those expressed or implied in our forward-looking statements.

Readers are urged to carefully review and consider all of the information in this Form 10-K and in other documents we file from time to time with the Securities and Exchange Commission, or SEC. We undertake no obligation to update any forward-looking statements made in this Form 10-K to reflect events or circumstances after the date of this filing 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. Our forward-looking statements do not reflect the potential impact of any future acquisitions, mergers, dispositions, joint ventures or investments we may make.

When we use the terms "Twist," "Twist Bioscience," the "Company," "we," "us" or "our" in this report, we are referring to Twist Bioscience Corporation and its consolidated subsidiaries unless the context requires otherwise. Sequence space and the Twist logo are trademarks of Twist Bioscience Corporation. All other company and product names may be trademarks of the respective companies with which they are associated.

* * * * *

PART I

Item 1. *Business*

At Twist Bioscience Corporation, we work in service of customers who are changing the world for the better. In fields such as health care, food/agriculture, industrial chemicals/materials, academic research and data storage, by using our synthetic DNA tools, our customers are developing ways to better lives and improve the sustainability of the planet. We believe that the faster our customers succeed, the better for all of us, and we believe Twist Bioscience is uniquely positioned to help accelerate their efforts.

We have developed a disruptive DNA synthesis platform to industrialize the engineering of biology that provides DNA for a wide range of uses and markets. The core of our platform is a proprietary technology that pioneers a new method of manufacturing synthetic DNA by "writing" DNA on a silicon chip. We have miniaturized traditional chemical DNA synthesis reactions to write over one million short pieces of DNA on each silicon chip, approximately the size of a large mobile phone. We have combined our silicon-based DNA writing technology with proprietary software, scalable commercial infrastructure and an e-commerce platform to create an integrated technology platform that enables us to achieve high levels of quality, precision, automation, and manufacturing throughput at a significantly lower cost than our competitors.

We have applied our unique technology to manufacture a broad range of synthetic DNA-based products, including synthetic genes, tools for next generation sequencing (NGS) sample preparation, and antibody libraries for drug discovery and development, all designed to enable our customers to conduct research more efficiently and effectively. Additionally, we are expanding our footprint by harnessing our proprietary platform to disrupt and innovate within larger market opportunities, such as discovery partnerships for biologic drugs, and completely new applications for synthetic DNA, such as digital data storage, to expand the overall reach and impact of DNA-based products. We sell our synthetic DNA and synthetic DNA-based products to a global customer base of approximately 2,900 customers across a broad range of industries.

DNA is the fundamental building block of biology. The ability to design DNA and engineer biology, a field known as synthetic biology, is growing rapidly, and we believe this field represents one of the most exciting areas of growth and technological innovation in the 21st century. The ability to modify DNA to improve health and the sustainability of the planet is leading to a broad range of applications for synthetic DNA and synthetic DNA-based products across multiple industries, including:

- healthcare for the identification, prevention, diagnosis and treatment of disease (antibody discovery and optimization technology);
- chemicals/materials for cost-effective and sustainable production of new and existing specialty chemicals and materials, such as spider silk, nylon, rubber, fragrances, food flavors and food additives;
- food/agriculture for more effective and sustainable crop production;
- academic research for a broad range of education and discovery applications; and
- technology for potential use as an alternative long-term data storage medium.

Background

We currently generate revenue through our synthetic biology and next-generation sequencing, or NGS, tools product lines. In addition, we are leveraging our platform to expand our portfolio to include other synthetic DNA-based products and address additional market opportunities, including vertical market opportunities in biological drug discovery and development and digital data storage.

As part of our synthetic biology continuum offering, we have commercialized a custom DNA library solution which we believe can be leveraged to facilitate other proprietary tools to provide an end-to-end solution in biologics drug discovery and early development, from target to investigational new drug, or IND, application, adding value as a partner to biotechnology and pharmaceutical companies. We are also leveraging this capability for our internal antibody discovery efforts.

In fiscal year 2021 we served approximately 2,900 customers and reported $132.3 million in revenue, including $34.5 million in revenue to the chemicals/materials sector, $71.2 million in revenue to the healthcare sector, $25.3 million in revenue to the academic research sector and $1.3 million in revenue to the food/agriculture sector.

COVID-19 considerations

In March 2020, the World Health Organization declared the COVID-19 outbreak to be a pandemic. During the twelve months ended September 30, 2021, our revenues were not significantly affected by the COVID-19 pandemic. We did introduce important tools to fight the COVID-19 pandemic, although revenue from that product line has not been material. Similarly, to date we have not experienced a decline in revenue due to the impact of the COVID-19 pandemic on our customers. The extent to which the COVID-19 pandemic affects our future financial results and operations will depend on future developments which are highly uncertain and cannot be predicted, including the recurrence, severity and/or duration of the ongoing pandemic, and current or future domestic and international actions to contain and treat COVID-19.

We are following public and private sector policies and initiatives to reduce the transmission of COVID-19 and we have taken and continue to take a variety of measures to ensure the availability and functioning of our critical infrastructure, to promote the safety and security of our employees and to support the communities in which we operate. These measures include increasing our inventory, requiring remote working arrangements for employees not integral in physically making and shipping our products or who need specialized equipment to perform their work, investing in personal protective equipment, and providing paid sick leave to affected employees. On July 20, 2020 we commenced weekly testing of our employees working on site and we require all U.S. employees have been vaccinated as of October 25, 2021.

Due to the speed with which the situation may change, we are not able at this time to estimate the effect of COVID-19 on our financial results and operations, but the effect could be material for fiscal year 2022 and/or during any future period affected either directly or indirectly by this pandemic. For further discussion of the risks relating to COVID-19, see “We are subject to risks associated with COVID-19” under the section titled “Risk factors.”

Our Markets

Synthetic Biology

Our products serve life sciences researchers including those working in the field of synthetic biology, which is undergoing an era of rapid innovation and transformation. Synthetic biology is the engineering of biology to build new biological systems or re-design existing biological systems. The ability to design DNA and engineer biology is creating advances and benefits for a broad and growing range of applications for synthetic DNA and synthetic DNA-based products across multiple industries, including

- healthcare for the discovery and production of new vaccines, therapeutics and molecular diagnostics;
- chemicals/materials for cost-effective and sustainable production of new and existing specialty chemicals and materials, such as spider silk, nylon, rubber, fragrances food flavors and food additives;
- food/agriculture for more effective and sustainable crop production;
- academic research for a broad range of applications; and
- technology for potential use as an alternative long-term data storage medium.

Synthetic DNA is the fundamental building block of synthetic biology. Researchers at a wide range of institutions can design synthetic DNA to regulate the production of proteins and other molecules to achieve a specific functional purpose. While synthetic DNA has been produced for more than 40 years, the complexities of biology and the production constraints inherent in legacy processes have historically limited the applications and market opportunities for DNA synthesis.

Next-Generation Sequencing

Our NGS tools play an integral role in the way our customers prepare their patient samples to be sequenced. NGS has transformed many markets in recent years by changing the landscape of diagnosing disease and disorders and offers a path to prevent or treat disease. Some of the markets impacted by NGS include oncology, reproductive health, food/agriculture, consumer genomics, infectious disease research and drug discovery. As NGS technology improves and the cost of sequencing declines, new emerging markets that were once considered impractical, such as population-scale sequencing, liquid biopsy (a test that detects multiple types of cancer from a single blood sample), minimal residual disease testing and single cell sequencing, have become major areas of interest and investment.

Historically, a significant constraint in many NGS applications has been the high cost and long turnaround time of oligonucleotide production. Highly accurate and reproducible oligonucleotide production is required to produce high quality target enrichment data. Traditionally, the lack of options for oligonucleotide production forced researchers to choose between using less precise methods or to reduce the number of samples in their study.

The ability of the Twist DNA synthesis platform to precisely manufacture target enrichment probes at large scale has dramatically increased the types of projects that can now be addressed using NGS technologies. Our platform has unlocked new applications, improved data quality, and dramatically expanded the types of scientific questions that can be answered using NGS. In addition, the speed of our DNA synthesis platform enables customers to quickly deploy NGS technologies to applications where the time to answer is critical.

Our platform

We developed the Twist Bioscience DNA synthesis platform to address the limitations of throughput, scalability, and cost inherent in legacy DNA synthesis methods. Our platform stems from extensive analyses and improvements to the existing gene synthesis and assembly workflows. Our core technologies combine expertise in silicon, software, fluidics, chemistry, and motion and vision control to miniaturize thousands of parallel chemical reactions on silicon and write thousands of strands of DNA in parallel. With a footprint that is similar to the size of a 96-well plate that historically can only produce one gene, we are able to produce 9,600 genes in parallel. Based on current production needs, we have intentionally designed our latest chip to make 6,144 genes in parallel, but we have the current capability to increase this to 9,600 genes, as needed. We have combined our DNA synthesis technology with propriety software and a scalable commercial infrastructure to create our vertically integrated DNA synthesis platform capable of delivering very large volumes of high-quality synthetic DNA at low cost.

Enzymatic Synthesis

Several companies are pursuing an emerging gene synthesis process that uses enzymatic chemistry rather than phosphoramidite chemistry. While the promise of enzymatic synthesis to deliver longer genes in a shorter timeframe provides excitement for the industry, this technology is at the proof-of-concept stage and has not yet been proven to be scalable or commercially viable. If, in the future, enzymatic synthesis proves commercially scalable, we have the ability to include this chemistry within our established commercial infrastructure.

Our products

We have developed multiple products derived from synthetic DNA and our versatile DNA synthesis technology. Our current offering consists of two primary product lines, synthetic biology tools and NGS tools, that address different needs of our customers across a variety of applications, such as synthetic genes, oligo pools, SARS-CoV-2 tools and DNA libraries.

Synthetic Biology Products

Synthetic genes and gene fragments

Synthetic genes are manufactured strands of DNA. Customers order our synthetic genes to conduct a wide range of research, including product development for chemicals/materials, food/agriculture, therapeutics, diagnostics, data storage as well as a multitude of emerging applications within academic research. Virtually all research and development of this type requires trial and error, and our customers require many variations of genes to find the DNA sequence that achieves their objectives.

We offer two primary categories of synthetic genes: genes of perfect quality, clonal genes, in a vehicle to carry the DNA, also called a vector; and genes of near-perfect quality, non-clonal genes or fragments, that customers can place in their own vector. Within these two categories, customers can order different lengths of DNA depending on their required final gene construct. Customers can order longer genes or shorter genes and can stitch genes together to create longer or shorter constructs if desired.

Currently, we manufacture genes of up to 5,000 base pairs in length, yielding a clonally perfect piece of DNA that our customers can immediately use for their research. We offer non-clonal genes of up to 1,800 base pairs in length, which we believe addresses the vast majority of demand for non-clonal genes with an error rate of 1:7500 base pairs. We also offer larger quantities of DNA for customers who require it for their development efforts.

Oligonucleotide, or Oligo pools

Oligo pools, or high diversity collections of oligonucleotides, are utilized in many applications, including targeted NGS, CRISPR gene editing, mutagenesis experiments, DNA origami (the nanoscale folding of DNA to create two- and three-dimensional shapes at the nanoscale), DNA computing and data storage in DNA, among others. Our oligo pools are also used for high-throughput reporter assays that are used to study cell signaling pathways, gene regulation, and the structure of cell regulatory elements. For these applications, we provide customers with accurate and uniform synthetic oligos to precisely match their required designs.

We sell a diverse, customizable set of oligo pools, ranging from a few hundred oligos to over one million, and offer oligonucleotides of up to 300 nucleotides in length, with an error rate of 1:2000 nucleotides.

IgG proteins

Pairing the automation in our synthetic biology platform along with our expertise in antibody discovery, we introduced an immunoglobulin G (IgG) protein offering for our customers focused on drug discovery and development. In the process of antibody discovery, antibody fragments (Fab, small chain fragment variable (scFv) or VHH) must be reformatted to full IgGs. Leveraging its silicon-based synthesis platform, we provide customers with a high throughput IgG capability, removing this bottleneck from the antibody discovery process.

NGS tools

Building from our DNA synthesis platform, we have developed products for the growing NGS market. In particular, we are focused on addressing the demand for better sample preparation products that improve sequencing workflow, increase sequencing accuracy, and reduce sequencing costs. Using our silicon-based DNA synthesis platform, we are able to synthesize exact sequences of interest. In the target enrichment process, our synthetic DNA probes bind to the sequence of interest within the sample, acting like a magnet to isolate and physically extract the targeted segment of DNA.

Our NGS products are primarily used for diagnostic tests for various indications including rare disease, SARS-CoV-2 and cancer through liquid biopsy. In addition, customers use our NGS tools for population genetics research and biomarker discovery, translational research, microbiology and applied markets research. Our customers are primarily diagnostic companies and hospitals, research institutions, agricultural biotechnology companies, and consumer genetics companies conducting diagnostic tests for a wide range of applications.

We offer a wide variety of NGS tools for our customers including library preparation kits, human exome kits, fixed and custom panels as well as Alliance panels, which are customer-curated content sold through Twist. In addition, we offer specific workflow solutions including a methylation detection kit for cancer, rare and inherited disease study, as well as a fast hybridization solution (FastHyb), which allows researchers to go from sample to sequencer in a single day.

Synthetic Viral Controls, Infectious Disease Research Tools

Leveraging our DNA synthesis platform, we launched a new product line of synthetic viral controls in response to the rapid spread of COVID-19. We offer fully synthetic SARS-CoV-2 RNA reference sequences as positive controls for the development of both NGS and reverse transcription-polymerase chain reaction (RT-PCR) assays. Our SARS-CoV-2 controls are now included on the U.S. Food and Drug Administration website as reference materials.

In addition, we offer a wide range of respiratory viral controls including for influenzas, respiratory syncytial virus, rhinoviruses, SARS, MERS and other coronaviruses. These controls can be used to provide quality control for the development, verification and ongoing validation of diagnostic tests. These controls for SARS-CoV-2 and other respiratory diseases allow researchers to develop tests safely and effectively, without working with live virus samples.

In addition, we introduced the SARS-CoV - 2 Research Panels, the Twist Respiratory Virus Panel and the Pan-Viral Research Panel, for the detection of disease in a research setting. All products can be used for environmental monitoring and surveillance testing, while also providing insight into the full sequence information for monitoring of viral evolution and strain origin.

Drug and Target Discovery Solutions

Precision DNA libraries

Our platform allows customers to customize every antibody sequence variation and construct a precise library systematically to target the entire region of interest. We can create single-site libraries in which we change a single amino acid (which is encoded by a group of three DNA nucleobases) within the sequence or single-site saturation libraries in which we change every amino acid within the sequence for a more comprehensive approach. We can also generate combinatorial libraries in which we introduce changes to multiple sites within the same gene in specific ratios and combinations. These libraries can be used for antibody engineering, affinity maturation, and humanization, which simplifies downstream screening and identifies more lead molecules. Our libraries are explicitly developed for a specific area of the genome or tailored to a specific disease, with antibody compounds evenly represented across all desired areas of the genome.

We have also developed a comprehensive antibody optimization solution to enable simultaneous optimization of multiple characteristics of a given antibody. We have developed custom software for the optimization of antibody hits, antibody compounds that meet pre-specified criteria for therapeutic development. We have added our high throughput and hyper-variant antibody library capabilities to create a comprehensive antibody optimization solution for potential partners. We are now using this solution to design, build and test hyper-variant, tightly controlled antibody libraries that follow the rules of the human repertoire and mitigate the pitfalls associated with traditional optimization methods. By following the rules of the human repertoire, which means including only DNA sequences known to occur in humans, we have created a “Library of Libraries” made up of many different individual libraries. These libraries are natural in composition and are expected to generate better drug development candidates. The libraries also have a large degree of synthetic variation, enabling simultaneous optimization of several antibody characteristics and the discovery of antibodies with high affinity and specificity to drug targets.

Identification and validation of antibodies for diagnosis and treatment of COVID-19

In 2020, we initiated antibody discovery using our biopharma platform, identifying potential antibodies that could be used for the diagnosis and treatment of COVID-19 for research purposes. In addition, we tested several of these antibody candidates in live virus and advanced a subset through preclinical testing. In September 2021, The Coronavirus Immunotherapy Consortium (CoVIC), a joint academic-industry, non-profit collaborative research effort, performed the blinded analysis, confirming that our internally-developed antibody TB202-3 completely blocked the SARS-CoV-2 spike protein from binding to the human ACE2 receptor. The results were published in the peer-reviewed journal Science. TB202-3 binds to a majority of known mutations, with the exception of the L452R mutation present in the Delta and Epsilon variants. Twist developed a new antibody which also binds and neutralizes the Delta and Epsilon variants, that is now advancing through late-stage discovery and validation testing.

Partnerships with leading companies

We believe we have several avenues available to monetize our antibody discovery program. In general, partnerships for our antibody development platform require us to provide rapid, on-demand (high affinity) antibodies based on one or more targets provided by the customer. These agreements typically have three elements with respect to the program:

- We license and also utilize our “Library of Libraries,” a panel of synthetic antibody phage display libraries derived only from sequences that exist in the human body.
- We work to discover, validate and optimize new antibody candidates against a specific target.
- The customers pay Twist annual technology licensing fees, and increasingly, we receive project milestones for completion of various Twist activities and development milestones as our customers progress and commercialize the products. In many cases, we also receive royalties on any products coming out of the partnerships.

Customers can design and purchase libraries, and we work with partners that bring us a target, to discover antibody leads against that target. These partnerships generate revenue in up-front fees, through the license of libraries and service revenue. In addition, many of our partnerships include success-based milestones for key clinical, regulatory and commercial achievements and/or royalties on any product sales resulting from our collaboration.

In addition, for our internal development efforts, we have selected several promising targets and have identified antibody leads to these targets. We intend to out-license these compounds at later stages of preclinical development to optimize both the up-front revenue and larger milestones and royalties. By out-licensing antibody leads to experts in development and commercialization of biotechnology products, we can continue to focus on improving health through our proprietary platform. To date, we have generated antibody leads to Adora 2a, GLP1R (agonist and antagonists), SARS-CoV-2, TIGIT, PD-L1, CXCR4, CD3 as well as several undisclosed targets.

As of September 30, 2021, we had signed 34 revenue-generating partnerships. We have 41 completed programs and 41 active programs with 35 of the programs including milestones and/or royalties. Some of our partners include Boehringer Ingelheim GmbH, Takeda Pharmaceutical Company Limited, Adicet Bio, Kyowa Kirin, Invetx, Inc., and Neogene Therapeutics, Inc. In addition, we collaborate with companies that bring complementary technologies to expand our opportunities and reach.

Our growth strategy

Our objective is to be the leading provider of synthetic DNA and DNA-based products worldwide and to leverage our platform to build a leadership position in other life sciences markets in which we have a competitive advantage. We intend to accomplish this objective by executing on the following:

- maintain and expand our position as the provider of choice for high-quality, affordable synthetic genes and DNA to customers across multiple industries;
- become a leading supplier of NGS sample preparation products;
- conduct antibody therapeutic discovery and optimization for our current customers and future partners;
- continue to explore development of DNA as a digital data storage medium through internal research and government and industry partnerships; and
- expand our global presence.

Beyond these opportunities, we are working with industry partners to create new markets for our products by leveraging our platform.

Sales and marketing

We have built a versatile and scalable commercial platform that enables us to reach a diverse customer base that we estimate consists of over 100,000 synthetic DNA users, and many additional potential customers of our NGS library preparation products today. In order to address this diverse customer base, we have employed a multi-channel strategy comprised of a direct sales force targeting synthetic DNA customers, a direct sales force focusing on the NGS market and an e-commerce platform that serves both commercial channels. Our sales force is focused on customer acquisition, support, and management across industries, and is highly trained on both the technical aspects of our platform and how synthetic DNA can be used in a wide range of industries. Our easy-to-use e-commerce platform allows customers to design, validate, and place on-demand orders of customized DNA online, and enable them to receive real-time customized quotes for their products and track their order status through the manufacturing and delivery process. This is a critical part of our strategy to address our large market and diverse customer base, as well as drive commercial productivity, enhance the customer experience, and promote loyalty. We target customers of our NGS products through a direct sales team focused on the NGS tools market and which is separate from our synthetic DNA sales force. Our direct NGS sales representatives are focused on supporting our early adopters and providing a high level of service in order to familiarize customers with our product offerings.

We sell our products through a worldwide commercial organization that includes direct sales personnel, commercial consultants in Europe and Asia, an ecommerce platform and distributors. As of September 30, 2021, we employed 203 people in sales, marketing and customer support.

Research and development

We are engaged in ongoing research and development efforts focused on enhancements to existing products and the development of new products. Currently, we are pursuing research and development projects with respect to the following:

- process development for higher quality oligos;

- building a massively parallel fast turnaround time SynBio pipeline;
- optimization, automation and miniaturization of gene and NGS pipelines;
- silicon process and chemistry development for our data storage initiative;
- buildout of a massively parallel screening facility for our biopharma initiatives that allows us to screen over a dozen antibody phage display campaigns per week; and
- expansion of our product offerings for oligo, gene, NGS library preparation and target enrichment, and DNA Libraries NGS products.

In June 2020, we executed a firm fixed-price subcontract with Georgia Institute of Technology to develop the DNA synthesis portion of the Molecular Information Storage program. The total cost for this subcontract is $6.5 million, and we are responsible for providing a minimum contribution of $2.0 million toward the cost of the program, with the remaining $4.5 million to be funded by the U.S. Director of Central Intelligence. We will receive such $4.5 million in funding in fixed amounts over a period from September 2019 to June 2022.

In December 2020, we executed a firm fixed-price subcontract for fulfilling an organization's primary obligation to perform discovery activities and conduct applied research for technological innovations to improve human health. The subcontract was a $1.0 million research & development cost-reimbursement arrangement. The cost was reimbursed over a period from September 2020 to December 2020.

Research and development activities are conducted in collaboration with manufacturing activities to help expedite new products from the development phase to manufacturing and to more quickly implement new process technologies. From time to time, our research and development efforts have included participation in technology collaborations with universities and research institutions.

As of September 30, 2021, we employed 192 people in our research and development team.

Patents and other intellectual property rights

As of September 30, 2021, we own 33 issued U.S. patents and 24 issued international patents; four in China, three in Europe, six in South Korea, four in Taiwan, three in Japan, one in Eurasia, one in Singapore, one in Australia, and one in Hong Kong. There are 262 pending patent applications, including 72 in the United States, 176 international applications and 14 applications filed under the Patent Cooperation Treaty. Additionally, we have exclusively licensed a patent portfolio containing ten issued patents, including one U.S. patent and nine international patents, and nine pending applications, including one in the U.S. and eight international applications. We have also licensed a patent portfolio containing two pending applications, including one in the US and one PCT. Our policy is to file patent applications to protect technology, inventions and improvements that are important to our business.

Manufacturing and facilities

The production of our products is a highly complex and precise process. We currently manufacture all of our products and multiple sub-assemblies at our manufacturing facility in South San Francisco, California. We also outsource some of our sub-assemblies to third party manufacturers. All of our products originate from synthetic DNA obtained from nanostructured clusters fabricated on our proprietary silicon technology platform. Due to its on-demand nature, the gene synthesis business requires manufacturing operations to be in operation 24 hours a day, seven days a week, 365 days per year. For synthetic genes, we have built a highly scalable gene production process with what we believe is industry-leading capacity to address the growing demand of scalable, high-quality, affordable synthetic genes. As of September 30, 2021, we employed 177 people in our manufacturing and facilities team.

In addition to synthetic genes, we manufacture oligo pools. The pooling process has been fully automated through a mixture of custom proprietary and over-the-counter liquid handling equipment. We are currently only utilizing approximately two thirds of our production capacity for synthetic genes and oligos. We have the capacity to make many millions of high-quality oligos per month that can be used to make genes and gene fragments of various lengths, oligo pools of various sizes, DNA libraries and NGS tools products. We intend to increase our shipments to leverage our production capacity through our e-commerce platform, which we believe will expand both our market opportunity and our customer base.

The manufacturing process for our NGS tools is highly flexible given the efficiency of our production capability. We have automated the entire workflow using proprietary and over-the-counter laboratory equipment. We have built dedicated production capabilities for our NGS products.

ISO Certification

In 2018, we certified our Quality Management System (QMS) to the ISO 9001:2015 (Quality Management Systems—Requirements) standard and ISO 13485:2016 standard (Medical devices—Quality management systems—Requirements for regulatory purposes). ISO is a global network of national standards with over 18,000 standards for nearly every aspect of technology and business. ISO has standard bodies in 163 countries. ISO Surveillance Audits are carried out twice within a three-year period by the registrar (certification body) to ensure we maintain our system in compliance with ISO standards. Recertification is required every three years and we have been successfully recertified since obtaining our original ISO certification. Most recently, we were registered with the FDA as a manufacturer of “Reagents, 2019-novel coronavirus nucleic acid”.

In January 2019, our quality management systems for manufacturing our NGS Target Enrichment Panels in our Mission Bay San Francisco offices received ISO 9001:2015 and 13485:2016 certifications, the latter for medical device applications. In 2020, these certifications were extended to our South San Francisco offices. In addition to continuing to provide NGS tools to our current customer base, we now have the ability to support customers in more regulated markets that require ISO certification from their key reagent suppliers.

In July 2021, we withdrew from the ISO 9001:2015 certification and expanded the scope of our ISO 13485:2016 scope. The expansion introduced additional products, which conform to the ISO 13485:2016 standard. As our product portfolio expands, our customers demand that our reagents and controls conform to ISO 13485:2016. The new scope statement is, "Design, development, manufacture and distribution of oligonucleotide sequences and reagents used for development of next-generation sequencing (NGS) assays, reverse transcription polymerase chain reaction (RT-PCR) assays and quality control measures".

Supply chain

We have historically purchased many of the components and raw materials used in our products from numerous suppliers worldwide. For reasons of quality assurance, sole source availability or cost effectiveness, certain components and raw materials used in the manufacture of our products are available only from one supplier. We have worked closely with our suppliers to develop contingency plans to assure continuity of supply while maintaining high quality and reliability, and in some cases, we have established long-term supply contracts with our suppliers. During the COVID-19 pandemic, we increased our supply of several materials and sourced additional suppliers for key materials to mitigate supply chain disruptions and ensure ongoing operations. The COVID-19 pandemic could disrupt our supply chain and although we continue to take steps to increase our safety stock and qualify other suppliers as it is very difficult to predict the future impact of the pandemic on our supply chain. As outbreaks of the virus continue to occur, we could potentially face disruption which could mean supply chain lead times are lengthened or we experience shortages and consequently this could impact our ability to produce and negatively impact our revenue.

Competition

The synthetic biology industry is intensely competitive and is characterized by price competition, technological change, international competition, product turnaround time and manufacturing yield problems. The competitive factors in the market for our products include:

- price;
- product quality, reliability and accuracy;
- product offerings & complexity;
- turnaround time;
- breadth of product line;
- design and introduction of new products;
- market acceptance of our products and those of our customers;

- throughput and scale; and
- technical support and service.

Regarding these factors, we face competition from a broad range of providers of core synthetic biology products such as GenScript Biotech Corporation, DNA Script, Inc., GENEWIZ (owned by Brooks Automation), Integrated DNA Technologies, Inc. (owned by Danaher), ATUM, GeneArt (owned by Thermo Fisher Scientific Inc.), Eurofins Genomics LLC, Sigma-Aldrich Corporation (an indirect wholly owned subsidiary of Merck & Company), Promega Corporation, OriGene Technologies, Inc., Blue Heron Biotech, LLC and others. Additionally, we compete with both large and emerging providers in the life sciences tools and diagnostics industries focused on sample preparation for NGS such as Thermo Fisher Scientific Inc., Illumina, Inc., Integrated DNA Technologies, Inc., Agilent Technologies, Inc. ("Agilent"), and Roche NimbleGen, Inc. In the antibody discovery market, we compete with clinical research organizations, such as LakePharma (mouse hybridoma, llama immune libraries, XOMA phage display library) and Aldevron, LLC (genetic mouse immunization coupled with hybridoma), and antibody discovery biotechnology companies, such as Iontas (human phage display libraries, human phage display library focused on ion channels), Abcellera (AI-powered antibody discovery platform), Adimab (human synthetic yeast display libraries), and Distributed Bio, Inc. ("Distributed Bio") (human synthetic phage display library, lead optimization libraries) (owned by Charles River). In the field of DNA digital data storage, we compete with Catalog Technologies, Inc., ETH Zurich, Helixworks, Iridia, Inc., North Shore Bio and Roswell.

Environmental, social, governance (ESG) and human capital

We are at the forefront of the synthetic biology revolution, and our products are increasingly being used to empower our customers, who are diagnostic, therapeutic and healthcare companies, agricultural biotech companies, chemical companies, academic institutions and government entities, around the world to address large societal challenges. All of our work supports our mission to provide synthetic DNA and DNA product to improve health and sustainability.

Our employees are a key factor in our ability to serve our customers and achieve our mission to provide synthetic DNA to improve health and sustainability. The ability to hire and retain highly skilled professionals remains key to our success in the marketplace. To attract develop and motivate our employees, we offer a challenging work environment, ongoing skills development initiatives, attractive career advancement, opportunities and a culture that rewards entrepreneurial initiative and exceptional execution.

Guiding Principles and Business Ethics

Our guiding principles of grit, impact, service and trust serve as our cultural pillars. Our guiding principles set the tone for how we work together, provide a framework for giving feedback and increase the power of our brand. Service is at the core of our business and our interactions with one another. We relentlessly focus on exceeding internal and external customer needs.

We have 12 dedicated, full-time employees who oversee all aspects of our human resources processes including attracting, retaining and motivating our employees. We are consistently looking at new opportunities and avenues to recruit talented individuals to work in our organization.

Diversity, equity, inclusion and belonging

Diversity is in our DNA. Our employees come from numerous countries and bring diversity to our workplace across many critical categories. We believe our company is stronger because of the variety of experiences and backgrounds our employees bring to their work every day.

We are committed to creating and maintaining a diverse, inclusive and safe work environment where our employees can bring their best selves to work each day. Our commitment to diversity extends through our recruitment, retention, learning and engagement and community partnerships. As part of our diversity, equity, inclusion and belonging strategy, we made an active decision to pursue opportunities for learning and engagement that bring people from different backgrounds together into conversation. We've initiated monthly Culture Conversations where we explore identities and systems of power using an intersectional lens each month. Past topics include: disability, LGBTQIA+, ageism, Latinx identity, and more. Our objective is to appreciate each other as individuals with unique lived experiences, rather than define one another by a single trait such as race, sexual orientation or geographical location. To assess our efforts toward building a diverse workforce, we have included questions in our engagement survey to measure employee perception of inclusive culture.

In addition, we mandate training for all employees and managers to prevent workplace harassment. The course equips leaders and employees with the tools they need to identify and address unwelcome conduct in non-adversarial, respectful terms.

Recruiting

We believe that our employees are our most important asset. Beginning with the pre-recruitment process, we provide internship opportunities for students interested in biotechnology and the science, technology, engineering and mathematics (STEM) fields in both scientific and non-scientific departments. We engage with local communities to provide expert speakers sharing nontraditional career pathways for the biotechnology field. We partner with community colleges, historically black colleges and universities and Hispanic-focused institutions to build our brand within diverse communities as a source of diverse, high-quality candidates for every role with the goal of identifying the best possible candidate to fill open positions within the company. We implemented a remote work policy which has resulted in a broader applicant pool because they aren't limited to geographic location.

We actively engage with future scientists through organizations including the International Genetically Engineered Machine (iGEM), a non-profit organization dedicated to furthering the field of synthetic biology. In addition, we have provided internships through the Gloucester Biotechnology Academy, a hands-on training program prepares students for careers as entry-level technicians in cutting-edge laboratories; and Eastside Preparatory Academy, a high school dedicated to serving students historically underrepresented in higher education.

With an active program in place for our employees, we are striving to further support our female and underrepresented employees in advancing their careers while continuing to focus on hiring diverse talent, particularly at more senior positions.

Compensation and benefits, health and wellness

We strive to provide pay, comprehensive benefits and services that help meet the varying needs of our employees. Our generous total rewards package includes above-market pay; fully covered healthcare benefits for employees, with family member healthcare benefits covered at 90%; a health savings account that is fully funded for individuals and their families; approximately four weeks of paid vacation; a minimum of four months of parental leave for all employees globally; flexible work schedules; and onsite services. In addition, we offer every full-time employee, both exempt and non-exempt, the benefit of equity ownership in the company through stock option grants and our employee stock purchase plan.

We have an expert-built educational platform to assist employee's fertility & family building needs with the help of treatment, fostering or adopting, plus dedicated resources for egg freezers, egg donation, LGBTQ+ families, and solo parents.

We have increased our well-being benefits, by offering programs that help workers monitor and reduce their stress levels, providing apps to support sleep and relaxation. We implemented a Walking Challenge to promote physical health and employee connections. We have further addressed employees' emotional health and well-being by providing meditation sessions and using telehealth programs to offer mental health counseling.

COVID-19 employee safety and benefits

Many of our customers require our synthetic DNA products to provide critical tools for global health. Twist continues to take extra precautions to reduce the risk of virus exposure for all employees. All of our employees who were able to work from home will continue to do so through January 2022. For those employees who remain onsite to produce our products, we reduced the number of people in the office significantly with the remote work option. In addition, we comply with all local, state and federal mandates requiring masks indoors. We require all U.S. employees to be vaccinated and continue to provide PCR based testing of all on-site employees weekly. As a benefit for all employees, we provide flu shots for the employee and their family.

For any employee who contracts COVID-19, we provide full pay for their entire recovery and quarantine time, regardless of the guidelines of their home country. Twist pays sick leave for all affected employees at 100% of their salary or average hourly wages.

Employee health and safety

We remain steadfast in our commitment to promote the health and safety of our employees. We require annual workplace safety training to reinforce workplace safety procedures that may be useful in the event of emergency situations and to assist our employees in helping to prevent workplace accidents. Our Employee Health and Safety Committee, which is comprised of numerous cross-departmental members meets on a quarterly basis to review workplace safety and adherence to safety policies. As part of our efforts, all employees and managers complete workplace harassment and sexual harassment training that includes details on how to report any violation of these policies.

Conduct and ethics

Our Board of Directors adopted and regularly reviews the Code of Conduct, which applies to all of our employees, directors and officers. We believe it is imperative that the board of directors and senior management strongly support a no-tolerance stance for workplace harassment, biases and unethical behavior. All employees are required to abide by, review and confirm compliance to the company's Code of Business Conduct and Ethics Policy, our Anti-Money Laundering Policy, our Anti-Corruption Policy. We have established a reporting hotline and email address that enables employees to anonymously report any suspected violations of the Code of Conduct.

In addition, because synthetic DNA is considered to be a dual use technology, we invest substantial financial and human resources in biosecurity to help ensure that our products are used for responsible research. We abide by all local, national and international regulations as well as trade compliance requirements and are an active member of the International Gene Synthesis Consortium and the Australia Group. We maintain an active relationship with the governing body for synthetic DNA within the U.S. Department of Homeland Security.

In 2021, our employees participated, through the Engineering Biology Research Consortium (EBRC), in a 'Malice Analysis' (MA) - a methodology for teaching synthetic biology researchers about both the importance of, and the how-to of, thinking through any security implications of their own research activities.

Growth and development

We invest significant financial and support resources to develop the talent we need to remain at the cutting edge of innovation to ensure Twist Bioscience is an employer of choice. We recently launched a new performance management system to support our culture, maintain consistency with our guiding principles and to focus on continuous learning and development. Our success in the market depends on employees understanding and embracing how their job contributes to the company's overall strategy. We encourage cross team communication as well as integrated departmental communication. We believe this broadens our employee's skill set and provides opportunity for growth and advancement. We invest in our next generation of leaders through a one-year leadership program for mid-level managers. In addition, we offer tuition reimbursement aimed at growth and career development.

We have made a significant investment in an online learning platform with on-demand, video-based content. Employees have the opportunity to refine or develop professional skills, learn new software, and explore as they plan their career growth. The platform also offers tremendous potential for managers and employees to create development plans as part of the performance review process.

Communications and engagement

We employ a variety of tools to facilitate open and direct communication including open forums with executives, employee surveys and engagement through focus groups, forums and committees. We endeavor to further refine our employee programs through our employee engagement survey as well as follow up quarterly pulse surveys. Based on the most recent survey conducted in July 2021 where 88% of our employees responded:

- 96% of employees understand Twist's mission
- 93% understand how they contribute to the mission of the company
- 93% understand how their goals contribute to Twist

The executive leadership team identified key initiatives within their organizations that tie directly back to the survey feedback to further increase employee engagement moving forward.

We hold All Hands meetings twice per month as well as a monthly managers meeting for all people managers.

Community engagement, social and relationship capital

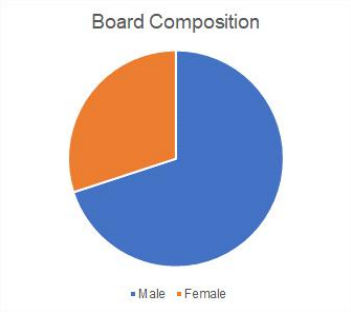
We are endeavoring to develop relationships, give back to our communities and engage in corporate social responsibility and sustainability initiatives. We provide all employees with eight fully paid hours each year to give back to the community at an organization of their choice. We are working to engage with the local community organizations to provide volunteer opportunities for our employees. As we grow our employee base, we will extend our efforts in these areas.

Employee population

As of September 30, 2021, we had 652 employees, which includes our team of 81 dedicated commercial consultants. Of these employees, 192 were primarily engaged in engineering as well as research and development activities; 203 were primarily engaged in marketing, sales and customer support; 80 were primarily engaged in general and administrative activities; and 177 were primarily engaged in operations and manufacturing, of which there are 160 full-time employees dedicated to manufacturing our synthetic genes, oligo pools, NGS tools and DNA libraries. Of these employees, 494 hold engineering or science degrees including 118 Ph.D.'s. None of our employees is represented by a labor union, and we consider our employee relations to be good.

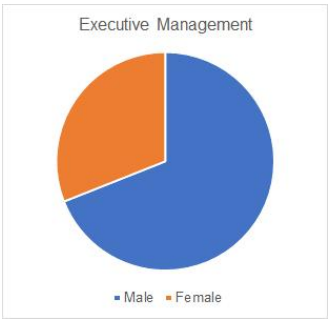
Board of Directors

Board Member	Gender
Nicolas Barthelemy	Male
Nelson C. Chan	Male
Robert Chess	Male
Keith Crandell	Male
Jan Johannessen	Male
Xiaoying Mai	Female
Robert Ragusa	Male
Melissa A. Starovasnik	Female
Emily Leproust	Female
William Banyai	Male
Female	**30%**
Male	**70%**
Total	10



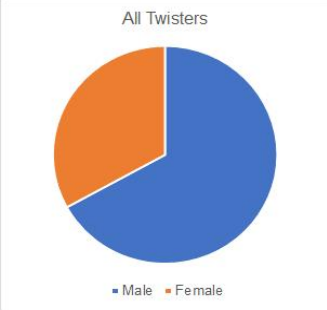
Executives

Executive Team Member	Gender
Emily Leproust	Female
Jim Thorburn	Male
Bill Banyai	Male
Angela Bitting	Female
Siyuan Chen	Male
Dennis Cho	Male
Patrick Finn	Male
Paula Green	Female
Steffen Hellmold	Male
Martin Kunz	Male
Aaron Sato	Male
Erin Smith	Female
Patrick Weiss	Male
Female	**31%**
Male	**69%**
Total	13

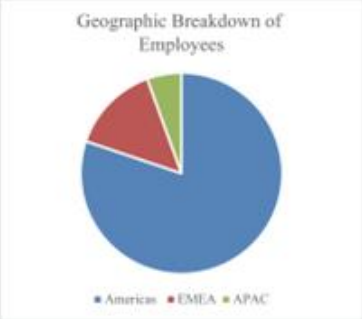


All Twisters (inclusive of executives)

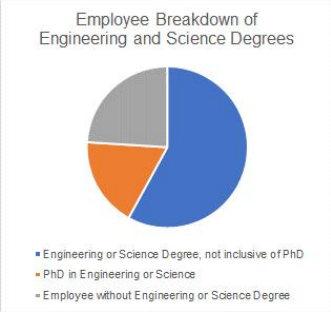
Gender	Percent of all Twisters
Female	**33%**
Male	**67%**
Total	652



Region	Percent of all Twisters
Americas	80%
EMEA	14%
APAC	6%
Total	652



Degree	Percent of all Twisters
Engineering or Science Degree, not inclusive of Ph.D	58%
PhD in Engineering or Science	18%
Employee without Engineering or Science Degree	24%
Total	652



Environmental management

Many gene synthesis companies rely on oligonucleotide, or oligo (short pieces of DNA) synthesis on a plastic 96-well plate format. The 96-well plate allows researchers to create 96 oligos in parallel, one in each well. While this process can successfully achieve DNA synthesis, it requires high volumes of phosphoramidites, an expensive raw material, as well as other ancillary chemical reagents such as activator, wash, deblock, oxidizer and capping reagents, many of which are toxic and environmentally harmful. The reagent consumption levels vary depending on the DNA synthesizer and its setup.

At Twist, we developed an ultra-high-throughput DNA synthesis platform to address the limitations of throughput, scalability, and cost inherent in legacy DNA synthesis methods like that described above. With a footprint that is similar to the size of a 96-well plate that produces 96 oligos or 1 or 2 genes, we are able to produce approximately 1,000,000 oligos or 9,600 genes in parallel.

With the Twist ultra-high-throughput DNA synthesizer, we believe we are able to achieve at least a 99.8% volume reduction (when compared to a standard manufacturer of oligos) in chemical consumption under the right circumstances compared to legacy oligo synthesis. For the more expensive chemical reagents (e.g., phosphoramidite and activator reagents), we have achieved nearly a 1,000,000-fold volume reduction. This drastic volume reduction is achieved through various engineering breakthroughs, including using of inkjet printing to deliver phosphoramidites and activator reagents (10 picoliter per droplet), and the development of proprietary flow cell chambers and reagent recipes, among other proprietary developments.

In addition, the legacy oligo synthesis process often produces significantly more oligos than is typically required for most subsequent processes. In contrast, the Twist system includes a fully-integrated and miniaturized molecular biology workflow to assemble genes using nearly 100% of the oligos we produced, yielding nearly zero wasted synthesized oligos and reducing the usage of molecular biology reagents (e.g., polymerase and other enzymes, and dNTP).

Overall, Twist's process to synthesize DNA significantly reduces the quantity of chemicals used, overproduced product and waste, for a more sustainable production process.

Government regulation

Our synthetic DNA products are intended for "Research Use Only" (RUO). We sell these products for non-diagnostic and non-clinical purposes to academic institutions, life sciences and research laboratories, and biopharmaceutical and biotechnology companies. Our products are neither intended nor promoted for clinical use, diagnostic procedures, or use as components of our customers products. Rather, they are intended to be used as research tools that enable our customers to develop a wide spectrum of commercial products. However, in the future we may be subject to a variety of specialized regulatory requirements, including potential regulation by the U.S. Food and Drug Administration, or the FDA. For example, in December 2010, the Presidential Commission for the Study of Bioethical Issues recommended that the federal government oversee, but not regulate, synthetic biology research. The Presidential Commission also recommended that the federal government lead an ongoing review of developments in the synthetic biology field and that the federal government conduct a reasonable risk assessment before the field release of synthetic organisms.

Aside from certain labeling requirements, we believe that our products, as currently marketed, are largely unregulated by governmental bodies, including the FDA. As we expand our product development to include products for clinical applications, we may be subject to a variety of specialized regulatory requirements, including regulation by the FDA, any of which could have a material effect on the business.

RUO is a term applicable to our target enrichment products for the next-generation sequencing (NGS) market and is applied to kits sold to this market segment. It is intended to restrict use of the kits to non-in vitro diagnostic purposes. Our NGS target enrichment and library preparation products are used in a more comprehensive workflow for next generation sequencing for research purposes only. In the future, we may develop this larger workflow as an in vitro diagnostic, for which we will obtain prior authorization from FDA or other applicable regulatory authorities before commercialization.

FDA

Pursuant to its authority under the Federal Food, Drug, and Cosmetic Act, or the FDC Act, the FDA has jurisdiction over medical devices. The FDA regulates, among other things, the research, testing, manufacturing, safety, labeling, storage, recordkeeping, premarket clearance or approval, marketing and promotion and sales and distribution of medical devices in the United States to ensure that medical products distributed domestically are safe and effective for their intended uses. In addition, the FDA regulates the import and export of medical devices.

Medical device regulation in general

The FDC Act classifies medical devices into one of three categories based on the risks associated with the device and the level of control necessary to provide reasonable assurance of safety and effectiveness. Devices deemed by the FDA to pose the greatest risk, such as life-sustaining, life-supporting or implantable devices, or devices deemed not substantially equivalent to a previously 510(k) cleared devices are generally categorized as Class III. These devices typically require submission and approval of a Premarket Approval Application, or PMA. However, FDA can reclassify or use "de novo classification" for a device that meets the FDC Act standards for a class II device, permitting the device to be marketed without PMA approval. Devices deemed to pose lower risk are categorized as either Class I or II. Class II classification usually requires the manufacturer to submit to the FDA a premarket notification submission requesting clearance of the device for commercial distribution in the United States pursuant to Section 510(k) of the FDC Act, referred to as 510(k) clearance. Most Class I devices are exempt from this requirement, as are some lower risk Class II devices. When a 510(k) is required, the manufacturer must submit to the FDA a premarket notification submission demonstrating that the device is "substantially equivalent" to: (i) a device that was legally marketed prior to May 28, 1976, for which PMA approval is not required, (ii) a legally marketed device that has been reclassified from Class III to Class II or Class I, or (iii) another legally marketed, similar device that has been cleared through the 510(k) process.

All clinical studies of investigational medical devices to determine safety and effectiveness must be conducted in accordance with FDA's investigational device exemption (IDE) regulations, including the requirement for the study sponsor to submit an IDE application to FDA, unless exempt, which must become effective prior to commencing human clinical studies. PMA reviews generally last between one and two years, although they can take longer. Both the 510(k) and the PMA processes can be expensive and lengthy and may not result in clearance or approval. If we are required to submit our products for pre-market review by the FDA, we may be required to delay marketing and commercialization while we obtain premarket clearance or approval from the FDA. There would be no assurance that we could ever obtain such clearance or approval.

All medical devices, including in vitro diagnostics, or IVDs, that are regulated by the FDA are also subject to the Quality System Regulation. Obtaining the requisite regulatory approvals, including the FDA quality system inspections that are required for PMA approval, can be expensive, may involve delay, and could conclude without such products being approved by the FDA. 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. This may negatively affect our ability to obtain or maintain FDA or comparable regulatory clearance or approval of our products in the future.

IVDs are a category of medical devices that include reagents, instruments, and systems intended for use in diagnosis of disease or other conditions, including a determination of the state of health, in order to cure, mitigate, treat, or prevent disease or its sequelae. IVDs are intended for use in the collection, preparation, and examination of specimens taken from the human body. A RUO IVD product is an IVD product that is in the laboratory research phase of development. As such, an RUO IVD is not intended for use in clinical investigations or in clinical practice. Such RUO products do not require premarket clearance or approval from the FDA, provided that they be labeled "For Research Use Only. Not For Use In Diagnostic Procedures" pursuant to FDA regulations.

As noted above, although our products are currently intended for research purposes only, the regulatory requirements related to marketing, selling, and supporting such products could be uncertain and depend on the totality of circumstances. This uncertainty exists even if such use by our customers occurs without our consent. If the FDA or other regulatory authorities assert that any of our RUO products are subject to regulatory clearance or approval, our business, financial condition, or results of operations could be adversely affected.

According to the FDA, merely including the RUO labeling statement will not necessarily render the device exempt from FDA premarket clearance, approval, or other regulatory requirements if the totality of circumstances surrounding the distribution of the product indicate that the manufacturer intended its IVDs for diagnostic use. Such circumstances may include, but are not limited to, the product's advertising, labeling, or promotion, or the manufacturer's assistance of a clinical laboratory in validating or verifying a test that incorporates products labeled RUO. This uncertainty exists even if such use by our customers occurs without our consent. If the FDA or other regulatory authorities assert that any of our RUO products are subject to regulatory clearance or approval, our business, financial condition, or results of operations could be adversely affected.

EU Regulation

In the European Union (EU), the new In Vitro Diagnostic Device Regulation (EU) 2017/746, or IVDR, imposes stricter requirements for the marketing and sale of applicable medical devices, including in the area of clinical evaluation requirements, quality systems and post-market surveillance. The IVDR is expected to become effective in May 2022. We likely will be impacted by this new regulation, either directly as a manufacturer of IVDs, or indirectly as a supplier to customers who are placing IVDs in the EU market for clinical or diagnostic use. Complying with the IVDR requirements may require us to incur significant expenditures. Failure to meet these requirements could adversely impact our business in the EU and other regions that tie their product registrations to the EU requirements.

FSAP

The Federal Centers for Disease Control and Prevention (CDC) and the Animal and Plant Health Inspection Service (APHIS) administer requirements of the Federal Select Agent Program, or FSAP. FSAP requirements govern possession, use, and transfer of select agents and toxins consisting of biological materials that have the potential to pose a severe threat to public, animal or plant health or to animal or plant products. The FSAP currently lists approximately 67 select agents and toxins, and approximately 247 entities were registered under FSAP to possess a select agent or toxin. The registered entities primarily consist of academic, federal and non-federal government, commercial, and private facilities that conduct research studies or diagnostic activities. We are not a registered entity under FSAP and it is our policy generally not to produce or otherwise work with any biological material that is subject to FSAP license requirements. To the extent that we may possess, use, or transfer any material considered a select agent or toxin under FSAP prospectively, we would seek to register with FSAP and obtain all necessary permits for possession, transfer, importation, or any other regulated activity.

Export controls

Some sequences and synthetic controls we produce may be subject to licensing requirements for export outside of the United States under the U.S. Export Administration Regulations (EAR). Given the evolving nature of our industry, legislative bodies or regulatory authorities may adopt additional regulation or expand existing regulation to include our service. Changes to the current regulatory framework, including the imposition of additional or new regulations, could arise at any time, and we may be unable to obtain or maintain comparable regulatory approval or clearance of our service, if required. These regulations and restrictions may materially and adversely affect our business, financial condition, and results of operations.

Available information

Our corporate website address is *www.twistbioscience.com*. We use the investor relations page of our website for purposes of compliance with Regulation FD and as a routine channel for distribution of important information, including news releases, analyst presentations, financial information and corporate governance practices. Our filings with the SEC are posted on our website and available free of charge as soon as reasonably practical after they are electronically filed with, or furnished to, the SEC. The SEC's website, *www.sec.gov*, contains reports, proxy statements and other information regarding issuers that file electronically with the SEC. The content on any website referred to in this Form 10-K is not incorporated by reference in this Form 10-K unless expressly noted. Further, the Company's references to website URLs are intended to be inactive textual references only.

Item 1A. ***Risk factors***

Risk Factor Summary

Investing in our common stock involves a high degree of risk. You should carefully consider all information in this Annual Report on Form 10-K prior to investing in our common stock. These risks are discussed more fully in the section titled "Risk Factors." These risks and uncertainties include, but are not limited to, the following:

- We are subject to risks associated with COVID-19;
- We have incurred net losses in every period to date, and we expect to continue to incur significant losses as we develop our business and may never achieve profitability;
- We will require additional financing to achieve our goals, and a failure to obtain this necessary capital when needed on acceptable terms, or at all, could force us to delay, limit, reduce or terminate our product manufacturing and development and other operations;
- If we are unable to maintain adequate revenue growth or do not successfully manage such growth, our business and growth prospects will be harmed;
- Rapidly changing technology and extensive competition in synthetic biology could make the products we are developing and producing obsolete or non-competitive unless we continue to develop and manufacture new and improved products and pursue new market opportunities;
- The continued success of our business relies heavily on our disruptive technologies and products and our position in the market as a leading provider of synthetic DNA using a silicon chip;
- We depend on one single-source supplier for a critical component for our DNA synthesis process. The loss of this supplier or its failure to supply us with the necessary component on a timely basis, could cause delays in the future capacity of our DNA synthesis process, and adversely affect our business;
- We depend on the continuing efforts of our senior management team and other key personnel. If we lose members of our senior management team or other key personnel or are unable to successfully retain, recruit and train qualified researchers, engineering and other personnel, our ability to develop our products could be harmed, and we may be unable to achieve our goals;
- We may engage in strategic transactions, including acquisitions and divestitures that could disrupt our business, cause dilution to our stockholders, reduce our financial resources, or prove not to be successful;
- Our products could in the future be subject to additional regulation by the U.S. Food and Drug Administration or other domestic and international regulatory agencies, which could increase our costs and delay our commercialization efforts, thereby materially and adversely affecting our business and results of operations;
- If we fail to maintain proper and effective internal controls, our ability to produce accurate financial statements on a timely basis could be impaired, which would adversely affect our business;
- Our ability to protect our intellectual property and proprietary technology through patents and other means is uncertain; and
- If we are unable to obtain, maintain and enforce intellectual property protection, others may be able to make, use, or sell products and technologies substantially the same as ours, which could adversely affect our ability to compete in the market.

The following discussion of risk factors contains forward-looking statements. These risk factors may be important to understanding other statements in this Annual Report on Form 10-K. The following information should be read in conjunction with Part II, Item 7, “Management’s discussion and analysis of financial condition and results of operations” and the consolidated financial statements and related notes in Part II, Item 8, “Consolidated financial statements and supplementary data” of this Form 10-K. The risks and uncertainties described below are not the only ones we face. Additional risk and uncertainties not presently known to us or that we presently deem less significant may also impair our business operations. If any of the events or circumstances described in the following risk factors actually occur, our business, operating results, financial condition, cash flows, and prospects could be materially and adversely affected. In that event, the market price of our common stock could decline, and you could lose part or all of your investment.

Our business, financial condition and operating results can be affected by a number of factors, whether currently known or unknown, including but not limited to those described below, any one or more of which could, directly or indirectly, cause our actual financial condition and operating results to vary materially from past, or from anticipated future, financial condition and operating results. Any of these factors, in whole or in part, could materially and adversely affect our business, financial condition, operating results and stock price.

Because of the following factors, as well as other factors affecting our financial condition and operating results, past financial performance should not be considered to be a reliable indicator of future performance, and investors should not use historical trends to anticipate results or trends in future periods.

Risks related to our business

We are subject to risks associated with COVID-19.

Our global operations expose us to risks associated with COVID-19 that has spread globally. In the past year, the continued spread of COVID-19 has led to disruption to business and economic activity and related uncertainty and volatility in the global capital markets, which increases the cost of, and adversely impacts access to, capital and increases economic uncertainty. The COVID-19 pandemic has caused an economic slowdown and will likely continue to impact business and economic activity globally. While our financial results for the fiscal year 2021 have not been significantly affected by the COVID-19 outbreak, impacts from COVID-19 may, in the future, adversely affect our operations, supply chains, distribution systems and customer demand, including as a result of impacts associated with preventive and precautionary measures that we, other businesses and governments are taking or may take in the future. Due to the health risks caused by the COVID-19 pandemic to employees who operate and monitor our internal controls and due to the previous requirement and potential future requirements that a large number of employees work remotely, the COVID-19 pandemic impact on staffing could cause challenges for the effective operation of our internal controls. The unanticipated loss or unavailability of key employees due to the COVID-19 outbreak could harm our ability to operate or execute our business strategy. We may not be successful in finding and integrating suitable successors in the event of key employee loss or unavailability. The effectiveness of our sales teams may be negatively impacted by the lack of travel and their reduced ability to engage with decision-makers. Our NGS business may be negatively impacted by the sequencing capacity dedicated to COVID-19 related orders. Our shipments may be subject to higher freight costs. Our customers may delay payments for shipments received. A significant portion (approximately 19%) of our business is in the academic markets and the demand for our products in this customer segment have been affected by a reduction in their research grants and may continue to be so affected in the future. Supply chain disruptions may result in the lack of raw materials, delay in the release of new products or compressed margins due to an increase in material costs. Due to these impacts and measures, we may experience significant and unpredictable reductions in demand for our products and our customers may postpone or cancel their existing orders. Due to the COVID-19 pandemic, we and many other employers in the United States and Europe have required all employees whose duties can be performed remotely, to work from home and not to go into our offices. This increase in employee telecommuting activity could increase the risk of a security breach of our information technology systems. If the COVID-19 pandemic continues and business and economic conditions persist or worsen, we may experience a decline in sales activities and customer orders or cancelations of existing orders, and it remains uncertain what impact these declines will have on future sales and customer orders once conditions begin to improve. In addition to existing travel restrictions, some countries have closed their borders to U.S. travelers and may continue to impose or further expand travel restrictions and impose or resume prolonged quarantines, which would significantly impact our ability to support our business operations and customers in those locations and the ability of our employees to access their places of work to produce products, or significantly hamper our products from moving through the supply chain. For example, we may face a shortage of dry ice and other materials which are essential to delivering our products to our customers due to the increased demand for such products due to the COVID-19 vaccination distribution, COVID-19 testing and COVID-19 antibody development. As a result, given the evolving nature of the business and economic conditions in response to the virus, and the uncertainty as to how quickly and effectively mitigation measures, such as vaccines, will be widely available and adopted by the public, the COVID-19 pandemic may negatively affect our revenue growth, and it is uncertain how materially COVID-19 will affect our global operations if these impacts persist or worsen over an extended period of time. Any of these impacts would have an adverse effect on our business, financial condition and results of operations, and at this point, the extent of the impact of COVID-19 remains uncertain. In addition, our ability to raise capital in the future may also be negatively affected.

We have incurred net losses in every period to date, and we expect to continue to incur significant losses as we develop our business and may never achieve profitability.

We have incurred net losses each year since inception and have generated limited revenue from product sales to date. We expect to incur increasing costs as we grow our business. We cannot be certain if or when we will produce sufficient revenue from our operations to support our costs. Even if profitability is achieved, we may not be able to sustain profitability. We incurred net losses of $152.1 million, $139.9 million and $107.7 million for the years ended September 30, 2021, 2020 and 2019, respectively. As of September 30, 2021, we had an accumulated deficit of $610.6 million. We expect to incur substantial losses and negative cash flow for the foreseeable future. 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 Form 10-K, the market acceptance of our products, business and economic conditions resulting from the ongoing COVID-19 pandemic, future product development, and our market penetration and margins.

We may require additional financing to achieve our goals, and a failure to obtain this necessary capital when needed on acceptable terms, or at all, could force us to delay, limit, reduce or terminate our product manufacturing and development and other operations.

Since our inception, substantially all of our resources have been dedicated to the development of our DNA synthesis platform and our sample preparation kit for NGS. We believe that we will continue to expend substantial resources for the foreseeable future as we continue to expand our production capabilities and enter additional markets we may choose to pursue, including new COVID-19 testing products, pharmaceutical biologics drug discovery and digital data storage in DNA. These expenditures are expected to include costs associated with research and development, increasing manufacturing and supply capabilities as well as marketing and selling existing and new products. In addition, other unanticipated costs may arise.

We expect that our existing cash and cash equivalents will be sufficient to fund our planned operating expenses, capital expenditure requirements and debt service payments through at least the next 12 months. However, our operating plan may change as a result of factors currently unknown to us, and as a result, we have sought and may in the future need to seek additional funds sooner than planned, through public or private equity or debt financings or other sources, such as strategic collaborations. In addition, we may seek additional capital due to favorable market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans. Such financing may result in dilution to stockholders, imposition of debt covenants and repayment obligations, or other restrictions that may adversely affect our business.

Our future capital requirements depend on many factors, including:

- the number and characteristics of any additional products or manufacturing processes we develop or acquire to serve new or existing markets;
- the scope, progress, results and costs of researching and developing future products or improvements to existing products or manufacturing processes, including increasing our manufacturing capabilities;
- the cost of manufacturing our DNA synthesis equipment and tools, our NGS sample preparation kits, and any future products we successfully commercialize;
- our ability to establish and maintain strategic collaborations, licensing or other arrangements and the financial terms of such agreements;
- the costs of expanding our sales and marketing capabilities in the United States and in other geographies;
- any lawsuits related to our products or commenced against us or any regulatory actions or proceedings commenced;
- the expenses needed to attract and retain skilled personnel;
- the costs associated with being a public company;
- the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing patent claims, including litigation costs and the outcome of such litigation; and
- the timing, receipt and amount of sales of, or royalties on, any future approved products, if any.

Additional funds may not be available when we need them, on terms that are acceptable to us, or at all. If adequate funds are not available to us on a timely basis, we may be required to:

- delay, limit, reduce or terminate our manufacturing, research and development activities; or
- delay, limit, reduce or terminate our establishment of sales and marketing capabilities or other activities that may be necessary to generate revenue and achieve profitability.

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

We have experienced significant revenue growth in a short period of time. We may not achieve similar growth rates in future periods. Investors should not rely on our operating results for any prior periods as an indication of our future operating performance. To effectively manage our anticipated future growth, we must continue to maintain and enhance our manufacturing, sales, financial and customer support 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 manufacturing 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 may suffer, which could negatively affect our reputation and harm our ability to retain and attract customers.

Our quarterly and annual operating results and cash flows have fluctuated in the past and might continue to fluctuate, causing the value of our common stock 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 difficult. 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 common stock could decline substantially.

Our operating results have varied in the past. As a result, our operating results could be unpredictable, particularly on a quarterly basis. 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 are further described in “Risk factors—Risks relating to owning our stock.”

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 might decrease our gross margins and could cause significant changes in our operating results from quarter to quarter. If this occurs, the trading price of our common stock could fall substantially.

If we are unable to attract new customers and retain and grow sales from our existing customers, our business will be materially and adversely affected.

In order to grow our business, we must continue to attract new customers and retain and grow sales from our existing customers on a cost-effective basis. To do this, we aim to attract new and existing buyers of synthetic DNA and NGS tool kits, convert makers of synthetic DNA into buyers of synthetic DNA, monetize our antibody discovery platform by entering into partnerships and achieve widespread market acceptance by delivering both our current product offerings and new products and technologies at low cost, with high-quality, reliable turn around times and throughput, superior e-commerce services and effective technical support. We cannot guarantee that our efforts to provide these key requirements will be consistently acceptable to, and meet the performance expectations of, our customers and potential customers. If we are unable to successfully attract and retain customers, our business, financial position and results of operations would be negatively impacted.

If we experience a significant disruption in, or breach in security of, our information technology systems, or if we fail to implement new systems and software successfully, our business could be adversely affected. Cyberattacks and security vulnerabilities could lead to reduced revenue, increased costs, liability claims, or harm to our reputation or competitive position.

We rely on several centralized information technology systems throughout our company to provide products, keep financial records, process orders, manage inventory, process shipments to customers and operate other critical functions. In addition, we currently generate a growing portion of our revenue through sales on our e-commerce platform. We manage our website and e-commerce platform internally and as a result any compromise of our security or misappropriation of proprietary information could have a material adverse effect on our business, financial condition and results of operations. We rely on encryption and authentication technology licensed from third parties to provide the security and authentication necessary to effect secure Internet transmission of confidential information, such as credit and other proprietary information. We announced on February 12, 2020 that our information security management system received ISO 27001:2013 certification, an information security standard published by the International Organization for Standardization (ISO), the world's largest developer of voluntary international standards, and the International Electrotechnical Commission. Even though our information security management system received ISO 27001:2013 certification, our information technology systems may still be susceptible to damage, disruptions or shutdowns due to power outages, hardware failures, computer viruses, attacks by computer hackers, telecommunication failures, user errors, catastrophes or other unforeseen events. Our information technology systems also may experience interruptions, delays or cessations of service or produce errors in connection with system integration, software upgrades or system migration work that takes place from time to time. If we were to experience a prolonged system disruption in the information technology systems that involve our interactions with customers or suppliers, including negatively impacting our order fulfillment and order entry on our e-commerce platform, it could result in the loss of sales and customers and significant incremental costs, which could adversely affect our business. In addition, security breaches of our information technology systems could result in the misappropriation or unauthorized disclosure of confidential information belonging to us or to our employees, partners, customers or suppliers, which could result in our suffering significant financial or reputational damage. Further, such a breach may require notification to governmental agencies, the media or individuals pursuant to various federal and state privacy and security laws. We would also be exposed to a risk of litigation and potential liability, which could materially adversely affect our business, results of operations and financial condition.

Our actual operating results may differ significantly from our guidance.

From time to time, we may release guidance in our quarterly earnings conference calls, quarterly earnings releases, or otherwise, regarding our future performance that represents our management's estimates as of the date of release. This guidance, which includes forward-looking statements, is based on projections prepared by our management. This guidance is not prepared with a view toward compliance with published guidelines of the American Institute of Certified Public Accountants (AICPA) regarding projections or the SEC regarding forward-looking statements, and neither our independent registered public accounting firm nor any other independent expert or outside party compiles or examines the projections. Accordingly, no such person will express any opinion or any other form of assurance with respect to the projections.

Projections are based upon a number of assumptions and estimates that, while presented with numerical specificity, are inherently subject to significant business, economic and competitive uncertainties and contingencies, many of which are beyond our control and are based upon specific assumptions with respect to future business decisions, some of which will change. Our aim is to state possible outcomes as high and low ranges to provide a sensitivity analysis as variables are changed but are not intended to imply that actual results could not fall outside of the suggested ranges. The principal reason that we release guidance is to provide a basis for our management to discuss our business outlook with analysts and investors. We do not accept any responsibility for any projections or reports published by any such third parties.

Guidance is necessarily speculative in nature, and it can be expected that some or all of the assumptions underlying the guidance furnished by us will not materialize or will vary significantly from actual results. Accordingly, our guidance is only an estimate of what management believes is realizable as of the date of release. Actual results may vary from our guidance and the variations may be material. In light of the foregoing, investors are urged not to rely upon our guidance in making an investment decision regarding our common stock.

Any failure to successfully implement our operating strategy or the occurrence of any of the events or circumstances set forth in the "Risk factors" section in this Form 10-K could result in the actual operating results being different from our guidance, and the differences may be adverse and material.

Rapidly changing technology and extensive competition in synthetic biology could make the products we are developing and producing obsolete or non-competitive unless we continue to develop and manufacture new and improved products and pursue new market opportunities.

The synthetic biology industry is characterized by rapid and significant technological changes, frequent new product introductions and enhancements and evolving industry demands and standards. Our future success will depend on our ability to continually improve the products we are developing and producing, to develop and introduce new products that address the evolving needs of our customers on a timely and cost-effective basis and to pursue new market opportunities that develop as a result of technological and scientific advances. These new market opportunities may be outside the scope of our proven expertise or in areas which have unproven market demand, and the utility and value of new products and services developed by us may not be accepted in the markets served by the new products. Our inability to gain market acceptance of existing products in new markets or market acceptance of new products could harm our future operating results. Our future success also depends on our ability to manufacture these new and improved products to meet customer demand in a timely and cost-effective manner, including our ability to resolve manufacturing issues that may arise as we commence production of any new products we develop. Unanticipated difficulties or delays in replacing existing products with new products we introduce or in manufacturing improved or new products in sufficient quantities to meet customer demand could diminish future demand for our products and harm our future operating results.

In addition, there is extensive competition in the synthetic biology industry, and our future success will depend on our ability to maintain a competitive position with respect to technological advances. Technological development by others may result in our technologies, as well as products developed using our technologies, becoming obsolete. Our ability to compete successfully will depend on our ability to develop proprietary technologies and products that are technologically superior to and/or are less expensive than our competitors' technologies and products. Our competitors may be able to develop competing and/or superior technologies and processes and compete more aggressively and sustain that competition over a longer period of time.

The continued success of our business relies heavily on our disruptive technologies and products and our position in the market as a leading provider or synthetic DNA using a silicon chip.

Our future profitability will depend on our ability to successfully execute and maintain a sustainable business model and generate continuous streams of revenue. Our business model is premised on the fact that we are the only DNA synthesis provider to synthesize DNA on a silicon chip on a large commercial level and the competitive advantages this creates. Our DNA synthesis methods, among other things, reduce the amount of raw materials required, speed up the synthesis process and deliver large volumes of high-quality synthetic DNA at low unit cost. However, if other competitors develop and commercialize a manufacturing process using a silicon chip or other similar technologies providing for the development of competitive synthetic DNA products at scale, this could be disruptive to our business model and could adversely affect our business prospects, financial condition and results of operations. If we are unable to convert sufficient number of current manufacturers of synthetic DNA to buyers of our synthetic DNA, surpass our competitors regarding certain industry-related data points, and effectively implement our e-commerce platform which facilitates efficient order entry and fulfillment for our customers, our business, prospects, financial condition and results of operation will be adversely affected.

If we are unable to expand into adjacent addressable markets, our business may be materially and adversely affected.

Our future revenue growth and market potential may depend on our ability to leverage our DNA synthesis platform together with our custom libraries and other proprietary tools, such as our antibody discovery and optimization platform, in adjacent businesses such as pharmaceutical biologics drug discovery and digital data storage in DNA. There can be no assurance that we can continue to utilize our antibody libraries to accelerate the lead identification and lead optimization steps of antibody discovery or to discover more effective antibody drugs. In addition, our technology may not develop in a way that allows data storage in DNA to become cost competitive with traditional data storage media or in a way that otherwise enables us to address the markets opportunities that we believe exist. If we are unable to expand into adjacent addressable markets, our business, financial position and results of operations could be negatively impacted.

A significant portion of our sales depends on customers' budgets that may be subject to significant and unexpected variation, including seasonality.

Our customers' spending on research and development impacts our sales and profitability. Our customers and potential customers include chemicals/materials, diagnostics, therapeutics, food/agriculture, and their budgets can have a significant effect on the demand for our products. Their research and development budgets are based on a wide variety of factors, including factors beyond our control, such as:

- the allocation of available resources to make purchases;
- funding from government sources;
- funding from research grants;
- changes in government programs that provide funding to research institutions and companies;
- the spending priorities among various types of research equipment;
- policies regarding capital expenditures during recessionary periods;
- political climate or macroeconomic conditions, including economic downturns or market uncertainty or reduced spending in response to emergency situations, such as the outbreak of COVID-19;
- changes in the regulatory environment;
- differences in budgetary cycles; and
- market acceptance of relatively new technologies, such as ours.

Any decrease in spending or change in spending priorities of our customers and potential customers could significantly reduce the demand for our products. As we expand into new geographic markets, our revenue may be impacted by seasonal trends in the different regions, the seasonality of customer budgets in those regions and the mix of domestic versus international sales. Moreover, we have no control over the timing and volume of purchases by these customers and potential customers, and as a result, revenue from these sources may vary significantly due to factors that can be difficult to forecast. Any delay or reduction in purchases by customers and potential customers or our inability to forecast fluctuations in demand could harm our future operating results.

We generally do not have long-term contracts with our customers requiring them to purchase any specified quantities from us.

We generally do not have long-term contracts with our customers requiring them to purchase any specified quantities from us and without such contracts our customers are not obligated to order or reorder our products. As a result, we cannot accurately predict our customers' decisions to reduce or cease purchasing our products. Additionally, even where we enter into contracts with our customers, there is no guarantee that such agreements will be negotiated on terms that are commercially favorable to us in the long-term. Therefore, if many of our customers were to substantially reduce their transaction volume or cease ordering products from us, this could materially and adversely affect our financial performance.

We may be unable to successfully increase our market share and expand our customer base.

Our ability to achieve profitability depends on our being able to increase our market share and expand our customer base. Although members of our sales and marketing teams have considerable industry experience and have engaged in marketing activities for our products, in the future we must expand our sales, marketing, distribution and customer support capabilities with the appropriate technical expertise to effectively market our products. Furthermore, it takes six to nine months to recruit, onboard and ramp sales personnel to full capability and both new hires and sales personnel who operate at full capability are currently encountering challenging sales conditions due to business and operational difficulties arising from the COVID-19 pandemic, and may not be fully productive while these conditions persist or worsen. To perform sales, marketing, distribution and customer support successfully, we will face a number of risks, including that:

- we may not be able to attract, retain and manage the sales, marketing and service workforce necessary to publicize and gain broader market acceptance of our technology;

- the time and cost of establishing a specialized sales, marketing and service force for a particular product or service, which may be difficult to justify in light of the revenue generated;
- our field sales personnel may not be able to access our customers' premises which could delay the adoption and ordering of our products; and
- our sales, marketing and service force may be unable to initiate and execute successful commercialization activities with respect to new products or markets we may seek to enter.

If our sales and marketing efforts, or those of any third-party sales and distribution partners, are not successful, our new technologies and products may not gain market acceptance, which could materially impact our business operations.

The United Kingdom's ("U.K.") referendum to exit from the European Union ("E.U.") will continue to have uncertain effects and could adversely impact our business, results of operations and financial condition.

As a result of a referendum in June 2016, the U.K. withdrew from the E.U. ("Brexit") on January 31, 2020. It began a transition period in which to negotiate a new trading relationship for goods and services that ended on December 31, 2020. During the time since the June 2016 referendum, there have been periods of significant volatility in the global stock markets and currency exchange rates, as well as challenging market conditions in the U.K. On December 24, 2020, the U.K. and E.U. announced they had entered into a post-Brexit deal on certain aspects of trade and other strategic and political issues. We are continuing to evaluate our own risks and uncertainty related to ascertain what financial, trade, regulatory and legal implications this new Brexit trade deal could have on our U.K. and European business operations, including our ability to ship our products into the U.K. This uncertainty also includes the impact on our customers' business operations and capital planning as well as the overall impact on the biotechnology industry in the U.K. While we have not experienced any direct material financial impact since the 2016 referendum, we cannot predict its future implications, and Brexit and its related effects could result in a negative impact on our consolidated financial position and results of operations.

If we are unable to expand our DNA synthesis manufacturing capacity, we could lose revenue and our business could be harmed.

In order to expand our manufacturing capacity of new and existing products, we need to either build additional internal manufacturing capacity, contract with one or more partners, or both. We are currently building a new production facility in Wilsonville, Oregon but we cannot guarantee that such facility will allow us to effectively increase our manufacturing capacity. Our technology and the production process for our DNA synthesis equipment and tools are complex, involving specialized parts, and we may encounter unexpected difficulties in the manufacture, improvement or increasing the capacity of our DNA synthesis equipment and tools, and addressing these difficulties may cause us to divert our time and resources from our other product offerings. There is no assurance that we will be able to continue to increase manufacturing capacity internally or that we will find one or more suitable partners to help us towards this objective, in order to meet the volume and quality requirements necessary for success in our existing and potential markets. Manufacturing and product quality issues may arise as we continue to increase the scale of our production. If our DNA synthesis equipment and tools do not consistently produce DNA products that meet our customers' performance expectations, our reputation may be harmed, and we may be unable to generate sufficient revenue to become profitable. Any delay or inability in expanding our manufacturing capacity could diminish our ability to develop or sell our products, which could result in lost revenue and materially harm our business, financial condition and results of operations.

We are substantially dependent on the success of our synthetic DNA products.

To date, we have invested a substantial portion of our efforts and financial resources towards the research and development and commercialization of our synthetic DNA products. The DNA synthesis business is very capital intensive, particularly for early-stage companies that do not have significant off-setting revenues and which are making significant investments in the commercialization and marketing of their products.

Substantially all of our revenue generated to date is from our synthetic DNA products. Our financial results are dependent on strengthening our core business while diversifying into other developing sectors such as pharmaceutical biologics drug discovery, creating useful DNA libraries and data storage.

Our near-term prospects, including our ability to finance our research and development activities and initiatives and enter into strategic collaborations, will depend heavily on the successful development and commercialization of our synthetic DNA products. These initiatives will be substantially dependent on our ability to generate revenue from our synthetic DNA products and obtain other funding necessary to support these initiatives. Our inability to continue these initiatives and initiate new research and development efforts could result in a failure to develop new products, improve upon existing products such that sectors like pharmaceutical

biologics drug discovery, DNA library creation and data storage may never be fully developed, and expand our addressable market, which could have a material and adverse impact on our sales, business, financial position and results of operations.

We depend on one single-source supplier for a critical component for our DNA synthesis process. The loss of this supplier or its failure to supply us with the necessary component on a timely basis, could cause delays in the future capacity of our DNA synthesis process and adversely affect our business.

We depend on one single-source supplier for a critical component for our DNA synthesis process. We do not currently have the infrastructure or capability internally to manufacture this component. Although we have a reserve of supplies and although alternative suppliers exist for this critical component of our synthesis process, our existing DNA synthesis manufacturing process has been designed based on the functions, limitations, features and specifications of the components that we currently utilize. We have a supply agreement in place with this component supplier. However, there can be no assurance that our supply of this component will not be limited, interrupted, or of satisfactory quality or continue to be available at acceptable prices. Additionally, we do not have any control over the process or timing of the acquisition or manufacture of materials by our supplier and cannot ensure that it will deliver to us the component we order on time, or at all.

The loss of this component provided by this supplier could require us to change the design of our manufacturing process based on the functions, limitations, features and specifications of the replacement components.

In addition, the lead time needed to establish a relationship with a new supplier can be lengthy, and we may experience delays in meeting demand in the event we must switch to a new supplier. The time and effort to qualify a new supplier could result in additional costs, diversion of resources or reduced manufacturing yields, any of which would negatively impact our operating results. Further, we may be unable to enter into agreements with a new supplier on commercially reasonable terms, which could have a material adverse impact on our business. Our dependence on this single-source supplier exposes us to certain risks, including the following:

- our supplier may cease or reduce production or deliveries, raise prices or renegotiate terms;
- we may be unable to locate a suitable replacement on acceptable terms or on a timely basis, if at all;
- if there is a disruption to our single-source supplier’s operations, and if we are unable to enter into arrangements with alternative suppliers, we will have no other means of completing our synthesis process until they restore the affected facilities or we or they procure alternative manufacturing facilities or sources of supply;
- delays caused by supply issues may harm our reputation, frustrate our customers and cause them to turn to our competitors for future projects; and
- our ability to progress our DNA synthesis products could be materially and adversely impacted if the single-source supplier upon which we rely were to experience a significant business challenge, disruption or failure due to issues such as financial difficulties or bankruptcy, issues relating to other customers such as regulatory or quality compliance issues, or other financial, legal, regulatory, operational or reputational issues.

Moreover, to meet anticipated market demand, our single-source supplier may need to increase manufacturing capacity, which could involve significant challenges. This may require us and our supplier to invest substantial additional funds and hire and retain the technical personnel who have the necessary experience. Neither we nor our supplier may successfully complete any required increase to existing manufacturing capacity in a timely manner, or at all.

We must continue to secure and maintain sufficient and stable supplies of raw materials.

Although historically we have not experienced price increases due to unexpected raw material shortages and other unanticipated events, there is no assurance that our supply of raw materials will not be significantly adversely affected in the future, adversely affecting our business, prospects, financial condition and results of operation.

In addition, as we grow, our existing suppliers may not be able to meet our increasing demand, and we may need to find additional suppliers. There is no assurance that we will always be able to secure suppliers who provide raw materials at the specification, quantity and quality levels that we demand (or at all) or be able to negotiate acceptable fees and terms of services with any such suppliers. Identifying a suitable supplier is an involved process that requires us to become satisfied with their quality control, responsiveness and service, financial stability and labor and other ethical practices. Even if we are able to expand existing sources, we

may encounter delays in production and added costs as a result of the time it takes to train suppliers in our methods, products and quality control standards.

We typically do not enter into agreements with our suppliers but secure our raw materials on a purchase order basis. Our suppliers may reduce or cease their supply of raw materials and outsourced services and products to us at any time in the future. If the supply of raw materials and the outsourced services and products is interrupted, our production processes may be delayed. If any such event occurs, our operation and financial position may be adversely affected.

A deterioration of our relationship with any of our suppliers, or problems experienced by these suppliers, could lead to shortages in our production capacity for some or all of our products. In such case, we may not be able to fulfill the demand of existing customers or supply new customers. A raw material shortage or an increase in the cost of the raw materials we use could result in decreased revenue or could impair our ability to maintain or expand our business.

In the event of significant price increases for raw materials, we may have to pass the increased raw materials costs to our customers. However, we cannot assure you that we will be able to raise the prices of our products sufficiently to cover increased costs resulting from increases in the cost of our raw materials or overcome the interruption of a sufficient supply of qualified raw materials for our products. As a result, a price increase for our raw materials may negatively impact our business, financial position and results of operations.

We may encounter difficulties in managing our growth, and these difficulties could impair our profitability.

Currently, we are working simultaneously on multiple projects, expanding our capacity as well as targeting several market sectors, including activities in the chemicals/materials, diagnostics, therapeutics, food and data storage sectors. In addition, we work to renew our ISO certifications from time to time. These diversified operations and activities place significant demands on our limited resources and require us to substantially expand the capabilities of our technical, administrative and operational resources.

If we are unable to manage this growth and the periodic ISO recertification of our manufacturing facilities effectively, our shipments to our customers could be impacted, our time and resources could be diverted from other products and offerings and our business and operating results could suffer. Our ability to manage our operations and costs, including research and development, costs of components, manufacturing, sales and marketing, requires us to continue to enhance our operational, financial and management controls, reporting systems and procedures and to attract and retain sufficient numbers of talented employees. Failure to attract and retain sufficient numbers of talented employees will further strain our human resources and could impede our growth.

Our revenue, results of operations, cash flows and reputation in the marketplace may suffer upon the loss of a limited number of large customers.

We have derived, and believe we may continue to derive, a significant portion of our revenues from a limited number of large customers. Our customers may buy less of our products depending on their own technological developments, end-user demand for our products and internal budget cycles. In addition, existing customers may choose to produce some or all of their synthetic DNA requirements internally by using or developing manufacturing capabilities organically or by using capabilities from acquisitions of assets or entities from third parties with such capabilities. The loss of any significant customer or a significant reduction in the amount of product ordered by any significant customer would adversely affect our revenue, results of operations, cash flows and reputation in the marketplace.

Our credit facility contains restrictions that limit our flexibility in operating our business.

In September 2017, we entered into an amended and restated loan and security agreement with Silicon Valley Bank (SVB) which provides a $10.0 million revolving credit facility and a $10.0 million term loan. The credit agreement contains various covenants that limit our ability to engage in specified types of transactions. These covenants limit our ability to, among other things:

- sell, transfer, lease or otherwise dispose of our assets;
- create, incur or assume additional indebtedness;
- engage in certain changes in business, management, control, or business location
- encumber or permit liens on certain of our assets;

- make restricted payments, including paying dividends on, repurchasing or making distributions with respect to our common stock;
- make specified investments (including loans and advances);
- consolidate, merge, sell or otherwise dispose of all or substantially all of our assets or acquire other entities;
- make or permit any payment on any subordinated debt; and
- enter into certain transactions with our affiliates.

Our incurrence of this debt, and any future increases in our aggregate level of debt, may adversely affect our operating results and financial condition by, among other things:

- increasing our vulnerability to downturns in our business, to competitive pressures and to adverse economic and industry conditions;
- requiring the dedication of an increased portion of our expected cash flows from operations to service our indebtedness, thereby reducing the amount of expected cash flows available for other purposes, including capital expenditures, acquisitions and dividends; and
- limiting our flexibility in planning for, or reacting to, changes in our business and our industry.

A breach of any of these covenants could result in a default under our credit facility. Upon the occurrence of an event of default under our credit facility, SVB could elect to declare all amounts outstanding under our credit facility to be immediately due and payable and terminate all commitments to extend further credit. If we were unable to repay those amounts, the lenders under our credit facility could proceed against the collateral granted to them to secure such indebtedness. We have pledged substantially all of our assets, other than our intellectual property, as collateral under our credit facility.

We depend on the continuing efforts of our senior management team and other key personnel. If we lose members of our senior management team or other key personnel or are unable to successfully retain, recruit and train qualified researchers, engineering and other personnel, our ability to develop our products could be harmed, and we may be unable to achieve our goals.

Our future success depends upon the continuing services of members of our senior management team and scientific and engineering personnel. We are highly dependent on Dr. Emily Leproust, our President and Chief Executive Officer, who is employed “at will,” meaning we or she may terminate the employment relationship at any time. In particular, our researchers and engineers are critical to our future technological and product innovations, and we will need to hire additional qualified personnel. We may not be able to attract and retain qualified personnel on acceptable terms, or at all. In addition, to the extent we hire personnel from competitors, we may be subject to allegations that they have been improperly solicited or that they have divulged proprietary or other confidential information, or that their former employers own their research output. Our industry, particularly in the San Francisco Bay Area, is characterized by high demand and intense competition for talent, and the turnover rate can be high. We compete for qualified management and scientific personnel with other life science companies, academic institutions and research institutions, particularly those focusing on genomics. Many of these employees could leave our company with little or no prior notice and would be free to work for a competitor. If one or more of our senior executives or other key personnel were unable or unwilling to continue in their present positions, we might not be able to replace them easily or at all, and other senior management may be required to divert attention from other aspects of the business. In addition, we do not have “key person” life insurance policies covering members of our management team or other key personnel except Dr. Leproust. The loss of any of these individuals or our inability to attract or retain qualified personnel, including researchers, engineers and others, could prevent us from pursuing collaborations and adversely affect our product development and introductions, business growth prospects, results of operations and financial condition.

We may engage in strategic transactions, including acquisitions that could disrupt our business, cause dilution to our stockholders, reduce our financial resources, or prove not to be successful.

In the future, we may enter into transactions to acquire other businesses, products or technologies and our ability to do so successfully cannot be ensured. While historically we have not completed many acquisitions, we recently closed the acquisition of iGenomX International Genomics Corporation ("iGenomX") in the third quarter of 2021 and we are continuing to pursue opportunities in the life sciences industry that complement and expand our synthetic DNA product, products and markets both locally and internationally. If we identify suitable opportunities, we may not be able to make such acquisitions on favorable terms or at all. Any acquisitions we make may not strengthen our competitive position, and these transactions may be viewed negatively by customers or investors. We may decide to incur debt in connection with an acquisition or issue our common stock or other equity securities to the stockholders of the acquired company, as we did for the iGenomX acquisition, which would reduce the percentage ownership of our existing stockholders. We could incur losses resulting from undiscovered liabilities of the acquired business that are not covered by any indemnification we may obtain from the seller. In addition, we may not be able to successfully integrate the acquired personnel, technologies and operations into our existing business in an effective, timely and non-disruptive manner. Acquisitions may also divert management attention from day-to-day responsibilities, increase our expenses and reduce our cash available for operations and other uses. In addition, we cannot guarantee that we will be able to fully recover the costs of such acquisitions or that we will be successful in leveraging any such strategic transactions into increased business, revenue or profitability. We also cannot predict the number, timing or size of any future acquisitions or the effect that any such transactions might have on our operating results.

From time to time, we may consider other strategic transactions, including collaborations. The competition for collaborators is intense, and the negotiation process is time-consuming and complex. Any new collaboration may be on terms that are not optimal for us, and we may not be able to maintain any new collaboration. Any such collaboration may require us to incur non-recurring or other charges, increase our near- and long-term expenditures and pose significant integration or implementation challenges or disrupt our management or business. These transactions would entail numerous operational and financial risks, including exposure to unknown liabilities, disruption of our business and diversion of our management's time and attention to manage a collaboration, incurrence of substantial debt or dilutive issuances of equity securities to pay transaction consideration or costs, higher than expected collaboration, acquisition or integration costs, write-downs of assets or goodwill or impairment charges, increased amortization expenses, difficulty and cost in facilitating the collaboration or combining the operations and personnel of any acquired business, impairment of relationships with key suppliers, manufacturers or customers of any acquired business due to changes in management and ownership and the inability to retain key employees of any acquired business. Antitrust or other competition laws may also limit our ability to acquire or work collaboratively with certain businesses or to fully realize the benefits of a strategic transactions to acquire or collaborate with other businesses. Accordingly, although there can be no assurance that we will undertake or successfully complete any collaborations, any transactions that we do complete may be subject to the foregoing or other risks and have a material and adverse effect on our business, financial condition, results of operations and prospects. Conversely, any failure to enter any collaboration or other strategic transaction that would be beneficial to us could delay the development and potential commercialization of our products and technologies.

As we expand our development and commercialization activities outside of the United States, we will be subject to an increased risk of inadvertently conducting activities in a manner that violates the U.S. Foreign Corrupt Practices Act and similar laws. If that occurs, we may be subject to civil or criminal penalties which could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

We are subject to the U.S. Foreign Corrupt Practices Act, or the FCPA, which prohibits corporations and individuals from paying, offering to pay, or authorizing the payment of anything of value to any foreign government official, government staff member, political party, or political candidate in an attempt to obtain or retain business or to otherwise influence a person working in an official capacity. We are also subject to the UK Anti-Bribery Act, which prohibits both domestic and international bribery, as well as bribery across both public and private sectors. We require that our employees review our Code of Business Conduct and Ethics, our Anti-Money Laundering Policy and our Anti-Corruption Policy on an annual basis.

In the course of establishing and expanding our commercial operations and complying with non-U.S. regulatory requirements, we will need to establish and expand business relationships with various third parties and we will interact more frequently with foreign officials, including regulatory authorities. Expanded programs to maintain compliance with such laws will be costly and may not be effective. Any interactions with any such parties or individuals where compensation is provided that are found to be in violation of such laws could result in substantial fines and penalties and could materially harm our business. Furthermore, any finding of a violation under one country's laws may increase the likelihood that we will be prosecuted and be found to have violated another country's laws. We require that our employees annually certify that they understand and will comply with our Code of Business Conduct and Ethics Policy, our Anti-Money Laundering Policy, our Anti-Corruption Policy as well as the UK Modern Slavery Act of 2015. Even so, if our business practices outside the United States are found to be in violation of the FCPA, UK Anti-Bribery Act, antitrust or other similar laws, we may be subject to significant civil and criminal penalties which could have a material adverse effect on our financial condition and results of operations.

We could engage in exporting or related activity that contravenes international trade restraints, or regulatory authorities could promulgate more far-reaching international trade restraints, which could give rise to one or more of substantial legal liability, impediments to our business and reputational damage.

Our international business activities must comport with U.S. export controls and other international trade restraints, including the U.S. Department of Commerce's Export Administration Regulations and economic sanctions regulations administered by the U.S. Treasury Department's Office of Foreign Assets Controls.

We have established an international trade compliance program that encompasses best practices for preventing, detecting and addressing noncompliance with international trade restraints. Furthermore, to date our exports have not been licensable under export controls; however, we could fail to observe the compliance program requirements in a manner that leaves us in noncompliance with export controls or other international trade restraints. In addition, authorities could promulgate international trade restraints that impinge on our ability to pursue our business as planned. One or more of resulting legal penalties, restraints on our business or reputational damage could have material adverse effects on our business and financial condition.

We operate in a highly competitive industry and if we are not able to compete effectively, our business and operating results will likely be harmed.

We face competition from a broad range of providers of core synthetic biology products such as GenScript Biotech Corporation, DNA Script, Inc., GENEWIZ (owned by Brooks Automation), Integrated DNA Technologies, Inc. (owned by Danaher Corporation), DNA 2.0 Inc. d/b/a/ ATUM, GeneArt (owned by Thermo Fisher Scientific Inc.), Eurofins Genomics LLC, Sigma-Aldrich Corporation (owned by Charles River Laboratories, Inc.) (an indirect wholly owned subsidiary of Merck & Company), Promega Corporation, OriGene Technologies, Inc., Blue Heron Biotech, LLC and others. Additionally, we compete with both large and emerging providers in the life sciences tools and diagnostics industries focused on sample preparation for NGS such as Thermo Fisher Scientific Inc., Illumina, Inc., Integrated DNA Technologies, Inc., Agilent, and Roche NimbleGen, Inc. In the antibody discovery market, we compete with clinical research organizations, such as LakePharma and Aldevron, LLC and antibody discovery biotechnology companies, such as Iontas, Adimab, Distributed Bio (owned by Charles River) and AbCellera Biologics Inc. In the field of DNA digital data storage, we compete with Catalog Technologies, Inc., ETH Zurich, Helixworks, Iridia, Inc., North Shore Bio and Roswell. We may not be successful in maintaining our competitive position for a number of reasons. Some of our current competitors, as well as many of our potential competitors, have significant name recognition, substantial intellectual property portfolios, longer operating histories, greater resources to invest in new technologies, substantial experience in new product development and manufacturing capabilities and more established distribution channels to deliver products to customers than we do. These competitors may be able to respond more quickly and effectively than we can to new or changing opportunities, technologies, standards or customer requirements. Our competitors may develop disruptive technologies or products that are comparable or superior to our technologies and products. In light of these advantages, even though we believe our technology is superior to the products offerings of our competitors, current or potential customers might accept competitive products in lieu of purchasing our products. Increased competition is likely to result in continued pricing pressures, which could harm our sales, profitability or market share. Our failure to continue competing effectively or winning additional business with our existing customers could materially and adversely affect our business, financial condition or results of operations.

We may be subject to significant pricing pressures.

Over time, increasing customer demand for lower prices could force us to discount our products and result in lower margins. The impact may be further exacerbated if we are unable to successfully control production costs. Alternatively, if due to rising market prices, our suppliers increase prices or reduce discounts on their supplies, we may be unable to pass on any cost increase to our customers, thereby resulting in reduced margins and profits. Furthermore, changes in our product mix may negatively affect our gross margins. Overall, these pricing pressures may adversely affect our business, financial position and results of operations.

Ethical, legal and social concerns surrounding the use of genetic information could reduce demand for our technology.

Our products may be used to create DNA sequences of humans, agricultural crops and other living organisms. Our products could be used in a variety of applications, which may have underlying ethical, legal and social concerns. Governmental authorities could, for safety, social or other purposes, impose limits on or implement regulation of the use of gene synthesis. Such concerns or governmental restrictions could limit the use of our DNA synthesis products, which could have a material adverse effect on our business, financial condition and results of operations. In addition, public perception about the safety and environmental hazards of, and ethical concerns over, genetically engineered products and processes could influence public acceptance of our technologies, products and processes. These concerns could result in increased expenses, regulatory scrutiny, delays or other impediments to our programs.

We use biological and hazardous materials that require considerable expertise and expense for handling, storage and disposal and may result in claims against us.

We work with materials, including chemicals, biological agents, and compounds and DNA samples that could be hazardous to human health and safety or the environment. Our operations also produce hazardous and biological waste products. Federal, state and local laws and regulations govern the use, generation, manufacture, storage, handling and disposal of these materials and wastes. Compliance with applicable environmental laws and regulations is expensive, and current or future environmental laws and regulations may restrict our operations. If we do not comply with applicable regulations, we may be subject to fines and penalties.

In addition, we cannot eliminate the risk of accidental injury or contamination from these materials or wastes, which could cause an interruption of our commercialization efforts, research and development programs and business operations, as well as environmental damage resulting in costly clean-up and liabilities under applicable laws and regulations. Furthermore, environmental laws and regulations are complex, change frequently and have tended to become more stringent. We cannot predict the impact of such changes and cannot be certain of our future compliance. While our property insurance policy provides limited coverage in the event of contamination from hazardous and biological products and the resulting cleanup costs, we do not currently have any additional insurance coverage for legal liability for claims arising from the handling, storage or disposal of hazardous materials. Accordingly, in the event of contamination or injury, we could be liable for damages or penalized with fines in an amount exceeding our resources and our operations could be suspended or otherwise adversely affected.

We could develop DNA sequences or engage in other activity that contravenes biosecurity requirements, or regulatory authorities could promulgate more far-reaching biosecurity requirements that our standard business practices cannot accommodate, which could give rise to substantial legal liability, impede our business and damage our reputation.

The Federal Select Agent Program, or the FSAP, involves rules administered by the Centers for Disease Control and Prevention and Toxins and the Animal and Plant Health Inspection Service that regulate possession, use and transfer of biological select agents and toxins that have the potential to pose a severe threat to public, animal or plant health or to animal or plant products.

We have established a comprehensive, biosecurity program under which we follow biosafety and biosecurity best practices and avoid DNA synthesis activities that implicate FSAP rules; however, we could err in our observance of compliance program requirements in a manner that leaves us in noncompliance with FSAP or other biosecurity rules. In addition, authorities could promulgate new biosecurity requirements that restrictions our operations. One or more resulting legal penalties, restraints on our business or reputational damage could have material adverse effects on our business and financial condition.

Third parties may use our products in ways that could damage our reputation.

After our customers have received our products, we do not have any control over their use and our customers may use them in ways that are harmful to our reputation as a supplier of synthetic DNA products. In addition, while we have established a biosecurity program designed to comply with biosafety and biosecurity requirements and perform export control screening in an effort to ensure that third parties do not obtain our products for malevolent purposes, we cannot guarantee that these preventative measures will eliminate or reduce the risk of the domestic and global opportunities for the misuse of our products. Accordingly, in the event of such misuse, our reputation, future revenue and operating results may suffer.

Any damage to our reputation or brand may materially and adversely affect our business, financial condition and results of operations.

We believe that developing and maintaining our brand is important to our success and that our financial success is influenced by the perception of our brand by our customers. Furthermore, the importance of our brand recognition may become even greater to the extent that competitors offer more products similar to ours. Many factors, some of which are beyond our control, are important to maintaining our reputation and brand. These factors include our ability to comply with ethical, social, product, labor and environmental standards. Any actual or perceived failure in compliance with such standards could damage our reputation and brand.

Because we are subject to existing and potential additional governmental regulation, the markets for our products may be narrowed.

We are subject, both directly and indirectly, to the adverse impact of existing and potential future government regulation of our operations and markets. For example, the export of our products is subject to strict regulatory control in a number of jurisdictions. The failure to satisfy export control criteria or obtain necessary clearances could delay or prevent the shipment of products, which could adversely affect our revenues and profitability. Moreover, the life sciences industry, which is currently the primary market for our technology, has historically been heavily regulated. There are, for example, laws in several jurisdictions restricting research in genetic engineering, which can operate to narrow our markets. Given the evolving nature of this industry, legislative bodies or regulatory authorities may adopt additional regulation that adversely affects our market opportunities. Our business is also directly affected by a wide variety of government regulations applicable to business enterprises generally and to companies operating in the life science industry in particular. Failure to comply with these regulations or obtain or maintain necessary permits and licenses could result in a variety of fines or other censures or an interruption in our business operations which may have a negative impact on our ability to generate revenues and could increase the cost of operating our business.

Our products could in the future be subject to additional regulation by the U.S. Food and Drug Administration or other domestic and international regulatory agencies, which could increase our costs and delay our commercialization efforts, thereby materially and adversely affecting our business and results of operations.

The FDA regulates medical devices, including in vitro diagnostics, or IVDs. IVDs are a category of medical devices that include reagents, instruments, and systems intended for use in diagnosis of disease or other conditions, including a determination of the state of health, in order to cure, mitigate, treat, or prevent disease or its sequelae. IVDs are intended for use in the collection, preparation, and examination of specimens taken from the human body. A RUO IVD product is an IVD product that is in the laboratory research phase of development. As such, an RUO IVD is not intended for use in clinical investigations or in clinical practice. Such RUO products do not require premarket clearance or approval from the FDA, provided that they are labeled “For Research Use Only. Not For Use In Diagnostic Procedures” pursuant to FDA regulations. Our IVD products are not intended for clinical or diagnostic use, and we market and label them as RUO. However, the FDA may disagree with our assessment that our products are properly marketed as RUO and may determine that our products are subject to pre-market clearance, approval, or other regulatory requirements. If the FDA determines that our products are subject to such requirements, we could be subject to enforcement action, including administrative and judicial sanctions, and additional regulatory controls and submissions for our tests, all of which could be burdensome.

In the future, certain of our products or related applications could be subject to additional FDA regulation. Even where a product is not subject to FDA clearance or approval requirements, the FDA may impose restrictions as to the types of customers to which we can market and sell our products. Such regulation and restrictions may materially and adversely affect our business, financial condition and results of operations. Other regulatory regimes that do not currently present material challenges but that could in the future present material challenges include export controls and biosecurity.

Many countries have laws and regulations that could affect our products and which could limit our ability to sell our products in those countries. The number and scope of these requirements are increasing. We may not be able to obtain regulatory approvals in such countries or may incur significant costs in obtaining or maintaining foreign regulatory approvals. For example, the European Union, or EU, is transitioning from the existing European Directive 98/79/EC on in vitro diagnostic medical devices, or IVD Directive (IVDD), to the In Vitro Diagnostic Device Regulation (EU) 2017/746, or IVDR, which imposes stricter requirements for the marketing and sale of medical devices, including in the area of clinical evaluation requirements, quality systems and post-market surveillance. The IVDR is expected to become effective in May 2022. It is likely that we will be impacted by this new regulation, either directly as a manufacturer of IVDs, or indirectly as a supplier to customers who are placing IVDs in the EU market for clinical or diagnostic use. Complying with the requirements of the IVDR may require us to incur significant expenditures. Failure to meet these requirements could adversely impact our business in the EU and other regions that tie their product registrations or chemical regulations to the EU requirements.

Certain of our potential customers may require that we become certified under the Clinical Laboratory Improvement Amendments of 1988.

Although we are not currently subject to the Clinical Laboratory Improvement Amendment of 1988, or CLIA, we may in the future be required by certain customers to obtain a CLIA certification. CLIA, which extends federal oversight over clinical laboratories by requiring that they be certified by the federal government or by a federally approved accreditation agency, is designed to ensure the quality and reliability of clinical laboratories 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. If our customers require a CLIA certification, we will have to continually expend time, money and effort to ensure that we meet the applicable quality and safety requirements, which may divert the attention of management and disrupt our core business operations.

Our manufacturing operations in the United States currently depend primarily on one facility. If this facility is destroyed or we experience any manufacturing difficulties, disruptions, or delays, this could limit supply of our product or adversely affect our ability to sell products or conduct our clinical trials, and our business would be adversely impacted.

While we are in the process of building out a second manufacturing facility in Wilsonville, Oregon, a substantial portion of our manufacturing currently takes place at our headquarters in South San Francisco, California. If regulatory, manufacturing, or other problems require us to discontinue production at this facility, we will not be able to manufacture our synthetic genes, oligo pools or NGS tool or create our DNA libraries, which would adversely impact our business. If this facility or the equipment in it is significantly damaged or destroyed by fire, flood, power loss, or similar events, or is shut down for health and safety or other reasons, we may not be able to quickly or inexpensively replace our manufacturing capacity or replace the facility at all. In the event of a temporary or protracted loss of this facility or equipment, we might not be able to transfer manufacturing to another third party. Even if we could transfer manufacturing from one facility to another, the shift would likely be expensive and time-consuming, particularly if we were to maintain the current manufacturing standards procedures at such alternative facility.

Natural disasters, public health crises, political crises, and other catastrophic events or other events outside of our control may damage our facilities or the facilities of third parties on which we depend and could impact our ability to sell products.

Our headquarters in South San Francisco is located near known earthquake fault zones and is vulnerable to damage from earthquakes. An earthquake or other natural disaster or power shortages or outages could disrupt operations or impair critical systems at our headquarters or at any of our other facilities throughout the world. We, our suppliers, third-party service providers and customers are vulnerable to damage from natural disasters, including fire, floods or monsoons, power loss, communications failures, public health crises, such as pandemics and epidemics, political crises, such as terrorism, war, political instability or other conflict and similar events. If any disaster were to occur, our ability to operate our business at any of our facilities could be seriously, or potentially completely, impaired. In addition, the nature of our activities could cause significant delays in our research programs and commercial activities and make it difficult for us to recover from a disaster. The insurance we maintain may not be adequate to cover our losses resulting from disasters or other business interruptions. Accordingly, an earthquake or other disaster could materially and adversely harm our ability to conduct business.

Delivery of our products could be delayed or disrupted by factors beyond our control, and we could lose customers as a result.

We rely on third-party carriers for the timely delivery of our products. As a result, we are subject to carrier disruptions and increased costs that are beyond our control, including travel restrictions, employee strikes, inclement weather and increased fuel costs. Any failure to deliver products to our customers in a timely and accurate manner may damage our reputation and brand and could cause us to lose customers. If our relationship with any of these third-party carriers is terminated or impaired or if any of these third parties are unable to deliver our products, the delivery and acceptance of our products by our customers may be delayed which could harm our business and financial results. The failure to deliver our products in a timely manner may harm our relationship with our customers, increase our costs and otherwise disrupt our operations.

Doing business internationally creates operational and financial risks for our business.

During our fiscal years ended September 30, 2021, 2020 and 2019, 42%, 36%, and 34%, respectively, of our revenue was generated from customers located outside of the United States. In connection with our growth strategy, we intend to further expand in international markets. Conducting and launching operations on an international scale requires close coordination of activities across multiple jurisdictions and time zones and consumes significant management resources. If we fail to coordinate and manage these activities effectively, our business, financial condition or results of operations could be adversely affected. International sales entail a variety of risks, including longer payment cycles and difficulties in collecting accounts receivable outside of the United States, currency exchange fluctuations, challenges in staffing and managing foreign operations, tariffs and other trade barriers (including tariffs enacted and proposed by the U.S. government on various imports from China and by the Chinese government on certain U.S. goods), unexpected changes in legislative or regulatory requirements of foreign countries into which we sell our products, difficulties in obtaining export licenses or in overcoming other trade barriers, laws and business practices favoring local companies, political and economic instability, difficulties protecting or procuring intellectual property rights, and restrictions resulting in delivery delays and significant taxes or other burdens of complying with a variety of foreign laws.

Changes in the value of the relevant currencies may affect the cost of certain items required in our operations. Changes in currency exchange rates may also affect the relative prices at which we are able to sell products in the same market. Our revenue from international customers may be negatively impacted as increases in the U.S. dollar relative to our international customers' local currency could make our products more expensive, impacting our ability to compete. Our costs of materials from international suppliers may increase if in order to continue doing business with us they raise their prices as the value of the U.S. dollar decreases relative to their local currency. Foreign policies and actions regarding currency valuation could result in actions by the United States and other countries to offset the effects of such fluctuations. The recent global financial downturn has led to a high level of volatility in foreign currency exchange rates and that level of volatility may continue, which could adversely affect our business, financial condition or results of operations.

Our ability to use our net operating loss carryforwards to offset future taxable income may be subject to certain limitations.

In general, under Section 382 of the Internal Revenue Code of 1986, as amended, or the Code, a corporation that undergoes an "ownership change" is subject to limitations on its ability to use its pre-change net operating loss carryforwards, or NOLs, to offset future taxable income. If the Internal Revenue Service challenges our analysis that our existing NOLs will not expire before utilization due to previous ownership changes, our ability to use our NOLs could be limited by Section 382 of the Code. Future changes in our stock ownership, some of which are outside of our control, could result in an ownership change under Section 382 of the Code. Furthermore, our ability to use NOLs of companies that we may acquire in the future may be subject to limitations. For these reasons, we may not be able to use a material portion of the NOLs reflected on our balance sheet, even if we attain profitability.

The enactment of legislation implementing changes in taxation of international business activities, the adoption of other corporate tax reform policies, or changes in tax legislation or policies could impact our future financial position and results of operations.

Corporate tax reform, base-erosion efforts and tax transparency continue to be high priorities in many tax jurisdictions where we intend to have business operations. As a result, policies regarding corporate income and other taxes in numerous jurisdictions are under heightened scrutiny and tax reform legislation is being proposed or enacted in a number of jurisdictions. For example, the Tax Cuts and Jobs Act of 2017, or the Tax Act, signed into law on December 22, 2017, adopting broad U.S. corporate income tax reform, among other things, reduced the U.S. corporate income tax rate, but imposed base-erosion prevention measures on non-U.S. earnings of U.S. entities as well as a one-time mandatory deemed repatriation tax on accumulated non-U.S. earnings of U.S. entities.

In addition, many countries are beginning to implement legislation and other guidance to align their international tax rules with the Organization for Economic Co-operation and Development's Base Erosion and Profit Shifting recommendations and action plan that aim to standardize and modernize global corporate tax policy, including changes to cross-border tax, transfer-pricing documentation rules, and nexus-based tax incentive practices.

Such legislative initiatives may materially and adversely affect our plans to expand internationally and may negatively impact our financial condition and results of operations generally.

Our inability to collect on our accounts receivable by a significant number of customers may have an adverse effect on our business, financial condition and results of operations.

Sales to our customers are generally made on open credit terms. Management maintains an allowance for potential credit losses. If our customers' cash flow, working capital, financial conditions or results of operations deteriorate, they may be unable or even unwilling to pay trade receivables owed to us promptly or at all. As a result, we could be exposed to a certain level of credit risk. If a major customer experiences, or a significant number of customers experience, financial difficulties, the effect on us could be material and have an adverse effect on our business, financial condition and results of operations.

Risks related to being a public company

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

As a public company, we are required to comply with Section 404 of the Sarbanes Oxley Act of 2002 ("SOX"), which requires, among other things, that companies maintain disclosure controls and procedures to ensure timely disclosure of material information, and that management review the effectiveness of those controls on a quarterly basis. Because we ceased to be an "emerging growth company" as defined in the Jumpstart Our Business Startups Act of 2012 (the "JOBS Act") with our transition to large accelerated filer status as of September 30, 2020, we are also now subject to Section 404(b) of SOX, which requires that our independent registered public accounting firm provide an attestation report on the effectiveness of our internal control over financial reporting in this Annual Report on Form 10-K for the year ended September 30, 2021, among other additional requirements. Effective internal controls are necessary for us to provide reliable financial reports and to help prevent fraud, and our management and other personnel devote a substantial amount of time to these compliance requirements. These rules and regulations also increase our legal and financial compliance costs and make some activities more time-consuming and costly.

As disclosed in Part II—Item 9A, "Controls and Procedures", of this Annual Report on Form 10-K, we identified material weaknesses in our internal control over financial reporting related to controls surrounding our journal entry process, revenue order entry process, and information technology general controls. As a result, management concluded that our internal control over financial reporting was not effective as of September 30, 2021. A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement in a company's annual or interim financial statements will not be prevented or detected on a timely basis. The material weaknesses identified in Item 9A in this Annual Report on Form 10-K did not result in any misstatement of our financial statements for any period presented. We have designed and have begun implementation of a remediation plan for these material weaknesses. However, our remediation efforts may be inadequate, and we may in the future discover other areas of our internal controls that require remediation.

We cannot be certain that we will be able to maintain adequate controls over our financial processes and reporting in the future. If we fail to maintain effective internal controls, investors may lose confidence in the accuracy and completeness or our financial reports, the market price of our securities may be negatively affected, and we could be subject to sanctions or investigation by regulatory authorities, such as the SEC or Nasdaq.

The requirements of being a public company may strain our resources and require a substantial amount of management's attention.

As a public company, we are subject to the reporting requirements of the Exchange Act, the Sarbanes-Oxley Act, the Dodd-Frank Wall Street Reform and Consumer Protection Act, or the Dodd-Frank Act, the Nasdaq listing requirements and other applicable securities rules and regulations. The SEC and other regulators have continued to adopt new rules and regulations and make additional changes to existing regulations that require our compliance. 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, in ways we cannot currently anticipate, the manner in which we operate our business. Compliance with these rules and regulations may cause us to incur additional accounting, legal and other expenses. We also incur costs associated with corporate governance requirements, including requirements under securities laws, as well as rules and regulations implemented by the SEC and Nasdaq, particularly as a large accelerated filer. These rules and regulations have increased our legal and financial compliance costs and we devote significant time to comply with these requirements. We are currently evaluating and monitoring developments with respect to these rules and regulations, and we cannot predict or estimate the amount of additional costs we may incur or the timing of such costs.

Risks related to our intellectual property

Our ability to protect our intellectual property and proprietary technology through patents and other means is uncertain.

Our commercial success depends in part on our ability to protect our intellectual property and proprietary technologies. We rely on patent protection, where appropriate and available, as well as a combination of copyright, trade secret and trademark laws, and nondisclosure, confidentiality and other contractual restrictions to protect our proprietary technology. However, these legal means afford only limited protection and may not adequately protect our rights or permit us to gain or keep any competitive advantage.

As of September 30, 2021, we own 33 issued U.S. patents and 24 issued international patents; four in China, three in Europe, six in South Korea, four in Taiwan, three in Japan, one in Eurasia, one in Singapore, one in Australia, and one in Hong Kong. There are 262 pending patent applications, including 72 in the United States, 176 international applications and 14 applications filed under the Patent Cooperation Treaty. Additionally, we have exclusively licensed a patent portfolio containing ten issued patents, including one U.S. patent and nine international patents, and nine pending applications, including one in the U.S. and eight international applications. We have also licensed a patent portfolio containing two pending applications, including one in the US and one PCT. Our policy is to file patent applications to protect technology, inventions and improvements that are important to our business.

Several patent applications covering our technologies have been filed recently. We cannot offer any assurances about which, if any, patents will issue, the breadth of any such patent, or whether any issued patents will be found invalid and unenforceable or will be threatened by third parties. Any successful opposition to these patents or any other patents owned by or, if applicable in the future, licensed to us could deprive us of rights necessary for the practice of our technologies or the successful commercialization of products that we may develop. Since patent applications in the United States and most other countries are confidential for a period of time after filing, we cannot be certain that we were the first to file any patent application related to our technologies or products. Furthermore, an interference proceeding can be provoked by a third party or instituted by the U.S. Patent and Trademark Office, or the USPTO, to determine who was the first to invent any of the subject matter covered by the patent claims of our applications.

Patent law can be highly uncertain and involve complex legal and factual questions for which important principles remain unresolved. In the United States and in many international jurisdictions, policy regarding the breadth of claims allowed in patents can be inconsistent. The U.S. Supreme Court and the Court of Appeals for the Federal Circuit have made, and will likely continue to make, changes in how the patent laws of the United States are interpreted. Similarly, international courts have made, and will likely continue to make, changes in how the patent laws in their respective jurisdictions are interpreted. We cannot predict future changes in the interpretation of patent laws or changes to patent laws that might be enacted into law by U.S. and international legislative bodies.

If we are unable to obtain, maintain and enforce intellectual property protection, others may be able to make, use, or sell products and technologies substantially the same as ours, which could adversely affect our ability to compete in the market.

We may not pursue or maintain patent protection for our products in every country or territory in which we sell our products and technologies. In addition, our pending U.S. and foreign patent applications may not issue as patents or may not issue in a form that will be sufficient to protect our proprietary technology and gain or keep our competitive advantage. Any patents we have obtained or do obtain may be subject to re-examination, reissue, opposition or other administrative proceedings, or may be challenged in litigation, and such challenges could result in a determination that the patent is invalid or unenforceable.

Patents have a limited lifespan. Patent terms may be shortened or lengthened by, for example, terminal disclaimers, patent term adjustments, supplemental protection certificates, and patent term extensions. Although extensions may be available, the life of a patent, and the protection it affords, is limited. Patent term extensions and supplemental protection certificates, and the like, may be impacted by the regulatory process and may not significantly lengthen patent term. Non-payment or delay in payment of patent fees or annuities, delay in patent filings or delay in extension filing, whether intentional or unintentional, may also result in the loss of patent rights important to our business. In such an event, competitors might be able to enter the market earlier than would otherwise have been the case. In addition, certain countries have compulsory licensing laws under which a patent owner may be compelled to grant licenses to other parties. Furthermore, many countries limit the enforceability of patents against other parties, including government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of any patents.

We cannot be certain that the steps we have taken will prevent unauthorized use or unauthorized reverse engineering of our technology. In addition, competitors may be able to design alternative methods or devices that avoid infringement of our patents. To the extent our intellectual property, including licensed intellectual property, offers inadequate protection, or is found to be invalid or unenforceable, we are exposed to a greater risk of direct competition. If our intellectual property does not provide adequate protection against our competitors' products, our competitive position could be adversely affected, as could our business. Both the patent application process and the process of managing patent disputes can be time consuming and expensive.

Monitoring unauthorized use of our intellectual property is difficult and costly. From time to time, we review our competitors' products, and may in the future seek to enforce our patents or other rights against potential infringement. However, the steps we have taken to protect our proprietary rights may not be adequate to prevent misappropriation of our intellectual property. We may not be able to detect unauthorized use of, or take appropriate steps to enforce, our intellectual property rights. We cannot guarantee that any of our patent searches or analyses, including but not limited to the identification of relevant patents, the scope of patent claims or the expiration of relevant patents, are complete or thorough, nor can we be certain that we have identified each and every third-party patent and pending application in the United States and abroad that is relevant to or necessary for the commercialization of our products in any jurisdiction. For example, U.S. applications filed before November 29, 2000 and certain U.S. applications filed after that date that will not be filed outside the United States remain confidential until patents issue. Patent applications in the United States and elsewhere are published approximately 18 months after the earliest filing for which priority is claimed. Therefore, patent applications covering our product candidates or technologies could have been filed by others without our knowledge. Additionally, pending patent applications that have been published can, subject to certain limitations, be later amended in a manner that could cover our platform technologies, our products or the use of our products or technologies. The scope of a patent claim is determined by the interpretation of the law, the written disclosure in a patent and the patent's prosecution history. Our interpretation of the relevance or the scope of a patent or a pending application may be incorrect, which may negatively impact our ability to market our products. We may incorrectly determine that our products are not covered by a third-party patent or may incorrectly predict whether a third party's pending application will issue with claims of relevant scope. Our determination of the expiration date of any patent in the United States or abroad that we consider relevant may be incorrect, which may negatively impact our ability to develop and market our product candidates.

A court or other judicial body may decide that the patent we seek to enforce is invalid or unenforceable or may refuse to stop the other party from using the technology at issue on the grounds that the patent in question does not cover the technology in question. An adverse result in any litigation could put one or more of our patents at risk of being invalidated or interpreted narrowly. Some of our competitors may be able to devote significantly more resources to intellectual property litigation and may have significantly broader patent portfolios to assert against us if we assert our rights against them.

We may not be able to protect our intellectual property rights throughout the world.

Filing, prosecuting and defending patents on our technologies and products in all countries throughout the world would be prohibitively expensive. In addition, the laws of some non-U.S. countries do not protect intellectual property rights to the same extent as the laws of the United States, and many companies have encountered significant problems in protecting and defending such rights in foreign jurisdictions. Consequently, we may not be able to prevent third parties from using our inventions in countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own technologies and products and, may export otherwise infringing products to territories where we have patent protection. These products may compete with our products, and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

The legal systems of certain countries, particularly China and certain other 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. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial cost and divert our efforts and attention from other aspects of our business, put our own patents at risk of being invalidated or interpreted narrowly, put our patent applications at risk of not being issued, and 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. Certain countries in Europe and developing countries, including China and India, have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In those countries, we may have limited remedies if any of our patents are infringed or if we are compelled to grant a license to a third party, which could materially diminish the value of those patents. This could limit our potential revenue opportunities. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

If we are unable to protect the confidentiality of our proprietary information and know-how, the value of our technology and products could be adversely affected.

In addition to pursuing patents on our technology, we take steps to protect our intellectual property and proprietary technology by entering into confidentiality agreements and intellectual property assignment agreements with our employees, consultants, corporate partners and, when needed, our advisors. Such agreements may not be enforceable or may not provide meaningful protection for our trade secrets 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. Monitoring unauthorized disclosure is difficult, and we do not know whether the steps we have taken to prevent such disclosure are, or will be, adequate. If we were to enforce a claim that a third party had illegally obtained and was using our trade secrets, it would be expensive and time consuming, and the outcome would be unpredictable. In addition, courts outside the United States may be less willing to protect trade secrets.

Trade secrets and know-how can be difficult to protect as trade secrets, and know-how will over time be disseminated within the industry through independent development, the publication of journal articles, and the movement of personnel skilled in the art from company to company. In addition, because we may rely on third parties in the development of our products, we may, at times, share trade secrets with them. We seek to protect our proprietary technology in part by entering into confidentiality agreements and, if applicable, material transfer agreements, consulting agreements or other similar agreements with third parties prior to beginning research or disclosing proprietary information. These agreements typically limit the rights of the third parties to use or disclose our confidential information, including our trade secrets. Despite the contractual provisions employed when working with third parties, the need to share trade secrets and other confidential information increases the risk that such trade secrets become known by our competitors, are inadvertently incorporated into the technology of others, or are disclosed or used in violation of these agreements. If we are unable to prevent unauthorized material disclosure of the intellectual property related to our technologies to third parties, we will not be able to establish or maintain a competitive advantage in our market, which could materially adversely affect our business, results of operations and financial condition.

Despite our efforts to protect our trade secrets, our competitors may discover our trade secrets, either lawfully or through breach of our agreements with third parties, independent development or publication of information by any of our third-party collaborators. Competitors could willfully infringe our intellectual property rights, design around our protected technology or develop their own competitive technologies that fall outside of our intellectual property rights. In addition, if any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent such competitor from using that technology or information to compete with us, which could harm our competitive position. Given that our proprietary position is based, in part, on our know-how and trade secrets, a competitor’s discovery of our trade secrets or other unauthorized use or disclosure would impair our competitive position and may have an adverse effect on our business and results of operations.

We may be involved in lawsuits to protect or enforce our patents and proprietary rights, to determine the scope, coverage and validity of others' proprietary rights, or to defend against third party claims of intellectual property infringement that could require us to spend significant time and money and could prevent us from selling our products or impact our stock price.

Litigation may be necessary for us to enforce our patent and proprietary rights and/or to determine the scope, coverage and validity of others' proprietary rights. Litigation on these matters has been prevalent in our industry and we expect that this will continue. As the biotechnology and synthetic biology industries expand and more patents are issued, the risk increases that there may be patents issued to third parties that relate to our technologies and products of which we are not aware or that we may need to challenge to continue our operations as currently contemplated. In addition, our competitors and others may have patents or may in the future obtain patents and claim that the use of our products or processes infringes these patents. As we move into new markets and applications for our products and processes, incumbent participants in such markets may assert their patents and other proprietary rights against us as a means of slowing our entry into such markets or as a means to extract substantial license and royalty payments from us.

Patent infringement suits can be expensive, lengthy and disruptive to business operations and the outcome following legal assertions of invalidity and unenforceability is unpredictable. We could incur substantial costs and divert the attention of our management and technical personnel in prosecuting or defending against any claims and may harm our reputation. Some of our competitors may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. There can be no assurance that we will prevail in any suit initiated against us by third parties, successfully settle or otherwise resolve patent infringement claims. If we are unable to successfully settle claims on terms acceptable to us, we may be required to engage in or continue costly, unpredictable and time-consuming litigation and may be prevented from or experience substantial delays in marketing our technologies and products. Furthermore, parties making claims against us may be able to obtain injunctive or other relief, which could block our ability to develop, commercialize and sell products, and could result in the award of substantial damages against us, including treble damages and attorneys' fees and costs in the event that we are found to be a willful infringer of third party patents.

In the event of a successful claim of infringement against us, we may be required to obtain one or more licenses from third parties, which we may not be able to obtain at a reasonable cost, if at all. We could therefore incur substantial costs related to royalty payments for licenses obtained from third parties, which could negatively affect our gross margins. In addition, we could encounter delays in product introductions while we attempt to develop alternative methods or products to avoid infringing third-party patents or proprietary rights. Defense of any lawsuit or failure to obtain any required licenses on favorable terms could prevent us from commercializing our products, and the risk of a prohibition on the sale of any of our products could adversely affect our ability to grow and gain market acceptance for our products.

We may also be subject to claims that former employees, collaborators or other third parties have an ownership interest in our patents or other intellectual property. We were previously involved in litigation of this kind with Agilent. While we have settled this dispute, there can be no assurance that future litigation will not be initiated by these parties. Some of our employees were previously employed at universities or biotechnology or biopharmaceutical companies, including our competitors or potential competitors. We may be subject to claims that these employees or we have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers. Litigation may be necessary to defend against these and other claims challenging inventorship or ownership. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights. A loss of key research personnel or their work product could hamper our ability to commercialize, or prevent us from commercializing, our products and technologies. Such an outcome could have a material adverse effect on our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and distraction to management and other employees.

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. In addition, during the course of this kind of litigation, there could be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities. Finally, any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise the funds necessary to continue our operations.

In addition, our agreements with some of our suppliers, distributors, customers and other entities with whom we do business may require us to defend or indemnify these parties to the extent they become involved in infringement claims against us, including the claims described above. We could also voluntarily agree to defend or indemnify third parties in instances where we are not obligated to do so if we determine it would be important to our business relationships. If we are required or agree to defend or indemnify any of these third parties in connection with any infringement claims, we could incur significant costs and expenses that could adversely affect our business, operating results, or financial condition.

We may not be successful in obtaining or maintaining necessary rights to our products and technologies through acquisitions and in-licenses, and our intellectual property agreements with third parties may involve unfavorable terms or be subject to disagreements over contract interpretation.

We may find that our programs require the use of proprietary rights held by third parties, and the growth of our business may depend in part on our ability to acquire, in-license or use these proprietary rights. We may be unable to acquire or in-license compositions, methods of use, processes or other third-party intellectual property rights from third parties that we identify as necessary for our products and technologies. The licensing and acquisition of third-party intellectual property rights is a competitive area, and other companies may also be pursuing strategies to license or acquire third-party intellectual property rights that we may consider attractive. These companies may have a competitive advantage over us due to their size, financial resources and greater commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. Moreover, collaboration arrangements are complex and time-consuming to negotiate, document, implement and maintain. We may not be successful in our efforts to establish and implement collaborations or other alternative arrangements should we so choose to enter into such arrangements. We also may be unable to license or acquire third-party intellectual property rights on terms that would be favorable to us or would allow us to make an appropriate return on our investment.

We engage in discussions regarding other possible commercial and cross-licensing agreements with third parties from time to time. There can be no assurance that these discussions will lead to the execution of commercial license or cross-license agreements or that such agreements will be on terms that are favorable to us. Even if we are able to obtain a license to intellectual property of interest, we may not be able to secure exclusive rights, in which case others could use the same rights and compete with us. In addition, if we enter into cross-licensing agreements, there is no assurance that we will be able to effectively compete against others who are licensed under our patents.

In addition, provisions in our licensing and other intellectual property agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could affect the scope of our rights to the relevant intellectual property or technology or affect financial or other obligations under the relevant agreement, either of which could have a material adverse effect on our business, financial condition, results of operations and prospects.

We have not yet registered some of our trademarks in all of our potential markets, and failure to secure those registrations could adversely affect our business.

Some of our trademark applications may not be allowed for registration, and our registered trademarks may not be maintained or enforced. In addition, in the U.S. Patent and Trademark Office and in comparable agencies in many foreign jurisdictions, third parties are given an opportunity to oppose pending trademark applications and to seek to cancel registered trademarks. Opposition or cancellation proceedings may be filed against our trademarks, and our trademarks may not survive such proceedings.

In addition, third parties may file first for our trademarks in certain countries. If they succeed in registering such trademarks, and if we are not successful in challenging such third-party rights, we may not be able to use these trademarks for marketing our products and technologies in those countries. Over the long-term, if we are unable to establish name recognition based on our trademarks, then our marketing abilities may be materially adversely impacted.

We depend on certain technologies that are licensed to us. We do not control these technologies and any loss of our rights to them could prevent us from selling our products.

We rely on, or may in the future rely on, licenses in order to be able to use various proprietary technologies that are material to our business. We do not or will not own the patents that underlie these licenses. Our rights to use the technology we license are subject to the negotiation of, continuation of and compliance with the terms of those licenses. In some cases, we do not or will not control the prosecution, maintenance, or filing of the patents to which we hold licenses, or the enforcement of these patents against third parties. Some of our patents and patent applications were either acquired from another company who acquired those patents and patent applications from yet another company or are licensed from a third party. For example, Twist Bioscience acquired Genome Compiler Corporation in 2016, and Genome Compiler had a non-exclusive license to U.S. Patent No- 7,805,252 owned by DNA 2.0. Thus, these patents and patent applications are not written by us or our attorneys, and we did not have control over the drafting and prosecution. The former patent owners and our licensors might not have given the same attention to the drafting and prosecution of these patents and applications as we would have if we had been the owners of the patents and applications and had control over the drafting and prosecution. We cannot be certain that drafting and/or prosecution of the licensed patents and patent applications by the licensors have been or will be conducted in compliance with applicable laws and regulations or will result in valid and enforceable patents and other intellectual property rights.

Our rights to use the technology we license is subject to the validity of the owner's intellectual property rights. Enforcement of our licensed patents or defense or any claims asserting the invalidity of these patents is often subject to the control or cooperation of our licensors. Legal action could be initiated against the owners of the intellectual property that we license. Even if we are not a party to these legal actions, an adverse outcome could harm our business because it might prevent these other companies or institutions from continuing to license intellectual property that we may need to operate our business.

Our licenses contain or will contain provisions that allow the licensor to terminate the license upon specific conditions. Our rights under the licenses are subject to or will be subject to our continued compliance with the terms of the license, including the payment of royalties due under the license. Termination of these licenses could prevent us from marketing some or all of our products. Because of the complexity of our products and the patents we have licensed, determining the scope of the license and related royalty obligation can be difficult and can lead to disputes between us and the licensor. An unfavorable resolution of such a dispute could lead to an increase in the royalties payable pursuant to the license. If a licensor believed we were not paying the royalties due under the license or were otherwise not in compliance with the terms of the license, the licensor might attempt to revoke the license. If such an attempt were successful, we might be barred from producing and selling some or all of our products.

Risks relating to owning our common stock

We have never paid dividends on our capital stock and we do not intend to pay dividends for the foreseeable future. Consequently, any gains from an investment in our common stock will likely depend on whether the price of our common stock increases.

We have never declared or paid any dividends on our common stock and do not intend to pay any dividends in the foreseeable future. We anticipate that we will retain all of our future earnings for use in the operation of our business and for general corporate purposes. Any determination to pay dividends in the future will be at the discretion of our board of directors. Accordingly, investors must rely on sales of their common stock after any price appreciation as the only way to realize any future gains on their investments. Furthermore, we are party to a credit agreement with SVB which contains negative covenants that limit our ability to pay dividends. For more information, see the section of this Form 10-K captioned "Management's discussion and analysis of financial condition and results of operation—Liquidity and capital resources." For more information regarding the negative covenants in our loan and security agreement with Silicon Valley Bank, see "Risk factors—Our credit facility contains restrictions that limit our flexibility in operating our business."

Our charter documents and Delaware law could prevent a takeover that stockholders consider favorable and could also reduce the market price of our stock.

Our amended and restated certificate of incorporation and our amended and restated bylaws contain provisions that could delay or prevent a change in control of our company. These provisions could also make it more difficult for stockholders to elect directors and take other corporate actions. These provisions include:

- providing for a classified board of directors with staggered, three-year terms;
- authorizing our board of directors to issue preferred stock with voting or other rights or preferences that could discourage a takeover attempt or delay changes in control;

- prohibiting cumulative voting in the election of directors;
- providing that vacancies on our board of directors may be filled only by a majority of directors then in office, even though less than a quorum;
- prohibiting the adoption, amendment or repeal of our amended and restated bylaws or the repeal of the provisions of our amended and restated certificate of incorporation regarding the election and removal of directors without the required approval of at least 66.67% of the shares entitled to vote at an election of directors;
- prohibiting stockholder action by written consent;
- limiting the persons who may call special meetings of stockholders; and
- requiring advance notification of stockholder nominations and proposals.

These provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors, which is responsible for appointing the members of our management. In addition, the provisions of Section 203 of the Delaware General Corporate Law, or the DGCL, govern us. These provisions may prohibit large stockholders, in particular those owning 15% or more of our outstanding voting stock, from merging or combining with us for a certain period of time without the consent of our board of directors.

These and other provisions in our amended and restated certificate of incorporation and our amended and restated bylaws and under Delaware law could discourage potential takeover attempts, reduce the price investors might be willing to pay in the future for shares of our common stock and result in the market price of our common stock being lower than it would be without these provisions.

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 will be the exclusive forum for substantially all disputes between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or other employees.

Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware is the sole and exclusive forum for any derivative action or proceeding brought on our behalf, any action asserting a breach of fiduciary duty owed by any of our directors, officers or other employees to us or our stockholders, any action asserting a claim against us arising pursuant to any provisions of the DGCL, our amended and restated certificate of incorporation or our amended and restated bylaws, any action or proceeding asserting a claim as to which the Delaware General Corporation Law confers jurisdiction upon the Court of Chancery of the State of Delaware or any action asserting a claim against us that is governed by the internal affairs doctrine, subject in each case to the Court of Chancery having personal jurisdiction over the parties named as defendants therein. The exclusive forum provision will not apply to suits brought to enforce any liability or duty created by the Exchange Act or any other claim for which the federal courts have exclusive jurisdiction. The choice of forum provision may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees, which may discourage such lawsuits against us and our directors, officers and other employees. If a court were to find the choice of forum provision contained in our amended and restated certificate of incorporation to be inapplicable or unenforceable in an action, we might incur additional costs associated with resolving such action in other jurisdictions.

In addition, our amended and restated certificate of incorporation provides that the U.S. federal district courts are the exclusive forum for the resolution of any complaint asserting a cause of action arising under the Securities Act. Our exclusive forum provision will not relieve us of our duties to comply with the federal securities laws and the rules and regulations thereunder, and our stockholders will not be deemed to have waived our compliance with these laws, rules and regulations.

The enforceability of similar federal court choice of forum provisions in other companies' certificates of incorporation has been challenged in legal proceedings, and it is possible that a court could find our federal court choice of forum provision to be inapplicable or unenforceable. If a court were to find either of the choice of forum provisions contained in our amended and restated certificate of incorporation to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions. Additionally, while the Delaware Supreme Court recently determined that choice of forum provisions for actions arising under the Securities Act are facially valid, a stockholder may nevertheless seek to bring such a claim arising under the Securities Act against us, our directors, officers, or other employees in a venue other than in the federal district courts of the United States of America. 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, and this may require significant additional costs associated with resolving such action in other jurisdictions.

General risk factors

The market price of our common stock is likely to be volatile and could fluctuate or decline, resulting in a substantial loss of your investment.

The market price of our common stock could be subject to wide fluctuations in response to, among other things, the factors described in this "Risk factors" section or otherwise, and other factors beyond our control, such as fluctuations in the valuations of companies perceived by investors to be comparable to us.

Furthermore, the stock markets have experienced price and volume fluctuations that have affected and continue to affect the market prices of equity securities of many companies. These fluctuations often have been unrelated or disproportionate to the operating performance of those companies. These broad market fluctuations, as well as general economic, systemic, political and market conditions, such as recessions, interest rate changes or international currency fluctuations, may negatively affect the market price of our common stock.

Factors that could cause the market price of our common stock to fluctuate significantly include:

- actual or anticipated fluctuations in our financial condition and operating results, including fluctuations in our quarterly and annual results;
- announcements of technological innovations by us or our competitors;
- overall conditions in our industry and the markets in which we operate;
- addition or loss of significant customers, or other developments with respect to significant customers;
- changes in laws or regulations applicable to our products;
- actual or anticipated changes in our growth rate relative to our competitors;
- announcements by us or our competitors of significant acquisitions, strategic partnerships, joint ventures or capital commitments;
- additions or departures of key personnel;
- competition from existing products or new products that may emerge;
- issuance of new or updated research or reports by securities analysts;
- fluctuations in the valuation of companies perceived by investors to be comparable to us;
- disputes or other developments related to proprietary rights, including patents, litigation matters and our ability to obtain intellectual property protection for our technologies;
- announcement or expectation of additional financing efforts;
- sales of our common stock by us or our stockholders;

- The addition or removal of our stock to or from a stock index fund;
- share price and volume fluctuations attributable to inconsistent trading volume levels of our shares;
- the expiration of contractual lock-up agreements with our executive officers, directors and stockholders, which we have entered into and may enter into in the future from time to time;
- general economic and market conditions, including economic downturns or uncertainty in financial markets; and
- other factors beyond our control, such as terrorism, war, natural disasters and pandemics.

In the past, many companies that have experienced volatility in the market price of their stock have become subject to securities class action litigation. We may be the target of this type of litigation in the future. Securities litigation against us could result in substantial costs and divert our management's attention from other business concerns, which could harm our business.

If securities or industry analysts do not publish research or reports about our business or publish negative reports about our business, our share price and trading volume could decline.

The trading market for our common stock will depend on the research and reports that securities or industry analysts publish about us or our business and we will not have any control over such analysts. If one or more of the analysts who cover us downgrade our shares or change their opinion of our shares, our share price would likely decline. If one or more of these analysts cease coverage of our company or fail to regularly publish reports on us, we could lose visibility in the financial markets, which could cause our share price or trading volume to decline.

Future sales and issuances of our common stock or rights to purchase common stock, including pursuant to our equity incentive plans, could result in additional dilution of the percentage ownership of our stockholders and could cause the stock price of our common stock to decline.

As we have in the past, we may sell common stock, convertible securities or other equity securities in one or more transactions at prices and in a manner, we determine from time to time. We have also issued and expect to issue common stock to employees and directors pursuant to our equity incentive plans. If we sell common stock, convertible securities or other equity securities in future transactions, or common stock is issued pursuant to equity incentive plans, investors may be materially diluted. New investors in such subsequent transactions could gain rights, preferences and privileges senior to those of holders of our common stock.

Claims for indemnification by our directors and officers may reduce our available funds to satisfy successful third-party claims against us and may reduce the amount of money available to us.

Our amended and restated certificate of incorporation and amended and restated bylaws provide that we will indemnify our directors and officers, in each case to the fullest extent permitted by Delaware law.

In addition, as permitted by Section 145 of the DGCL, our amended and restated bylaws and our indemnification agreements that we have entered into with our directors and officers provide that:

- we will indemnify our directors and officers for serving us in those capacities or for serving other business enterprises at our request, to the fullest extent permitted by Delaware law, which provides that a corporation may indemnify such person if such person acted in good faith and in a manner such person reasonably believed to be in or not opposed to the best interests of the registrant and, with respect to any criminal proceeding, had no reasonable cause to believe such person's conduct was unlawful;
- we may, in our discretion, indemnify employees and agents in those circumstances where indemnification is permitted by applicable law;
- we are required to advance expenses, as incurred, to our directors and officers in connection with defending a proceeding, except that such directors or officers shall undertake to repay such advances if it is ultimately determined that such person is not entitled to indemnification;

- we will not be obligated pursuant to our amended and restated bylaws to indemnify a person with respect to proceedings initiated by that person against us or our other indemnitees, except with respect to proceedings authorized by our board of directors or brought to enforce a right to indemnification;
- the rights conferred in our amended and restated bylaws are not exclusive, and we are authorized to enter into indemnification agreements with our directors, officers, employees and agents and to obtain insurance to indemnify such persons; and
- we may not retroactively amend our amended and restated bylaw provisions to reduce our indemnification obligations to directors, officers, employees and agents.

Evolving expectations around corporate responsibility practices, specifically related to environmental, social and governance ("ESG") matters, may expose us to reputational and other risks.

Investors, stockholders, customers, suppliers and other third parties are increasingly focusing on ESG and corporate social responsibility endeavors and reporting. Certain institutional investors, investment funds, other influential investors, customers, suppliers and other third parties are also increasingly focused on ESG practices. Companies that do not adapt to or comply with the evolving investor or stakeholder expectations and standards, or which are perceived to have not responded appropriately, may suffer from reputational damage and result in the business, financial condition and/or stock price of a company being materially and adversely affected. Further, this increased focus on ESG issues may result in new regulations and/or third-party requirements that could adversely impact our business, or certain shareholders reducing or eliminating their holdings of our stock. Additionally, an allegation or perception that we have not taken sufficient action in these areas could negatively harm our reputation.

Item 1B. *Unresolved staff comments*

None.

Item 2. *Properties*

Our principal facilities are described below:

Principal Facilities	Approximate Square Footage	Lease Expiration	Use	Owned or Leased
South San Francisco, CA	91,791	2028	General & Administration, R&D and Manufacturing	Leased
Carlsbad, CA	7,206	2023	Sales & Marketing	Leased
Tel Aviv, Israel	9,332	2022	R&D	Leased
Guangzhou, China	11,583	2024	Office Space & Biopharma Services facility	Leased
Singapore	1,353	2022	Sales & Marketing	Leased
Wilsonville, Oregon	211,995	2034	DNA Data Storage facility	Leased
Brisbane, CA	15,538	2026	General & Administration	Leased
Shanghai, China	2,067	2022	Sales & Marketing	Leased

The Company believes its existing facilities are in good operating condition and are suitable for the conduct of its business.

Item 3. *Legal proceedings*

We are subject to various legal proceedings and claims arising in the ordinary course of business. Although occasional adverse decisions or settlements may occur, management believes that the final disposition of such matters will not have a material adverse effect on our business, financial position, results of operations or cash flows.

Item 4. *Mine safety disclosures*

Not applicable.

PART II

Item 5. ***Market for registrant's common equity, related stockholder matters and issuer purchases of equity securities***

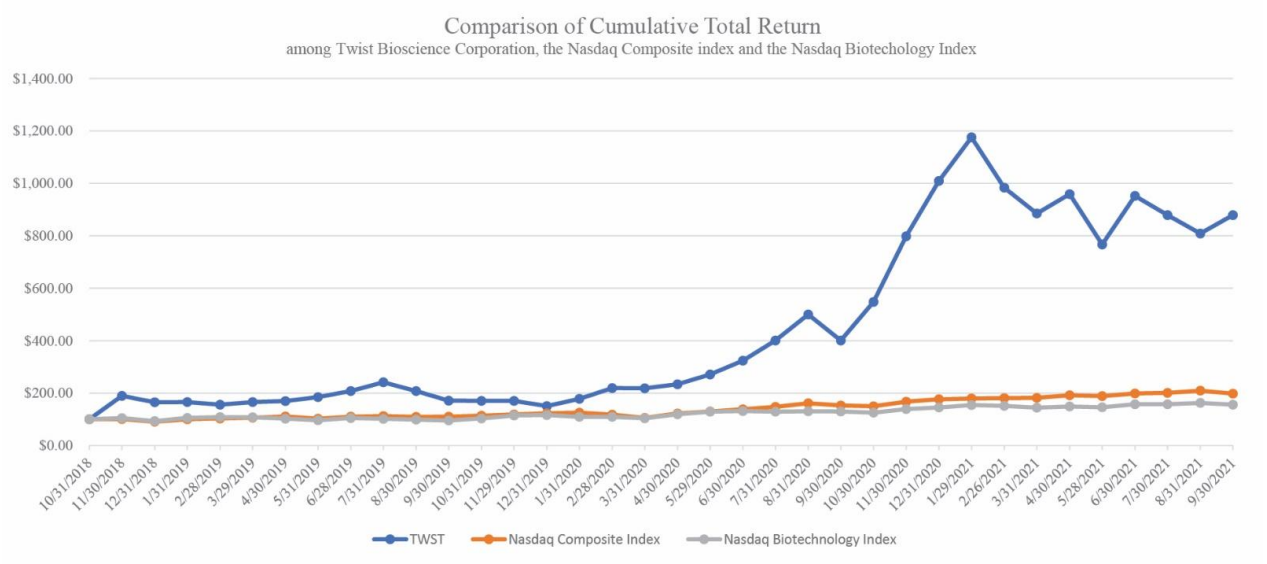
Market information for common stock

Our common stock began trading on The Nasdaq Global Market under the symbol "TWST" on October 31, 2018 in connection with the initial public offering of our common stock. Prior to that date, there was no public market for our common stock.

Performance Graph

This graph is not "soliciting material" or subject to Regulation 14A, deemed "filed" with the SEC for purposes of Section 18 of the Exchange Act, or otherwise subject to liabilities under that section, and shall not be deemed incorporated by reference into any filing of the Company under the Securities Act or the Exchange Act, whether made before or after the date hereof and irrespective of any general incorporation language in any such filing.

The following graph compares the cumulative total return to stockholder return on our common stock relative to the cumulative total returns of the Nasdaq Composite Index and the Nasdaq Biotechnology Index. An investment of $100 is assumed to have been made in our common stock and each index on October 31, 2018 (the first day of trading of our common stock) and its relative performance is tracked through September 30, 2021. Pursuant to applicable SEC rules, all values assume reinvestment of the full amount of all dividends, however no dividends have been declared on our common stock to date. The stockholder returns shown on the graph below are based on historical results and are not necessarily indicative of future performance, and we do not make or endorse any predictions as to future stockholder returns.



* $100.00 invested on October 31, 2018 in stock or index, including reinvestment of dividends.

	12/31/2018	3/29/2019	6/28/2019	9/30/2019	12/31/2019	3/31/2020	6/30/2020	9/30/2020	12/31/2020	3/31/2021	6/30/2021	9/30/2021
Twist Bioscience Corporation	$ 164.93	$ 165.57	$ 207.21	$ 170.57	$ 150.00	$ 218.43	$ 323.57	$ 400.29	$ 1,009.21	$ 884.71	$ 951.79	$ 878.93
Nasdaq Composite Index	90.82	105.80	$ 09.59	109.49	122.81	105.40	137.68	152.86	176.41	181.32	198.52	197.77
Nasdaq Biotechnology Index	92.92	107.22	104.65	95.48	115.60	103.56	131.19	129.95	145.29	144.25	157.16	155.24

Holders of Record

As of November 18, 2021, there were approximately 53 holders of record of our common stock. Because many of our shares of common stock are held by brokers and other institutions on behalf of stockholders, we are unable to estimate the total number of stockholders represented by these record holders.

Dividend Policy

We have never declared or paid, and do not anticipate declaring or paying in the foreseeable future, any cash dividends on our capital stock. Any future determination to declare cash dividends will be made 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 may deem relevant.

Securities authorized for issuance under equity compensation plans

Equity compensation plan information

The following table presents information as of September 30, 2021 with respect to compensation plans under which shares of our common stock may be issued.

Plan	Shares issuable upon exercise of outstanding plan options, warrants and rights (a)	Weighted-average exercise price of outstanding options, warrants and rights (b)	Shares remaining available for future issuance under plan (excluding those reflected in column (a)(c)
Equity compensation plan approved by security holders[1] [2]	3,131,353	$ 27.15	2,083,298 [2]
Equity compensation plans not approved by security holders	—	—	—
Total	3,131,353	$ 27.15	2,083,298

(1) Includes our 2013 Stock Plan, 2018 Equity Incentive Plan and our 2018 Employee Stock Purchase Plan.

(2) Includes 355,082 shares that remain available for purchase under the 2018 Employee Stock Purchase Plan and 1,728,216 shares of common stock that remain available for grant under the 2018 Equity Incentive Plan. There are no shares of common stock available for issuance under our 2013 Plan, but the plan continues to govern the terms of stock options granted thereunder. Any shares of common stock that are subject to outstanding awards under the 2013 Plan that are issuable upon the exercise of stock options that expire or become unexercisable for any reason without having been exercised in full will generally be available for future grant and issuance under our 2018 Equity Incentive Plan. In addition, the 2018 Plan provides for an automatic increase in the number of shares reserved for issuance thereunder on the first day of each fiscal year for the remaining term of the plan equal to the least of (a) 4.0% of the number of issued and outstanding shares of common stock outstanding at that time, (b) 999,900 shares, or (c) a lesser amount as approved by the board each year. Also, the 2018 Employee Stock Purchase Plan provides for an automatic annual increase in the number of shares reserved for issuance thereunder on the first day of each fiscal year for the remaining term of the plan equal to the least of (a) 1.0% of the number of issued and outstanding shares of common stock outstanding, (b) 249,470 shares, or (c) a lesser amount as approved by the Board each year.

Sales of unregistered securities

None.

Issuer Purchases of Equity Securities

None.

Item 6. [Reserved].

Item 7. ***Management's discussion and analysis of financial condition and results of operations***

The following Management's Discussion and Analysis of Financial Condition and Results of Operations (MD&A) is intended to promote understanding of the results of operations and financial condition. The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our consolidated financial statements and the related notes to those statements included elsewhere in this Form 10-K. In addition to historical financial information, the following discussion and analysis contains forward-looking statements that involve risks, uncertainties and assumptions. Our actual results and timing of selected events may differ materially from those anticipated in these forward-looking statements as a result of many factors, including those discussed under "Risk factors" and elsewhere in this Form 10-K. The last day of our fiscal year is September 30, and we refer to our fiscal year ended September 30, 2019 as fiscal year 2019 or 2019, September 30, 2020 as fiscal year 2020 or 2020 and our fiscal year ended September 30, 2021 as fiscal year 2021 or 2021.

Overview

We are an innovative synthetic biology and genomics company that has developed a scalable DNA synthesis platform to industrialize the engineering of biology. The core of our platform is a proprietary technology that pioneers a new method of manufacturing synthetic DNA by "writing" DNA on a silicon chip. We have miniaturized traditional chemical DNA synthesis reactions to write over one million short pieces of DNA on each silicon chip, approximately the size of a large mobile phone. We have combined this technology with proprietary software, scalable commercial infrastructure and an e-commerce platform to create an integrated technology platform that enables us to achieve high levels of quality, precision, automation, and manufacturing throughput at a significantly lower cost than our competitors. We are leveraging our unique technology to manufacture a broad range of synthetic DNA-based products, including synthetic genes, tools for next generation sample preparation, and antibody libraries for drug discovery and development.

Additionally, we believe our platform will enable new value-added opportunities, such as discovery partnerships for biologic drugs, and will enable new applications for synthetic DNA, such as digital data storage. We sell our synthetic DNA and synthetic DNA-based products to a customer base of approximately 2,900 customers in fiscal year 2021 across a broad range of industries.

We launched the first application of our platform, synthetic genes and oligo pools, in April 2016 to disrupt the gene synthesis market and make legacy DNA synthesis methods obsolete.

We have grown rapidly and generated revenues of $132.3 million in the year ended September 30, 2021, $90.1 million in the year ended September 30, 2020 and $54.4 million in the year ended September 30, 2019, while incurring net losses of $152.1 million, $139.9 million and $107.7 million in the years ended September 30, 2021, 2020 and 2019, respectively. Since our inception, we have incurred significant operating losses and have accumulated net deficit of $610.6 million. To support our growth, we have increased our number of employees and increased investment in our manufacturing capabilities. Our ability to generate product revenue sufficient to achieve profitability will depend heavily on the success of our existing products and development and commercialization of additional products in the synthetic biology industry, biologic drug industry and the data storage industry.

In 2021, 2020 and 2019 we served approximately 2,900, 2,200 and 1,300 customers, respectively.

Highlights from fiscal year 2021 compared with fiscal year 2020 included

- Revenue growth of 47% to $132.3 million from $90.1 million in 2020, primarily due to order growth in NGS tools and Biopharma Libraries;
- Our gross margin increased to 39.1% in 2021 from 31.8% in 2020; and
- In December 2020 we announced the "Factory of the Future" which expands our manufacturing operations in the Portland area and entered into a 12-year lease of approximately 111,000 square feet to expand our manufacturing operations and in April 2021 we announced a further expansion by leasing additional 101,000 square feet in the same industrial campus in the Portland area. We anticipate Phase 1 of our expansion will commence operations in the 3rd Quarter of fiscal year 2022.

We have built a scalable commercial platform that enables us to reach a diverse customer base in a variety of industries including industrial chemicals/materials, academic research, healthcare, food, agriculture and data storage. To address this diverse customer base, we have employed a multi-channel strategy comprised of a direct sales force targeting synthetic DNA customers, international distributors, and an e-commerce platform. We launched our proprietary, innovative, and easy-to-use e-commerce platform in October 2017 to existing customers and expanded access to the general public in January 2018. Our platform allows customers to design, validate and place on-demand orders of customized DNA online. This is a key component of our strategy to address and support our diverse and growing customer base, as well as support commercial productivity, enhance the customer experience, and promote loyalty.

Seasonality

Over the years, we have experienced a pattern, although not consistently, of our third-quarter revenue growth being lower than revenue growth in other quarters due to a decrease in demand from certain potentially significant customers during such quarter and periodic revenue fluctuations in our NGS tools. As we grow our NGS tools, our revenue may continue to fluctuate from quarter to quarter. As our European and APAC businesses become larger percentage of our revenues, we anticipate reduced revenue in our fourth quarter due to the seasonal slowdown caused by summer vacations and European holiday schedules.

Key business metrics

We regularly review the following key business metrics to evaluate our business, measure our performance, identify trends affecting our business, formulate financial projections and make strategic decisions. We believe that the following metrics are representative of our current business. However, we anticipate these will change or may be substituted for additional or different metrics as our business grows.

Value of orders received

We believe that the value of orders we receive is a leading indicator of our ability to generate revenue in subsequent quarters, although there can be no assurance orders will translate into revenue. We define an order as a contract with a customer or purchase order from a customer, which outlines the promised goods at an agreed upon-price. In some cases, we receive a blanket purchase order from our customers, which includes pricing, payment and other terms and conditions, with quantities defined at the time each customer subsequently issues periodic releases against the blanket purchase order. We regularly assess trends relating to the value of orders we receive, including with respect to our customer concentration.

Orders may never convert into actual revenue and the timing of delivery of our orders and recognition of revenue, if any, may vary based on the nature of the order, and there can be no assurance that orders will result in recognized revenue. The following table lists the value of orders received during the periods indicated:

	Year ended September 30,		
(in thousands)	**2021**	**2020**	**2019**
Order value	$ 159,545	$ 116,717	$ 69,947

Number of customers

We believe that the number of customers who have purchased from us since inception is representative of our ability to drive adoption of our products. We define customers as separate legal entities or persons who have purchased and directly paid for our products. This means that if a parent company is a customer of ours, it is counted as one customer, and if its subsidiary also purchases our products from us, and the subsidiary makes a payment directly to us, we count the subsidiary as a separate customer. We apply this methodology of counting customers because it is not possible for our e-commerce platform and other data tracking software to distinguish accurately between affiliated purchasers.

Percentage of revenue from new and repeat customers

We believe that the percentage of revenue that we generate from both new and repeat customers is an indicator of our ability to drive adoption of our products amongst existing customers while also generating a robust pipeline of new customers. We define a new customer as a customer who, as a separate legal entity or person, has not had multiple purchases in the current fiscal year. We define a repeat customer as any customer who, as a separate legal entity or person, has purchased products or services from us more than once in the current fiscal year.

We shipped products to approximately 2,900, 2,200, and 1,300 customers in fiscal years ended 2021, 2020, and 2019, respectively. Our percentage of revenue from repeat customers were 98%, 97% and 97% for the fiscal years ended 2021, 2020, and 2019, respectively.

Financial overview

The following table summarizes certain selected historical financial results:

	Year ended September 30,		
(in thousands)	**2021**	**2020**	**2019**
Revenues	$ 132,333	$ 90,100	$ 54,385
Loss from operations	(152,726)	(140,079)	(108,850)
Net loss attributable to common stockholders	(152,098)	(139,931)	(107,669)

Revenues

We generate revenue from sales of synthetic genes, oligo pools, NGS tools and Biopharma libraries. Our ability to increase our revenues will depend on our ability to further penetrate the domestic and international markets, generate sales through our direct sales force and over time from our e-commerce platform and launch new products.

Revenues by geography

We have one reportable segment from the sale of synthetic DNA products. The following table shows our revenues by geography, based on our customers' shipping addresses. Americas consists of United States of America, Canada, Mexico and South America; EMEA consists of Europe, Middle East and Africa; and APAC consists of Japan, China, South Korea, India, Singapore, Malaysia and Australia.

	Year ended September 30,					
(in thousands, except percentages)	**2021**	**%**	**2020**	**%**	**2019**	**%**
Americas	$ 77,909	59 %	$ 59,164	65 %	$ 36,932	68 %
EMEA	44,124	33 %	25,821	29 %	14,692	27 %
APAC	10,300	8 %	5,115	6 %	2,761	5 %
Total revenues	$ 132,333	100 %	$ 90,100	100 %	$ 54,385	100 %

Revenues by products

The table below sets forth revenues by products:

	Year ended September 30,					
(in thousands, except percentages)	**2021**	**%**	**2020**	**%**	**2019**	**%**
Synthetic genes	$ 38,964	29 %	$ 35,192	39 %	$ 26,712	49 %
Oligo pools	8,039	6 %	4,545	5 %	4,594	8 %
DNA and Biopharma libraries	12,663	10 %	6,348	7 %	2,036	4 %
NGS tools	72,667	55 %	44,015	49 %	21,043	39 %
Total revenues	$ 132,333	100 %	$ 90,100	100 %	$ 54,385	100 %

Revenues by industry

Revenues by industry were as follows:

	Year ended September 30,					
(in thousands, except percentages)	**2021**	**%**	**2020**	**%**	**2019**	**%**
Industrial chemicals/materials	$ 34,475	26 %	$ 29,054	32 %	$ 21,927	40 %
Academic research	25,299	19 %	19,642	22 %	13,835	26 %
Healthcare	71,241	54 %	40,036	44 %	17,424	32 %
Food/agriculture	1,318	1 %	1,368	2 %	1,199	2 %
Total revenues	$ 132,333	100 %	$ 90,100	100 %	$ 54,385	100 %

Revenues and accounts receivable concentration

There are no major customers who accounted for 10% or more of our revenue for the fiscal year ended September 30, 2021. There were two major customers who accounted for 12% and 10% of our revenue for the fiscal year ended September 30, 2020. There was one major customer who accounted for 17% of our revenue for the financial year ended September 30, 2019. There are no major customers who accounted for 10% or more of the net accounts receivable as of September 30, 2021. There was one customer who accounted for 36% of net accounts receivable as of September 30, 2020.

Product shipments including synthetic genes

Shipments of number of genes in years ended September 30, 2021, 2020 and 2019 were as follows:

	Year ended September 30,		
(in thousands, except shipments)	**2021**	**2020**	**2019**
Number of genes shipped	372,284	338,550	288,424

Cost of revenues

Cost of revenues reflects the aggregate cost incurred in the production and delivery of our products and consists of production materials, personnel costs, cost of expensed equipment and consumables, laboratory supplies, depreciation of capitalized equipment, production overhead costs and allocations of information technology(“ IT”) and facility costs. Personnel costs consist of salaries, employee benefit costs, bonuses, and stock-based compensation expenses. We expect that our cost of revenues will vary with changes in our revenues and our revenue mix.

Research and development

Research and development expenses consist primarily of costs incurred for the development of our products, which include personnel costs, laboratory supplies, consulting costs and allocated overhead, including IT and facility costs. We expense our research and development expenses in the period in which they are incurred. We expect to increase our research and development expenses as we continue to invest in new product development.

Selling, general and administrative

Selling expenses consist of personnel costs, customer service expenses, direct marketing expenses, educational and promotional expense, market research and analysis. General and administrative expenses include executive, finance and accounting, legal and human resources. These expenses consist of personnel costs, audit and legal expenses, consulting costs and allocated IT and facility costs. We expense all selling, general and administrative expenses as incurred. We expect our selling and marketing costs will continue to increase in absolute dollars, primarily driven by our efforts to expand our commercial capability, with an increased presence both within and outside the United States, and to expand our brand awareness and customer base through targeted marketing initiatives. We expect general and administrative expenses will increase as well as we scale our operations.

Change in fair value of contingent consideration and indemnity holdback

Change in fair value of contingent consideration and indemnity holdback consists of remeasurement of contingent consideration and indemnity holdback related to the acquisition of iGenomX.

Interest expense

Interest expense is attributable to borrowing under our senior secured term loan and our equipment financing facility.

Interest income

Interest income consists primarily of interest earned on our cash, cash equivalents, and short-term investments.

Other income (expense), net

Other income (expense), net consists of realized foreign exchange gains and losses and loss on disposal of property and equipment.

Results of operations

The following table sets forth selected consolidated statements of operations data for the fiscal years indicated and the percentage change in such data from year to year. These historical operating results may not be indicative of the results for any future period.

	Year ended September 30,		
(in thousands)	**2021**	**2020**	**2019**
Revenues	$ 132,333	$ 90,100	$ 54,385
Operating expenses:			
Cost of revenues	80,620	61,406	47,426
Research and development	69,072	43,006	35,683
Selling, general and administrative	135,901	103,267	80,126
Change in fair value of contingent consideration and indemnity holdback	(534)	—	—
Litigation settlement	—	22,500	—
Total operating expenses	285,059	230,179	163,235
Loss from operations	(152,726)	(140,079)	(108,850)
Interest income	435	1,499	3,032
Interest expense	(367)	(787)	(1,294)
Other income (expense), net	(1,370)	(182)	(265)
Provision for income taxes	1,930	(382)	(292)
Net loss attributable to common stockholders	$ (152,098)	$ (139,931)	$ (107,669)

Comparison of the years ended September 30, 2021, 2020 and 2019

Revenues

	Year ended September 30,			Change			
(in thousands, except percentages)	**2021**	**2020**	**2019**	**2021-2020**		**2020-2019**	
Revenues	$ 132,333	$ 90,100	$ 54,385	$ 42,233	47 %	$ 35,715	66 %

Revenues increased from $90.1 million to $132.3 million in the year ended September 30, 2021, which was an increase of $42.2 million, or 47%, as compared to the same period in 2020. The increase in revenue was primarily due to an increase in revenue from NGS tools, which grew from $44.0 million in 2020 to $72.7 million in 2021, and an increase of $6.4 million in revenue from DNA & Biopharma libraries, which grew from $6.3 million to $12.7 million primarily due to growth in our revenues from antibody discovery project services. Our synthetic genes revenue grew from $35.2 million in 2020 to $39.0 million in 2021, mainly due to growth in the pharma industry. In the year ended September 30, 2021, we shipped approximately 372,000 genes, including approximately 28,000 adapters-off non-clonal genes that were introduced in December 2020, compared to approximately 339,000 genes in the year ended September 30, 2020, an increase of 10%. Synthetic gene pricing to our customers was relatively constant period-over-period. NGS tools revenue growth was primarily attributable to the adoption of our product by a larger customer base. We do not believe that pricing changes had a meaningful impact on revenue from NGS tools period-over-period.

Revenues increased from $54.4 million to $90.1 million in the year ended September 30, 2020, which was an increase of $35.7 million, or 66%, as compared to the same period in 2019. The increase in revenue was primarily due to an increase in revenue from NGS tools which grew from $21.0 million in 2019 to $44.0 million in 2020, and an $8.5 million increase in revenue from synthetic genes. The increase in synthetic genes revenue was primarily due to higher sales of 5.0KB genes and 3.2KB genes. In the year ended September 30, 2020, we shipped approximately 339,000 genes compared to approximately 288,000 genes in the year ended September 30, 2019, an increase of 17%. Synthetic gene pricing to our customers was relatively constant period-over-period, but the product mix changed with the introduction of our 5.0KB gene product and customers purchasing our 3.2KB genes. NGS tools revenue growth was primarily attributable to the adoption of our product by a larger customer base. We do not believe that pricing changes had a meaningful impact on revenue from NGS tools period-over-period.

A discussion of our revenues for the year ended September 30, 2019 can be found on page 63 of our Annual Report on Form 10-K for the fiscal year ended September 30, 2020 filed with the SEC on November 27, 2020, or our 2020 Annual Report.

Cost of revenues

(in thousands, except percentages)	Year ended September 30, 2021	2020	2019	Change 2021-2020		2020-2019	
Cost of revenues	$ 80,620	$ 61,406	$ 47,426	$ 19,214	31 %	$ 13,980	29 %

Cost of revenue increased from $61.4 million in the prior year to $80.6 million in the year ended September 30, 2021, which was an increase of $19.2 million, or 31%. The increase was primarily due to an increase in the cost of consumption of reagents and production materials costs of $9.6 million associated with increased product shipments. The increase in payroll and stock-based compensation expense of $5.3 million was due to increased expenses related to supporting new product portfolio launches and an increase in volume of products shipped. Outside services increased by $1.5 million, depreciation increased by $1.1 million and information technology costs increased by $1.6 million. Our cost of revenues was 61% and 68% of total revenues for the year ended September 30, 2021 and 2020, respectively. The favorable change in cost of revenues to total revenues was mainly due to an increase in volume of product sold and change in the mix of products sold during the current year.

Cost of revenue increased from $47.4 million in the prior year to $61.4 million in the year ended September 30, 2020, which was an increase of $14.0 million, or 29%. The increase was primarily due to the increase in personnel costs of $4.6 million related to supporting new product portfolio launches and increase in volume of products shipped and $1.0 million related to shelter-in-place pay premiums. Consumption of reagents and production materials increased by $6.3 million associated with the increased product shipments and higher revenue. Facilities and information technology costs increased by $2.4 million which included the effect of consolidating our manufacturing operations into one facility in South San Francisco. Our cost of revenues was 68% and 87% of total revenues for the year ended September 30, 2020 and 2019, respectively. The favorable change in cost of revenues to total revenues was mainly due to an increase in volume of product sold and change in the mix of products sold during the current year.

A discussion of our cost of revenues for the year ended September 30, 2019 can be found on page 64 of our 2020 Annual Report.

Research and development expenses

(in thousands, except percentages)	Year ended September 30, 2021	2020	2019	Change 2021-2020		2020-2019	
Research and development	$ 69,072	$ 43,006	$ 35,683	$ 26,066	61 %	$ 7,323	21 %

Research and development costs increased by $26.1 million to $69.1 million for the year ended September 30, 2021, as compared to the same period 2020. The increases were mainly in payroll and stock-based compensation expense of $18.4 million associated with increasing our research and development headcount, and an increase in outside services of $8.1 million primarily associated with the development activities for our data storage technology.

Research and development costs increased by $7.3 million to $43.0 million for the year ended September 30, 2020, as compared to the same period 2019. The increase was due to costs related to expanding our DNA synthesis research and development capabilities which included increases in outside services of $3.4 million and increases of facilities and information technology of $1.8 million. Personnel costs increased by $4.8 million, which included $0.4 million of shelter-in-place pay premiums. The increase was offset by a $2.5 million reimbursement received from Georgia Institute of Technology related to the development of the DNA synthesis portion of the Molecular Information Storage program.

A discussion of our research and development expenses for the year ended September 30, 2019 can be found on page 64 of our 2020 Annual Report.

Selling, general and administrative expenses

(in thousands, except percentages)	Year ended September 30, 2021	2020	2019	Change 2021-2020		2020-2019	
Selling, general and administrative	$ 135,901	$ 103,267	$ 80,126	$ 32,634	32 %	$ 23,141	29 %

Selling, general and administrative expenses increased by $32.6 million to $135.6 million for the year ended September 30, 2021, compared to the same period for 2020. The increase was primarily due to increases in payroll expenses and related costs by $30.5 million as a result of increased headcount in our commercial organization, and included $11.7 million higher of stock-based compensation expenses and $2.5 million higher of sales commission. Outside services, including audit costs, COVID-19 testing costs and advisory services, increased by $11.0 million, depreciation expense increased by $1.8 million, merger & acquisition costs increased by $1.4 million, computer software costs increased by $1.0 million and rent expense increased by $1.9 million, mainly due to our Wilsonville facility lease expense. The increase in SG&A expenses was offset by a decrease of $11.8 million in legal expenses as our litigation with Agilent Technologies, Inc. (“Agilent”) concluded on February 6, 2020, a decrease of $3.0 million in consulting costs and a decrease of $1.2 million in travel costs.

Selling, general and administrative expenses increased by $23.1 million to $103.3 million for the year ended September 30, 2020, compared to the same period for 2019. The increase was primarily due to increases in personnel costs related to increased headcount, partially offset by a $0.6 million decreases in legal expenses. Salaries and related costs increased by $20.0 million, as a result of increased headcount, including $5.0 million higher stock-based compensation expense. Outside services and insurance increased by $2.4 million and facilities and information technology increased by $1.6 million. The increase was offset by a decrease in travel expenses of $1.7 million, primarily due to COVID-19 travel restrictions.

A discussion of our selling, general and administrative expenses for the year ended September 30, 2019 can be found on page 65 of our 2020 Annual Report.

Change in fair value of contingent consideration and indemnity holdback

	Year ended September 30,			Change			
(in thousands, except percentages)	2021	2020	2019	2021-2020		2020-2019	
Change in fair value of contingent consideration and indemnity holdback	$ (534)	$ —	$ —	$ (534)	100 %	$ —	— %

Change in the fair value was $0.5 million for the year ended September 30, 2021 associated with the contingent consideration and indemnity holdback related to the acquisition of iGenomX as a result of the change in fair value of our stock price as of September 30, 2021.

Interest, and other income (expense), net

	Year ended September 30,			Change			
(in thousands, except percentages)	2021	2020	2019	2021-2020		2020-2019	
Interest income	$ 435	$ 1,499	$ 3,032	$ (1,064)	(71)%	$ (1,533)	(51)%
Interest expense	(367)	(787)	(1,294)	420	(53)%	507	(39)%
Other income (expense)	(1,370)	(182)	(265)	(1,188)	653 %	83	(31)%
Total interest, and other income (expense), net	$ (1,302)	$ 530	$ 1,473	$ (1,832)	(346)%	$ (943)	(64)%

Interest income was $0.4 million in the year ended September 30, 2021, $1.5 million in the year ended September 30, 2020 and $3.0 million in the year ended September 30, 2019, resulting from our short-term investments. Interest expense was $0.4 million in fiscal year 2021, $0.8 million in fiscal year 2020 and $1.3 million in fiscal year 2019 related to our outstanding debt. Other expense was $1.4 million in fiscal year 2021, $0.2 million in fiscal year 2020 and $0.3 million in fiscal year 2019, mainly due to one-time costs not related to our normal business activities.

Provision for income taxes

	Year ended September 30,			Change			
(in thousands, except percentages)	2021	2020	2019	2021-2020		2020-2019	
Provision for income taxes	$ 1,930	$ (382)	$ (292)	$ 2,312	(605)%	$ (90)	31 %

We recorded income tax benefit of $1.9 million in 2021 mainly as a result of the business acquisition of iGenomX. We recorded provision for income taxes of $0.4 million in 2020 and $0.3 million in 2019.

Liquidity and capital resources

Sources of liquidity

To date, we have financed our operations principally through public equity raises, private placements of our convertible preferred stock, borrowings from credit facilities and revenue from our commercial operations.

Since our inception on February 4, 2013 and through September 30, 2021, we have received an aggregate of $1,063.9 million in net proceeds from the issuance of equity securities and an aggregate of $13.8 million from debt. As of September 30, 2021, we had a balance of $465.8 million of cash and cash equivalents and $12.0 million in short-term investments.

Loan and Security Agreement

In September 2017, we entered into a Fourth Amended and Restated Loan and Security Agreement, or the Fourth Loan, with SVB, which allowed for borrowings aggregating up to $20.0 million in a series of three advances.

The first advance—which was effectuated in September 2017—provided a principal amount of $10.0 million, the second optional advance allowed for a principal amount of $5.0 million and the third optional advance allowed for a principal amount of $5.0 million during their respective drawdown periods; however, the drawdown periods for the second and third tranches under this agreement have expired as of January 31, 2018 and June 30, 2018, respectively.

In connection with the first advance, we issued warrants to purchase 64,127 shares of common stock at an exercise price of $6.24 per share. The Fourth Loan contains a subjective acceleration clause under which the Fourth Loan could become due and payable to SVB in the event of a material adverse change in our business. The term of the loan was 51 months with an interest rate of prime plus 3.00% and a final payment fee of $0.7 million.

In addition, we obtained a $10.0 million revolving facility from SVB in September 2017 as part of the Fourth Loan. The principal amount outstanding under the revolving line accrues interest at a floating per annum rate equal to one percentage point (1.00%) above the prime rate, which interest is payable monthly. The amounts available under the revolving line are limited by an advance rate which is a percentage of our account receivables balance. As of September 30, 2021, we have not borrowed against the $10.0 million revolving facility.

Our credit facilities contain customary representations and warranties and customary affirmative and negative covenants applicable to us and our subsidiaries, including, among other things, restrictions on changes in business, management, ownership or business locations, indebtedness, encumbrances, investments, mergers or acquisitions, dispositions, maintenance of collateral accounts, prepayment of other indebtedness, distributions and transactions with affiliates. The credit facilities contain customary events of default subject in certain cases to grace periods and notice requirements, including (a) failure to pay principal, interest and other obligations when due, (b) material misrepresentations, (c) breach of covenants, conditions or agreements in the credit facilities, (d) default under material indebtedness, (e) certain bankruptcy events, (f) a material adverse change; (g) attachment, levy or restraint on business, (h) default with respect to subordinated debt, (i) cross default under our credit facilities, and (j) government approvals being revoked. As part of the Fourth Loan, all rights, title and interest to our personal property with the exception of our intellectual property, have been pledged as collateral, including cash and cash equivalents, short-term investments, accounts receivable, contractual rights to payment, license agreements, general intangibles, inventory and equipment. We were in compliance with all covenants under the Fourth Loan as of September 30, 2021.

Future maturities of the loan as of September 30, 2021 are as follows:

(in thousands) Year ending September 30,	Principal	Interest	Total
2022	$ 833	$ 9	$ 842
	$ 833	$ 9	$ 842
Less: Interest			(9)
Total amount of loan principal			833
Less unamortized debt discount			(4)
Add accretion of final payment fee			723
			$ 1,552

Capital resources

Our primary cash needs are for operating expenses, working capital and capital expenditures to support the growth in our business. As of September 30, 2021, we had cash, cash equivalents and short-term investments of $477.9 million.

We believe that our existing cash, cash equivalents and short-term investments are sufficient to fund our operating expenses, capital expenditure requirements and debt service payments for at least one year from the issuance of these consolidated financial statements. In the future, we may still need to obtain additional financing to fund operations beyond this period, and there can be no assurance that we will be successful in raising additional financing on terms which are acceptable to us. In addition, our operating plan may change as a result of factors currently unknown to us, and we may need to seek additional funds sooner than planned. Such financing may result in dilution to stockholders, imposition of debt covenants and repayment obligations, or other restrictions that may adversely affect our business. In addition, we may seek additional capital due to favorable market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans. Our future capital requirements will depend on many factors. See “Risk factors—We will require additional financing to achieve our goals, and a failure to obtain this necessary capital when needed on acceptable terms, or at all, could force us to delay, limit, reduce or terminate our product manufacturing and development and other operations.”

Inflation Risk

We do not believe that inflation has had a material effect on our business, financial condition or results of operations. If our costs were to become subject to significant inflationary pressures, we may not be able to fully offset such higher costs through price increases. Our inability or failure to do so could adversely affect our business, financial condition and results of operations.

Operating capital requirements

Our primary uses of capital are, and we expect will continue to be for the near future, compensation and related expenses, manufacturing costs, laboratory and related supplies, legal and other regulatory expenses, and general overhead costs and the capital expenditures for the Wilsonville, Oregon facility expansion. We had $67.4 million and $6.0 million in commitments for capital expenditures as of September 30, 2021 and 2020, respectively.

Cash flows

The following table summarizes our sources and uses of cash and cash equivalents:

	Year ended September 30,		
(in thousands)	2021	2020	2019
Net cash used in operating activities	$ (112,244)	$ (142,255)	$ (87,937)
Net cash provided by (used in) investing activities	(156,155)	(114,650)	(104,810)
Net cash provided by financing activities	329,182	303,732	158,578

Operating activities

Net cash used in operating activities was $112.2 million in fiscal year 2021 and consisted primarily of a net loss of $152.1 million adjusted for non-cash items including depreciation and amortization expenses of $9.8 million, stock-based compensation expense of $37.0 million, a change in operating assets and liabilities of $9.4 million, and a net total of other non-cash items of $2.5 million. The change in operating assets and liabilities was mainly due to increase in inventory of $19.5 million, other non-current assets of $4.7 million, accounts receivable of $2.2 million and decrease in accounts payable of $8.5 million and accrued compensation of $7.4 million.

Net cash used in operating activities was $142.2 million in fiscal year 2020 and consisted primarily of a net loss of $139.9 million adjusted for non-cash items including depreciation and amortization expenses of $6.7 million, stock-based compensation expense of $17.1 million, a change in operating assets and liabilities of $25.2 million, and a net total of other non-cash items of $0.9 million. The change in operating assets and liabilities was mainly due to increase in accounts receivable of $14.3 million, inventory of $5.0 million, prepaid expenses and other current assets of $3.7 million, accounts payable of $5.5 million, accrued expenses of $2.6 million and decrease in accrued expenses of $4.5 million.

A discussion of our net cash used in operating activities for the fiscal year 2019 can be found on page 69 of our 2020 Annual Report.

Investing activities

In fiscal year 2021, our net cash provided by the investing activities was $156.2 million primarily as a result of net impact of purchases and maturity of investments of $183.7 million and purchases of laboratory property, equipment and computers of $27.1 million.

In fiscal year 2020, our investing activities used net cash of $114.7 million. The use of net cash resulted primarily from the net impact of purchases and maturity of investments of $104.8 million and purchases of laboratory property, equipment and computers of $9.9 million.

A discussion of our net cash used in investing activities for the fiscal year 2019 can be found on page 69 of our 2020 Annual Report.

Financing activities

Net cash provided by financing activities was $329.2 million in fiscal year 2021, which consisted of $323.9 million in proceeds from a public offering of our common stock, net of underwriting discounts and commissions and offering expenses, $4.9 million from proceeds from issuance of shares under the 2018 ESPP and $14.6 million from the exercise of stock options, offset by $3.3 million in principal payments on long term debt and $10.8 million in repurchases of common stock for income tax withholdings.

Net cash provided by financing activities was $303.7 million in fiscal year 2020, which consisted of $48.0 million in net proceeds from our at-the-market offering, $247.5 million in net proceeds from the issuance of common stock in public offerings, $3.4 million from proceeds from issuance of shares under the 2018 ESPP and $10.5 million from the exercise of stock options, offset by $3.3 million in principal payments on long term debt and $2.4 million in repurchases of common stock for income tax withholdings.

A discussion of our net cash provided by financing activities for the fiscal year 2019 can be found on page 69 of our 2020 Annual Report.

Off-balance sheet arrangements

We do not have any off-balance sheet arrangements other than our indemnification agreements as described in Note 7 of the consolidated financial statements included elsewhere in this Form 10-K.

Contractual obligations and other commitments

In September 2016, we entered into a collaboration agreement with Distributed Bio to offer therapeutic antibody design and optimization services, as well as an exclusive library targeting G-protein coupled receptors to our customers. Upon successful commercialization, we agreed on a profit-sharing and license arrangement for an Antibody Optimization Software and GPCR-Targeting Antibody Library, which includes royalty payments for discovered pharmaceutical products in a tiered structure, which ranges from 25% to 35% of net revenue generated. During the year ended September 30, 2021, we exercised our option to purchase all rights to the G-coupled protein receptor library and its proprietary Twist Antibody Optimization software, both developed in collaboration with Distributed Bio.

In December 2020, we entered into a 12-year operating lease for an approximately 111,000-square foot facility in Wilsonville, Oregon to further expand our operations. Subject to certain conditions pursuant to the lease, we expect monthly rent payments on the new facility to commence in the first quarter of 2022. We will pay an initial annual base rent of approximately $1.7 million, which is subject to scheduled 3% annual increases, plus certain operating expenses. We have been provided a tenant improvement allowance of $13.3 million. We have the right to sublease the facility, subject to landlord consent. We also have the option to extend the lease for two terms of five years each. The lease commenced on April 15, 2021. The total future minimum lease payments under the agreement are $27.9 million.

On April 13, 2021, we entered into the First Lease Amendment, which amends the terms of the Wilsonville, Oregon lease agreement dated December 18, 2020. The First Lease Amendment increases the premises originally leased within the same building by approximately 101,000 square feet. We intend to use the additional premises to support our additional product offerings, including DNA data storage, or other high value growth product lines. The First Lease Amendment also extends the termination date until April 1, 2034 and modifies our option to extend the term to an additional 10-year term for the premises. Additional rent under the First Lease Amendment for the additional premises commences April 1, 2022 with approximately $1.2 million in rent payments due the first year and approximately $17.6 million in aggregate estimated rent payments due over the total initial term of the First Lease Amendment. In addition, the First Lease Amendment increases the base rental payments relating to the original premises by 3% for the period in which the First Lease Amendment extends the term of the original premises. We are obligated to pay approximately 26% of the operating expenses and utilities applicable to the additional premises. The landlord will provide a tenant improvement allowance in connection with our improvements to the additional premises of approximately $4.3 million.

On April 14, 2021, we entered into a five-year operating lease for a 15,500-square foot warehouse in Brisbane, California to further expand our operations. Upon execution of the lease agreement, we provided the landlord an approximately $0.2 million security deposit. We will pay an initial annual base rent of approximately $0.3 million, which is subject to 3% annual increases, plus certain operating expenses. We have the right to sublease the facility, subject to landlord consent. The future minimum lease payments under the agreement are $2.2 million.

On July 28, 2021, we entered into a 7-year operating lease for an approximately 21,000 square-feet of office space located in South San Francisco, California, to further expand our operations. Upon execution of the lease agreement, we provided the landlord an approximately $0.2 million security deposit. We will pay an initial annual base rent of approximately $1.7 million, which is subject to scheduled 3% annual increases, plus certain operating expenses. We have the right to sublease the facility, subject to landlord consent. The lease had not commenced as of September 30, 2021 as the office space was not vacated by the landlord. The total future minimum lease payments under the agreement are $13.1 million.

Critical accounting policies and significant management estimates

The discussion and analysis of our financial condition and results of operations are based upon our audited consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States of America. The preparation of these financial statements requires management to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses, and related disclosures of contingent assets and liabilities. On an ongoing basis, management evaluates the reasonableness of its estimates. Management bases its estimates on historical experience and on various assumptions that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily available from other sources. Actual results may differ materially from these estimates under different assumptions or conditions.

We believe the following critical accounting policies require that we make significant judgments and estimates in preparing our consolidated financial statements.

Revenue recognition

Our revenue is generated through the sale of synthetic biology tools, such as synthetic genes, or clonal genes and fragments, oligonucleotide pools, or oligo pools, NGS tools and DNA libraries. We recognize revenue when control of the products is transferred to the customer and at a transaction price that is determined based on the agreed upon rates in the applicable order or master supply agreement applied to the quantity of synthetic DNA that was manufactured and shipped to the customer.

Contracts with customers are in the written form of a purchase order or a quotation, which outline the promised goods and the agreed upon price. Such orders are often accompanied by a Master Supply or Distribution Agreement that establishes the terms and conditions, rights of the parties, delivery terms, and pricing. We assess collectability based on a number of factors, including past transaction history and creditworthiness of the customer.

For all of our contracts to date other than Biopharma contracts, the customer orders a specified quantity of a synthetic DNA sequence; therefore, the delivery of the ordered quantity per the purchase order is accounted for as one performance obligation.

The transaction price is determined based on the agreed upon rates in the purchase order or master supply agreements applied to the quantity of synthetic DNA that was manufactured and shipped to the customer. Our contracts include only one performance obligation—the shipment of the product to the customer. Accordingly, all of the transaction price, net of any discounts, is allocated to the one performance obligation. The Company's sales are subject to Ex Works (as defined in Incoterms 2010) delivery terms and revenue is recorded at the point in time when products are picked up by the customer's freight forwarder, as the Company has determined that this is the point in time that product control transfers to the customer. Therefore, upon shipment of the product, there are no remaining performance obligations. Our shipping and handling activities are performed before the customer obtains control of the goods and therefore are considered a fulfillment cost. We have elected to exclude all sales and value added taxes from the measurement of the transaction price. We have not adjusted the transaction price for significant financing since the time period between the transfer of goods and payment is less than one year. We have elected the practical expedient of not disclosing the consideration allocated to remaining performance obligations and an explanation of when those amounts are expected to be recognized as revenue since the duration of our contracts is less than one year.

We recognize revenue at a point in time when control of the products is transferred to the customer.

Our Biopharma revenue currently primarily consists of research and development agreements with third parties that provide for up-front and milestone-based payments. We also enter into research and development agreements that do not include up-front or milestone-based payments and recognize revenue on these types of agreements based on the timing of development activities. Our research and development agreements may include more than one performance obligation. At the inception of the agreement, we assess whether each obligation represents a separate performance obligation or whether such obligations should be combined as a single performance obligation. The transaction price for each agreement is determined based on the amount of consideration we expect to be entitled to for satisfying all performance obligations within the agreement. We assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress for purposes of recognizing revenue. In agreements where we satisfy performance obligation(s) over time, we recognize development revenue typically using an input method based on our costs incurred relative to the total expected cost which determines the extent of our progress toward completion. As part of the accounting for these arrangements, we must develop estimates and assumptions that require judgment to determine the transaction price and progress towards completion. We review our estimate of the transaction price and progress toward completion based on the best information available to recognize the cumulative progress toward completion as of the end of each reporting period and make revisions to such estimates as necessary. Also, these research and development agreements may include license payments. We recognize revenue from functional license agreements when the license is transferred to the customer and the customer is able to use and benefit from the license. A functional license has significant standalone functionality because it can be used "as is" for performing a specific task.

We had contract assets of $2.0 million and contract liabilities of $1.1 million as of September 30, 2021. For all periods presented, we did not recognize revenue from amounts that were included in the contract liability balance at the beginning of each period. In addition, for all periods presented, there was no revenue recognized in a reporting period from performance obligations satisfied in previous periods.

Based on the nature of our contracts with customers which are recognized over a term of less than 12 months, we have elected to use the practical expedient whereby costs to obtain a contract are expensed as they are incurred.

We state our revenues net of any taxes collected from customers that are required to be remitted to various government agencies. The amount of taxes collected from customers and payable to governmental entities is included on the balance sheet as part of "Accrued expenses and other current liabilities."

Stock-based compensation

We have granted stock-based awards, consisting of stock options and restricted stock, to our employees, certain non-employee consultants and certain members of our board of directors. We measure stock-based compensation expense for restricted stock and stock options granted to our employees and directors on the date of grant and recognize the corresponding compensation expense of those awards over the requisite service period, which is generally the vesting period of the respective award. We measure stock-based compensation expense for restricted stock and stock options granted to non-employee consultants on the date of grant and recognize the corresponding compensation expense of those awards over the period in which the related services are received. We adjust for actual forfeitures as they occur.

We have granted performance-based stock units (PSUs) to executive officers and senior level employees. We use the Black-Scholes method to calculate the fair value at the grant date without regard to the vesting condition and will recognize compensation cost for the units that are expected to vest.

We estimate the fair value of stock options granted to our employees, directors and non-employee consultants on the grant date, and rights to acquire stock granted under our Employee Stock Purchase Plan, and the resulting stock-based compensation expense, using the Black-Scholes option-pricing model. The Black-Scholes option-pricing model requires the use of highly subjective assumptions which determine the fair value of stock-based awards. These assumptions include:

- *Expected Term*. Our expected term represents the period that our stock-based awards are expected to be outstanding and is determined using the simplified method (based on the mid-point between the vesting date and the end of the contractual term), as we do not have sufficient historical data to use any other method to estimate expected term.
- *Expected Volatility*. As we have very limited trading history of our common stock, the expected volatility is estimated based on the average volatility for comparable publicly traded biopharmaceutical companies over a period equal to the expected term of the stock option grants. The comparable companies are chosen based on their similar size, stage in the life cycle or area of specialty.
- *Risk-Free Interest Rate*. The risk-free interest rate is based on the U.S. Treasury zero coupon issues in effect at the time of grant for periods corresponding with the expected term of the stock option grants.

Expected Dividend. We have never paid dividends on our common stock and have no plans to pay dividends on our common stock. Therefore, we use an expected dividend yield of zero.

Business Combinations

Accounting for business acquisition require management to make significant estimates and assumptions as of acquisition date which are inherently uncertain. Intangible assets we have recognized from such transaction includes goodwill, development technology and customer relationships. Significant judgment was exercised in determining the fair value of the developed technology intangible assets acquired, which included estimates and assumptions related to the projected revenues (specifically volume of sales), discount rate, and technology obsolescence curve.

Critical estimates in valuing certain of the intangible assets we have acquired include, but are not limited to, projected revenues, technology obsolescence and discount rate. The rates used to discount expected future cash flows to present value are typically derived from a weighted-average cost of capital analysis and adjusted to reflect inherent risks. Unanticipated events and circumstances may occur that could affect either the accuracy or validity of such assumptions, estimates or actual results.

Goodwill

Determining when to test for impairment, the reporting unit, the assets and liabilities of the reporting unit, and the fair value of the reporting unit requires significant judgment and involves the use of significant estimates and assumptions. We test goodwill for impairment in our fourth quarter each year, or more frequently if indicators of an impairment exist, to determine whether it is more likely than not that the fair value of the reporting unit with goodwill is less than its carrying value. For reporting units for which this assessment concludes that it is more likely than not that the fair value is more than its carrying value, goodwill is considered not impaired and we are not required to perform the goodwill impairment test. Qualitative factors considered in this assessment include industry and market considerations, overall financial performance, and other relevant events and factors affecting the fair value of the reporting unit. For reporting units for which this assessment concludes that it is more likely than not that the fair value is below the carrying value, goodwill is tested for impairment by determining the fair value of the reporting unit and comparing it to the carrying value of the net assets assigned to the reporting unit. If the fair value of the reporting unit exceeds its carrying value, goodwill is considered not impaired. If the carrying value of the reporting unit exceeds its fair value, we would record an impairment loss up to the difference between the carrying value and implied fair value. For 2021, our qualitative assessment indicated that the fair value of our reporting unit substantially exceeded the carrying value and that a quantitative assessment was unnecessary.

Recently issued accounting pronouncements

For a description of accounting changes and recent accounting pronouncements, including the expected dates of adoption and estimated effects, if any, on our consolidated financial statements, see Note 2, “Summary of Significant Accounting Policies” in the

Notes to Consolidated Financial Statements in Item 8 of this Annual Report on Form 10-K for a further discussion of the impairment analysis of acquisition-related intangible assets.

Item 7A. ***Quantitative and qualitative disclosures about market risk***

Interest rate sensitivity

We are exposed to market risk related to changes in interest rates. We had cash, cash equivalents and marketable securities of $477.9 million as of September 30, 2021, which consisted primarily of money market funds and marketable securities, largely composed of investment grade, short to intermediate term fixed income securities.

The primary objective of our investment activities is to preserve capital to fund our operations. We also seek to maximize income from our investments without assuming significant risk. To achieve our objectives, we maintain a portfolio of investments in a variety of securities of high credit quality and short-term duration, according to our board-approved investment policy. Our investments are subject to interest rate risk and could fall in value if market interest rates increase. A hypothetical 10% relative change in interest rates during any of the periods presented would not have a material impact on our consolidated financial statements.

Foreign currency sensitivity

The majority of our transactions occur in U.S. dollars. However, we do have certain transactions that are denominated in currencies other than the U.S. dollar, primarily the Euro, Chinese Yuan, and British Pound, and we therefore are subject to foreign exchange risk. The fluctuation in the value of the U.S. dollar against other currencies affects the reported amounts of expenses, assets and liabilities primarily associated with a limited number of manufacturing activities.

We do not use derivative financial instruments for speculative trading purposes, nor do we hedge foreign currency exchange rate exposure in a manner that entirely offsets the effects of changes in foreign currency exchange rates. The counterparties to these forward foreign currency exchange contracts are creditworthy multinational commercial banks, which minimizes the risk of counterparty nonperformance. We regularly review our hedging program and may, as part of this review, make changes to the program.

Item 8. ***Consolidated financial statements and supplementary data***

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Report of Independent Registered Public Accounting Firm

To the Board of Directors and Stockholders of Twist Bioscience Corporation

Opinions on the Financial Statements and Internal Control over Financial Reporting

We have audited the accompanying consolidated balance sheets of Twist Bioscience Corporation and its subsidiaries (the "Company") as of September 30, 2021 and 2020, and the related consolidated statements of operations and comprehensive loss, of redeemable convertible preferred stock and stockholders' equity and of cash flows for each of the three years in the period ended September 30, 2021, including the related notes (collectively referred to as the "consolidated financial statements"). We also have audited the Company's internal control over financial reporting as of September 30, 2021, based on criteria established in *Internal Control - Integrated Framework* (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO).

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of the Company as of September 30, 2021 and 2020, and the results of its operations and its cash flows for each of the three years in the period ended September 30, 2021 in conformity with accounting principles generally accepted in the United States of America. Also in our opinion, the Company did not maintain, in all material respects, effective internal control over financial reporting as of September 30, 2021, based on criteria established in *Internal Control - Integrated Framework* (2013) issued by the COSO because material weaknesses in internal control over financial reporting existed as of that date related to (i) ineffective controls related to segregation of duties to timely detect and independently review instances where individuals with access to post a journal entry may also have edited or created the journal entry, (ii) ineffective controls related to the accuracy and occurrence of the accounting for revenues, including ineffective controls over the accuracy of edits to customer order entry data and segregation of duties during the order entry and revenue processes, and (iii) ineffective information technology general controls for information systems that are relevant to the preparation of the financial statements, including ineffective controls over user access and segregation of duties, and user access to certain financial applications and data.

A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of the annual or interim financial statements will not be prevented or detected on a timely basis. The material weaknesses referred to above are described in Management's Report on Internal Control Over Financial Reporting appearing under Item 9A. We considered these material weaknesses in determining the nature, timing, and extent of audit tests applied in our audit of the 2021 consolidated financial statements, and our opinion regarding the effectiveness of the Company's internal control over financial reporting does not affect our opinion on those consolidated financial statements.

Change in Accounting Principle

As discussed in Note 2 to the consolidated financial statements, the Company changed the manner in which it accounts for leases in fiscal 2020.

Basis for Opinions

The Company's management is responsible for these consolidated financial statements, for maintaining effective internal control over financial reporting, and for its assessment of the effectiveness of internal control over financial reporting, included in management's report referred to above. Our responsibility is to express opinions on the Company's consolidated financial statements and on the Company's internal control over financial reporting based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud, and whether effective internal control over financial reporting was maintained in all material respects.

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

as evaluating the overall presentation of the consolidated financial statements. Our audit of internal control over financial reporting included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audits also included performing such other procedures as we considered necessary in the circumstances. We believe that our audits provide a reasonable basis for our opinions.

Definition and Limitations of Internal Control over Financial Reporting

A company's 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 for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Critical Audit Matters

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

Revenue Recognition

As described in Notes 2 and 14 to the consolidated financial statements, the Company's revenue for certain products is generated through the sale of synthetic biology tools, such as synthetic genes, oligo pools, and next generation sequencing tools. Management recognizes revenue for certain products when control of the product is transferred to the customer and at a transaction price that is determined based on the agreed upon rates in the applicable order or master supply agreements applied to the quantity of synthetic DNA that was manufactured and shipped to the customer. The Company's revenue for certain products generated from synthetic genes, oligo pools, and next generation sequencing tools was $119.7 million for the year ended September 30, 2021. The accuracy and occurrence of revenues is dependent on customer orders being accurately entered and maintaining appropriate segregation of duties during the Company's order entry and revenue processes.

The principal considerations for our determination that performing procedures relating to revenue recognition is a critical audit matter are the high degree of auditor judgment, subjectivity and effort in performing procedures and evaluating audit evidence related to revenue recognition for certain products in response to a material weakness. As described above in the "Opinions on the Financial Statements and Internal Control over Financial Reporting" section, a material weakness was identified as of September 30, 2021 related to ineffective controls related to accuracy and occurrence of the accounting for revenues, including ineffective controls over the accuracy of edits to customer order entry data and segregation of duties during the order entry and revenue processes.
Addressing the matter involved performing procedures and evaluating audit evidence in connection with forming our overall opinion on the consolidated financial statements. These procedures included, among others, evaluating the recognition of revenue for a sample of revenue transactions by obtaining and inspecting source documents, including invoices, customer purchase orders, customer master supply agreements, shipping documents and cash receipts from customers. These procedures also included evaluating the nature and extent of audit procedures performed and evidence obtained.

Valuation of Developed Technology Related to the iGenomX Acquisition

As described in Note 15 to the consolidated financial statements, on June 14, 2021, the Company acquired all of the outstanding stock of iGenomX International Genomics Corporation (iGenomX). The acquisition date fair value of the consideration transferred for iGenomX was approximately $27.3 million. The total estimated purchase price was allocated to the tangible and intangible assets acquired and liabilities assumed based on their relative fair values, which resulted in developed technology of $17.9 million. Management estimated the fair value of the developed technology intangible asset using a discounted cash flow model. Significant judgment was exercised in determining the fair value of the developed technology intangible asset acquired, which included estimates and assumptions related to the projected revenues (specifically volume of sales), discount rate, and technology obsolescence curve.
The principal considerations for our determination that performing procedures relating to the valuation of developed technology related to the iGenomX acquisition is a critical audit matter are (i) the significant judgment by management when determining the fair value of the developed technology; (ii) a high degree of auditor judgment, subjectivity, and effort in performing procedures related to the fair value of the developed technology and in evaluating management's significant assumptions related to projected revenues (specifically volume of sales), discount rate and technology obsolescence curve; and (iii) the audit effort involved the use of professionals with specialized skill and knowledge.

Addressing the matter involved performing procedures and evaluating audit evidence in connection with forming our overall opinion on the consolidated financial statements. These procedures included testing the effectiveness of controls relating to the acquisition accounting, including controls over management's valuation of the developed technology, and controls over the development of the significant assumptions related to projected revenues (specifically volume of sales), discount rate and technology obsolescence curve. These procedures also included, among others, (i) reading the purchase agreement; (ii) testing management's process for determining the fair value of the developed technology; (iii) evaluating the reasonableness of the discounted cash flow model; (iv) testing the completeness and accuracy of underlying data provided by management and used in the model; and (v) evaluating the appropriateness of the significant assumptions used by management related to projected revenues (specifically volume of sales), discount rate and technology obsolescence curve. Evaluating management's assumptions related to the projected revenues (specifically volume of sales) and technology obsolescence curve involved (i) evaluating the consistency with external market and industry data; (ii) benchmarking of peer companies; and (iii) evaluating whether these assumptions were consistent with evidence obtained in other areas of the audit. Professionals with specialized skill and knowledge were used to assist in the evaluation of the Company's discounted cash flow model and assumptions related to the discount rate and technology obsolescence curve.

/s/ PricewaterhouseCoopers LLP
San Jose, California
November 22, 2021

We have served as the Company's auditor since 2015.

Twist Bioscience Corporation
Consolidated Balance Sheets

(In thousands)	September 30, 2021	September 30, 2020
Assets		
Current assets:		
Cash and cash equivalents	$ 465,829	$ 93,667
Short-term investments	12,034	196,335
Accounts receivable, net	28,549	26,376
Inventories	31,800	12,289
Prepaid expenses and other current assets	8,283	6,203
Total current assets	$ 546,495	$ 334,870
Property and equipment, net	44,122	25,466
Operating lease right-of-use assets	61,580	33,699
Goodwill	22,434	1,138
Intangible assets, net	18,262	307
Restricted cash, non-current	1,530	579
Other non-current assets	7,674	2,823
Total assets	$ 702,097	$ 398,882
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 14,900	$ 4,830
Accrued expenses	6,437	3,901
Accrued compensation	22,327	14,945
Current portion of operating lease liability	8,213	6,409
Current portion of long-term debt	1,552	3,333
Other current liabilities	9,623	2,611
Total current liabilities	$ 63,052	$ 36,029
Operating lease liability, net of current portion	53,156	24,837
Long-term debt, net of current portion	—	1,403
Other non-current liabilities	5,068	351
Total liabilities	$ 121,276	$ 62,620
Commitments and contingencies (Note 7)		
Stockholders' equity		
Common stock, $0.00001 par value—100,000 and 100,000 shares authorized at September 30, 2021 and 2020, respectively; 49,499 and 45,083 shares issued and outstanding at September 30, 2021 and 2020, respectively	—	—
Additional paid-in capital	1,190,828	794,630
Accumulated other comprehensive income	546	87
Accumulated deficit	(610,553)	(458,455)
Total stockholders' equity	$ 580,821	$ 336,262
Total liabilities and stockholders' equity	$ 702,097	$ 398,882

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

Twist Bioscience Corporation
Consolidated Statements of Operations and Comprehensive Loss

(In thousands, except per share data)	Year ended September 30, 2021	2020	2019
Revenues	$ 132,333	$ 90,100	$ 54,385
Operating expenses:			
Cost of revenues	$ 80,620	$ 61,406	$ 47,426
Research and development	69,072	43,006	35,683
Selling, general and administrative	135,901	103,267	80,126
Change in fair value of contingent consideration and indemnity holdback	(534)	—	—
Litigation settlement	—	22,500	—
Total operating expenses	$ 285,059	$ 230,179	$ 163,235
Loss from operations	$ (152,726)	$ (140,079)	$ (108,850)
Interest income	435	1,499	3,032
Interest expense	(367)	(787)	(1,294)
Other income (expense), net	(1,370)	(182)	(265)
Loss before income taxes	$ (154,028)	$ (139,549)	$ (107,377)
Benefit from (provision for) income taxes	1,930	(382)	(292)
Net loss attributable to common stockholders	$ (152,098)	$ (139,931)	$ (107,669)
Other comprehensive loss:			
Change in unrealized gain (loss) on investments	$ (14)	$ (34)	$ 49
Foreign currency translation adjustment	473	(60)	45
Comprehensive loss	$ (151,639)	$ (140,025)	$ (107,575)
Net loss per share attributable to common stockholders—basic and diluted	$ (3.15)	$ (3.57)	$ (3.92)
Weighted average shares used in computing net loss per share attributable to common stockholders—basic and diluted	48,251	39,190	27,462

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

Twist Bioscience Corporation
Consolidated Statements of Redeemable Convertible Preferred Stock and Stockholders' Equity

(In thousands)	Series A convertible preferred stock		Series B convertible preferred stock		Series C convertible preferred stock		Series D convertible preferred stock		Common stock		Additional paid-in capital	Accumulated other comprehensive income	Accumulated deficit	Total stockholders' equity
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount				
Balances as of September 30, 2018	2,818	$ 9,141	3,316	$ 25,900	2,491	$ 36,726	10,326	$ 218,716	3,206	$ —	$ 9,346	$ 87	$ (210,855)	$ (201,422)
Issuance of common stock in public offerings, net of underwriting discounts, commissions and offering expenses of $17,210	—	—	—	—	—	—	—	—	10,063	—	153,852	—	—	153,852
Vesting of restricted stock units	—	—	—	—	—	—	—	—	8	—	—	—	—	—
Issuance of shares under the employee stock purchase plan	—	—	—	—	—	—	—	—	219	—	2,700	—	—	2,700
Exercise of stock options	—	—	—	—	—	—	—	—	331	—	2,264	—	—	2,264
Conversion of redeemable convertible preferred stock warrant liability to equity	—	—	—	—	—	—	—	—	—	—	631	—	—	631
Conversion of redeemable convertible preferred stock to common stock	(2,818)	(9,141)	(3,316)	(25,900)	(2,491)	(36,726)	(10,326)	(218,716)	18,951	—	290,462	—	—	290,462
Stock-based compensation	—	—	—	—	—	—	—	—	—	—	11,170	—	—	11,170
Net exercise of stock warrants	95	—	—	—	—	—								
Other comprehensive income	—	—	—	—	—	—	—	—	—	—	—	94	—	94
Net loss	—	—	—	—	—	—	—	—	—	—	—	—	(107,669)	(107,669)
Balances as of September 30, 2019	—	$ —	—	$ —	—	$ —	—	$ —	32,873	$ —	$ 470,425	$ 181	$ (318,524)	$ 152,082
Issuance of common stock in public offerings, net of underwriting discounts, commissions and offering expenses of $18,916	—	—	—	—	—	—	—	—	11,064	—	295,563	—	—	295,563
Vesting of restricted stock units	—	—	—	—	—	—	—	—	178	—	—	—	—	—
Issuance of shares under the employee stock purchase plan	—	—	—	—	—	—	—	—	126	—	3,428	—	—	3,428
Exercise of stock options	—	—	—	—	—	—	—	—	915	—	10,539	—	—	10,539
Repurchase of early exercised stock options	—	—	—	—	—	—	—	—	(2)	—	—	—	—	—
Stock-based compensation	—	—	—	—	—	—	—	—	—	—	17,096	—	—	17,096
Net exercise of stock warrants	—	—	—	—	—	—	—	—	—	—	—	—	—	—
Other comprehensive income	—	—	—	—	—	—	—	—	—	—	—	(94)	—	(94)
Repurchase of common stock for income tax withholdings	—	—	—	—	—	—	—	—	(71)	—	(2,421)	—	—	(2,421)
Net loss	—	—	—	—	—	—	—	—	—	—	—	—	(139,931)	(139,931)
Balances as of September 30, 2020	—	$ —	—	$ —	—	$ —	—	$ —	45,083	$ —	$ 794,630	$ 87	$ (458,455)	$ 336,262
Issuance of common stock in public offering, net of underwriting discounts and commissions and offering expenses of $21,139	—	—	—	—	—	—	—	—	3,136	—	323,861	—	—	323,861
Net exercise of stock warrants	—	—	—	—	—	—	—	—	22	—	—	—	—	—
Vesting of restricted stock units	—	—	—	—	—	—	—	—	237	—	—	—	—	—
Exercise of stock options	—	—	—	—	—	—	—	—	804	—	14,471	—	—	14,471
Issuance of shares under the employee stock purchase plan	—	—	—	—	—	—	—	—	74	—	4,944	—	—	4,944
Repurchases of early exercised stock options	—	—	—	—	—	—	—	—	(2)	—	—	—	—	—
Business acquisition	—	—	—	—	—	—	—	—	237	—	26,773	—	—	26,773
Repurchases of common stock for income tax withholding	—	—	—	—	—	—	—	—	(92)	—	(10,849)	—	—	(10,849)
Stock-based compensation	—	—	—	—	—	—	—	—	—	—	36,998	—	—	36,998
Other comprehensive income	—	—	—	—	—	—	—	—	—	—	—	459	—	459
Net loss	—	—	—	—	—	—	—	—	—	—	—	—	(152,098)	(152,098)
Balances as of September 30, 2021	—	$ —	—	$ —	—	$ —	—	$ —	49,499	$ —	$ 1,190,828	$ 546	$ (610,553)	$ 580,821

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

Twist Bioscience Corporation
Consolidated Statements of Cash Flows

(in thousands)	Year ended September 30, 2021	2020	2019
Cash flows from operating activities			
Net loss	$ (152,098)	$ (139,931)	$ (107,669)
Adjustments to reconcile net loss to net cash used in operating activities			
Depreciation and amortization	9,750	6,677	6,111
Non-cash lease expense	2,243	(1,043)	—
Loss on disposal of property and equipment	2	—	189
Stock-based compensation	36,998	17,096	11,170
Discount (premium) accretion on investment securities	593	(214)	(1,249)
Realized gain on investments	(5)	—	—
Allowance for doubtful accounts	40	—	—
Change in fair value of contingent consideration and indemnity holdback	(534)	—	—
Non-cash interest expense	67	152	233
Amortization of debt discount	81	184	282
Changes in assets and liabilities:			
Accounts receivable, net	(2,202)	(14,272)	(6,685)
Inventories	(19,489)	(4,956)	(1,302)
Prepaid expenses and other current assets	(2,058)	(3,683)	746
Other non-current assets	(4,653)	(554)	(2,064)
Accounts payable	8,542	(5,506)	3,278
Accrued expenses	3,115	(2,648)	4,210
Accrued compensation	7,392	4,465	5,060
Other liabilities	(28)	1,978	(247)
Net cash used in operating activities	(112,244)	(142,255)	(87,937)
Cash flows from investing activities			
Purchases of property and equipment	(27,061)	(9,868)	(14,757)
Proceeds from sale of property and equipment	—	—	21
Business acquisition, net of cash acquired	(483)	—	—
Purchases of investments	(58,795)	(202,882)	(177,574)
Proceeds from maturity of investments	242,494	98,100	87,500
Net cash provided by (used in) investing activities	156,155	(114,650)	(104,810)
Cash flows from financing activities			
Proceeds from exercise of stock options	14,559	10,495	2,170
Proceeds from public offerings, net of underwriting discounts, commissions and offering expenses	323,861	295,563	156,208
Proceeds from issuance under employee stock purchase plan	4,944	3,428	2,700
Repayments of long-term debt	(3,333)	(3,333)	(2,500)
Repurchases of common stock for income tax withholding	(10,849)	(2,421)	—
Net cash provided by financing activities	329,182	303,732	158,578
Effect of exchange rates on cash, cash equivalents and restricted cash	20	21	30
Net increase (decrease) in cash, cash equivalents and restricted cash	373,113	46,848	(34,139)
Cash, cash equivalents, and restricted cash at beginning of year	94,246	47,398	81,537
Cash, cash equivalents, and restricted cash at end of year	$ 467,359	$ 94,246	$ 47,398
Supplemental disclosure of cash flow information			
Interest paid	$ 167	$ 438	$ 779
Income taxes paid, net of refunds	101	172	291
Non-cash investing and financing activities			
Property and equipment additions included in accrued expenses and accounts payable	$ 2,011	$ 1,333	$ 170
Operating lease right-of-use assets obtained in exchange for operating lease liabilities	33,617	3,718	—
Conversion of redeemable convertible preferred stock warrant liability to equity	—	—	631
Conversion of redeemable convertible preferred stock to common stock	—	—	290,462
Issuance of common stock in connection with the iGenomX acquisition	26,773	—	—

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

Twist Bioscience Corporation

Notes to Consolidated Financial Statements

1. The company

Twist Bioscience Corporation (the Company) was incorporated in the state of Delaware on February 4, 2013. The Company is a synthetic biology company that has developed a disruptive DNA synthesis platform. DNA is used in many applications across different industries: industrial chemicals/materials, academic, healthcare and food/agriculture.

The core of the Company's platform is a proprietary technology that pioneers a new method of manufacturing synthetic DNA by "writing" DNA on a silicon chip. The Company has combined this technology with proprietary software, scalable commercial infrastructure and an e-commerce platform to create an integrated technology platform that enables the Company to achieve high levels of quality, precision, automation, and manufacturing throughput at a significantly lower cost than its competitors. The Company is leveraging its unique technology to manufacture a broad range of synthetic DNA-based products, including synthetic genes, tools for next generation sample preparation, and antibody libraries for drug discovery and development.

The Company has a limited operating history and its prospects are subject to risks, expenses and uncertainties frequently encountered by companies in this industry. These risks include, but are not limited to, the uncertainty of availability of additional financing, market acceptance of its products, the ability to retain and attract new customers, and the uncertainty of achieving future profitability.

The Company has generated net losses in all periods since inception. As of September 30, 2021, the Company had an accumulated deficit of $610.6 million and has not generated positive cash flows from operations since inception. Losses are expected to continue as the Company continues to invest in product development, manufacturing, and sales and marketing.

Since its inception, the Company has received an aggregate of $1,063.9 million in net proceeds from the issuance of equity securities and an aggregate of $13.8 million from debt. Management believes that these proceeds combined with existing cash balances on hand will be sufficient to fund operations for at least one year from the issuance of these consolidated financial statements. However, if the Company needs to obtain additional financing to fund operations beyond this period, there can be no assurance that it will be successful in raising additional financing on terms which are acceptable to the Company.

2. Summary of significant accounting policies

Basis of presentation and use of estimates

The presentation of consolidated financial statements in conformity with accounting principles generally accepted in the United States requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities as of the date of the consolidated financial statements and the reported amounts of revenue and expenses during the reporting period. Such estimates include the valuation of deferred tax assets, stock-based compensation expense, determination of the net realizable value of inventory, and the fair value of the Company's common stock and redeemable convertible preferred stock warrant liabilities. Actual results could differ from those estimates. The Company's consolidated financial statements include its wholly-owned subsidiaries. All intercompany balances and accounts are eliminated in consolidation.

Risks and uncertainties

The Company relies on third parties for the supply and manufacture of its products, including a single-source supplier for a critical component, as well as third-party logistics providers. In instances where these parties fail to perform their obligations, the Company may be unable to find alternative suppliers to satisfactorily deliver its products to its customers on time, if at all.

The Company operates in a dynamic and highly competitive industry and believes that changes in any of the following areas could have a material adverse effect on the Company's future financial position, results of operations, or cash flows: ability to obtain future financing; advances and trends in new technologies and industry standards; market acceptance of the Company's products; development of sales channels; certain strategic relationships; litigation or claims against the Company regarding intellectual property, patent, product, regulatory, or other factors; and the ability to attract and retain employees necessary to support its growth.

The Company has expended and expects to continue to expend substantial funds to complete the research and development of its production process. The Company may require additional funds to commercialize its products and may be unable to entirely fund these efforts with its current financial resources. Additional funds may not be available on acceptable terms, if at all. If adequate funds

are unavailable on a timely basis from operations or additional sources of financing, the Company may have to delay the sale of the Company's products and services which would materially and adversely affect its business, financial condition and operations.

During the year ended September 30, 2021, financial results of the Company were not significantly affected by the COVID 19 pandemic, which continues to have global impact. The Company has considered all information available as of the date of issuance of these financial statements and the Company is not aware of any specific events or circumstances that would require an update to its estimates or judgments, or a revision to the carrying value of its assets or liabilities. These estimates may change as new events occur and additional information becomes available. The extent to which the COVID 19 outbreak affects the Company's future financial results and operations will depend on future developments which continue to evolve and are difficult to predict, including new information concerning mutations in the SARS-CoV 2 virus, which may make it more contagious, and current or future domestic and international actions to contain it and treat it.

Concentration of credit risk

Financial instruments that potentially subject the Company to a concentration of credit risk consist of cash and cash equivalents, short-term investments and accounts receivable. Substantially all of the Company's cash is held by one financial institution that management believes is of high credit quality. Such deposits may, at times, exceed federally insured limits. The Company's investment policy addresses the level of credit exposure by establishing a minimum allowable credit rating and by limiting the concentration in any one investment.

The Company's accounts receivable is derived from customers located principally in the United States and Europe. The Company performs ongoing credit evaluations of its customers and maintains allowances for potential credit losses on customers' accounts when deemed necessary. The Company does not typically require collateral from its customers. Credit losses historically have not been material. The Company continuously monitors customer payments and maintains an allowance for doubtful accounts based on its assessment of various factors including historical experience, age of the receivable balances, and other current economic conditions or other factors that may affect customers' ability to pay.

Customer concentration

There are no major customers who accounted for 10% or more of the Company's revenue for the fiscal year ended September 30, 2021. There were two major customers who accounted for 12% and 10% of the Company's revenue for the fiscal year ended September 30, 2020. There was one major customer who accounted for 17% of the Company's revenue for the fiscal year ended September 30, 2019.

There are no major customers who accounted for 10% or more of the net accounts receivable as of September 30, 2021. There was one customer who accounted for 36% of net accounts receivable as of September 30, 2020.

Cash and cash equivalents

Cash equivalents that are readily convertible to cash are stated at cost, which approximates fair value. The Company considers all highly liquid investments with an original or remaining maturity of three months or less at the time of purchase to be cash equivalents. Cash equivalents consist of investments in money market funds as of September 30, 2021 and 2020.

Short-term investments

The Company invests in various types of securities, including United States government, commercial paper, and corporate debt securities. It classifies its investments as available-for-sale and records them at fair value based upon market prices at period end. Unrealized gains and losses that are deemed temporary in nature are recorded in accumulated other comprehensive income as a separate component of stockholders' equity. Dividend and interest income are recognized when earned. Realized gains and losses are included in earnings and are derived using the specific identification method for determining the cost of investments sold. The Company may sell these securities at any time for use in current operations.

Accounts receivable

Trade receivables include amounts billed and currently due from customers, recorded at the net invoice value and are not interest bearing. The amounts due are stated at their net estimated realizable value. The Company maintains an allowance for doubtful accounts to provide for the estimated amounts of receivables that will not be collected. The allowance is based upon an assessment of customer creditworthiness, historical payment experience, the age of outstanding receivables and collateral to the extent applicable.

The Company re-evaluates such allowance on a regular basis and adjusts its allowance as needed. Once a receivable is deemed to be uncollectible, such balance is charged against the allowance.

The Company has a short order-to-invoice lifecycle, as most products can be manufactured within one month. Upon delivery of the products to the customer, the Company invoices the customer. The typical timing of payment is net 30 days.

Fair value of financial instruments

The carrying amounts of the Company's financial instruments including cash equivalents, short term investments, and accounts receivable approximate fair value due to their relatively short maturities. The carrying amounts of the redeemable convertible preferred stock warrant liability represent their fair values. Based on the borrowing rates currently available to the Company for loans with similar terms, the carrying value of the Company's long-term debt approximates its fair value (level 2 within the fair value hierarchy).

Inventories

Inventory is stated at the lower of cost or net realizable value. Cost is determined using the first-in, first-out method. Determining net realizable value of inventory involves judgments and assumptions, including projecting selling prices and costs to sell. Provisions are made to reduce excess and obsolete inventories to their estimated net realizable value based on forecasted demand, past experience, the age and nature of inventories.

Property and equipment

Property and equipment are stated at cost less accumulated depreciation and amortization. Depreciation and amortization are computed using the straight-line method over the estimated useful lives of the assets or the remaining lease term of the respective leasehold improvements assets, if any. The Company recorded depreciation and amortization expense of $9.8 million, $6.7 million, and $6.1 million for the years September 30, 2021, 2020 and 2019, respectively. Estimated lives of property and equipment are as follows:

Laboratory equipment	5 Years
Furniture, fixtures and other equipment	5 Years
Computer equipment	3 Years
Computer software	3 Years
Leasehold improvements	Lesser of useful life or facilities' lease term.

Maintenance and repairs are charged to expense as incurred. Betterments are capitalized and depreciated through the life of the lease. When assets are retired or otherwise disposed of, the cost and accumulated depreciation are removed from the balance sheet and any resulting gain or loss is reflected in operations in the period realized.

Capitalized software development costs

Costs associated with internal-use software systems, including those to improve e-commerce capabilities, during the application development stage are capitalized. Capitalization of costs begins when the preliminary project stage is completed, management has committed to funding the project, and it is probable that the project will be completed and the software will be used to perform the function intended. Capitalization ceases at the point when the project is substantially complete and is ready for its intended purpose. The capitalized amounts are included in property and equipment, net on the consolidated balance sheets.

Capitalized software development costs were $3.0 million and $2.4 million as of September 30, 2021 and 2020, respectively. Capitalized costs are amortized from the project completion date, using the straight-line method over an estimated useful life of the assets, which is three years.

Long-lived assets

The Company reviews property and equipment, right of use assets and intangibles subject to amortization for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Recoverability is measured by comparison of the carrying amount to the future undiscounted cash flows which the assets are expected to generate. If such assets

are considered to be impaired, the impairment to be recognized is measured by the amount by which the carrying amount of the assets exceeds their fair value. There have been no such impairments of long-lived assets during the years ended September 30, 2021, 2020 and 2019.

Intangible assets with finite lives are amortized over their estimated useful lives using the straight-line method. The Company reviews intangible assets for impairment whenever events or changes in business circumstances indicate that the carrying amounts of the assets may not be fully recoverable. Impairment assessments inherently involve judgment as to assumptions about expected future cash flows and the impact of market conditions on those assumptions. No impairment charges were recorded during the years ended September 30, 2021, 2020 and 2019.

Leases

On October 1, 2019, the Company adopted Topic 842 using the modified retrospective approach. The adoption had a material effect on the consolidated balance sheets but did not have a material effect on the consolidated statements of operations and comprehensive loss. Prior period amounts were not adjusted and continue to be reported in accordance with the previous accounting under ASC 840, Leases. The Company elected the package of practical expedients permitted under the transition guidance which, among other things, allows carrying forward the historical classification of existing leases as of October 1, 2019.

The Company determines if an arrangement is a lease at inception primarily based on the determination of the party responsible for directing the use of an underlying asset within a contract. Operating lease right-of-use assets represent the Company's right to use an underlying asset for the lease term and lease liabilities represent the Company's obligation to make lease payments arising from the lease. Operating lease right-of-use assets and liabilities are recognized at the lease commencement date based on the present value of lease payments over the lease term. In determining the present value of committed lease payments, the Company uses its incremental borrowing rate based on the information available at the lease commencement date which includes significant assumptions made including the Company's estimated credit rating, annual percentage yields from corporate debt financings of companies of similar size and credit rating over a loan term approximating the remaining term of each lease, and government bond yields for terms approximating the remaining term of each lease in countries where the leased assets are located. Certain leases include payments of operating expenses that are dependent and may be revised based on the landlord's estimate, and these variable payments are therefore excluded from the lease payments used to determine the operating lease right-of-use asset and lease liability. Lease terms may include options to extend or terminate the lease when it is reasonably certain that the Company will exercise any such options. Lease expense is recognized on a straight-line basis over the expected lease term.

The Company elected to not apply the recognition requirements of Topic 842 to short-term leases with terms of 12 months or less which do not include an option to purchase the underlying asset that the Company is reasonably certain to exercise. For short-term leases, lease payments are recognized as operating expenses on a straight-line basis over the lease term. The Company elected to account for lease and non-lease components as a single lease component.

Additional information and disclosures required by Topic 842 are contained in Note 7.

Goodwill and indefinite intangible assets

Goodwill is evaluated for impairment annually at the reporting unit level during the fourth quarter of the fiscal year or more frequently if events or changes in circumstances indicate that the carrying value of the asset may not be recoverable. If, based on a qualitative assessment, the Company determines it is more likely than not that goodwill is impaired, a quantitative assessment is performed to determine if the fair value of the Company's one reporting unit is less than its carrying value. During its goodwill impairment review, the Company assessed qualitative factors to determine whether it is more likely than not that the fair value of its reporting unit is less than its carrying value, including goodwill. The qualitative factors include, but are not limited to, industry and market considerations, and the Company's overall financial performance. The Company performed its annual assessment for goodwill impairment in the fourth quarter of the fiscal year noting no indication of impairment. There were no triggering events indicating potential for impairment through September 30, 2021.

Segment information

The Company has one business activity, which is manufacturing of synthetic DNA using its semiconductor-based silicon platform and operates as one reportable and operating segment. The Company's chief operating decision-maker, its Chief Executive Officer (CEO), reviews the Company's operating results on an aggregate basis for purposes of allocating resources and evaluating financial performance.

Revenue recognition

The Company's revenue is generated through the sale of synthetic biology tools, such as synthetic genes, oligo pools, next generation sequencing tools, and DNA and biopharma libraries. The Company recognizes revenue when control of the products is transferred to the customer and at a transaction price that is determined based on the agreed upon rates in the applicable order or master supply agreement applied to the quantity of synthetic DNA that was manufactured and shipped to the customer.

Contracts with customers are in the written form of a purchase order or a quotation, which outline the promised goods and the agreed upon price. Such orders are often accompanied by a Master Supply or Distribution Agreement that establishes the terms and conditions, rights of the parties, delivery terms, and pricing. The Company assesses collectability based on a number of factors, including past transaction history and creditworthiness of the customer.

For Company contracts to date other than Biopharma contracts, the customer orders a specified quantity of synthetic DNA sequence; therefore, the delivery of the ordered quantity per the purchase order is accounted for as one performance obligation.

The transaction price is determined based on the agreed upon rates in the purchase order or master supply agreements applied to the quantity of synthetic DNA that was manufactured and shipped to the customer. The Company's contracts include only one performance obligation – the shipment of the product to the customer. Accordingly, all of the transaction price, net of any discounts, is allocated to the one performance obligation. The Company's sales are subject to Ex Works (as defined in Incoterms 2010) delivery terms and revenue is recorded at the point in time when products are picked up by the customer's freight forwarder, as the Company has determined that this is the point in time that control transfers to the customer. Therefore, upon shipment of the product, there are no remaining performance obligations. The Company's shipping and handling activities are performed before the customer obtains control of the goods and therefore are considered a fulfillment cost. The Company has elected to exclude all sales and value added taxes from the measurement of the transaction price. The Company has not adjusted the transaction price for significant financing since the time period between the transfer of goods and payment is less than one year. The Company has elected the practical expedient to not disclose the consideration allocated to remaining performance obligations and an explanation of when those amounts are expected to be recognized as revenue since the duration of the contracts is less than one year.

The Company recognizes revenue at a point in time when control of the products is transferred to the customer.

The Company's Biopharma revenue currently primarily consists of research and development agreements with third parties that provide for up-front and milestone-based payments. The Company also enters into research and development agreements that do not include up-front or milestone-based payments and recognizes revenue on these types of agreements based on the timing of development activities. The Company's research and development agreements may include more than one performance obligation. At the inception of the agreement, the Company assesses whether each obligation represents a separate performance obligation or whether such obligations should be combined as a single performance obligation. The transaction price for each agreement is determined based on the amount of consideration the Company expects to be entitled to for satisfying all performance obligations within the agreement. The Company assesses the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress for purposes of recognizing revenue. In agreements where the Company satisfies performance obligation(s) over time, the Company recognizes development revenue typically using an input method based on costs incurred relative to the total expected cost which determines the extent of progress toward completion. As part of the accounting for these arrangements, the Company must develop estimates and assumptions that require judgment to determine the transaction price and progress towards completion. The Company reviews its estimate of the transaction price and progress toward completion based on the best information available to recognize the cumulative progress toward completion as of the end of each reporting period and makes revisions to such estimates as necessary. Also, these research and development agreements may include license payments. The Company recognizes revenue from functional license agreements when the license is transferred to the customer and the customer is able to use and benefit from the license. Functional license has significant standalone functionality because it can be used as is for performing a specific task.

The Company had contract assets of $2.0 million and contract liabilities of $1.1 million as of September 30, 2021. For all periods presented, the Company did not recognize revenue from amounts that were included in the contract liability balance at the beginning of each period. In addition, for all periods presented, there was no revenue recognized in a reporting period from performance obligations satisfied in previous periods.

Based on the nature of the Company's contracts with customers which are recognized over a term of less than 12 months, the Company has elected to use the practical expedient whereby costs to obtain a contract are expensed as they are incurred.

The Company states its revenues net of any taxes collected from customers that are required to be remitted to various government agencies. The amount of taxes collected from customers and payable to governmental entities is included on the balance sheet as part of "Accrued expenses and other current liabilities."

Refer to Note 14 for the disaggregation of revenues by geography, by product and by industry.

Research and development

Research and development expenses consist of compensation costs, employee benefits, subcontractors, research supplies, allocated facility related expenses and allocated depreciation and amortization. All research and development costs are expensed as incurred.

Advertising costs

Costs related to advertising and promotions are expensed to sales and marketing as incurred. Advertising and promotion expenses for the years ended September 30, 2021, 2020 and 2019, were $2.5 million, $1.2 million and $1.3 million, respectively.

Government contract payments

The Company has funded research and development arrangements with the Defense Advanced Research Projects Agency (DARPA) and is under a subcontract with the Georgia Institute of Technology funded by the United States Director of Central Intelligence (IARPA). The Company recognizes payments received from these arrangements when milestones are achieved and records them as a reduction of research and development expenses. The total expected cost for the IARPA development project is $6.5 million with IARPA funding $4.5 million and the Company responsible for providing a minimum contribution of $2.0 million, which remains outstanding as of September 30, 2021. In fiscal year 2021, 2020, and 2019, the Company received DARPA payments of $1.0 million, $0.2 million, and $0.5 million, respectively. In fiscal year 2021 and 2020, the Company received IARPA payments of $1.1 million, and $2.5 million, respectively. There were no IARPA payments received in fiscal year 2019.

Common stock warrants

Warrants to purchase the Company's common stock issued in conjunction with debt are recorded as additional paid-in-capital and classified as equity on the consolidated balance sheets. There were no common stock warrants issued during the years ended September 30, 2021 and 2020.

Stock-based compensation

The Company maintains performance incentive plans under which incentive and nonqualified stock options and restricted stock units are granted primarily to employees and may be granted to members of the board of directors and certain non-employee consultants, and employees may participate in an employee stock purchase plan.

The Company recognizes stock compensation in accordance with ASC 718, *Compensation—Stock Compensation*. ASC 718 requires the recognition of compensation expense, using a fair value-based method, for costs related to all stock-based payments including stock options, restricted stock units and employee stock purchase plan.

The Company recognizes fair value of stock options granted to non-employees as a stock-based compensation expense over the period in which the related services are received. The Company recognizes forfeitures as they occur. The Company believes that the estimated fair value of stock options is more readily measurable than the fair value of the services rendered.

For performance-based stock options, expense is recognized over the period from the grant date to the estimated attainment date, which is the derived service period of the award.

Net loss per share attributable to common stockholders

The Company calculates its basic and diluted net loss per share attributable to common stockholders in conformity with the two-class method required for companies with participating securities. In computing diluted net loss attributable to common stockholders, undistributed earnings are re-allocated to reflect the potential impact of dilutive securities. The Company's basic net loss per share attributable to common stockholders is calculated by dividing the net loss attributable to common stockholders by the weighted-average number of shares of common stock outstanding for the period. For purposes of the calculation of diluted net loss per share attributable to common stockholders, unvested shares of common stock issued upon the early exercise of stock options, shares issuable for employee stock purchase plan contributions received, warrants to purchase common stock, unvested restricted common stock, unvested restricted stock units and stock options to purchase common stock are considered potentially dilutive securities but have been excluded from the calculation of diluted net loss per share attributable to common stockholders as their effect is antidilutive.

Basic and diluted net loss per share of common stock attributable to common stockholders is calculated by dividing the net loss attributable to common stockholders by the weighted-average number of shares of common stock outstanding during the period, less shares subject to repurchase, and excludes any dilutive effects of employee stock-based awards and warrants. Because the Company has reported a net loss for the years ended September 30, 2021, 2020 and 2019, diluted net loss per common share is the same as the basic net loss per share for those years.

Reverse stock split

In October 2018, the Company's stockholders approved a one-for-0.101 reverse stock split of its common and redeemable convertible preferred stock which was affected on October 16, 2018. The par value of the common stock and redeemable convertible preferred stock were not adjusted as a result of the reverse stock split. Accordingly, all share and per share amounts for all periods presented in the consolidated financial statements and notes thereto have been adjusted retrospectively to reflect this reverse stock split.

Income taxes

The Company accounts for income taxes using the asset and liability method whereby deferred tax asset and liability accounts are determined based on differences between financial reporting and tax bases of assets and liabilities and are measured using the enacted tax rates and laws that are currently in effect. Valuation allowances are established where necessary to reduce deferred tax assets to the amounts expected to be realized.

Deferred offering costs

Deferred offering costs, which consist of direct incremental legal, consulting, banking and accounting fees relating to the Company's initial and subsequent issuance of common stock in public offering, were initially capitalized and subsequently offset against proceeds from the issuance of common stock in public offering within stockholders' equity. As of September 30, 2021 and 2020, there were no capitalized deferred offering costs on the consolidated balance sheets.

Business combinations

The Company accounts for business combinations using the acquisition method.

Under the acquisition method, the purchase price of the acquisition is allocated to the acquired tangible and identifiable intangible assets and assumed liabilities based on their estimated fair values at the time of the acquisition. This allocation involves a number of assumptions, estimates, and judgments that could materially affect the timing or amounts recognized in the Company's financial statements. As a result, the Company may record adjustments to the fair values of assets acquired and liabilities assumed within the measurement period (up to one year from the acquisition date) with the corresponding offset to goodwill. The most subjective areas of the acquisition accounting method include determining the fair value of the following:

- identifiable intangible assets, including the valuation methodology, estimates of projected revenues, technology obsolescence, and discount rates, as well as the estimated useful life of the intangible assets;
- contingent consideration; and
- goodwill, as measured as the excess of consideration transferred over the acquisition date fair value of the assets acquired, including the amount assigned to identifiable intangible assets, and the liabilities assumed.

The assumptions and estimates are based upon comparable market data and information obtained from the management of the acquired business.

Goodwill is assigned to reporting units that are expected to benefit from the synergies of the business combination as of the acquisition date.

Identifiable intangible assets with finite lives are amortized over their estimated useful lives in a pattern in which the asset is consumed. Acquisition-related costs, including advisory, legal, accounting, valuation, and other similar costs, are expensed in the periods in which those costs are incurred. The results of operations of acquired businesses are included in the Company's consolidated financial statements from the acquisition date.

Recent accounting pronouncements

In August 2018, the FASB issued ASU 2018-13, *Fair Value Measurement (Subtopic 820): Disclosure Framework—Changes to the Disclosure Requirements for Fair Value Measurement*, which modifies the disclosure requirements on fair value measurements. The amendments on changes in unrealized gains and losses, the range and weighted average of significant unobservable inputs used to develop Level 3 fair value measurements, and the narrative description of measurement uncertainty should be applied prospectively for only the most recent interim or annual period presented in the initial year of adoption. All other amendments should be applied retrospectively to all periods presented upon their effective date. The Company adopted this standard effective October 1, 2020. The adoption of ASU 2018-13 did not have an impact on the Company's consolidated financial statements for either period presented.

In November 2018, the FASB issued ASU 2018-18, *Collaborative Arrangements* (Topic 808): Clarifying the Interaction Between Topic 808 and Topic 606, which, among other things, provides guidance on how to assess whether certain collaborative arrangement transactions should be accounted for under Topic 606. The amendments in this ASU are effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2019, with early adoption permitted. The Company adopted this standard effective October 1, 2020. The adoption of ASU 2018-18 did not have an impact on the Company's consolidated financial statements for either period presented.

In June 2016, the FASB issued ASU 2016-13, Financial Instruments—Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments. The new standard requires entities to use the new "expected credit loss" impairment model for most financial assets measured at amortized cost, including trade and other receivables and held-to-maturity debt securities, and modifies the impairment model for available-for-sale debt securities. The standard is effective for the Company for the fiscal year ending September 30, 2024, including interim periods within that fiscal year. Early application is permitted. The Company is currently evaluating the impact that the adoption of this standard will have on its consolidated financial statements.

In January 2017, the FASB issued ASU 2017-04, *Intangibles—Goodwill and Other (Topic 350): Simplifying the Test for Goodwill Impairment.* This ASU simplifies the subsequent measurement of goodwill. The ASU eliminates step 2 from the goodwill impairment test, including for reporting units with a zero or negative carrying amount that fail a qualitative test. An entity still has the option to perform the qualitative assessment for a reporting unit to determine if the quantitative impairment test is necessary. This ASU should be applied on a prospective basis. This ASU should be applied on a prospective basis. This ASU is effective for annual or any interim goodwill impairment tests in fiscal years beginning after December 15, 2019. The Company adopted this standard effective October 1, 2020. The adoption of ASU 2017-04 did not have an impact on the Company's consolidated financial statements for either period presented.

In December 2019, the FASB issued ASU 2019-12, *Simplifying the Accounting for Income Taxes*. The ASU simplifies the accounting for income taxes by eliminating certain exceptions to the guidance in ASC 740, *Income Taxes*, related to the approach for allocating income tax expense or benefit for the year to continuing operations, discontinued operations, other comprehensive income, and other charges or credits recorded directly to shareholders' equity; the methodology for calculating income taxes in an interim period; and the recognition of deferred tax liabilities for outside basis differences. The ASU is effective for fiscal years beginning after December 15, 2020 and interim periods within those fiscal years, with early adoption permitted. The Company is currently assessing the impact of adoption on its disclosures.

3. Fair value measurement

The Company assesses the fair value of financial instruments based on the provisions of ASC 820, *Fair Value Measurements*. ASC 820 defines fair value as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. ASC 820 also establishes a fair value hierarchy which requires an entity to maximize the use of observable inputs

and minimize the use of unobservable inputs when measuring fair value. The standard describes three levels of inputs that may be used to measure fair value:

Level 1—Quoted prices in active markets for identical assets or liabilities.

Level 2—Observable inputs other than Level 1 prices such as quoted prices for similar assets or liabilities, quoted prices in markets that are not active, or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.

Level 3—Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

In determining fair value, the Company utilizes valuation techniques that maximize the use of observable inputs and minimize the use of unobservable inputs to the extent possible as well as considering counterparty credit risk in its assessment of fair value.

The following table sets forth the cash and cash equivalents, and short-term investments as of September 30, 2021:

(in thousands)	Amortized cost	Gross unrealized gains	Gross unrealized losses	Fair value
Cash and cash equivalents	$ 465,829	$ —	$ —	$ 465,829
Short-term investments	12,033	1	—	12,034
Total	$ 477,862	$ 1	$ —	$ 477,863

The following table sets forth the cash and cash equivalents, and short-term investments as of September 30, 2020:

(in thousands)	Amortized cost	Gross unrealized gains	Gross unrealized losses	Fair value
Cash and cash equivalents	$ 93,667	$ —	$ —	$ 93,667
Short-term investments	196,320	15	—	196,335
Total	$ 289,987	$ 15	$ —	$ 290,002

As of September 30, 2021, financial assets and liabilities measured and recognized at fair value are as follows:

(in thousands)	Level 1	Level 2	Level 3	Fair value
Assets				
Money market funds	$ 430,438	$ —	$ —	$ 430,438
U.S. government treasury bills	12,034	—	—	12,034
Total financial assets	$ 442,472	$ —	$ —	$ 442,472
Liabilities				
Contingent consideration and indemnity holdback	$ —	$ 9,856	$ —	$ 9,856
Total financial liabilities	$ —	$ 9,856	$ —	$ 9,856

As of September 30, 2020, financial assets and liabilities measured and recognized at fair value are as follows:

(in thousands)	Level 1	Level 2	Level 3	Fair value
Assets				
Money market funds	$ 73,413	$ —	$ —	$ 73,413
Commercial paper	—	94,840	—	94,840
U.S. government treasury bills	101,495	—	—	101,495
Total financial assets	$ 174,908	$ 94,840	$ —	$ 269,748

Contractual maturities of short-term investments, as of September 30, 2021, were less than 12 months.

4. Balance sheet components

The Company's accounts receivable, net balance consists of the following:

(in thousands)	September 30, 2021	2020
Trade Receivables	$ 26,549	$ 25,790
Other Receivables	2,337	951
Allowance for Doubtful Accounts	(337)	(365)
Accounts Receivable, net	$ 28,549	$ 26,376

Inventories consist of the following:

(in thousands)	September 30, 2021	2020
Raw Materials	$ 18,778	$ 9,237
Work-in-process	4,837	2,021
Finished Goods	8,185	1,031
	$ 31,800	$ 12,289

The work-in-process inventory included gross consigned inventory of $1.9 million as of September 30, 2021.

Property and Equipment, net consists of the following:

(in thousands)	September 30, 2021	2020
Laboratory equipment	$ 48,439	$ 37,338
Furniture, fixtures and other equipment	2,195	1,728
Computer equipment	2,977	2,834
Computer software	3,899	3,678
Leasehold improvements	5,066	4,669
Construction in progress	16,968	4,697
	79,544	54,944
Less: Accumulated depreciation and amortization	(35,422)	(29,478)
	$ 44,122	$ 25,466

Other non-current assets

The other non-current assets consist of the following:

(in thousands)	September 30, 2021	2020
Convertible note receivable	$ 3,021	$ —
Other non-current assets	4,653	2,823
	$ 7,674	$ 2,823

The Company entered into a convertible promissory note agreement with a privately held company ("Borrower") pursuant to which the Company agreed to loan to the Borrower up to an aggregate of $3.0 million in a series of loan installments, evidenced by a convertible promissory note having a maturity date of May 1, 2023 ("Convertible Note"). The Convertible Note accrues interest at a rate of 4% per annum. Outstanding principal and any unpaid accrued interest will be converted into preferred shares of the Borrower if before the repayment of the Note, the Borrower has an equity financing round.

Accrued expenses

The accrued expenses consist of the following:

(in thousands)	September 30, 2021	2020
Professional services fees payable	$ 5,057	$ 2,444
Other accrued expenses	1,380	1,457
	$ 6,437	$ 3,901

Accrued compensation

The accrued compensation consist of the following:

(in thousands)	September 30, 2021	2020
Accrued vacation	$ 4,643	$ 3,641
Accrued bonus	8,584	5,747
Accrued commissions	3,330	1,970
Accrued payroll and related taxes	4,676	2,711
Other accrued compensation	1,094	876
	$ 22,327	$ 14,945

Other current liabilities

The other current liabilities consist of the following:

(in thousands)	September 30, 2021	2020
Contingent consideration	$ 5,186	$ —
Income and sales taxes payable	2,440	719
Other current liabilities	1,997	1,892
	$ 9,623	$ 2,611

5. Goodwill and intangible assets

Goodwill and intangible assets increased from prior year by $21.3 million and $18.4 million, respectively, as a result of a business acquisition. See Note 15, “Business acquisition”. There were no changes to the carrying value of goodwill during the year ended September 30, 2020. Total amortization expense related to intangible assets were $0.5 million for the year ended September 30, 2021 and $0.2 million for each of the years ended September 30, 2020 and 2019.

The intangible assets balances are presented below:

(in thousands, except for years)	September 30, 2021 Weighted average Amortization period in years	Gross carrying amount	Accumulated amortization	Net book value
Developed Technology	16	$ 19,120	$ (1,361)	$ 17,759
Tradenames & Trademarks	2	20	(20)	—
Customer Relationships	1.5	510	(7)	503
Total indefinite-lived intangible assets		$ 19,650	$ (1,388)	$ 18,262

(in thousands, except for years)	September 30, 2020 Weighted average Amortization period in years	Gross carrying amount	Accumulated amortization	Net book value
Developed Technology	6	$ 1,220	$ (913)	$ 307
Tradenames & Trademarks	2	20	(20)	—
Total indefinite-lived intangible assets		$ 1,240	$ (933)	$ 307

Future annual amortization expense is as follows (in thousands):

Years ending September 30,	
2022	$ 1,593
2023	1,138
2024	1,053
2025	1,053
2026	1,053
Thereafter	12,372
	$ 18,262

6. Long-term debt

In September 2017, the Company entered into a Fourth Amended and Restated Loan and Security Agreement (the Fourth Loan) with SVB for loan amounts aggregating up to $20.0 million in a series of three advances. The first advance provides a principal amount of $10.0 million, the second advance provides a principal amount of $5.0 million and the third advance provides a principal amount of $5.0 million during their respective draw down periods. The draw down periods for the second and third advances under this agreement have expired as of January 31, 2018 and June 30, 2018, respectively and were not utilized.

In connection with the first advance the Company issued a warrant to purchase 64,127 shares of common stock at an exercise price of $6.24 per share. The Fourth Loan contains a subjective acceleration clause under which the Fourth Loan could become due and payable to SVB in the event of a material adverse change in the Company’s business. The term of the loan was 51 months with an interest rate of prime plus 3.0% and a final payment fee of $0.7 million.

The first advance, totaling $10.0 million, was drawn in September 2017 and comprised $7.8 million to refinance a prior loan and a new advance of $2.2 million. The debt provides for interest only payments through December 31, 2018 at which time monthly principal payments become due.

In addition, the Company obtained a revolving loan facility for a principal amount of up to $10.0 million for which the principal amount outstanding under the revolving line would accrue interest at a floating per annum rate equal to one percentage point (1.00%) above the prime rate, which interest shall be payable monthly. The Company accounted for this transaction as a debt modification and did not incur any gain or loss relating to the modification. The Company had no amounts outstanding under this revolving loan facility at September 30, 2021 and 2020. The fees related to maintaining the revolving loan facility is $0.1 million, payable in annual installments.

The Company's credit facilities contain customary representations and warranties and customary affirmative and negative covenants applicable to the Company and its subsidiaries, including, among other things, restrictions on changes in business, management, ownership or business locations, indebtedness, encumbrances, investments, mergers or acquisitions, dispositions, maintenance of collateral accounts, prepayment of other indebtedness, distributions and transactions with affiliates. The credit facilities contain customary events of default subject in certain cases to grace periods and notice requirements, including (a) failure to pay principal, interest and other obligations when due, (b) material misrepresentations, (c) breach of covenants, conditions or agreements in the credit facilities, (d) default under material indebtedness, (e) certain bankruptcy events, (f) a material adverse change; (g) attachment, levy or restraint on business, (h) default with respect to subordinated debt, (i) cross default under the Company's credit facilities, and (j) government approvals being revoked. As part of the Fourth Loan, all rights, title and interest to the Company's personal property with the exception of the Company's intellectual property, have been pledged as collateral, including cash and cash equivalents, short-term investments, accounts receivable, contractual rights to payment, license agreements, general intangibles, inventory and equipment. The Company was in compliance with all covenants under the loan and security agreement with SVB as of September 30, 2021 and 2020.

Future maturities of the Fourth Loan as of September 30, 2021 are as follows:

(in thousands)	Principal	Interest	Total
Years ending September 30, 2022	$ 833	$ 9	$ 842
	$ 833	$ 9	$ 842
Less: Interest			(9)
Total amount of loan principal			833
Less unamortized debt discount			(4)
Add: accretion of final payment fee			723
			$ 1,552

The effective interest rate of the Company's outstanding Fourth Loan was 11.6% at September 30, 2021.

7. Commitments and contingencies

Litigation

On February 3, 2016, Agilent filed a lawsuit against the Company and its Chief Executive Officer, Dr. Emily Leproust (the "Complaint"), in the Superior Court of California, Santa Clara County, or the Court. The Complaint also named Does 1 through 20, which are fictitious placeholder defendants. Agilent's complaint alleged three claims against Twist and Dr. Leproust: (1) alleged breach of contract, related to the use of confidential information and alleged breach of non-solicitation obligations against Dr. Leproust; (2) alleged breach of a duty of loyalty against Dr. Leproust; and (3) alleged misappropriation of trade secrets under the California Uniform Trade Secrets Act, or CUTSA, against all defendants.

On December 7, 2018, the Court granted Agilent's motion to amend its complaint, permitting Agilent to file its Second Amended Complaint. This new complaint added amended allegations against the Company and Dr. Leproust, and also new claims for breach of contract and trade secret misappropriation against two individuals: Dr. Siyuan Chen, a current Company employee and Solange Glaize, a former Company employee. The Court also set trial to begin on February 24, 2020.

On February 6, 2020, the Company, Dr. Leproust, Dr. Chen, Ms. Glaize (together, the Twist Group) and Agilent agreed to the terms of a settlement agreement (the "Settlement Agreement") pursuant to which the Twist Group and Agilent each agreed to request dismissal of all claims against each other. The Settlement Agreement resolves the litigation initially commenced by the Complaint and contains no admission of liability or wrongdoing. Pursuant to the Settlement Agreement, the Company agreed to pay Agilent $22.5 million in cash within 14 days of the Settlement Agreement. This amount has been accrued in the consolidated financial statements in the three months ended December 31, 2019. In addition, the Twist Group and Agilent each agreed to release the other party from all known and unknown claims related to the claims and counterclaims alleged or that could have been alleged in such litigation or that arise from the facts and events that gave rise to such litigation. Further, Agilent agreed to grant the Company a limited non-exclusive license to use the trade secrets asserted by Agilent in the litigation, which extends to the Company's supply chain, including its customers, suppliers, distributors and resellers. Agilent also agreed not to sue the Company for the infringement of any Agilent patent issued or pending as of the date of the Settlement Agreement or claim priority thereto, solely to the extent such patents claim a trade secret alleged in the litigation. There is no other covenant or release of claims for patent infringement.

The Court dismissed the case on February 14, 2020.

Indemnifications

In the ordinary course of business, the Company enters into agreements that may include indemnification provisions. Pursuant to such agreements, the Company may indemnify, hold harmless and defend the indemnified parties for losses suffered or incurred by the indemnified party. Some of the provisions will limit losses to those arising from third-party actions. In some cases, the indemnification will continue after the termination of the agreement. The maximum potential amount of future payments the Company could be required to make under these provisions is not determinable. To date, the Company has not incurred material costs to defend lawsuits or settle claims related to these indemnification provisions. The Company has also entered into indemnification agreements with its directors and officers that may require it to indemnify its directors and officers against liabilities that may arise by reason of their status or service as directors or officers to the fullest extent permitted by corporate law. The Company also has directors' and officers' insurance.

Leases

The Company leases certain of its facilities under non-cancellable operating leases expiring at various dates through 2034. The Company is also responsible for utilities, maintenance, insurance, and property taxes under these leases.

Certain leases include options to renew or terminate at the Company's discretion. The lease terms include periods covered by these options if it is reasonably certain the Company will renew or not terminate. The Company's lease agreements do not contain any material residual value guarantees or restrictive covenants.

Supplemental balance sheet information related to the Company's operating lease as of September 30, 2021, was the following:

(in thousands)	September 30, 2021
Assets:	
Operating lease right-of-use-asset	$ 61,580
Current liabilities:	
Current portion of operating lease liabilities	$ 8,213
Noncurrent liabilities:	
Operating lease liabilities, net of current portion	$ 53,156

Future minimum lease payments under all non-cancelable operating leases as of September 30, 2021 are as follows:

(in thousands)	Operating leases
Years ending September 30:	
2022	$ 8,986
2023	10,595
2024	10,333
2025	10,489
2026	9,083
Thereafter	84,753
Total minimum lease payments	$ 134,239
Less: imputed interest	(55,242)
Less: tenant improvement allowance (receipt anticipated in 2022)	(17,628)
Total operating lease liabilities	$ 61,369
Less: current portion	(8,213)
Operating lease liabilities, net of current portion	$ 53,156

For the year ending September 30, 2022, future minimum lease payments are comprised of the anticipated receipt of tenant improvement allowances totaling $17.6 million anticipated to be received in 2022, partially offset by non-cancelable operating lease payments of $9.0 million. The statement of cash flows for the year ended September 30, 2021, include changes in right-of-use assets and operating lease liabilities of $27.9 million and $30.1 million, respectively. For the year ended September 30, 2020, changes in right-of-use assets and operating lease liabilities were $2.1 million and $3.1 million, respectively.

Operating lease expense was $9.5 million and $7.9 million for the year ended September 30, 2021 and 2020 respectively. Cash payments for amounts included in the measurement of operating lease liabilities for the year ended September 30, 2021 were $8.0 million. As of September 30, 2021, the weighted-average remaining lease term was 17.3 years and the weighted-average discount rate was 6.4%.

In December 2020, the Company entered into a 12-year operating lease for an approximately 111,000 square-foot facility in Wilsonville, Oregon to further expand the Company operations. Upon execution of the lease agreement, the Company provided the landlord an approximately $1.0 million security deposit in the form of a letter of credit. Subject to certain conditions pursuant to the lease, the Company expects monthly rent payments on the new facility to commence in the first quarter of 2022. The Company will pay an initial annual base rent of approximately $1.7 million, which is subject to scheduled 3% annual increases, plus certain operating expenses. The Company has been provided a tenant improvement allowance of $13.3 million. The Company has the right to sublease the facility, subject to landlord consent. The Company also has the option to extend the lease for two terms of five years. The lease commenced on April 15, 2021. The future minimum lease payments under the agreement are $27.9 million.

On April 13, 2021, the Company entered into a first amendment (the “First Lease Amendment”), which amends the terms of the Wilsonville, Oregon lease agreement dated December 18, 2020. The First Lease Amendment increases the premises originally leased within the same building by approximately 101,000 square feet (the “Additional Premises”). The Company intends to use the Additional Premises to support its additional product offerings, including DNA data storage, or other high value growth product lines. The First Lease Amendment also extends the termination date until April 1, 2034 and modifies the Company’s option to extend the term to an additional 10-year term for the Premises. Additional rent under the First Lease Amendment for the Additional Premises commences April 1, 2022 with approximately $1.2 million in rent payments due the first year and approximately $17.6 million in aggregate estimated rent payments due over the total initial term of the First Lease Amendment. In addition, the First Lease Amendment increases the base rental payments relating to the Original Premises by 3% for the period in which the First Lease Amendment extends the term of the original premises. The Company is obligated to pay approximately 26% of the operating expenses and utilities applicable to the Additional Premises. The Landlord will provide the Company with a tenant improvement allowance in connection with the Company’s improvements to the Additional Premises of approximately $4.3 million.

On April 14, 2021, the Company entered into a 5-year operating lease for a 15,500-square-feet warehouse in Brisbane, California to further expand the Company operations. Upon execution of the lease agreement, the Company provided the landlord an approximately $0.2 million security deposit. The Company will pay an initial annual base rent of approximately $0.3 million, which is subject to scheduled 3% annual increases, plus certain operating expenses. The Company has the right to sublease the facility, subject to landlord consent. The total future minimum lease payments under the agreement are $2.2 million.

On July 28, 2021, the Company entered into a 7-year operating lease for approximately 21,000 square-feet of office space located in South San Francisco, California, to further expand the Company operations. Upon execution of the lease agreement, the Company provided the landlord an approximately $0.2 million security deposit. The Company will pay an initial annual base rent of approximately $1.7 million, which is subject to scheduled 3% annual increases, plus certain operating expenses. The Company has the right to sublease the facility, subject to landlord consent. The lease had not commenced as of September 30, 2021 as the landlord has not vacated the office space. The total future minimum lease payments under the agreement are $13.1 million.

8. Related party transactions

During the years ended September 30, 2021, 2020 and 2019, the Company purchased raw materials from a related party investor in the amount of $5.0 million, $3.4 million and $3.2 million, respectively. Payable balances and cash receipts and receivable balances with the related party were immaterial as of September 30, 2021, 2020 and 2019.

9. Income taxes

The Company recorded an income tax benefit of $1.9 million for the year ended September 30, 2021. The Company recorded provisions for income taxes of $0.4 million and $0.3 million for the years ended September 30, 2020 and 2019, respectively.

The domestic and foreign components of pre-tax loss for the year ended September 30, 2021, 2020, and 2019 are as follows:

	Year ended September 30,		
(in thousands)	2021	2020	2019
US	(149,533)	(138,016)	(107,847)
Foreign	(4,495)	(1,533)	470
Total	(154,028)	(139,549)	(107,377)

The components of the provision for income taxes for the year ended September 30, 2021, 2020, and 2019 are as follows:

	Year ended September 30,		
(in thousands)	2021	2020	2019
Current			
Federal	—	—	—
State	(29)	—	108
Foreign	108	382	184
Total Current	79	382	292
Deferred			
Federal	(2,268)	—	—
State	259	—	—
Foreign	—	—	—
Total Deferred	(2,009)	—	—
Total Provision	(1,930)	382	292

The following is a reconciliation of the statutory federal income tax rate to the Company's effective tax rate:

	Year ended September 30,		
	2021	2020	2019
Tax expense computed at the federal statutory rate	21 %	21 %	21 %
Change in valuation allowance	(33)%	(25)%	(22)%
Research and development credit benefit	3 %	1 %	1 %
Business combination	(2)%	—	—
Stock-based compensation	12 %	3 %	—
Total income tax expense	1 %	— %	— %

The significant components of the Company's deferred tax assets and liabilities are as follows:

(in thousands)	September 30, 2021	2020
Net operating loss carryforwards	$ 163,782	$ 112,434
Research and development credit carryforwards	20,163	9,407
Operating lease liability	14,890	7,506
Other	11,631	5,639
Gross deferred tax assets	210,466	134,986
Less: Valuation allowance	(190,428)	(127,336)
Net deferred tax assets	20,038	7,650
Fixed assets	(785)	(105)
Operating lease right-of-use asset	(14,893)	(7,498)
Intangible assets	(4,360)	(47)
Gross deferred tax liabilities	(20,038)	(7,650)
Total net deferred tax asset	$ —	$ —

Based on the available objective evidence, management believes it is more likely than not that the deferred tax assets will not be fully realizable. Accordingly, the Company has provided a full valuation allowance against its deferred tax assets at September 30, 2021 and 2020. The valuation allowance was $190.4 million and $127.3 million as of September 30, 2021, and 2020, respectively. The change in the valuation allowance was mainly due to an increase in the net operating loss and research and development credits during the fiscal year 2021.

The Company intends to continue maintaining a full valuation allowance on the Company's deferred tax assets until there is sufficient evidence to support the reversal of all or some portion of the allowance. The release of all, or a portion, of the valuation allowance would result in the recognition of certain deferred tax assets and a decrease to income tax expense for the period the release is recorded.

As of September 30, 2021, the Company had net operating loss carryforwards of approximately $664.5 million and $377.1 million available to reduce future taxable income, if any, for federal and state income tax purposes, respectively. The net operating losses will begin to expire in fiscal year 2032.

The Company also had federal and state research and development credit carryforwards of approximately $16.9 million and $12.5 million, respectively, at September 30, 2021. The federal credits will expire starting in 2033 if not utilized. The California research and development credits have no expiration date. Utilization of the net operating losses and tax credits is subject to annual limitation due to the ownership change limitations provided by the Internal Revenue Code and similar state provisions. Such annual limitations may result in the expiration of the net operating losses and tax credits before utilization.

The provisions of ASC 740-10, *Accounting for Uncertainty in Income Taxes*, prescribe a comprehensive model for the recognition, measurement, and presentation and disclosure in financial statements of any uncertain tax positions that have been taken or expected to be taken on a tax return. The Company has identified uncertain tax positions related to federal and state research and development credits and foreign jurisdictions.

The aggregate changes in the balance of gross unrecognized tax benefits are as follows:

(in thousands)	Federal and state
Balance as of September 30, 2018	$ 2,249
Increases related to tax positions taken during 2019	1,042
Balance as of September 30, 2019	$ 3,291
Increases related to tax positions taken during 2020	1,409
Balance as of September 30, 2020	$ 4,700
Increases related to tax positions taken during 2021	2,737
Balance as of September 30, 2021	$ 7,437

The Company does not expect a material change in unrecognized tax benefits in the next twelve months. As of September 30, 2021, approximately $0.1 million of unrecognized tax benefit would, if recognized, impact the Company's effective income tax rate.

It is the Company's policy to include penalties and interest expense related to income taxes as a component of other expense and interest expense, respectively, as necessary. The Company's management determined that no accrual for interest and penalties was required as of September 30, 2021 and 2020.

The Company's files federal and state income tax returns with varying statutes of limitations. All tax years remain open to examination due to the carryover of net operating losses or tax credits. The Company currently has no federal or state tax examinations in progress.

In March and December 2020, in response to the COVID-19 pandemic, the CARES Act and the Consolidated Appropriations Act, 2021 were passed into law and provide additional economic stimulus to address the impact of the COVID-19 pandemic. The Company does not expect any significant benefit to its income tax provision as a result of this legislation.

10. Warrants

In connection with its long-term debt agreements, the Company issued 18,854 and 7,531 warrants for its common stock on December 22, 2015 and March 28, 2016, respectively. As of September 30, 2020, there were 26,385 warrants outstanding. In October 2020, a total of 18,854 warrants with an exercise price of $14.85 per common share were exercised for a net 16,051 common shares issued by the Company. In November 2020, a total of 7,531 warrants with an exercise price of $21.24 per common share were exercised for a net 6,041 common shares issued by the Company. There are no outstanding warrants for the Company's common stock as of September 30, 2021.

11. Common stock

As of September 30, 2021, the Company reserved sufficient shares of common stock for issuance upon exercise of stock options. Each share of common stock is entitled to one vote. The holders of shares of common stock are also entitled to receive dividends whenever funds are legally available and when declared by the board of directors, subject to prior rights of the holders of preferred stock.

12. Stock option plan

2018 Equity Incentive Plan

On September 26, 2018, the board of directors adopted the 2018 Equity Incentive Plan (the 2018 Plan) as a successor to the 2013 Stock Plan (the 2013 Plan). The maximum aggregate number of shares that may be issued under the 2018 Plan is 6,856,405 shares of the Company's common stock. The number of shares reserved for issuance under the 2018 Plan will be increased automatically on the first day of each fiscal year, following the fiscal year in which the 2018 Plan became effective, by a number equal to the least of 999,900 shares, 4% of the shares of common stock outstanding at that time, or such number of shares determined by the Company's board of directors. The common shares issuable under the 2018 Plan were registered pursuant to a registration statement on Form S-8 on November 1, 2018.

On September 1, 2020, the board of directors approved the implementation of a revised annual equity award program for executive officers and senior level employees to be granted as performance-based stock units (PSUs) under the 2018 Plan. The number of PSUs ultimately earned under these awards is calculated based on the achievement of certain total revenue threshold during the fiscal year ending September 30, 2022. The percentage of performance stock units that vest will depend on the board of directors' determination of total revenue at the end of the performance period and can range from 0% to 150% of the number of units granted. The provisions of the PSU are considered a performance condition, and the effects of that performance condition are not reflected in the grant date fair value of the awards. The Company used the Black-Scholes method to calculate the fair value at the grant date without regard to the vesting condition and will recognize compensation cost for the units that are expected to vest. As of September 30, 2021, the Company determined that 256,665 shares are expected to vest based on the probability of the performance condition that will be achieved under this equity award program. The Company reassesses the probability of the performance condition at each reporting period and adjusts the compensation cost based on the probability assessment. During the year ended September 30, 2021, the Company changed its estimate of the probability of meeting the performance conditions for the PSU grants. The previous estimate was based on data and assumptions that were the best available information at the time. During the third quarter of 2021, the Company obtained new data, previously unavailable, from new, internal forecasts and projections. The new data indicate that the PSU grants are expected to be larger than previously estimated. As a result, the Company has changed its estimate of its PSU stock-based compensation on a prospective basis beginning in the third quarter of 2021. This change resulted in an increase of approximately $0.6 million in stock-based compensation expense for the year ended September 30, 2021. The weighted-average grant date fair value was determined to be $45.18 per share. As of September 30, 2021, the unrecognized compensation costs related to these awards were $5.6 million. The Company expects to recognize those costs over a weighted average period of 1.0 year.

Any shares subject to outstanding awards under the 2013 Plan that are canceled or repurchased subsequent to the 2018 Plan's effective date are returned to the pool of shares reserved for issuance under the 2018 Plan. Awards granted under the 2018 Plan may be nonstatutory stock options, stock appreciation rights, restricted stock, restricted stock units, performance shares, and performance units.

Activity under the equity incentive plans during the year ended September 30, 2021 is as follows:

(In thousands, except per share data)	Shares available	Options outstanding	Weighted average exercise price per share	Weighted average remaining contractual term (years)	Aggregate intrinsic value
Outstanding at September 30, 2020	1,034	3,913	$ 24.35	8.1	$ 204,365
Additional shares authorized	1,000	—	—		
Stock options granted	(175)	175	69.03		
Stock options exercised	—	(805)	18.05		
Stock options forfeited	151	(151)	39.25		
Restricted stock units granted	(436)	—	—		
Forfeiture of restricted stock units	61	—	—		
Shares withheld for payment of taxes	93	—	—		
Outstanding at September 30, 2021	1,728	3,132	$ 27.15	7.3	$ 251,343
Vested or expected to vest at September 30, 2021		3,132	$ 27.15	7.3	$ 251,343
Vested and exercisable at September 30, 2021		1,633	$ 18.05	6.6	$ 145,204

As of September 30, 2021, there was $26.3 million of total unrecognized compensation cost related to non-vested stock options under the equity incentive plans that are expected to be recognized over a weighted average period of 1.6 years. The weighted-average grant date fair value of stock options granted during the year ended September 30, 2021 was $69.03 per share.

2018 Employee Stock Purchase Plan

On September 26, 2018, the board of directors adopted the 2018 Employee Stock Purchase Plan (the 2018 ESPP). A total of 275,225 shares of the Company's common stock have been reserved for issuance under the 2018 ESPP. The number of shares reserved for issuance under the 2018 ESPP will be increased automatically on the first day of each fiscal year, following the fiscal year in which the 2018 ESPP becomes effective, by a number equal to the least of 249,470 shares, 1% of the shares of common stock outstanding at that time, or such number of shares determined by the Company's board of directors. The number of shares reserved for issuance as at September 30, 2021 is as follows:

(In thousands)	Shares available
Outstanding at September 30, 2020	179
Additional shares authorized	250
Shares issued during the period	(74)
Outstanding at September 30, 2021	355

Subject to any plan limitations, the 2018 ESPP allows eligible service providers (through qualified and non-qualified offerings) to contribute, normally through payroll deductions, up to 15% of their earnings for the purchase of the Company's common stock at a discounted price per share. The offering periods are beginning in February and August of each year, except the initial offering period which commenced with the initial public offering in October 2018 and ended on August 20, 2019. The common shares issuable under the 2018 ESPP were registered pursuant to a registration statement on Form S-8 on November 26, 2018.

Unless otherwise determined by the board of directors, the Company's common stock will be purchased for the accounts of employees participating in the 2018 ESPP at a price per share that is the lesser of 85% of the fair market value of the Company's common stock on the first trading day of the offering period, which for the initial offering period is the price at which shares of the Company's common stock were first sold to the public, or 85% of the fair market value of the Company's common stock on the last trading day of the offering period. During the years ended September 30, 2021 and 2020, activity under the 2018 ESPP was immaterial.

Restricted Stock Units

Restricted stock primarily consists of restricted stock unit awards (RSUs) which have been granted to employees. The value of an RSU award is based on the Company's stock price on the date of grant. The shares underlying the RSU awards are not issued until the RSUs vest. Upon vesting, each RSU converts into one share of the Company's common stock.

Activity with respect to the Company's restricted stock units during the year ended September 30, 2021 is as follows:

(in thousands, except per share data)	Number of Shares	Weighted average grant date fair value per share	Weighted average remaining contractual term (years)	Aggregate Intrinsic Value
Outstanding at September 30, 2020	569	$ 32.96	3.2	$ 43,260
Restricted stock units granted	436	$ 113.06	—	—
Restricted stock units vested	(237)	$ 44.36	—	—
Restricted stock units forfeited	(61)	$ 86.60	—	—
Outstanding at September 30, 2021	707	$ 73.86	2.7	$ 75,629
Expected to vest at September 30, 2021	707	$ 73.86	2.7	$ 75,629

As of September 30, 2021, there was $47.5 million of total unrecognized compensation cost related to these issuances that is expected to be recognized over a weighted average period of 2.7 years.

Stock-based compensation

Total stock-based compensation expense recognized were as follows:

	Year ended September 30,		
(in thousands)	2021	2020	2019
Cost of revenues	$ 2,678	$ 1,290	$ 1,345
Research and development	10,166	3,346	2,378
Selling, general and administrative	24,154	12,460	7,447
Total stock-based compensation	$ 36,998	$ 17,096	$ 11,170

The Company uses the Black-Scholes option pricing model to calculate the grant date fair value of a stock option. The Black-Scholes model requires various assumptions, including the fair value of the Company's common stock, expected term, expected dividend yield and expected volatility.

The expected volatility of the Company's stock options is estimated from the historical volatility of selected public companies with comparable characteristics to it, including similarity in size and lines of business. The expected term of stock options represents the period that the Company's stock-options are expected to be outstanding before being exercised. The risk-free interest rate is based on the implied yield currently available on U.S. treasury notes with terms approximately equal to the expected life of the option. The expected dividend rate is zero as the Company currently has no history or expectation of declaring cash dividends on the Company's common stock.

The fair value of options granted during the years ended September 30, 2021, 2020 and 2019, respectively, were calculated using the weighted average assumptions set forth below:

	Year ended September 30,		
	2021	2020	2019
Expected term (years)	6.1	6.2	6.4
Expected volatility	64.4 %	62.1 %	60.2 %
Risk-free interest rate	1.0 %	1.3 %	2.7 %
Dividend yield	— %	— %	— %

Weighted average grant date fair value of options granted during the years ended September 30, 2021, 2020 and 2019 were $42.80, $20.76 and $15.06, respectively.

Shares subject to repurchase

The Company has a right of repurchase with respect to unvested shares issued upon early exercise of options at an amount equal to the original exercise price of each unvested share being repurchased. The Company's right to repurchase these shares lapses pursuant to the vesting schedule of the original grant, which is generally 25% on the first anniversary of the original grant and ratably on a monthly basis over the remaining 36 months. As of September 30, 2021, 2,741 shares remain subject to the Company's right of repurchase.

13. Net loss per share attributable to common stockholders

The following table sets forth the computation of the Company's basic and diluted net loss per share attributable to common stockholders:

	Year ended September 30,		
(in thousands, except per share data)	**2021**	**2020**	**2019**
Numerator:			
Net loss attributable to common stockholders	$ (152,098)	$ (139,931)	$ (107,669)
Denominator:			
Weighted-average shares used in computing net loss per share, basic and diluted	48,251	39,190	27,462
Net loss per share attributable to common stockholders, basic and diluted	$ (3.15)	$ (3.57)	$ (3.92)

The potentially dilutive common shares that were excluded from the calculation of diluted net loss per share because their effect would have been antidilutive for the periods presented are as follows:

	Year ended September 30,		
(in thousands)	**2021**	**2020**	**2019**
Shares subject to options to purchase common stock	3,131	3,948	3,551
Unvested restricted shares of common stock	—	—	24
Unvested restricted stock units	707	569	462
Unvested shares of common stock issued upon early exercise of stock options	3	17	38
Shares subject to employee stock purchase plan	27	33	76
Shares subject to warrants to purchase common stock	—	26	26
Total	3,868	4,593	4,177

14. Geographic, product and industry information

The table below sets forth revenues by geographic region, based on ship-to destinations. Americas consists of the United States of America, Canada, Mexico and South America; EMEA consists of Europe, the Middle East, and Africa; and APAC consists of Japan, China, South Korea, India, Singapore, Malaysia and Australia.

	Year ended September 30,		
(in thousands)	**2021**	**2020**	**2019**
Americas	$ 77,909	$ 59,164	$ 36,932
EMEA	44,124	25,821	14,692
APAC	10,300	5,115	2,761
Total	$ 132,333	$ 90,100	$ 54,385

The table below sets forth revenues by products.

(in thousands)	Year ended September 30, 2021	2020	2019
Synthetic genes	$ 38,964	$ 35,192	$ 26,712
Oligo pools	8,039	4,545	4,594
DNA and Biopharma libraries	12,663	6,348	2,036
NGS tools	72,667	44,015	21,043
Total	$ 132,333	$ 90,100	$ 54,385

The table below sets forth revenues by industry.

(in thousands)	Year ended September 30, 2021	2020	2019
Industrial chemicals/materials	$ 34,475	$ 29,054	$ 21,927
Academic research	25,299	19,642	13,835
Healthcare	71,241	40,036	17,424
Food/agriculture	1,318	1,368	1,199
Total revenues	$ 132,333	$ 90,100	$ 54,385

Long-lived assets located in the United States are $40.6 million and $22.5 million as of September 30, 2021 and 2020. Long-lived assets located outside of the United States were $3.5 million and $3.0 million as of September 30, 2021 and 2020.

15. Business acquisition

On June 14, 2021, the Company acquired all of the outstanding stock of iGenomX International Genomics Corporation (iGenomX). iGenomX offers multiplex library preparation tools for next-generation sequencing (NGS) workflows. The Company's acquisition is expected to enhance its capabilities to support multiplex sequencing preparations across multiple markets and to accelerate the Company's conversion of customers from static microarray platforms to genotyping by sequencing workflows.

The acquisition date fair value of the consideration transferred for iGenomX was approximately $27.3 million consisting of a combination of cash totaling $0.5 million and 237,409 shares of the Company's common stock valued at $26.8 million based on the Company's closing stock price on June 14, 2021 and contingent consideration of up to 48,478 shares valued at $5.5 million based on the Company's closing stock price on June 14, 2021 and indemnity holdback of up to 43,662 shares valued at $4.9 million based on the Company's closing stock price on June 14, 2021. The contingent consideration is subject to the completion of certain transition milestones, which are expected to be entirely satisfied. The contingent consideration becomes payable between six and twelve months from the acquisition date and will be settled in shares of the Company's common stock, subject to completion of the transition milestones. The Company maintains an indemnity holdback for the purposes of providing security against any adjustment to the amounts at closing. The indemnity holdback period extends for 18 months from the anniversary of the closing date.

This acquisition has been accounted for using the acquisition method of accounting in accordance with the business combination guidance in FASB ASC 805. Under the acquisition accounting method, the total estimated purchase price was allocated to the tangible and intangible assets acquired and liabilities assumed based on their relative fair values. The excess of the purchase price over the net tangible and intangible assets acquired and liabilities assumed has been recorded as goodwill. Management's estimate of the fair values of the acquired intangible assets at June 14, 2021 is preliminary and subject to change and is based on established and accepted valuation techniques performed with the assistance of third-party valuation specialists. Additional information, which existed as of the acquisition date but is yet unknown to the Company, may become known to the Company during the remainder of the measurement period, which will not exceed twelve months from the acquisition date. Changes to amounts will be recorded as adjustments to the provisional amounts recognized as of the acquisition date and may result in a corresponding adjustment to goodwill in the period in which new information becomes available. The goodwill that arose from the acquisition consists of synergies expected from integrating iGenomX into the Company's operations and customer base. The goodwill recognized is not expected to be deductible for income tax purposes. The goodwill acquired from the iGenomX transaction was assigned to the Company's only reportable and operating segment business activity, which is manufacturing of synthetic DNA using its semiconductor-based silicon platform.

The estimated fair value of the consideration as of the acquisition date was approximately $37.7 million.

The following table summarizes the preliminary fair value amounts of the assets acquired and liabilities assumed as of the acquisition date, as well as the purchase consideration:

(in thousands)	June 14, 2021
Assets acquired	
Cash and cash equivalents	$ 7
Accounts receivable	37
Inventories	14
Intangible assets	18,410
Goodwill	21,538
Liabilities assumed	
Accounts payable	57
Accrued expenses	44
Deferred tax liability	2,252
Fair value of assets acquired and liabilities assumed	$ 37,653
Consideration transferred	
Cash	$ 490
Company common stock	26,772
Contingent consideration	5,467
Indemnity holdback	4,924
Fair value of purchase consideration	$ 37,653

The following table summarizes the preliminary estimate of the intangible assets as of the acquisition date:

(in thousands, except for years)	Estimated Weighted Average Useful Lives in Years	Estimated Fair Value
Developed technology	17	$ 17,900
Customer relationships	1.5	510
Estimated fair value of acquired intangible assets		$ 18,410

The Company estimated the fair value of the developed technology intangible asset using a discounted cash flow model. Significant judgment was exercised in determining the fair value of the developed technology intangible assets acquired, which included estimates and assumptions related to the projected revenues (specifically volume of sales), discount rate, and technology obsolescence curve. The Company estimated the fair value of the customer relationships intangible asset using a cost approach. These fair value measurements were based on significant inputs not observable in the market and thus represent a Level 3 measurement. Key assumptions include the level and timing of expected future cash flows, conditions and demands specific to each intangible asset over its remaining useful life, and discount rates, the Company believes to be consistent with the inherent risks associated with each type of asset, which was approximately 8.5%. The fair value of these intangible assets is primarily affected by the projected revenues, gross margins, operating expenses, the technology obsolescence curve, and the anticipated timing of the projected income associated with each intangible asset coupled with the discount rates used to derive their estimated present values. The Company believes the level and timing of expected future cash flows appropriately reflects market participant assumptions.

The Company has included the financial results of iGenomX in its consolidated financial statements from the date of acquisition, which were not material. The Company incurred transaction costs related to the acquisition of $0.8 million, which were recognized as an expense on the consolidated statements of operations and comprehensive loss for the year ended September 30, 2021.

The estimated fair value of the contingent consideration and indemnity holdback decreased from $10.4 million as of June 14, 2021 to $9.9 million as of September 30, 2021. For the year ended September 30, 2021, the Company recognized a gain of $0.5 million as change in fair value of acquisition consideration in its consolidated statement of operations due to the change in fair value of such liabilities, as a result of the change in the Company’s stock price as of September 30, 2021.

The post-combination effect from net deferred tax liability assumed from the iGenomX acquisition also caused a release of the Company’s income tax valuation allowance. The release resulted in an income tax benefit of $2.0 million.

The following pro forma financial information presents the combined results of operations for the Company and iGenomX as if the iGenomX acquisition had occurred on October 1, 2019. The pro forma financial information has been prepared for comparative purposes only and does not purport to be indicative of the actual operating results that would have been recorded had the iGenomX acquisition actually taken place on October 1, 2019 and should not be taken as indicative of future consolidated operating results. Additionally, the pro forma financial results do not include any anticipated synergies or other expected benefits from the iGenomX acquisition.

	Year ended September 30,	
(in thousands)	**2021**	**2020**
Revenues	$ 132,599	$ 90,650
Net loss attributable to common stockholders	(153,007)	(141,054)

16. Subsequent events

Revelar Biotherapeutics, Inc.

On November 1, 2021, the Company contributed certain assets and licensed certain intellectual property rights to the newly formed Revelar Biotherapeutics, Inc. (“Revelar”), an independently operated, new biotechnology company to develop and commercialize an antibody, discovered and optimized by Twist Biopharma, a division of the Company, that neutralizes all known variants of concern of the SARS-CoV-2 virus in preclinical studies. The Company granted a license to Revelar for the exclusive development of an antibody lead along with a series of back up compounds for the potential treatment of SARS-CoV-2. The Company is eligible to receive success-based milestone payments totaling over $100.0 million for the achievement of key development, regulatory and commercial milestones, as well as mid-single digit royalties on any future net sales. The Company’s receipt of such payments, if any, will depend on Revelar’s ability to successfully develop and commercialize compounds, obtain and maintain necessary regulatory approvals, complete clinical site initiation and finalize clinical trial agreements, none of which can be assured. In addition, Revelar may license up to five additional antibody therapeutics over the next four years, each of which will be subject to additional upfront, milestone and royalty payments to the Company. The Company committed to invest up to $10.0 million in seed funding based on Revelar’s progress in the development of the lead antibody and the potential licensing of additional antibody therapeutics, of which the Company has invested $5.0 million in a simple agreement for future equity (“SAFE”) as of the issuance of these consolidated financial statements. In exchange assignment of certain contractual rights and the license to the antibody, and its back-up compounds, the Company received stock of Revelar amounting to an ownership percentage as of the date of these financial statements of 49.80%, excluding shares and options reserved for future stock awards and further excluding shares that Revelar may issue to the Company upon conversion of its SAFEs.

AbX Biologics, Inc. Business Acquisition

On November 19, 2021, the Company entered into a definitive agreement to acquire AbX Biologics, Inc. (“Abveris”), a privately-held company providing in vivo antibody discovery services. Abveris offers animal-based antibody discovery services using its proprietary DiversimAb and DivergimAb mouse models, which the Company can humanize using its antibody optimization solution. In addition, Abveris provides antibody screening for its customers. The purchase consideration payable at the closing consists of up to $140.0 million of the Company’s common stock which is subject to customary adjustments for cash, net working capital, outstanding indebtedness and unpaid transaction expenses, plus approximately $10.0 million in cash consideration. The number of shares will be determined based upon the average closing price of the Company’s common stock, subject to the provisions of the agreement. In addition, the contingent purchase consideration consists of up to $40.0 million of the Company’s common stock contingent on and subject to Abveris achieving a revenue target for the calendar year 2022. The closing is expected to occur on December 1, 2021, subject to satisfaction of specified conditions.

* * * * *

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 disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, are designed to ensure that information required to be disclosed in the reports that we file or submit under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in the rules and forms of the Securities and Exchange Commission and to ensure that such information required to be disclosed is accumulated and communicated to management, including our principal executive and financial officers, as appropriate to allow timely decisions regarding required disclosure.

The Chief Executive Officer (CEO) and the Chief Financial Officer (CFO), with assistance from other members of management, have evaluated the effectiveness of our disclosure controls and procedures as of September 30, 2021 and, based on their evaluation, the CEO and CFO have concluded that the disclosure controls and procedures were not effective as of such date due to the material weaknesses in internal control over financial reporting described in "Management's Annual Report on Internal Control Over Financial Reporting" below.

In light of the material weaknesses described below, the Company performed additional analysis and other post-closing procedures to determine its consolidated financial statements are prepared in accordance with generally accepted accounting principles. Accordingly, management concluded that the financial statements included in this report fairly present in all material respects the Company's financial condition, results of operations and cash flows for the periods presented.

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 is defined in Exchange Act Rules 13a-15(f) and 15d-15(f). Our internal control over financial reporting is a framework designed under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, and effected by our board of directors, management, and other personnel, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of our financial statements for external purposes in accordance with US GAAP.

Because of the inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

As of September 30, 2021, our management conducted an evaluation of the effectiveness of our internal control over financial reporting based on the criteria for effective internal control over financial reporting established by the Committee of Sponsoring Organization of the Treadway Commission (COSO) in Internal Control – Integrated Framework (2013). Based on its assessment, management has concluded that our internal control over financial reporting was not effective as of September 30, 2021, due to the material weaknesses described below.

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

We identified the following material weaknesses in our internal control over financial reporting as of September 30, 2021:

- We did not appropriately design and maintain effective segregation of duties controls to timely detect and independently review instances where individuals with access to post a journal entry may also have edited or created the journal entry;
- We did not appropriately design and maintain effective controls relating to the accuracy and occurrence of our accounting for revenues, specifically to ensure the accuracy of edits to customer order entry data, including price and quantity, and appropriate segregation of duties during the order entry and revenue processes; and
- We did not design and maintain effective controls over certain information technology general controls (ITGCs) for information systems that are relevant to the preparation of our financial statements. Specifically, we did not design and

maintain user access controls to ensure appropriate segregation of duties and that adequately restrict user access to certain financial applications and data to appropriate Company personnel. These IT deficiencies, when aggregated, could impact maintaining effective segregation of duties that could result in misstatements potentially impacting all financial statement accounts and disclosures that would not be prevented or detected. Accordingly, management has determined these deficiencies in the aggregate constitute a material weakness.

These control deficiencies did not result in a misstatement to the consolidated financial statements; however, they could result in misstatements of account balances or disclosures that would result in a material misstatement to the annual or interim consolidated financial statements that would not have been prevented or detected. Accordingly, management has determined that these control deficiencies constitute material weaknesses.

Because of these material weaknesses, our management has concluded that our internal control over financial reporting was not effective as of September 30, 2021, based on the criteria in Internal Control Integrated Framework (2013) issued by the COSO.

The effectiveness of our internal control over financial reporting as of September 30, 2021 has been audited by PricewaterhouseCoopers LLP, an independent registered public accounting firm, as stated in their report included in Part II, Item 8 of this Annual Report on Form 10-K.

Remediation of Material Weaknesses

We have devoted substantial effort to remediating the deficiencies and continued to perform a risk assessment process to identify, design, implement, and re-evaluate the control activities. Furthermore, building on our efforts during 2020, with the oversight of the Audit Committee of our board of directors, and have continued throughout 2021 to dedicate significant resources to take steps to remediate the material weaknesses identified in our internal control over financial reporting.

The following remediation efforts were completed in 2021:

- Enhanced our Corporate Governance Protocols and Entity Level Controls.
- During the third quarter, we hired a Chief Accounting Officer who brings significant industry experience and depth of knowledge in technical accounting matters and internal controls commensurate with our public company reporting requirements.
- Enhanced our manual controls related to the monitoring of journal entry posting rights and responsibilities to ensure appropriate segregation of duties.
- Enhanced the design and performance of order entry system application controls to enforce post-production sales order change workflows.
- Performed a control environment and design review making changes to the control environment by redesigning certain ITGC controls to be aligned with the Control Objectives for Information Technologies (“COBIT”) framework and designing additional controls to ensure the risks relating to user access and change management are addressed.

We are continuing to enhance our overall control environment and are devoting substantial effort by enhancing our manual or automated processes to remediate the identified material weaknesses through the remediation efforts outlined in the following:

- ***Financial Reporting:*** We are continuing analysis to identify high-risk SAP transaction codes that could potentially allow segregation of duties (“SOD”) conflict and through either automated or manual processes align role-based access provisioning to eliminate SOD posting conflicts.
- ***Revenue Processes:*** We are designing and implementing processes and controls to ensure that any edits to customer order entry data, including price and quantity, are appropriately reviewed. Additionally, we are redesigning our segregation of duties framework within the revenue cycle to ensure appropriate segregation of duties throughout the order entry and revenue processes.
- ***IT General Controls (ITGC):*** We are designing and implementing improved processes and controls for requesting, authorizing, and reviewing user access to key information systems which impact our financial reporting, including identifying access to roles where manual business process controls may be required. This implementation will include

the addition of new preventative control activities associated with user access provisioning within our key applications which impact our financial reporting, as well as certain detective controls which review user access and activity logs.

Our management is committed to remediating identified control deficiencies (including both those that rise to the level of a material weakness and those that do not), fostering continuous improvement in our internal controls and enhancing our overall control environment. Our management believes that these remediation actions, when fully implemented, will remediate the material weaknesses we have identified and strengthen our internal control over financial reporting. We are committed to improving our internal control processes and intend to continue to review and improve our financial reporting controls and procedures. As we continue to evaluate and work to improve our internal control over financial reporting, we may take additional measures to address control deficiencies, or we may modify, or in appropriate circumstances not complete, certain of the remediation measures described above. These material weaknesses will not be considered remediated until the applicable controls operate for a sufficient period of time and management has concluded, through testing, that the enhanced controls are operating effectively.

Changes in Internal Control over Financial Reporting

There were no changes during the quarter ended September 30, 2021 in our internal control over financial reporting that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. ***Other information***

None.

PART III

Item 10. ***Directors, executive officers and corporate governance***

Incorporated by reference from our Definitive Proxy Statement to be filed in connection with the 2022 Annual Meeting of Stockholders.

Code of Conduct

We have adopted the Twist Bioscience Corporation Code of Business Conduct and Ethics, or Code of Ethics, with which every person, including executive officers, who works for Twist and every member of our board of directors is expected to comply. The full text of our Code of Ethics is posted on the investor relations section of our website at www.twistbioscience.com. If any substantive amendments are made to the Code of Ethics or any waiver is granted, we intend to satisfy the disclosure requirement under Item 5.05 of Form 8-K regarding such amendment to, or waiver from, a provision of this Code of Ethics by posting such information on our website, at the address and location specified above, or as otherwise required by the Nasdaq Global Select Market.

Item 11. ***Executive compensation***

Incorporated by reference from our Definitive Proxy Statement to be filed in connection with the 2022 Annual Meeting of Stockholders.

Item 12. ***Security ownership of certain beneficial owners and management and related stockholder matters***

Incorporated by reference from our Definitive Proxy Statement to be filed in connection with the 2022 Annual Meeting of Stockholders.

Item 13. ***Certain relationships and related transactions, and director independence***

Incorporated by reference from our Definitive Proxy Statement to be filed in connection with the 2022 Annual Meeting of Stockholders.

Item 14. ***Principal accountant fees and services***

Incorporated by reference from our Definitive Proxy Statement to be filed in connection with the 2022 Annual Meeting of Stockholders.

PART IV

Item 15. ***Exhibits, financial statement schedules***

Documents filed as part of this report are as follows:

(a) Consolidated Financial Statements

Our Consolidated Financial Statements are included in the "Index to Consolidated Financial Statements" under Part II, Item 8 and filed as part of this Annual Report on Form 10-K.

(b) Consolidated Financial Statement Schedules

All financial statement schedules are omitted because the information called for is not required or is shown either in the consolidated financial statements or in the notes thereto.

(c) Exhibits

Set forth below is a list of exhibits that are being filed or incorporated by reference into this Annual Report on Form 10-K:

Exhibit Number	Description	Filed / Furnished / Incorporated by Reference from Form	Incorporated by Reference from Exhibit Number	Date Filed
3.1	Amended and Restated Certificate of Incorporation	8-K	3.1	11/7/2018
3.2	Amended and Restated Bylaws	8-K	3.2	11/7/2018
4.1	Form of common stock certificate	S-1/A	4.1	10/17/2018
4.2	Amended and Restated Registration Rights Agreement by and among Twist Bioscience Corporation and certain holders of its capital stock dated March 19, 2018	S-1/A	4.3	10/17/2018
4.3	Warrant to Purchase Stock by and between Twist Bioscience Corporation and Silicon Valley Bank, dated March 28. 2016.	S-1	4.7	10/3/2018
4.4	Description of Common Stock	10-K	4.5	11/20/2020
10.1+	2013 Stock Plan and forms of agreement thereunder	S-1	10.1	10/3/2018
10.2+	2018 Equity Incentive Plan and forms of agreement thereunder	S-1/A	10.2	10/17/2018
10.3+	2018 Employee Stock Purchase Plan	S-1/A	10.3	10/17/2018
10.4+	Executive Incentive Bonus Plan	S-1	10.4	10/3/2018

Exhibit Number	Description	Filed / Furnished / Incorporated by Reference from Form	Incorporated by Reference from Exhibit Number	Date Filed
10.5+	Form of Indemnification Agreement between Twist Bioscience Corporation and each of its Officers and Directors	S-1/A	10.8	10/17/2018
10.6	Fourth Amended and Restated Loan and Security Agreement by and between Twist Bioscience Corporation, Silicon Valley Bank and certain other co-borrowers, dated September 6. 2017	S-1	10.9	10/3/2018
10.7	Lease Agreement by and between Twist Bioscience Corporation and ARE-San Francisco No. 32. LLC dated March 21, 2018	S-1	10.11	10/3/2018
10.7.1	First Amendment to Lease by and between Twist Bioscience Corporation and ARE-San Francisco No. 32, LLC, dated March 21, 2019	10-Q	10.2	5/1/2019
10.8*	Lease Agreement by and between Twist Bioscience Corporation and PWII Owner, LLC, dated December 18, 2020	8-K	10.1	12/22/2020
10.8.1*	First Amendment to Lease between Twist Bioscience Corporation and PWII Owner, LLC, dated April 13, 2021	8-K	10.1	4/16/2021
10.9†	End User Supply Agreement by and between Twist Bioscience Corporation and FUJIFILM Dimatix, Inc., dated November 5, 2015	S-1	10.14	10/3/2018
21.1	List of subsidiaries of the Registrant	Filed herewith		
23.1	Consent of PricewaterhouseCoopers, Independent Registered Public Accounting Firm	Filed herewith		
31.1	Certification pursuant to Section 302 of the Sarbanes-Oxley Act of 2002, Rule 13(a)-14(a)/15d-14(a), by President and Chief Executive Officer.	Filed herewith		
31.2	Certification pursuant to Section 302 of the Sarbanes-Oxley Act of 2002, Rule 13(a)-14(a)/15d-14(a), by Chief Financial Officer.	Filed herewith		
32.1	Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, by President and Chief Executive Officer.	Furnished herewith		
32.2	Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, by Chief Financial Officer.	Furnished herewith		
101.INS	XBRL Instance Document	Filed herewith		

Exhibit Number	Description	Filed / Furnished / Incorporated by Reference from Form	Incorporated by Reference from Exhibit Number	Date Filed
101.SCH	XBRL Taxonomy Extension Schema Document	Filed herewith		
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document	Filed herewith		
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document	Filed herewith		
101.LAB	XBRL Taxonomy Extension Label Linkbase Document	Filed herewith		
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document	Filed herewith		
104	Cover page from the Company's Annual Report on Form 10-K for the year ended September 30, 2021, formatted in Inline XBRL			

+ Indicates a management contract or compensatory plan.

* Registrant has omitted schedules and exhibits pursuant to Item 601(a)(5) of Regulation S-K. The Registrant agrees to furnish supplementally a copy of the omitted schedules and exhibits to the SEC upon request.

† Portions of this exhibit (indicated by asterisks) have been omitted pursuant to a request for confidential treatment that was separately filed with the SEC.

Item 16. ***Form of 10-K summary***

Not applicable

SIGNATURES

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

November 22, 2021

Twist Bioscience Corporation

By: /s/ Emily M. Leproust
Emily M. Leproust
President and Chief Executive Officer

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

Signature	Title	Date
/s/ Emily M. Leproust Emily M. Leproust	President, Chief Executive Officer and Chair of the Board of Directors (principal executive officer)	November 22, 2021
/s/ James M. Thorburn James M. Thorburn	Chief Financial Officer (principal financial officer)	November 22, 2021
/s/ Kevin B. Yankton Kevin B. Yankton	Chief Accounting Officer (principal accounting officer)	November 22, 2021
/s/ William Banyai William Banyai	Director	November 22, 2021
/s/ Nicolas Barthelemy Nicolas Barthelemy	Director	November 22, 2021
/s/ Nelson C. Chan Nelson C. Chan	Director	November 22, 2021
/s/ Robert Chess Robert Chess	Director	November 22, 2021
/s/ Keith Crandell Keith Crandell	Director	November 22, 2021
/s/ Jan Johannessen Jan Johannessen	Director	November 22, 2021
/s/ Xiaoying Mai Xiaoying Mai	Director	November 22, 2021
/s/ Robert Ragusa Robert Ragusa	Director	November 22, 2021
/s/ Melissa Starovasnik Melissa Starovasnik	Director	November 22, 2021

Exhibit 21.1

Twist Bioscience Corporation Subsidiaries

Twist Bioscience Corporation has the following subsidiaries:

1. Twist Bioscience Worldwide, a Cayman Islands exempted company.
2. Genome Compiler Corporation, a Delaware corporation, which itself owns Twist Bioscience Israel Ltd. (formerly "Genome Compiler Israel Ltd."), an Israeli company.
3. Twist Bio Computing, LLC, a Delaware limited liability company.
4. Twist Pharmaceutical Solutions, LLC, a Delaware limited liability company.
5. Twist Bioscience Singapore PTE. LTD., a Singapore company, which itself owns Twist Bioscience (China) LLC, a Chinese limited liability company.
6. iGenomX International Genomics, LLC, a Delaware limited liability company.
7. Twist Bioscience Netherlands B.V., a private limited company incorporated under Dutch law, which itself owns each of Twist Bioscience UK Limited, a private limited company incorporated under the laws of England and Wales and Twist Bioscience Germany GmbH, a German limited liability company.

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the incorporation by reference in the Registration Statements on Form S-3 (Nos. 333-238906 and 333-234538) and Form S-8 (Nos. 333-236373, 333-228547, 333-228123, and 333-258639) of Twist Bioscience Corporation of our report dated November 22, 2021 relating to the financial statements and the effectiveness of internal control over financial reporting, which appears in this Form 10-K.

/s/ PricewaterhouseCoopers LLP

San Jose, California
November 22, 2021

Exhibit 31.1

CERTIFICATION OF CHIEF EXECUTIVE OFFICER
PURSUANT TO
RULES 13A-14(A) AND 15D-14(A) UNDER THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Emily M. Leproust, certify that:

1. I have reviewed this Annual Report on Form 10-K of Twist Bioscience Corporation;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize, and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 22, 2021

By: /s/ Emily M. Leproust
Emily M. Leproust
President & Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION OF CHIEF FINANCIAL OFFICER
PURSUANT TO
RULES 13A-14(A) AND 15D-14(A) UNDER THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, James M. Thorburn, certify that:

1. I have reviewed this Annual Report on Form 10-K of Twist Bioscience Corporation;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize, and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 22, 2021

By: /s/ James M. Thorburn
James M. Thorburn
Chief Financial Officer
(Principal Financial Officer)

Exhibit 32.1

CERTIFICATION OF
CHIEF EXECUTIVE OFFICER
PURSUANT TO
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

I, Emily M. Leproust, certify pursuant to Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, (the "Exchange Act") and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350), as adopted pursuant to §906 of the Sarbanes-Oxley Act of 2002, that the Annual Report on Form 10-K of Twist Bioscience Corporation for the fiscal year ended September 30, 2021, fully complies with the requirements of Section 13(a) or 15(d) of the Exchange Act and that the information contained in such Annual Report on Form 10-K fairly presents, in all material respects, the financial condition and result of operations of Twist Bioscience Corporation.

Date: November 22, 2021

By: /s/ Emily M. Leproust
Emily M. Leproust
President & Chief Executive Officer
(Principal Executive Officer)

Exhibit 32.2

CERTIFICATION OF
CHIEF FINANCIAL OFFICER
PURSUANT TO
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

I, James M. Thorburn, certify pursuant to Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, (the "Exchange Act") and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350), as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that the Annual Report on Form 10-K of Twist Bioscience Corporation for the fiscal year ended September 30, 2021, fully complies with the requirements of Section 13(a) or 15(d) of the Exchange Act and that the information contained in such Annual Report on Form 10-K fairly presents, in all material respects, the financial condition and result of operations of Twist Bioscience Corporation.

Date: November 22, 2021

By: /s/ James M. Thorburn
James M. Thorburn
Chief Financial Officer
(Principal Financial Officer)