# **UNITED STATES** SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

# **FORM 10-K**

(Mark One)

 $\mathbf{X}$ ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended December 31, 2022

OR

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

For the transition period from

Commission file number 001-40497

to



(Exact name of registrant as specified in its charter)

Delaware (State or other jurisdiction of

incorporation or organization)

10431 Wateridge Circle, Suite 150 San Diego, CA (Address of Principal Executive Offices)

(I.R.S. Employer **Identification No.)** 

(Zip Code)

(858) 228-4115

Registrant's telephone number, including area code

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

Title of each class Common Stock, \$0.0001 par value per share

TBIO

Name of each exchange on which registered Nasdaq Global Select Market

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

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

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 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 and posted on its corporate web site, if any, every Interactive Data File required to be submitted and posted 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 and post such files). Yes 🗵 No 🗌

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

Accelerated filer
Smaller reporting company
Emerging growth company

|X|

 $\times$ 

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

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

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

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

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes  $\Box$  No  $\boxtimes$ 

The aggregate market value of voting stock held by non-affiliates of the Registrant on June 30, 2022, based on the closing price of \$1.80 for shares of the Registrant's common stock as reported by the Nasdaq Global Select Market, was approximately \$16.8 million. In determining the market value of non-affiliate common stock, shares of common stock beneficially owned by each executive officer, director, and holder of more than 5% of our 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 registrant had outstanding 29,647,091 shares of common stock as of February 28, 2023.

#### DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive Proxy Statement relating to the 2023 Annual Meeting of Stockholders are incorporated herein by reference in Part III of this Annual Report on Form 10-K to the extent stated herein. The proxy statement will be filed with the Securities and Exchange Commission within 120 days of the registrant's fiscal year ended December 31, 2022.

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# TABLE OF CONTENTS

		Page
Part I		
Item 1.	Business	4
Item 1A.	Risk Factors	32
Item 1B.	Unresolved Staff Comments	65
Item 2.	Properties	66
Item 3.	Legal Proceedings	66
Item 4.	Mine Safety Disclosures	66
Part II		
Item 5.	Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities	67
Item 6.	[Reserved]	67
Item 7.	Management's Discussion and Analysis of Financial Condition and Results of Operations	68
Item 7A.	Quantitative and Qualitative Disclosures About Market Risk	83
Item 8.	Financial Statements and Supplementary Data	F-1
Item 9.	Changes in and Disagreements with Accountants on Accounting and Financial Disclosure	100
Item 9A.	Controls and Procedures	100
Item 9B.	Other Information	100
Item 9C.	Disclosure Regarding Foreign Jurisdictions that Prevent Inspections	100
Part III		
Item 10.	Directors, Executive Officers and Corporate Governance	101
Item 11.	Executive Compensation	101
Item 12.	Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters	101
Item 13.	Certain Relationships and Related Party Transactions, and Director Independence	101
Item 14.	Principal Accounting Fees and Services	101
Item 15.	Exhibits, Financial Statement Schedules	102
Item 16.	Form 10-K Summary	104
Signatures		105

#### SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K for the fiscal year ended December 31, 2022 (Annual Report), contains forward-looking statements that are based on our management's beliefs and assumptions and on information currently available to our management. All statements other than statements of historical facts contained in Annual Report, including statements regarding our future results of operations and financial position, business strategy, development plans, expected research and development costs, regulatory strategy, timing, and likelihood of success, as well as plans and objectives of management for future operations, are forward-looking statements. In some cases, you can identify forward-looking statements by terms such as "aim," "anticipate," "assume," "believe," "contemplate," "continue," "could," "due," "estimate," "expect," "goal" "intend," "may," "objective" "plan," "predict," "potential," "project," "seek," "should," "target," "will," "would," and other similar expressions that are predictions of or indicate future events and future trends, or the negative of these terms or other comparable terminology. Forward-looking statements contained in this Annual Report include, but are not limited to, statements about:

- estimates of the synthetic biology market, market growth, and new market expansion;
- our future revenue, expenses, inflationary pressures, capital requirements and our needs for additional financing;
- our expectations regarding the rate and degree of market acceptance of our BioXp systems, BioXp kits and benchtop reagents;
- the ability of our products to facilitate the *screen-design-build-test* paradigm of synthetic biology;
- the size and growth of the synthetic biology market and competitive companies and technologies and our industry;
- our ability to manage and grow our business;
- our ability to develop and successfully commercialize new products;
- our ability to establish and maintain intellectual property protection for our products or avoid or defend claims of infringement;
- our ability to effectively manufacture our products;
- the performance of third-party manufacturers and suppliers and our ability to qualify second-source suppliers;
- the potential effects of government regulation and our compliance with these regulations;
- our ability to hire and retain key personnel and to manage our future growth effectively;
- our ability to obtain additional financing in future offerings;
- the volatility of the trading price of our common stock;
- the impact of local, regional, and national and international economic conditions and events;
- the impact of COVID-19 on our business;
- our expectations about market trends; and
- other risks and uncertainties, including those listed in the section titled "Risk Factors."

We have based these forward-looking statements largely on our current expectations and projections about our business, the industry in which we operate and financial trends that we believe may affect our business, financial condition, results of operations and prospects, and these forward-looking statements are not guarantees of future performance or development. These forward-looking statements speak only as of the date of this Annual Report and are subject to a number of risks, uncertainties and assumptions described in the section titled "Risk Factors" and elsewhere in this Annual Report. Because forward-looking statements are inherently subject to risks and uncertainties, some of which cannot be predicted or quantified, you should not rely on these forward-looking statements as predictions of future events. The events and circumstances reflected in our forward-looking statements may not be achieved or occur and actual results could differ materially from those projected in the forward-looking statements. Except as required by applicable law, we do not plan to publicly update or revise any forward-looking statements contained herein until after we file this Annual Report, whether as a result of any new information, future events or otherwise.

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

We use the Telesis Bio logo, BioXp, Gibson Assembly, RapidAMP, Vmax, CleanCap and other marks as trademarks in the United States and other countries. This Annual Report contains references to our trademarks and service marks and to those belonging to other entities. Solely for convenience, trademarks and trade names referred to in this Annual Report, including logos, artwork and other visual displays, may appear without the ® or TM symbols, but such references are not intended to indicate in any way that we will not assert, to the fullest extent under applicable law, our rights or the rights of the applicable licensor to these trademarks and trade names. We do not intend our use or display of other entities' trade names, trademarks or service marks to imply a relationship with, or endorsement or sponsorship of us by any other entity.

# Part I BUSINESS

#### Overview

We are a leader in automated multi-omic and synthetic biology solutions focused on providing applications to enable researchers to rapidly, accurately and reproducibly build or "write" high-quality synthetic DNA and mRNA and short oligonucleotides, such as CRISPR guides, that are ready to use in many downstream synthetic biology enabled markets. Our solutions address the bottlenecks across the multi-step process of building DNA and mRNA, as well as the significant limitations of existing solutions that prevent the rapid building of high-quality DNA and mRNA at a useable scale. A key part of our on-market solution is our BioXp systems, which are end-to-end automated workstations that fit on the benchtop or in the lab and are broadly accessible due to their ease-of-use and hands-free automation. We believe our BioXp systems and future product offerings can democratize synthetic biology by simplifying the process of building DNA and mRNA, preparing samples for next generation sequencing (NGS) and building on-demand CRISPR guides for gene editing, thereby accelerating the discovery, development and production of novel high-value products, including antibody-based biologics, mRNA-based vaccines and therapeutics and precision medicines.

Synthetic biology and NGS involve the reading and writing of biological components within multiple markets, including:

- healthcare, to discover, develop and produce novel therapeutics and vaccines;
- agriculture, to improve crop yields and create novel food sources;
- technology, to potentially store and retrieve digital data using DNA; and
- various consumer markets.

Synthetic biology is enabled by numerous technologies that facilitate the *screen-design-build-test* paradigm of new or modified biological components. Any inefficiency across these four phases can create a bottleneck hindering the rapid iteration within product development.

Within the initial screening phase, multiple technologies are utilized to screen targeted material, one of those is NGS. If cost is prohibitive or workflows are too cumbersome, scientists cannot screen the number of target materials. If errors in manual work or a lack of resources exists, all downstream work in the build phase will be limited in scope.

In the build phase, the process of writing synthetic DNA or mRNA for an improved biological function is characterized by multiple, complex processes that involve numerous time-consuming and technical steps, including DNA synthesis, DNA assembly, DNA cloning, and DNA scale-up in *E. coli* with multiple DNA purification steps in between. In the case of mRNA, the process continues with additional technical steps including mRNA synthesis, mRNA modifications at each end and multiple mRNA purification steps. Currently, these processes are carried out in laboratories by highly skilled researchers using multiple kits, each designed to perform one or more of the technical steps. Whether in-house or through a contract research organization (CRO), existing solutions for building synthetic DNA and mRNA have deficiencies, for instance:

- inconsistent levels of fidelity of DNA and mRNA fragments reducing overall yields of usable material;
- inability to construct stretches of DNA and mRNA sequence that have particular features;
- inability to construct DNA and mRNA sequences above a certain size; and
- inability to produce the end product in sufficient quantities for downstream applications.

All of these limitations produce bottlenecks across the build phase, which have significantly hindered the ability of synthetic biology to deliver on its full potential.

We develop solutions to address the significant unmet need in the market for an approach that can automate, integrate, optimize and standardize the process for building synthetic DNA and mRNA. Our on-market and our planned solutions are comprised of the following:

- *BioXp 3250 system*: which we believe are the first commercially available push-button, walkaway, end-to-end automated workstations that empower researchers to go from a digital DNA sequence to endpoint-ready synthetic DNA in as few as 8 hours and mRNA in less than 24 hours, exclusive of shipment time, with onboard NGS library preparation;
- *BioXp 9600 system*: a walkaway, higher throughput, next generation end-to-end automated workstation that empowers researchers to go from a digital DNA sequence to endpoint-ready synthetic DNA in as few as 8 hours and mRNA in less than 24 hours, exclusive of shipment time, with onboard NGS preparation

- *BioXp DBC:* will be our first entry into delivering on-demand enzymatic DNA synthesis with design-to-endpoint-ready synthetic RNA in as few as 24 hours
- *BioXp portal*: a user-friendly online portal that offers an intuitive guided workflow and design tools for building new DNA sequences and assembling them into vector(s) of choice;
- *BioXp De Novo kits*: will contain all the necessary building blocks and reagents, including our proprietary Gibson Assembly branded reagents, for specific synthetic biology workflow applications;
- BioXp Select kits: offer customers the ability to use non-Telesis Bio DNA while using the BioXp system to perform synthetic biology workflow applications such as cloning, mRNA generation from plasmid and cell free amplification;
- BioXp Next Generation Sequencing kits: will contain all the necessary reagents to go from DNA or RNA to a sequencerready library;
- *BioXp DBC kits:* will contain all the necessary building blocks to go from a stock kit DNA to CRISPR guides in a single run;
- Benchtop reagents: contain all the reagents necessary to proceed with a specific synthetic biology workflow on the benchtop using products generated on the BioXp system; and
- Short Oligo Ligation Assembly (SOLA) enzymatic DNA synthesis (EDS): is a sustainable, scalable, and cost-effective
  approach designed to significantly reduce timelines for constructing synthetic DNA, RNA, and proteins compared to
  traditional chemical synthesis, paving the way for more efficient and effective development of mRNA-based vaccines,
  diagnostics, therapeutics, and personalized medicines.

We believe that our integrated BioXp systems, BioXp kits and the DBC platform, when launched, will represent the industry's leading multi-omic molecular biology workflow automation solution and provide us with a first mover advantage in the rapidly growing synthetic biology market. As part of our continuing effort to improve the processes of synthetic biology, we are currently developing next-generation BioXp systems and BioXp kits with the goal of transforming rapid demand-response workflows in synthetic biology and consolidating supply chains and enabling global distributed manufacturing for discovery, pre-clinical and clinical applications.

Our vision is to empower researchers with the tools to build synthetic biology in their laboratory, without constraints. Our BioXp systems are intended to address the needs of the synthetic biology customer by providing an unmatched capability to rapidly synthesize high-quality DNA and mRNA. With future system releases and extensions, we plan to address the continuum of research needs across the central dogma of molecular biology by enabling cell-free production of high-quality synthetic DNA, mRNA and protein for the discovery, development and manufacturing of enabled products across a wide range of markets. We are strategically focused on providing workflow solutions for markets with high-value enabled products such as those in healthcare and technology.

We currently provide workflow solutions for the following areas:

- synthetic DNA for antibody and protein engineering of biologic drugs;
- synthetic DNA for genome editing;
- synthetic DNA for metabolic pathway engineering;
- immune monitoring;
- synthetic mRNA for infectious disease vaccine discovery and development;
- mRNA-based vaccines for precision medicine; and
- mRNA-based therapeutics.

We are currently developing workflow solutions for the following areas:

- global distributed manufacturing of vaccines; and
- synthetic protein for biologics discovery.

We have placed approximately 200 BioXp systems globally. As of December 31, 2022, our customer base was composed of 190 unique customers and included 105 unique biopharmaceutical companies in the world ranked by 2022 revenue, excluding affiliates of those companies.

## Early Access Collaboration and Licensing Agreement with Pfizer

In December 2021, we entered into a Research Collaboration and License Agreement with Pfizer Inc. (Pfizer) pursuant to which we agreed to collaborate with Pfizer to further develop our novel enzymatic DNA synthesis technology for Pfizer's use in its research and development of mRNA-based vaccines and biotherapies. In December 2022 we achieved, and were paid for, the first technical milestone under that agreement. We are also eligible to receive additional milestone payments based on the achievement of specified development, regulatory and commercialization goals associated with any products developed from the application of our technology developed and licensed under the agreement.

#### Acquisition of EtonBio, Inc.

In November 2021, we completed the acquisition of EtonBio Inc. (Eton), a San Diego-based biotech company specializing in synthetic biology products and services, including DNA sequencing and oligo synthesis, for the global academic research, pharmaceutical and biotechnology industries. Eton utilizes innovative techniques, sustainable practices and exceptional customer service to meet the research community's need for high-quality DNA sequencing and oligo synthesis. Eton also markets DNA prep services and products such as antibodies, peptides and metabolism assay kits.

#### **Industry Overview**

#### **Background on Synthetic Biology**

Synthetic biology is a well-established and rapidly expanding field of science that involves the engineering of biological components such as genes, mRNA, proteins, viruses and living cells starting from a digital DNA sequence, enabling the construction of those macromolecules and organisms with new and improved biological functions. The application of synthetic biology is constantly expanding, and new end markets are emerging, driven by continued innovation, a growing understanding of biology and access to novel research tools. For example, in healthcare, synthetic biology is being used to discover, develop and produce novel DNA-, mRNA-, and protein-based therapeutics and vaccines (e.g., antibody-based biologics, mRNA-based COVID-19 vaccines and personalized cancer therapeutics). In agriculture, synthetic biology is being utilized to improve crop yields and create novel food sources (e.g., plant-based meat products). Similarly, in technology, synthetic biology may lead to the ability to store and retrieve digital data using DNA.

In its March 2022 report, BCC Research estimated that the global synthetic biology market was \$5.9 billion in 2019 and projected that market to grow at a compound annual growth rate (CAGR) for 2021 to 2026 of 28.4%, reaching an estimated market size of \$33.2 billion by 2026. Of this \$33.2 billion market, BCC Research estimated that enabling technologies, such as our workflow solutions, represented an approximate \$2.7 billion market opportunity in 2020, and it is growing at a CAGR of 28.5% to reach a forecast market value of \$12.3 billion in 2026. Additionally, within this market, Transparency Market Research estimated that the *invitro* transcription template market (mRNA production) was \$118 million in 2020 and is growing at a CAGR of 19.8%, reaching an estimated market size of \$332 million by 2025.

Synthetic biology is particularly important in pharmaceuticals, as it allows companies to fully develop opportunity spaces for specific proteins. This is possible because the coding sequence for any particular protein can be mutated randomly and optimized using rapid DNA-synthesis formats. Synthetic biology tools can also be used to develop more efficient production systems for drugs, particularly antibiotics and vaccines. According to the March 2022 BCC Report, the estimated 2020 market for enabling products was worth \$2.7 billion, and it is forecast to grow at a 28.5% annual rate to reach a market value of \$12.3 billion in 2026.

Enabling products' growth is being driven by the use of new gene-editing tools (e.g., CRISPR) for drug discovery and development, as well as the strong demand for DNA sequencing to verify the fidelity of edited DNA constructs.

The synthetic biology market falls into two broad sectors:

- Enabling technologies: The molecular biology methods (e.g., DNA sequencing, DNA synthesis, DNA assembly, molecular cloning, mRNA production, protein synthesis and expression, genome editing, and bioinformatics software for DNA sequence design and analysis) that employ molecular biology components (e.g., oligonucleotides, enzymes, buffers, vectors, and competent cells) to engineer higher value products that have new or improved utility from a DNA sequence "blueprint".
- Enabled products: These are the end products and include, but are not limited to, therapeutics based on principles of antibody and protein engineering of biologic drugs, mRNA-based vaccines, genetic medicines (e.g. DNA and mRNA therapeutics), and sustainable foods and biofuels resulting from the use of synthetic biology, as well as DNA data storage solutions.

According to the BCC Research report, a driver of the rapid growth of the synthetic biology market is the advances in enabling technologies and the downstream benefits being realized in key enabled product markets like healthcare. These advances in enabling technologies have increased market demand for high-value products that can be produced by synthetic biology methods. This in turn

has resulted in a rapid growth of synthetic biology CROs and molecular biology reagent kits, which have been created to serve the higher demand requirements of an evolving synthetic biology market, particularly for drug discovery, agriculture, consumer and industrial products. Scientists increasingly want to build DNA and introduce those molecules into organisms to create cell-based discovery and production systems for new biologics and small-molecule drugs. Research clinicians are recognizing the importance of synthetic biology and beginning to apply the construction of synthetic DNA and mRNA to the development of precision medicines, in the form of mRNA-based cancer vaccines, particularly for immuno-oncology. Pharmaceutical companies have begun integrating synthetic biology approaches in their facilities to develop state-of-the-art vaccines and biologics that are DNA-, mRNA-, and protein-centric. All of these approaches require the ability to make high-quality synthetic DNA comprising entire gene sequences and, in some instances, expressing those genes to make synthetic mRNA and synthetic proteins. With the success of FDA-approved mRNA-based COVID-19 vaccines, it is expected that interest in mRNA-based therapeutics and vaccines utilizing synthetic biology technology will remain strong.

Synthetic biology is enabled by numerous technologies that facilitate highly-iterative experimental design. These technologies permit "reading" of the DNA code of a desired gene, engineering and synthetic construction of biological products using those blueprints, and testing of the constructed products to determine whether they perform in the desired manner. Once a DNA sequence is read, the gene of interest can be built or written from a pool of building blocks using molecular synthesis techniques. In addition, once a gene is read, researchers can redesign the gene to produce new and improved biological functionality, and then build the redesigned gene and analyze its activity in a fully biological system during a test phase. Reading is then used once again to confirm the DNA sequence that provides the desired function of the biological sample that was designed, built and tested. Reading and writing genes opens the door to a new synthetic biology paradigm for iterating on the *screen-design-build-test* phases and creates a powerful and flexible approach to developing a wide variety of enabled products, including mRNA-based vaccines and protein-based drugs. Decades of gene sequencing work and functional genetic studies to understand what genes do have produced a huge cache of content that researchers can use to design new or modified genetic material.

Over the last 20 years, synthetic biology has experienced a transformation, driven by numerous innovations in enabling technologies. The initial breakthrough was DNA sequencing for reading the DNA and beginning to understand DNA coding. However, early sequencing instruments were slow and expensive, creating a bottleneck in the use of genetic sequence data and its application to both additional research and commercial applications. More recently, the advent of high-performance, low-cost next-generation sequencing (NGS) systems has enabled wide adoption, with over 15,000 such systems installed in research labs globally, resulting in an increase in genetic discoveries in humans and a wide range of organisms, including bacteria, plants and insects and animals. These sequencing systems are generating large amounts of information about genetic composition and have led to the creation of private and public databases around the world containing DNA sequences. Recently, advances in computing power, machine learning and computational modeling have enabled biologists to better analyze this increasing amount of genomic information and inform experimental design or engineering of genes, genetic pathways and even complete chromosomes to achieve the desired biological improvement. Given the volume and understanding of DNA sequence content, the bottleneck in synthetic biology has shifted from reading to writing DNA in an effort to facilitate the rapid design of DNA and mRNA for use in the downstream synthetic biology enabled markets.

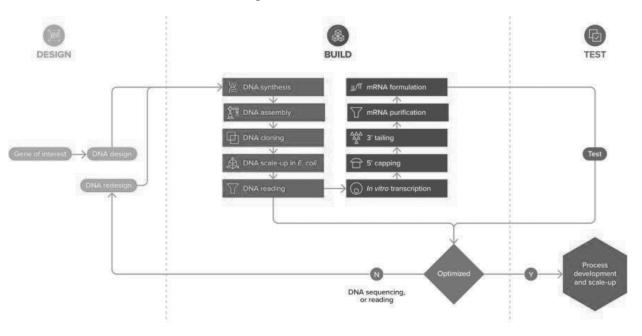
The next critical advancement in the field of synthetic biology was the ability to construct genetic sequences *de novo* from their chemical components via DNA synthesis. This enabled researchers to capitalize on the genetic discoveries and improvements in computational design to build or write engineered DNA. The advancements in enabling technologies for both reading and writing DNA have allowed synthetic biologists to engineer changes in genes, metabolic pathways and organisms with greater ease, precision and scale, resulting in a new paradigm with rapid iteration of product cycles and greater predictability of results. The following graphic illustrates this paradigm.

This new paradigm is characterized by four key steps—*screen, design, build, test*—which are continuously iterated to drive feedback into the design phase for the following iteration until the desired biological result is achieved. With DNA as the software of life, biologists can now write code like software engineers and write genes to perform as desired. The *screen-design-build-test* synthetic biology paradigm begins with the DNA sequencing or reading of a biological sample, providing a "blueprint" for the design phase. The outcome of the design phase is a DNA sequence that is chemically synthesized in the build phase and, as necessary, converted to mRNA or protein. The outcome of the build phase is synthetic DNA, mRNA or protein, which can then be readily assayed for desired function in the test phase.

Under the current paradigm, DNA readers are integrated within the build and test phases to confirm the blueprints are being generated as expected in the build phase for quality control and to identify the DNA sequence of the optimal blueprint discovered in the test phase. If the outcome of the test phase is that further optimization is desired, the process is iterated again, starting at the design phase. This *screen-design-build-test* paradigm highlights the importance and opportunity for products and technologies focused on enhancing the speed and scale of the design phase. This efficiency can be accomplished by placing scalable platform technologies for reading and writing in close proximity.

#### The Build Phase for Synthetic DNA and mRNA

Any inefficiencies across the screen, design, build, or test phase can create a bottleneck in the highly-iterative *screen-design-build-test* paradigm. This especially holds true for the build phase as the process of "writing" synthetic DNA for an improved biological function is characterized by multiple, complex processes that involve numerous time-consuming and technical steps, including (1) DNA synthesis; (2) DNA assembly; (3) DNA cloning; and (4) DNA scale-up in *E. coli*.



# Figure 1: The Build-Phase

### Writing synthetic DNA

- 1. *DNA synthesis*: DNA is made from four molecular building blocks called nucleotides: adenine (A), cytosine (C), guanine (G) and thymine (T). These closely related molecules form long linear chains consisting of thousands or more nucleotides. In the same way that the "zeroes" and "ones" in digital code can instruct a machine or other computer code to act, the specific order of nucleotides in a strand of DNA imparts the information for an organism to make proteins, which ultimately control the chemical reactions that enable cellular function.
  - The first step towards building synthetic DNA begins with determining the precise sequence of nucleotides of the gene to be synthesized. Computational tools are typically employed to modify, in silico, the sequence of the gene to achieve the desired improvement in biological function.
  - Next, due to challenges in synthetically manufacturing long sequences of DNA, various bioinformatics tools are used to break the desired in silico DNA sequence into short, overlapping pieces of approximately 60 nucleotides in length.
  - The in silico "blueprints" for the desired DNA fragment or gene are then converted into the physical pieces of DNA. To
    do so, each nucleotide of the desired short gene fragment specified in the blueprints is chemically synthesized and linked
    together to form oligonucleotides.
- 2. *DNA assembly*: During this process, overlapping oligonucleotides are "stitched" together using a complex series of chemical reactions, using enzymes, salts and buffers. These reactions are performed at various temperatures for a large number of cycles until the desired synthetic gene fragment or gene has been assembled.
- 3. *DNA cloning*: The resulting synthetic DNA product is typically combined with a DNA vector, which is a circular piece of DNA that acts as a vehicle to transport synthetic DNA fragments or genes, to create a recombinant DNA product for introduction into a host organism. Most commonly this host organism is *E. coli*, and it will easily grow into a large population for purposes of producing more of the desired synthetic DNA fragment or gene product.
- 4. *DNA scale-up in E. coli: E. coli* cells containing new DNA are plated on Petri dishes, and after a period of growth will result in individual colonies. The colonies of *E. coli* are placed in growth medium and incubated to produce a culture of cells containing the cloned vector. The synthetic DNA is isolated from the cultured cells, and is purified and further processed for DNA sequencing and then analyzed with DNA design tools. Introducing the recombinant DNA product into *E. coli* serves two purposes: first, the methodology filters out intended DNA sequences from unintended DNA sequences that arise from chemical synthesis of oligonucleotides, which is an imperfect process; and second, it permits exponential scaling up of the amount of synthetic DNA to meaningful quantities for use in downstream applications.

#### Writing synthetic mRNA

Recently, the building of mRNA has emerged as a highly attractive system for the development of both therapeutics and vaccines, with hundreds of such projects currently in various stages of development. The Moderna and Pfizer COVID-19 vaccines approved by the FDA are both mRNA products. Like DNA, mRNA takes the form of long chains of nucleotides. mRNA transports the instructions encoded in DNA to downstream molecules for molecular "fulfillment" of protein synthesis, in essence acting as DNA's messenger.

Similar to building synthetic DNA, the steps required to build mRNA are numerous, time-consuming and often fraught with difficulties, further, RNA is generally more unstable than DNA, increasing the challenge of synthesis and handling. The steps involved in synthesizing mRNA include all the steps necessary to make synthetic DNA in addition to those outlined below. DNA is used as a template to create mRNA, and this is completed as follows:

- 1. In vitro transcription: The cloned, circular synthetic DNA template is linearized and incubated in an enzymatic reaction containing all the components necessary to turn the synthesized DNA template into the desired mRNA that is then purified.
- 2. 5' capping: The mRNA is then further processed to include a "cap" at its 5' end to improve its efficiency as a driver of protein production within cells. The mRNA is then purified once more.
- 3. 3' tailing: The capped mRNA then has a poly A tail added at the 3' end to stabilize it and prevent its degradation and is then purified once more.
- 4. mRNA purification: The synthetic mRNA is treated with a DNase enzyme to remove any residual DNA template that may interfere with downstream applications and is then purified one final time.
- 5. mRNA formulation: The mRNA is then formulated by adding carrier molecules (e.g., lipid nanoparticles) to permit its delivery into cells.

Following these steps, the synthetic mRNA is ready to be used in downstream synthetic biology-enabled markets including, in the case of new drug development, biologics (antibody- and protein-based drugs), mRNA-based vaccines for infectious disease and precision medicine, genome and pathway engineering and many other markets.

#### Key limitations in writing synthetic DNA and mRNA

Despite these substantial advancements, including the accumulation of a large number of functional discoveries resulting from the wide-spread adoption of DNA sequencing instruments, the profound potential of synthetic biology has been hampered by the complexity within, and among, the multi-step process of writing synthetic DNA and mRNA, as well as significant limitations of existing solutions that prevent the rapid building of high-quality DNA and mRNA at a useable scale. Both limitations ultimately affect speed and quality of product delivery.

Currently, the process of writing synthetic DNA or mRNA for an improved biological function is carried out in laboratories by highly skilled researchers using multiple kits, each designed to perform one or more of the technical steps. Depending on the length and complexity of the desired synthetic DNA or mRNA product, the process may involve hundreds of manual steps, require numerous different kits and take days, weeks or months to complete. As an alternative solution, many, but not all, of these steps can be outsourced to a molecular biology CRO for completion, shifting those challenges from the end user to the CRO. However, outsourcing poses additional limitations, including lack of workflow control, unpredictable timelines and security issues. Ultimately, this reduces the amount of rapid iteration and refinement by the researcher since multiple *screen-design-build-test* cycles are often needed to optimize the synthesized DNA or mRNA.

Key limitations within the build phase of the synthetic biology paradigm lengthen time to market for a wide array of innovative products within the healthcare, consumer, agriculture and technology markets. Build iterations can take days, weeks or months, depending on project type, using conventional methods with either in-house manual kit-based processes or by outsourcing portions of the project to a CRO. In either case, the key limitations of the build phase include the following:

- long project timelines resulting from non-scalable, manual processes, or the need to use multiple suppliers or CROs. The turn-around-times from CROs differ widely, and the process, depending on the complexity of the product ordered, ranges from days to months. Some CROs will not accept certain projects due to their inherent difficulty. In addition, there are fewer CROs that produce mRNA at scale and limited in-house kit solutions for generating synthetic mRNA starting from DNA sequences;
- inconsistent quality and performance resulting from supply chain constraints or the use of different kits if performed inhouse, or resulting from using different CROs with inconsistent protocols;
- lack of data standardization across a project or organization which limits predictability and reproducibility;
- partial order fulfillment due to variations in project acceptance criteria, such as DNA sequence complexity;
- lack of workflow control and timing of project integration into parallel programs; and
- difficulty in controlling intellectual property and security concerns around sensitive DNA designs potentially becoming exposed to security vulnerabilities during transfer. Researchers would prefer to control their intellectual property, particularly within biopharmaceutical companies where hundreds of millions of dollars are spent on the development of proprietary DNA sequences.

## Existing solutions for writing synthetic DNA and mRNA are insufficient.

The current processes for building synthetic DNA have several significant limitations including:

- inconsistent levels of fidelity of DNA fragments resulting from DNA synthesis errors, thereby reducing overall yields of usable material;
- inability to construct some stretches of DNA sequence that have particular features, such as extreme imbalances in nucleotide content (%G+C vs. %A+T) and repetitive sequences;
- inability to construct DNA sequences above a certain size; and
- inability to scale the material to a suitable yield such that it is usable in downstream applications.

The current processes for building synthetic mRNA have the same inherent limitations as building DNA since the construction of synthetic DNA is a prerequisite for making mRNA. In addition, there are several other key challenges including:

- the handling requirements of the mRNA products, which are highly unstable and susceptible to rapid degradation;
- the multi-step processes involved in producing purified, biologically active mRNA; and
- scaling the mRNA to high yields from DNA templates.

These limitations produce bottlenecks across the build phase, which have significantly hindered the ability of the synthetic biology paradigm to deliver on its full potential. This inefficiency has created a significant unmet need in the market for an approach that can automate, integrate, optimize and standardize the process, and thereby enhance the speed, predictability and reproducibility of the *screen-design-build-test* paradigm.

### The Telesis Bio Solution

Our solution, which leverages our industry-standard Gibson Assembly method, is aimed at addressing the bottlenecks across the build phase in order to accelerate the *screen-design-build-test* paradigm. Key to our solution is our BioXp system, an end-to-end automated system for synthetic biology that fits on the benchtop and is broadly accessible due to its ease-of-use and hands-free automation. We have developed and commercialized two versions of the BioXp system, the BioXp 3250 system and the higher-capacity BioXp 9600 system. We believe our BioXp systems can democratize synthetic biology by making the build phase broadly accessible in terms of simplicity, accelerating applications and workflows, and greatly facilitating development of novel high-value products across a wide range of synthetic biology enabled markets. Our BioXp systems empower users to rapidly, accurately and reproducibly create high-quality synthetic DNA and mRNA that is ready for use in many downstream synthetic biology workflows.

Our solution is designed to offer the following benefits:

- *Consolidation of the build phase within a single end-to-end automated system:* We provide researchers all the hardware, software, materials and methodologies required to rapidly and accurately design and build large quantities of synthetic DNA and mRNA. Our BioXp systems reduce the turnaround time for such workflows to days or hours. Moreover, researchers no longer require multiple vendors to complete such workflows, eliminating related bottlenecks. We believe that using our BioXp systems save significant time and potentially accelerates time to market for critical products.
- Increased speed and scale: Our BioXp systems have the capacity to parallel process as many as 96 samples at once within an 8 to 24-hour period, depending on the BioXp system and kit being used. They also have the capacity to generate high quality and diverse libraries with short lead times, allowing innovation to be maintained in-house.
- Capacity to construct a wide array of product formats: Our BioXp systems were designed such that future applications would not require hardware upgrades but only software upgrades that could be installed remotely. This feature has facilitated new product development efforts to enhance current product specifications and to develop new kits that extend beyond the production of synthetic DNA. For example, since the BioXp systems were launched, new scripts have been developed to produce larger gene products, cell-free amplification of cloned DNA, and production of synthetic mRNA. Likewise, new scripts are currently being developed to enhance the mRNA product offering, allow for new entry points into the workflow, and to prepare NGS libraries for DNA sequencing. This capability provides substantial time-to-product and workflow control advantages for customers and gives them the flexibility to select the workflows that meet their unique needs.
- Ability to construct larger and more complex DNA and mRNA sequences: Our BioXp systems use proprietary protocols developed for robust DNA synthesis, assembly, and cloning enabling the construction of genes, mRNA, and clones across a wide range of sizes and complexity.
- Industry-leading quality and performance: Our BioXp systems use a proprietary two-step error correction process to generate high-quality synthetic genes every time. When compared to certain of our competitors, we have observed a 2.74 fold increase in sequence precision.
- Enhanced productivity: Our BioXp systems create finished DNA products in as few as eight hours. In addition, it includes protocols for the cell-free amplification of cloned DNA, obviating the need to use *E. coli*, reducing the time to product by days or even weeks. Altogether, we believe that this could represent at least a 20-fold productivity increase through accelerated iterations of the *screen-design-build-test* paradigm. Ultimately, product development cycles are accelerated because the desired biological results are identified more quickly.
- *Protection of proprietary vectors*: Our BioXp systems permit our customers to maintain their proprietary vectors on site, protecting their intellectual property throughout their entire development lifecycle.

• *Flexibility to use wider array of DNA to synthesize mRNA:* Our BioXp systems are enabled to allow a customer to "open" the system and use its own plasmid DNA to produce mRNA overnight with the push of a button.

#### **Our Products**

We have developed and commercialized products that include BioXp systems, BioXp kits for generating a wide array of synthetic DNA and mRNA formats, and benchtop reagents that complement the automated synthetic biology workflow applications and workflow solutions. We believe that the BioXp kits that we incorporate into our integrated system represent the industry's leading synthetic biology workflow automation solution. We believe our fully automated workflow solutions, coupled with our expanding menu of BioXp kits, will enable us to establish a first mover advantage in the rapidly growing synthetic biology market.

#### BioXp 3250 system

Our BioXp 3250 system was launched in September 2020, replacing the legacy BioXp 3200 system. We believe that it was the first commercially available fully automated benchtop instrument that enables numerous synthetic biology workflows by providing a turn-key, end-to-end solution for generating synthetic DNA and mRNA starting from DNA sequence. Through a combination of increased throughput and scale and reduced hands-on time, we estimate that the BioXp 3250 system offers the potential to significantly enhance productivity several fold, accelerating the development of critical new products in enabled markets. The BioXp 3250 system accelerates the *screen-design-build-test* phases of the customer's product development cycle by enabling rapid, automated synthesis of genes, clones, variant libraries and mRNA. Unlike traditional approaches that can take days, weeks or months, the BioXp 3250 system achieves these workflows in a single run, which can be completed in 8 to 24 hours



Figure 2: BioXp 3250 system

The BioXp 3250 system has the capacity to build 32 gene-fragments of up to 1.8 kilobase pairs (kb) in length or eight fragments of up to 7.2 kb in length and has a selection of off-the-shelf vectors, as well as the ability to bypass plasmid preps. It allows users to clone single or multiple genes into our, or customer-provided, vectors. In addition, it permits the synthesis of transfection-ready DNA quantities, variant libraries up to 800 bp in length in as few as 8 hours, exclusive of shipping time, and biologically active synthetic mRNA in as few as 24 hours, exclusive of shipping time.

Additionally, the BioXp 3250 system's ability to provide on-deck custom cloning obviates the need for subcloning or outsourcing development of proprietary vectors to CROs allowing laboratories to maintain complete control of intellectual property relating to their proprietary vectors.

#### BioXp 9600 system

In September 2022, we released our BioXp 9600 system. We believe this fully automated, high-throughput benchtop instrument for synthetic biology workflows can enable scientists to overcome inefficiencies in their workflows which limit their discovery.

This next-generation high-throughput platform is designed to revolutionize synthetic biology workflows and further accelerates the *screen-design-build-test* process of research and discovery by building biology overnight and at the push of a button. The fully-automated BioXp system enables scientists to overcome process limitations created by the turnaround time, cost or complexity of

alternative means of building or acquiring DNA and mRNA. The BioXp system provides overnight, automated synthesis of genes, clones, DNA libraries and mRNA, enabling users to more tightly integrate screen, design and build cycles, driving greater productivity and reducing time to answer.

### Figure 3: BioXp 9600 system



# Commercialized kits for the BioXp 3250 system and the BioXp 9600 system

BioXp De novo kits contain all the requisite Gibson Assembly branded reagents and allow our BioXp system to perform the steps required to produce various DNA and mRNA products designed for a range of synthetic biology applications.

- BioXp de novo DNA fragment synthesis kit. Contains all the Gibson Assembly reagents necessary to make errorcorrected, de novo synthetic genes of up to 1.8 kb in length.
- BioXp de novo DNA cloning kit. Contains all the Gibson Assembly reagents necessary to make error-corrected, *de novo* synthetic genes of up to 7.2 kb in length using a standard made-to-stock vector.
- BioXp de novo DNA cloning and amplification kit. Contains all the Gibson Assembly reagents necessary to amplify error-corrected genes cloned into either a made-to-stock or customer vector, to make an average of 10 micrograms of DNA per sample.
- BioXp de novo DNA library synthesis kit (site saturation scanning). Libraries with specific mutations distributed over the sequence space to achieve the desired diversity.
- BioXp de novo DNA library synthesis kit (alanine scanning). Libraries with varied single, contiguous amino acid sites, including site-saturation and alanine scanning libraries.
- BioXp de novo DNA library synthesis kit (combinatorial). Libraries with varied, multiple non-contiguous amino acids sites using degenerate bases to optimize protein binding and function.
- BioXp de novo mRNA synthesis kit. Contains all the Gibson Assembly reagents necessary to make biologically active synthetic mRNA samples using *de novo* synthesized, error-corrected gene fragments (mRNA template) of up to 1.8 kb in length.
- BioXp Select mRNA synthesis kit. Enables customers to synthesize purified capped and tailed mRNA between 0.4-10kb. The kit contains all the necessary reagents for on-demand synthesis of mRNA using a linear DNA template generated with a plasmid or PCR product for transcription.

By incorporating these application-specific BioXp kits into our BioXp systems, we are able to provide simple, push-button, walkaway, end-to-end automation of important synthetic biology workflows. We believe our products enable unrivalled time-to-product, quality, and workflow control advantages for our customers.

## Our benchtop reagents

We also offer benchtop reagents that are synergistic with our BioXp systems and BioXp kits to accelerate the build phase of the *screen-design-build-test* synthetic biology paradigm.

• Gibson Assembly HiFi and Ultra kit. Contains all the reagents necessary to simultaneously assemble as many as 10 DNA fragments into a vector to produce a final product that is several hundred kilobase pairs in length.

- Gibson Assembly RapidAMP kit. Contains all the reagents necessary to simultaneously assemble and clone DNA using Gibson Assembly, and then amplify the resultant product to produce an average of 10 micrograms of DNA per sample.
- Vmax X2 cells. Transformation-ready competent cells for introducing plasmids for protein expression applications.

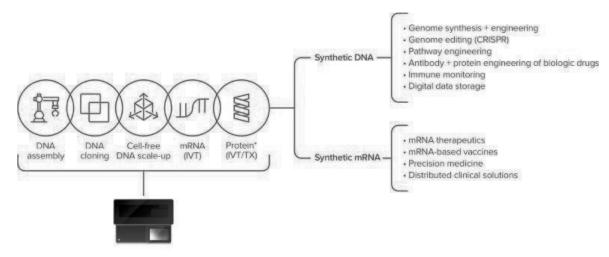
#### Our products in development

As part of our continuing effort to improve the processes of synthetic biology, we are currently developing next-generation automation systems and BioXp kits with an aim to radically transform rapid demand-response workflows in synthetic biology by consolidating supply chains and enabling global distributed manufacturing for both discovery and clinical applications. Our ultimate goal is to build what we describe as the Digital-to-Biological Converter (DBC). The DBC's approach would begin not with oligonucleotides, which can take days to procure, but with DNA sequence data. The system we envision would take data and produce synthetic genes, or even convert those automatically into mRNA or protein. This would enable the "sequence-in, vaccines-out" concept that could replace the months-long manufacturing processes required today with a process that can be carried out in a matter of days.

#### Workflow Solutions for Synthetic Biology Enabled Markets

Our BioXp systems are intended to address the needs of the synthetic biology customer across discovery and pre-clinical development by providing an unmatched capability to synthesize high-quality DNA in as few as 8 hours and mRNA in less than 24 hours, exclusive of shipment times. With future system releases and extensions, we plan to address the continuum of research needs across the central dogma of molecular biology by enabling cell-free production of high-quality synthetic DNA, mRNA and protein for the discovery, development and manufacturing of enabled products across a wide range of markets.





We are strategically focused on providing workflow solutions for markets with high-value enabled products such as those in healthcare and technology. These solutions are all based on our core portfolio of BioXp kits. Specific design software and BioXp kits (e.g., oligonucleotides) are employed depending on the desired enabled product. The appropriate application-specific BioXp kits are inserted into the BioXp system to perform the workflow solution tailored to meet the needs of the customer.

We target high-value application workflows within the synthetic biology-enabled markets. Key workflow examples are described below.

#### Synthetic DNA Application Workflows

We believe that with the BioXp system, scientists can perform rapid, high-throughput gene synthesis, regardless of vector size and complexity in a hands-free, automated fashion in 8 to 24 hours, exclusive of shipment times. We believe that our BioXp system offers a comprehensive value proposition that includes reduced turnaround time, increased throughput and scale, enhanced quality, complete workflow control and both synthetic DNA and mRNA formats. Our solutions allow customers to save time, improve scale and throughput and improve productivity for many synthetic biology enabled research and development workflows across multiple market segments, including the following: 1. Synthetic DNA for genome synthesis and engineering. DNA synthesis has become a fundamental tool throughout genetic research with increasing demand from scientists who are continuously looking to incorporate synthetic DNA into new cell-based discovery and production workflows. Addressing this growing demand requires the ability to quickly make large high-quality DNA molecules comprising entire gene sequences. Traditional molecular cloning and gene editing steps are tedious, manual in nature and require cellular transformation, which can take three to four weeks. Moreover, in addition to being time-consuming, classic genome engineering and DNA assembly techniques are limited in the size and complexity of constructs that can be engineered.

*BioXp system benefits*: Overall, our automated workflow solution allows users to: (1) engineer genomes and vaccine scaffolds that were previously inaccessible due to size, complexity and resource limitations; (2) engineer fully-synthetic genomes lacking pathogenicity through rational redesign; and (3) rapidly pursue research and development of emerging strains or modify existing genomic constructs based on experimental results. Our BioXp system overcomes these barriers and enables rapid synthesis within days to weeks, as well as the ability to modify large constructs and full-length genomes.

2. Synthetic DNA for genome editing. CRISPR-powered genome editing has enabled significant improvements in the ability to fine-tune genomes. Originally discovered as an mRNA-based adaptive immune response in *E. coli*, the CRISPR/Cas9 system contains both guide mRNA for sequence-specific targeting and a Cas9 endonuclease that removes foreign DNA and allows integration of synthetic DNA into the host genome. That synthetic DNA is designed to specifically target a region in the host genome and make alterations (e.g. add genes, remove genes, correct mutations).

BioX*p* system benefits: The system enhances productivity during the design phase of the customer's product development cycle by enabling rapid, automated synthesis of gene fragments, clones, and variant libraries. We believe that with the BioXp system, scientists can perform rapid, high-throughput gene synthesis and cloning of mRNA constructs into expression vectors, regardless of vector size and complexity, using Gibson Assembly. In addition, our Gibson Assembly RapidAMP technology, which permits cell-free amplification of microgram quantities of DNA, means plasmid design no longer has to be tethered to an *E. coli* cloning system. In addition, our Gibson Assembly RapidAMP technology combines cloning and vector amplification in smaller mini-circle plasmids absent *E. coli*-based genes, thus improving overall transfection efficiency.

3. *Synthetic DNA for metabolic pathway engineering*. Metabolic engineering involves reconstructing and optimizing biosynthetic pathways in model organisms, creating robust "cellular factories" designed to carry out a specific task. Pathway modifications typically rely on recombinant or novel genes or gene circuits. Using recombinant or novel genes or gene circuits, metabolic pathways are modified or introduced into genomes of microbe hosts like *E. coli* or yeast. These genetically engineered hosts are routinely employed to more effectively produce valuable biomolecules for a variety of biomedical, industrial and research applications.

BioX*p* system benefits: With the gene synthesis capabilities of our BioXp system and the complex genetic circuitry made possible with Gibson Assembly technology, we are able to improve the speed and accuracy of metabolic engineering for even the most complex genetic circuitry.

4. Synthetic DNA for antibody and protein engineering of biologic drugs. Biologics-based (e.g., antibody or protein) discovery of novel therapeutics is one of the most important areas of research for improving medical advances through engineering of antibodies or other proteins for cancer treatment, infectious diseases and inflammatory or autoimmune disorders. Monoclonal antibodies, antibody-drug conjugates, single-domain antibody variants, chimeric antigen receptor T cells (CAR-Ts) and T cell receptors (TCRs) have become invaluable therapies due to their robust recognition of targets and relatively lower side effects compared to traditional small molecule therapies.

Desirable properties for therapeutic antibody products include high antigen-binding affinity, specificity, low immunogenicity, solubility, stability, manufacturability and adequate pharmacokinetics. Researchers involved in biologics discovery and antibody and protein engineering often leverage DNA variant library screening as an essential step in the discovery workflow. A major constraint in antibody discovery has been long lead times associated with sourcing custom-built DNA libraries used to screen new antibody variants.

Customers are increasingly using our BioXp kits for variant libraries to accelerate the *screen-design-build-test* phases for their antibody screening and optimizations stages. Specifically, we believe that utilizing libraries on the BioXp system across library synthesis, affinity maturation and codon optimization workflows accelerates research by improving productivity and reducing the time and costs associated with certain drug discovery and development programs. Additionally, we believe, with our broad menu and wide selection of library types, including combinatorial, scanning and custom libraries, we provide flexibility in antibody screening and optimization analysis to serve different needs (e.g., stability, epitope optimization) at various points in the workflow. Furthermore, these libraries are synthesized with our proprietary error-correction technology, resulting in high-fidelity genes.

Protein engineering is another synthetic biology enabled workflow of significant importance and caters to the growing need for improved enzymes and bioproducts for industrial production. Enzyme engineering typically begins with research to find a candidate with the best starting properties to use as a template followed by engineering cycles to find enzymes with enhanced properties.

After enzyme discovery, the build phase involves iterative rounds of library synthesis with an improved variant from the previous round selected as the template for the subsequent round. Subsequent build phase construction is rate limiting because of its sequential nature: design iterations cannot be conducted in parallel because the output from the previous phase is required as input for the next phase. Finding ways to shorten the time in this phase is key to reducing the overall project timeline. A second consideration is the burden of screening. Library synthesis can generate thousands or even hundreds of thousands of variants that must be screened to identify beneficial ones. Limiting the number of variants with a rational approach to library design combined with an automation system that amplifies and assembles constructs with high fidelity is a key strategy to minimizing project timelines while also maximizing the probability of identifying the most beneficial variants in an unbiased manner.

*BioXp system benefits*: Our BioXp system provides an accelerated path for antibody and pathway engineering workflows and compared to comparable competing services, we estimate a reduction in build phase time by over 70%. A key part of the accelerated timeline is the BioXp system's ability to deliver up to 96 libraries in 8 to 24 hours once the reagents are received, compared to the traditional method, which, depending on the method used, can take days or weeks. We believe adopting the BioXp system into the antibody or protein engineering workflow often results in the increased generation of validated leads.

5. *Immune monitoring*. Immune monitoring for patients receiving cancer immunotherapy is vital for understanding the process and efficacy throughout the course of the treatment. Characterizing the immune status for insights into the therapy's potential is essential, particularly in patients who are receiving novel immune-modulating therapies. Speed and efficiency of immune assays allow for real-time feedback and the ability to be agile in a patient's treatment regimen.

*BioXp system benefits*: The BioXp system's high-throughput gene synthesis and flexible cloning modalities allow for quick screening and design of novel chimeric antigen receptors (CARs), engineered TCRs, and artificial transcription factors. Different CAR designs can therefore be investigated to enhance their tumor specificity or to fine-tune T cell activity. Further, the development of novel gene circuits or CARs to increase effectiveness of CAR-T therapy by engineering T cell mobility or mitigating immunosuppressive cues in the cancer microenvironment can help drive improved efficacy.

#### Synthetic mRNA Application Workflows

With the BioXp systems, scientists can perform rapid, high-throughput synthesis of biologically active mRNA in a hands-off, automated fashion within 24 hours once the reagents are received. Our BioXp systems are able to fully automate mRNA synthesis for the research market and offers what we believe to be a comprehensive value proposition that includes reduced turnaround time from weeks to days, enhanced quality and complete workflow control. Our solutions allow customers to address many target applications across multiple market segments.

1. Synthetic mRNA for infectious disease vaccine discovery and development. The need for rapid vaccine development in response to emerging pathogens has become increasingly clear during the COVID-19 pandemic. However, vaccine manufacturing is consistently complicated for manufacturers, regulators and public health officials, especially for endemic viruses (e.g., influenza), where manufacturers must adjust the vaccine to counter the virus' constant antigenic variation. To start a new influenza vaccine manufacturing campaign, a key material, the vaccine seed virus, must be changed frequently to match circulating strains in order to track the virus' antigenic evolution. The existing systems for accomplishing vaccine strain changes have required the shipment of viruses and other biological materials around the globe, which have caused delays in vaccine availability. Existing systems have also used legacy techniques such as egg-based virus cultivation, resulting in vaccine mismatches.

In comparison, mRNA vaccine production is simple, cost-effective and can be easily adapted to accommodate new candidates within an established manufacturing pipeline. Given this, vaccinology has recently seen a shift toward synthetic mRNA approaches, which allow for rapid, scalable and cell-free manufacturing of prophylactic and therapeutic vaccines. For development of mRNA vaccines, *de novo* gene synthesis allows for increased specificity of antigen proteins, more efficient vaccine adjuvants, and safer specialized vectors. Through codon-optimization of these genes and vectors, targeted and safe vaccines can be created rapidly to treat newly emerging viral threats, such as influenza, coronaviruses and Ebola.

Gene synthesis with codon-optimization and mutant libraries using the BioXp system is designed to accelerate the speed of vaccine development by improving the efficacy and safety of the resulting recombinant genes, adjuvants and vectors. Also, pairing antigen epitope mapping technology with the BioXp system's ability to rapidly iterate is accelerating rational design strategies for vaccine development.

*BioXp system benefits*: We believe our end-to-end solution for the rapid and accurate production of cell free synthetic DNA and mRNA, when combined with our BioXp protein kit that is currently in development, positions the BioXp system for rapid adoption within high-growth vaccine and therapeutic markets, as it allows for the acceleration of product development cycles by addressing critical bottlenecks. This is especially important for infectious disease vaccine development, such as for influenza, where the key bottleneck is the lack of quick strain *screen-design-build-test* cycles close to flu season that makes vaccine response unpredictable.

2. *mRNA-based vaccines for precision medicine*. Neoantigens, or tumor mutated specific antigens, are major tumor rejection antigens, allowing tumors to activate the immune system and induce an efficient anti-tumor response. As personalized medicine for cancer therapeutics ramps up and becomes more feasible and affordable, individual patient neoantigen development is increasingly important. Identification of these neoantigens has greatly improved with recent advancements in deep sequencing and bioinformatics technologies. Gene synthesis and mRNA production then allow for these predicted neoantigens to be synthesized and tested for T cell reactivity, differentiating true immunogenic neoepitopes from putative ones. Since patients' mutated antigens are largely unique to the individual, speed is one of the most important goals in identifying and verifying true neoantigens for induction of the T cell-mediated immune response.

*BioXp system benefits*: The BioXp system's on demand high-throughput gene and mRNA synthesis and flexible cloning into a variety of vectors allow for quick screening and development of the best personalized cancer treatments. In addition, our Gibson Assembly RapidAMP cloning and amplification process avoids the use of *E. coli*, thus eliminating endotoxin contamination and unwanted immunogenicity.

3. mRNA-based therapeutics. With COVID-19 vaccines leading the way, mRNA has become one of the more promising classes of therapeutics and is being validated by key industry players (e.g., Avantor, Inc., Moderna, Inc., and Maravai LifeSciences Holdings, Inc.) and emerging mRNA delivery companies (Precision NanoSystems Inc., Nutcracker Therapeutics, Inc.). Monoclonal antibody-based drugs require complex production and purification processes and aberrant post-translational modifications of the antibody are a problem. An mRNA-based approach is a possible solution, whereby the genetic information of the antibody, not the antibody itself, is delivered. Transient gene transfer aims at administering the mAb-encoding nucleotide sequences in DNA or mRNA form, rather than the mAb protein itself, directly to patients. This allows for the *in situ* production of biologicals in a cost- and labor-effective manner, potentially for a prolonged period of time. Although past research has been mainly focused on the development of plasmid DNA, the limitations associated with these "classical" approaches and the recent improvements in stability and translatability of *in vitro* transcribed (IVT) mRNA have recently led to an increased interest in mRNA as a delivery vector. In addition to safer pharmaceutical properties, such as no risk of genome integration, the transient expression of mRNA-encoded antibodies enables a more controlled exposure, with more protein production during peak expression compared to plasmid DNA.

*BioXp system benefits*: Our BioXp system can be used to rapidly produce small-scale, biologically active mRNA for accelerated iteration of the *screen-design-build-test* paradigm for the identification of therapeutic candidates. In addition, a wide menu of on demand automated library synthesis enables the customer to further speed up iterative *screen-design-build-test* paradigm during the drug discovery and development continuum. When library synthesis is used in combination with mRNA production, we estimate that a customer can reduce turnaround times by weeks or months when using the BioXp system for screening and optimizing the mRNA products that have the most desirable pharmaceutical properties.

4. CleanCap technology benefits: In July 2021, we signed a licensing and supply agreement with TriLink Biotechnologies, part of Maravai LifeSciences Holdings, Inc., for its industry-leading CleanCap technology. We integrated the mRNA capping technology into our suite of automated mRNA synthesis kits for the BioXp system. Together, the technologies are expected to increase productivity and yields for mRNA synthesis workflows, potentially opening the doors for a broader range of downstream therapeutic and vaccine applications.

#### **Our Technology**

Our systems are powered by many key innovations that provide unparalleled capabilities, notably:

#### Gene synthesis

Our robust gene synthesis process is proprietary and enables the simultaneous assembly of hundreds of oligonucleotide pools of up to several thousand kilobase pairs in length, including a wide range of complexity (e.g., 20-70% GC content, repetitive DNA sequence). Our proprietary error-correction process produces high-quality synthetic DNA sequences from beginning to end. BioXp gene synthesis kits leverage this proprietary gene synthesis technology, which involves:

• the design of single-stranded oligonucleotide sequences comprising a DNA sequence, and novel chemistry and thermal cycling parameters for the robust assembly of those chemically synthesized oligonucleotides into long double-stranded DNA products; and

• a two-step error-correction process where error-containing DNA products are removed through a combination of a mismatch-specific endonuclease working in concert with an exonuclease.

In the final step, only error-free genes are amplified by PCR resulting in high yields of error-free DNA. Because all applications currently rely on gene synthesis, this technology is used within every BioXp kit. We have also developed a second proprietary gene synthesis process that uses ultra-short oligonucleotides that assemble into high-fidelity synthetic genes without enzymatic error correction procedures.

## Library synthesis

Our robust gene synthesis technology enables the construction of several DNA variant library types including:

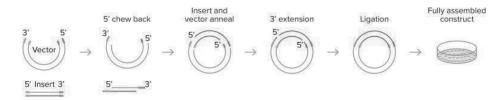
- scanning libraries with varied single, contiguous amino acid sites, including site-saturation and alanine scanning libraries;
- combinatorial libraries with varied, multiple non-contiguous amino acids sites using degenerate bases to optimize protein binding and function; and
- targeted libraries, with specific mutations distributed over the sequence space to achieve the desired diversity.

Our library synthesis technologies are powerful tools for manipulating protein structures for optimization studies in biologics discovery, protein engineering and several other disciplines. This technology is included in our BioXp library kits and enables the BioXp systems to generate as many as 96 libraries per instrument in a single 8 hour run, with each library containing an amino acid diversity as high as 10 to the 10th power.

### **DNA** cloning

Our robust molecular cloning method is proprietary and commonly referred to as Gibson Assembly across the industry. The method can simultaneously combine as many as 10 DNA fragments based on sequence identity. It requires that the DNA fragments contain approximately 20 to 40 base pair overlaps with adjacent DNA fragments. These DNA fragments are mixed with a cocktail of three enzymes, along with buffer components. The three required enzyme activities are: exonuclease, DNA polymerase, and DNA ligase. The exonuclease splits DNA from one of its ends resulting in single-stranded regions on adjacent DNA fragments, which can anneal to each other. The DNA polymerase incorporates nucleotides to fill in any gaps. The DNA ligase covalently joins the DNA of adjacent segments, thereby removing any imperfections in the DNA. The resulting product is different DNA fragments joined into one. Either linear or closed circular molecules can be assembled. With over 6,000 citations in scientific literature, Gibson Assembly is one of the most widely-used molecular cloning methods used to create recombinant DNA. It is named after its creator, Dr. Daniel Gibson, who is our Chief Technology Officer and co-founder. We believe that the Gibson Assembly method can be used to rapidly clone multiple DNA fragments into any vector in one hour or less without the use of restriction enzymes.

#### Figure 5: Gibson Assembly technologies for DNA assembly



The BioXp cloning kits leverage Gibson Assembly in a proprietary fashion to bring together up to four gene fragments in up to four vectors, permitting larger DNA to be constructed and providing increased flexibility in cloning strategies. Multi-fragment assembly and cloning on the BioXp system gives customers the power to design, build, test and iterate genes more rapidly.

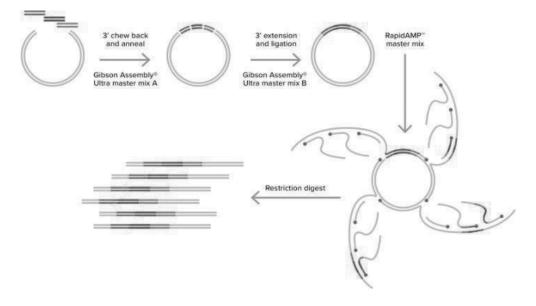
#### Cell-free amplification of cloned DNA

The Gibson Assembly process generates circular products that are permanently sealed by DNA ligase. We have taken advantage of these two essential features to develop a proprietary cell-free amplification process that combines our Gibson Assembly technology with components of the well-established rolling circle amplification (RCA) technology. Once the Gibson Assembly reactions are complete, reaction products are incubated for several hours in a mixture containing a DNA polymerase and random hexamers. The BioXp RapidAMP cell-free DNA amplification kit and the benchtop Gibson Assembly RapidAMP kit leverages this technology to allow users to assemble and amplify constructs to achieve transfection-ready DNA in a single day. With this technology, high-quality, high-fidelity DNA can be rapidly produced, all while eliminating tedious tasks associated with transformation, cell culture and *E. coli* 

harvest. Gibson Assembly RapidAMP reagents are available as a benchtop reagent kit or an automated cell-free amplification solution for the BioXp system. Benefits include:

- accelerated screen-design-build-test cycles;
- endotoxin-free DNA products;
- an alternative to amplification strategies that fail due to biological reasons within host organisms; and
- propagation of DNA without unwanted vector elements.

#### Figure 6: Gibson method for cell-free DNA production



#### System engineering and automation

The BioXp systems contain fluid processing and precise thermal control to run all applications, including the synthesis and scale-up of DNA and mRNA. The proprietary and highly reliable automation components of the BioXp system include patented thermalcycler technology and sample handling and sealing devices. Significant software development has resulted in an easy-to-use interface with robust diagnostics and error detection as well as remote access capability to quickly address any issues. Key features of the BioXp systems include:

- a high precision patented thermalcycler for precise control of thermal cycling parameters;
- a high precision fluid handling system for accurate transfer and mixing of reagents;
- a high reliability 5-axis motion control system for accurate positioning;
- an integrated camera system for confirmation of proper loading and reading barcodes on the components of BioXp kits;
- a touchscreen interface and integrated computer processor, which allows for simple, intuitive operation;
- internet connectivity enabling custom scripts to be loaded for each customer's needs, post-run data to be retrieved and remote service/updates to be performed;
- a proprietary sample handling system that allows movement of samples throughout the process; and
- a flexible system design that anticipates development of new protocols to continue collapsing customer workflows.

#### Cloud-based design and analytics

The BioXp portal includes design tools used to break down desired DNA sequences into building blocks sent to the user, ultimately to be synthesized and assembled on the BioXp system. Our predictive modeling of the complexity and level of difficulty ensures that the probability of success in building a DNA sequence is greater than 98%. The co-development process by our biologists and engineers has resulted in a proprietary combination of synthetic biology and automation. The BioXp system is highly flexible and is controlled by processing information from the cloud, tailored for a user's specific application. There is no need for the user to

develop custom processing scripts or modify parameters because our ordering software and associated BioXp barcodes ensure that the desired application is processed.

#### Large and complex DNA synthesis up to complete genomes

Our gene synthesis technology in combination with the Gibson Assembly cloning process is what enables us to excel in the automated synthesis and engineering of large and complex DNA constructs. Our proprietary tools combine novel DNA design, synthesis and assembly techniques to manufacture long DNA constructs, including the synthesis of a complete genome or chromosome. Using these technologies, our team has chemically synthesized several bacterial and viral genomes, including some of the largest chemically-defined structures ever synthesized in a laboratory.

The final genetic constructs required to develop many commercial applications are longer than those that can be readily synthesized using standard industry techniques. While a simple sequence of genes may be several thousand base pairs long, the genomes of many bacteria may be up to several million base pairs long, while the genomes of some viruses can exceed one million base pairs in length. Traditional DNA synthesis and assembly approaches are not practical for synthesizing genomes of that length.

#### Vmax host cell engineering

Vmax is an engineered form of *Vibrio natriegens*, which, under optimal conditions, has the fastest known growth rate of any non-pathogenic organism. Vmax has high-value applications in research and commercial production. Many high-value pharmaceuticals, industrial enzymes and chemicals are currently made in bacteria such as *E. coli*. We aim to improve the manufacturing of these products with Vmax, especially the high-value biologics. We have also developed, but not commercialized, an advantaged Vmax strain and reagents for molecular cloning (Vmax C1) and have developed an advantaged Vmax strain for protein expression (Vmax X2) applications. We believe that over time Vmax could be capable of challenging the dominance of the prevailing *E. coli cell-based production systems that are used to produce many high-value pharmaceuticals, industrial enzymes and chemicals.* We plan to monetize Vmax cell lines through arrangements with biopharmaceutical companies.

#### **Research and Development**

Our research and development team has been at the forefront of discovery and development of synthetic biology workflows for over 18 years, including more than 10 years of experience automating many of those processes. We believe that this experience gives us industry-leading know-how, intellectual property and time-to-market advantages with respect to new products. We have specific and valuable experience and knowledge related to problem solving and have a deep knowledge of applicable synthetic biology research and development methodologies. We have particularly strong technical core competencies related to constructing large and complex strands of DNA and automating synthetic biology applications across multiple end-to-end workflows.

The overarching goals of our research and development programs are to continue to bring new technologies to market that address the most pressing questions in synthetic biology solutions. Our research and development department hosts the key proprietary synthetic biology tools and technologies, with applications across a wide variety of industries, sponsors research and development efforts to apply those tools and develops new opportunities. To this end, we plan to focus our research and development efforts on the following areas:

- Strategic partnerships: We focus partnering efforts in the areas of mRNA vaccines, biologics discovery and cell
  engineering validating our technology systems.
- New capabilities and solutions for our current BioXp systems: We continue to expand the applications and workflows available on our BioXp platform to bring increased utility and value to our customers. We are developing workflows and reagent kits for the BioXp, branded as BioXp Select, that will allow customers to start with plasmid and linear DNA from other sources and perform cloning, cell-free amplification, and mRNA synthesis on our platform. We are also developing NGS workflows and reagent kits to enable customers to generate NGS libraries for Plasmid-seq, RNA-seq, and whole-genome workflows on our existing platforms, and expect to launch a separate platform targeted at this market. Finally we are developing the first commercial DBC platform and a kit that we anticipate will enable same-day CRISPR gRNA synthesis at the benchtop.
- *DMT synthesis technology:* We are developing a purpose-built DMT oligonucleotide synthesis platform that will form the basis of our internal oligo manufacturing process. This platform is a high-throughput small-scale DMT synthesizer that will be used internally to enable significant cost-reduction of the key starting materials for BioXp De novo kits.
- *New workflow solution-focused products*: In the near-to-medium term, our primary focus is on perfecting our enzymatic DNA synthesis reagent solution, which we refer to as SOLA. Once developed, this technology will be integrated into the

BioXp 9600 system as the front-end system for the on-demand enzymatic DNA synthesis manufacturing of synthetic DNA, which can also serve as a template for making other biological materials such as guide RNA, mRNA and proteins.

As of December 31, 2022, we employed 37 employees in R&D, primarily located in San Diego, California. The R&D team consists of two groups, a scientific team and an engineering team, with 19 and 18 employees, respectively.

- Scientific Team: Nineteen experienced scientists, approximately 53% of whom hold a Master's degree and 53% of whom hold a Ph.D. The majority of the scientists are molecular biologists with vast experience in building new technologies related to benchtop and automation procedures for DNA sequencing and synthetic biology workflows. The team is led by Dr. Daniel Gibson, who is responsible for some of the foundational discoveries in synthetic biology, including the Gibson Assembly method
- **Engineering Team**: Eighteen personnel with expertise in software, fluidics, mechanical, electrical and embedded firmware development in both RUO and good manufacturing practice (GMP) environments. The team has decades of experience in applications of state-of-the-art engineering designs and solving complex systems for laboratory and medical devices. They are experts in translating the latest molecular biology workflows into reliable, repeatable robotic fluid handling steps processed under precise temperature controls.

#### Manufacturing

We currently utilize single-source third parties for assembly of key components of our BioXp instruments and other suppliers to provide key reagents. We have identified a list of our single-source suppliers for key reagents and have started to identify and validate new second-source suppliers for those key reagents. Having dual sources for certain of our raw materials will reduce the risk of a potential production delay caused by a disruption in the supply of a critical raw material or component. Our mitigation plans for these single-source key reagents is to have six to twelve months of safety stock inventory on hand as we qualify new second-source suppliers. For the key reagents where we cannot find a suitable second-source supplier, we plan to continue to maintain our six to twelve month safety stock inventory.

We create validation protocols for each potential new second-source supplier and only add those new second-source suppliers once they have met the validation requirements. We require testing on three separate lots of the new key reagent and we validate key reagent performance and expiration dating compared to the current key reagent performance and dating criteria. Each validation protocol is different as each key reagent will have different characteristics and testing protocols as well as acceptance criteria and expiration dating.

BioXp 3250 and BioXp 9600 system manufacturing is currently contracted to D&K Engineering, Inc. (D&K), a third-party ISO 13485 Certified and FDA registered contract manufacturer located in San Diego, California. D&K services several of the largest life science instrument companies. It has proven capabilities related to design optimization, new product launches and product line extensions, as well as an ability to facilitate a substantial scale-up of unit volumes, thereby supporting our growth for the foreseeable future. Its capabilities include GMP-compliant manufacturing, which may be relevant to our future product launches. We do not have a long term supply agreement with D&K, and have relied on it to provide quotes and accept purchase orders that we issue from time-to-time. Our outsourced production strategy is intended to drive cost leverage and scale and avoid the high capital outlays and fixed costs related to constructing and operating a manufacturing facility. Under the terms of our relationship with D&K, we have historically benefited from volume-based pricing on our purchase orders. We perform final quality control testing of the BioXp 3250 system in-house at our facility in San Diego. Turnaround time for BioXp 3250 production is typically two to three weeks. We keep the contract manufacturer aware of our future supply needs based on a rolling three-quarter forecast[RC1]. Beginning in 2023, we plan to transition manufacturing of all our BioXp 3250 and BioXp 9600 systems in-house.

In October 2015, we entered into a Supply Agreement (the IDT Supply Agreement), with Integrated DNA Technologies, Inc., a division of Danaher Corporation (IDT), which was amended in March 2020 and June 2021 (the Supply Agreement), pursuant to which IDT agreed to supply us with oligonucleotides, which we use as reagents in our research and commercial operations. The prices of the oligonucleotides purchased pursuant to the Supply Agreement are fixed during the term of the Supply Agreement, subject to minimum ordering requirements. The Supply Agreement contains certain dedicated capacity representations, but does not commit IDT to supply any minimum amount of oligonucleotides outside of accepted purchase orders. The term of the Supply Agreement is nine years.

Reagent manufacturing and storage is completed within our headquarters in San Diego, California. All reagents are manufactured, quality-control tested and released to inventory by our quality assurance department certifying that our reagents meet our quality standards. We maintain safety stocks of key reagents in quantities that we believe mitigate the effects of any supply disruptions. Key components of the reagents are sourced from well-established third parties, most notably, IDT and Eurofins Scientific SE.

As of December 31, 2022, we had 118 employees dedicated to operations, with 87 supporting Eton service operations, 17 focused on reagent manufacturing, 7 focused on global logistics and supply chain, and 7 focused on quality control.

#### **Commercial Operations**

We commercially launched our current solution in September 2019, which now includes the BioXp 3250 system, BioXp kits with associated cloud-based application scripts, and benchtop reagent kits. From the initial launch of our solution through December 31, 2022, we have launched a total of eight BioXp kits, three benchtop reagent kits, and several other synthetic biology products, including 14 SARS-CoV-2 full-length genomes as well as our Vmax X2 cells. We have placed approximately 200 BioXp systems globally. We target customers in the fields of personalized medicine, biologics drug discovery, vaccine development, genome editing and cell and gene therapy. As of December 31, 2022, our customer base was composed of over 450 customers and included 15 of the 25 largest biopharmaceutical companies in the world ranked by 2020 revenue, excluding affiliates of those companies. Our customer base also includes leading academic research institutions, government institutions, CROs and synthetic biology companies. One customer, Pfizer, Inc., accounted for 24% of our revenue for the year ended December 31, 2022, based on a Research and License Agreement.

As of December 31, 2022, we employed a commercial team of 46 employees, many with significant industry experience. Of the 46 commercial employees, 36 were in sales and 10 were in marketing. As of December 31, 2022, our commercial team included 31 quota carrying sales professionals spanning business development managers, inside sales and field application scientists. We employ a direct sales model in North America and four major European markets (United Kingdom, Germany, France and Benelux), while selling through more than 20 channel partners across Europe, the Middle East, Africa and Asia Pacific.

Our commercial team is focused on driving active placements of BioXp systems and maximizing their utilization at the most iterative, costly and time-consuming steps across our customers' workflows. Potential customers can gain access to our system via direct purchases, services offerings or through strategic partnerships.

To maximize our commercial reach, we have distribution agreements with international channel partners for our products. These agreements allow us to reach approximately 60 countries globally, with key focus on networks in Europe, the Middle East, Africa and Asia Pacific. We have a key European logistics hub in Italy in partnership with Bright Bioworks S.r.l and a relationship with a European software engineering company, Solvd, Inc., to support our customer portal and to provide European customer and technical support. We sell our products directly in the U.S., providing instrument field services through a hybrid of in-house and third party-contracted engineering support.

As of December 31, 2022, we employed a service and support team of 15 employees focused on delivering an outstanding customer experience.

#### Competition

Our market is characterized by highly competitive and dynamic products, rapid technological advancements and continually evolving customer demands. We face competition from core synthetic biology companies and the broader NGS space, such as Thermo Fisher Scientific Inc.; Danaher Corporation; Azenta; GenScript Biotech Corporation; DNA Script SAS; Integrated DNA Technologies, Inc.; Eurofins; Synthego; Molecular Assemblies, Inc.; Nuclera Nucleics Ltd; Nutcracker Therapeutics, Inc.; Twist Bioscience Corporation; Aldevron, LLC; TriLink BioTechnologies, Inc.; Evonetix Ltd.; Illumina; Roche; and others. Our competitors and their products and services are focused on discrete steps across various synthetic biology applications including gene synthesis, enzymatic DNA synthesis, protein engineering, cell engineering, tools and automation, software, food and agriculture, materials, aquaculture, biopharmaceutical, health and others.

While our industry is composed of many companies offering services or discrete products, we believe there is a lack of an existing, comprehensive solution enabling end-to-end control of biologics and vaccine discovery and development workflows inhouse.

#### Arrangements with Commercial and Governmental Entities

We believe that our technology is applicable to discovery and development in the following fields: vaccines, biologics, diagnostics, agriculture, animal health and food science. In the ordinary course of business, we enter into arrangements with commercial channel partners and others to maximize our commercial reach.

#### Early Access Collaboration and Licensing Agreement with Pfizer

In December 2021, we entered into a Research Collaboration and License Agreement (Pfizer Agreement) with Pfizer Inc. (Pfizer), pursuant to which we agreed to collaborate with Pfizer to further develop our novel enzymatic DNA synthesis technology for Pfizer's use in its research and development of mRNA-based vaccines and biotherapies. The financial terms of the deal include an upfront payment from Pfizer to us, along with success-based technical milestone payments that could be earned in the near term. We are also eligible to receive additional milestone payments based on the achievement of specified development, regulatory and commercialization goals associated with any products developed from the application of our technology developed and licensed under the agreement.

We granted Pfizer a non-exclusive, worldwide license to use our enzymatic DNA synthesis technology for purposes of researching, developing, manufacturing and commercializing pharmaceutical and biopharmaceutical products and a limited-time option to convert such license to exclusive for specific applications. If Pfizer exercises its option for these application(s) within the applicable period, then the license to Pfizer will become exclusive for products for such application(s); provided that Pfizer may later convert the particular application back to non-exclusive.

Under the Pfizer Agreement, Pfizer made an upfront payment to us of \$8 million at the time of execution and a milestone payment of \$2.5 million in 2022 as a result of successful completion of our first technical milestone. If we meet the other technical milestones defined in the agreement, we will be eligible to receive an additional \$7.5 million in near-term milestone payments.

In addition to the upfront payment and technical milestone payments, Pfizer has agreed to make milestone payments to us upon the products meeting certain clinical milestones, with each product (other than exclusive products) being eligible for milestone payments up to \$20 million if it were to meet the applicable clinical milestones and the first exclusive product in each exclusive field being eligible for milestone payments up to \$55 million if it were to meet the applicable clinical milestones. Pfizer has also agreed to pay us up to \$60 million in sales milestones for products (other than exclusive products) if aggregate net sales of such products meet certain thresholds and up to \$180 million in sales milestones for exclusive products if aggregate net sales of the exclusive products meet certain thresholds. Provided the Pfizer Agreement remains in place, Pfizer will also pay escalating royalties from a low to midfraction of one percent of net sales of all products. Pfizer's obligations to pay royalties with respect to a product within a country will expire after specific criteria including such product no longer being covered by patent rights licensed to Pfizer by us in such country. Royalty payments are subject to reduction after the introduction of a biosimilar product in such country by a third party.

#### **Intellectual Property**

Protection of our intellectual property is fundamental to the long-term success of our business and is an important commercial strategy. Like other companies in the life sciences industry, we seek to protect our significant technologies by pursuing and maintaining patent protection. We also seek to protect aspects of our business as confidential know-how and as trade secrets. Our commercial success depends in part upon our ability to obtain and maintain protection afforded by laws directed toward intellectual property rights, to defend and enforce these rights and to operate without infringing the intellectual property rights of others.

The patent positions for high-technology, life sciences companies like ours are generally uncertain and can involve complex legal, scientific and factual issues. Issued patents are subject to interpretation as to their scope and applicability, and that uncertainty is typically not resolved in whole or in party except in litigation. Patent applications involve even more uncertainty because the scope of claims pending in a patent application may be significantly reduced or otherwise changed in order to obtain the grant of a patent. Moreover, even if granted, the scope, validity and enforceability of granted claims can be challenged in a variety of proceedings. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness or non-enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the relevant patent office, or made a misleading statement, during prosecution. Third parties may also raise similar claims before administrative bodies in the United States or abroad, outside of the context of litigation *per se*. Such mechanisms include *ex parte* re-examination, *inter partes* review, post-grant review, derivation and pre- and post-grant opposition proceedings.

As a result, we cannot guarantee that any of our products or technologies will be protected or remain protectable by enforceable patents. We cannot predict whether any particular patent application that we are currently pursuing in any particular jurisdiction will be granted as a patent or whether the claims of any patents we obtain will sufficiently exclude others from making, using or selling products or services in competition to us. Nor can we guarantee that third parties will not circumvent our patent claims by designing around them.

Changes in the patent laws or interpretation of the patent laws in the United States or in other jurisdictions could increase these uncertainties and the costs surrounding prosecution of patent applications and enforcement or defense of issued patents. For instance, under the Leahy-Smith America Invents Act (the America Invents Act), enacted in September 2011, the United States transitioned to a first inventor to file system in which, assuming that other requirements for patentability are met, the first inventor to file a patent application on a given invention is entitled to a patent on the invention regardless of whether a third party was the first to invent the

claimed invention. The America Invents Act also provides for third-party submission of prior art to the USPTO during patent prosecution and additional procedures to challenge the validity of a patent after grant, including post-grant review and *inter partes* review. The America Invents Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business, financial condition, results of operations and prospects.

Furthermore, the courts have held that patent claims that recite laws of nature are not patent eligible, but patent claims that recite sufficient additional features that provide practical assurance that claimed processes are genuine inventive applications of those laws may be patent eligible. But what constitutes a "sufficient" additional feature is the subject of uncertainty. The USPTO has published and continues to revise and publish guidelines for patent examiners to apply when examining claims for patent eligibility as the case law continues to evolve. Patent eligibility is also an area of the law under continual development in other jurisdictions around the world.

In addition, U.S. Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained.

Our patent portfolio includes more than 300 pending or issued cases worldwide. The portfolio focuses on instruments, devices and methods for synthesizing and assembling high-fidelity DNA, while also including genome engineering and editing technologies. The instrument portfolio includes domestic (U.S.) and foreign patents for the BioXp and the DBC instruments, which allow users to synthesize DNA molecules of specific sequence from pre-synthesized oligonucleotides or directly from digital DNA sequence using nucleotides, thus allowing users to rapidly synthesize DNA molecules on demand in their own laboratory. Further protection is provided by method patents relating to molecular biology processes performed on the instruments, patents protecting a key instrument component and a bio-security component useable with the instruments to counter misuse. The DNA synthesis portfolio features the widely used Gibson Assembly® method, a staple method in DNA laboratories around the world that allows users to join multiple DNA fragments in a single reaction. The portfolio also includes patent applications for our enzymatic DNA synthesis technology, known as SOLA (short oligonucleotide ligation assembly).

Other highlights of the portfolio include a genome editing technology that provides an alternative technique to CRISPR/Cas9, a technology for generating synthetic genomes that permits the user to "pop in" novel genome segments containing pre-programmed functions, and a "watermarking" DNA data storage method for encoding human readable text conveying a non-genetic message into nucleic acid sequences. The portfolio also includes issued patents directed to "endotoxin free" *Vibrio* organisms that provide researchers with the ability to use the ultra-fast-growing *Vibrio natriegens* (Vmax) organism in research and production applications with reduced risks of endotoxin in the product. More recently filed patent applications relate to a technology focused on building DNA molecules of ultra-high fidelity suitable for synthetic biology applications, and a technology permitting users to synthesize any possible DNA sequence at high fidelity from a library having a limited number of oligonucleotide members.

The portfolio contains U.S. patents or allowed U.S. applications relating to the BioXp and DBC instruments, and our Gibson Assembly methods and several foreign patents relating to the BioXp systems and Gibson Assembly. The portfolio also contains U.S. patents or allowed U.S. applications relating to our fast-growing *Vibrio natriegens* host cell organisms and numerous granted foreign patents for our various DNA synthesis methods.

The portfolio includes patents and pending patent applications in three main technology areas of instrumentation, DNA synthesis and assembly and genome engineering, as follows:

#### Instrumentation

As of March 1, 2023, this section of the portfolio contains one issued U.S. patent application relating to the BioXp and an issued U.S. patent for the DBC. In Australia, we have granted patents for both BioXp and DBC; and in Japan we have a granted patent for BioXp and a granted patent for the DBC. In Europe we have a granted patent for the BioXp, validated in seven European Patent Convention (EPC) member countries. In Europe we also have a pending application to the DBC. In Canada, we have an allowed application to the BioXp and a pending application to the DBC. In Singapore we have granted patents to the BioXp and DBC. Other patent applications are pending in China and India. In Israel, we have an allowed patent to the BioXp and a pending application to the DBC. The nominal terms of the foregoing patents (including any patents granted on the pending applications) will expire in 2033. In addition, the portfolio contains patents to a key instrument component, a lid engineered to enclose a sample retention area within the very small confines of a laboratory instrument, issued in the U.S., Australia, and China, with corresponding applications pending in 2035. This section of the portfolio also features two U.S. patents relating to a bio-security component to counter misuse of the BioXp and DBC instruments; the nominal term of these patents will expire in 2035.

#### DNA Synthesis and Assembly

This section of the portfolio features the Gibson Assembly patents, and contains patents in the U.S., Europe (validated in seven EPC member countries), Japan, China, India, Israel, Singapore, Australia, and Canada. The nominal terms of the foregoing OUS patents (including any patents granted on the pending applications) will expire in 2029. In addition, this section includes three filed U.S. applications and two filed PCT applications, each relating to advanced methods of enzymatic DNA synthesis from a pre-manufactured library of components. This section of the portfolio also includes foreign applications in Australia, Canada, China, Europe, India, Japan, and Singapore. Additionally, as of March 1, 2023, this section of the portfolio features:

- patents for our advanced error correction technology in the U.S., Europe (validated in seven EPC member countries), Japan, Australia, Singapore, Canada, Israel, and China, expiring in 2033; corresponding or additional applications are pending in Japan, India Europe, and Singapore. The portfolio also contains patents to an earlier error correction technology issued in the U.S., Europe (validated in six EPC member countries), Japan, Canada, and Australia, expiring in 2026;
- an issued U.S. patent to a "PCR variant" method for assembling DNA molecules. The nominal term of any patent granted on this application would expire in 2037;
- patents covering our earlier (pre-Gibson Assembly) DNA assembly methods issued in the U.S. (six patents), Canada (two patents), Malaysia (two patents), and Europe (two patents, each validated in six EPC member countries), expiring in 2026;
- patents relating to a method of sequencing and retrieving individualized or monoclonized nucleic acids from a solid support, issued in the U.S. (six patents) and Europe (three patents, each validated in eight EPC member countries), expiring in 2027;
- issued patents to a PEG-mediated DNA assembly method in Europe (validated in seven EPC member countries), Australia, Canada, Japan, India, Israel, and Singapore, expiring in 2033, with a corresponding application pending in China;
- patents relating to a method of building large DNA molecules, issued in the U.S., Europe (validated in six EPC member countries), Japan, India, China, Australia, Singapore, and Malaysia, expiring in 2028; and
- issued patents to our Rolling Circle Amplification method in the U.S., Europe (validated in six EPC member countries), China, India, Australia, Israel, Brazil, and Hong Kong, expiring in 2026.

#### Genome engineering

This portfolio family contains two U.S. patents covering a vector useful in Vibrio organisms and an engineered Vibrio organism, expiring in 2036 and 2037, respectively. This family also contains one issued patent for a low endotoxin *Vibrio natriegens* host cell in the U.S. and corresponding applications in Europe and Canada, which if granted as patents would expire in 2038. Additionally, this portfolio contains an issued U.S. patent relating to a Vibrio organism that remains culturable after storage at low temperatures, which expires in 2039. Additionally, this portfolio contains a pending European application, which if granted would expire in 2037. Additionally, as of March 1, 2023, this section of the portfolio features:

- one issued U.S. patent application covering our genome editing "pop in cassette" technology and a second, pending U.S. application, as well as pending foreign applications in Europe, Canada and Australia;
- one issued U.S. patent application relating to a method of editing a gene (an alternate method to CRISPR-Cas9). This family also includes patents relating to methods of cloning donor genomes and making synthetic cells issued in the U.S. (two patents), Europe (one patent validated in five EPC member countries and one pending), Canada (one patent), Singapore (one patent), Japan (three patents), China (two patents), India (one patent), Australia (one patent) and Israel (two patents), expiring in 2030;
- patents relating to methods of creating synthetic cells and nucleic acid constructs issued in the U.S. (two patents), Europe (two patents, each validated in six EPC member countries), Japan (one patent), India (one patent), Canada (one patent), Australia (two patents) and Taiwan (one patent), expiring in 2026;
- patents relating to transplantation of a Mycoplasma genome issued in the U.S., Europe (validated in five EPC member countries), Japan, China, India, Australia, Israel and Singapore, expiring in 2028;
- patents relating to encoding identifying watermark sequences into genomes issued in the U.S., Europe (validated in six EPC member countries), Canada, Australia and South Africa, expiring in 2030; and
- patents relating to a method of transferring a genome from a bacteria into a yeast host cell issued in the U.S. and Europe (validated in the UK, Belgium, Switzerland, Germany, and France), expiring in 2033.

We protect other valuable aspects of our business as confidential know-how, and, if eligible, as trade secrets. For example, we protect certain aspects of our manufacturing processes as trade secrets. Although trade secret protection does not expire as long as the protected information is kept secret from the public, it can be challenging to maintain such efforts. We implement measures designed to protect our trade secrets and other confidential proprietary information, including by physically restricting access to our premises and physically or electronically securing our confidential information, as well as by requiring our employees, consultants, scientific advisors, contractors and commercial partners to execute non-disclosure agreements. However, third parties may independently develop the subject matter of trade secrets that we hold, in which case we have no remedy if such parties should use such subject matter in furtherance of their own commercial interests. Further, while the law may provide remedies against third-party misappropriation or other unlawful access to our trade secrets and other proprietary information, such remedies may be difficult to obtain in practice and may not make our business whole even if successfully obtained. As a result, we may be unable to obtain meaningful benefits from laws intended to protect trade secrets or similar intellectual property rights.

In addition, third parties may initiate litigation against us alleging infringement, misappropriation or other violation of their proprietary rights or seeking a declaration of their noninfringement of our intellectual property rights. An adverse result in any such proceeding could include enjoining of the commercialization of our products, result in significant damages and have a material adverse effect on our business. Even if we are successful in any such litigation, we may be required to incur significant costs and dedicate significant personnel time in defending such litigation.

#### **Government Regulation**

#### FDA Medical Device Regulation

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

The FDA classifies medical devices into one of three classes. Devices deemed to pose lower risk to the patient are placed in either class I or II, which, unless an exemption applies, requires the manufacturer to submit a pre-market notification requesting FDA clearance for commercial distribution pursuant to Section 510(k) of the FDC Act. This process, known as 510(k) clearance, requires that the manufacturer demonstrate that the device is substantially equivalent to a previously cleared and legally marketed 510(k) device or a "pre-amendment" class III device for which pre-market approval applications (PMAs) have not been required by the FDA. This FDA review process typically takes from four to twelve months, although it can take longer. Most class I devices are exempted from this 510(k) premarket submission requirement. If no legally marketed predicate device can be identified for a new device to enable the use of the 510(k) pathway, the new device is automatically classified under the FDC Act as class III, which generally requires PMA approval. 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. To grant such a reclassification, FDA must determine that the FDC Act's general controls alone, or general controls and special controls together, are sufficient to provide a reasonable assurance of the device's safety and effectiveness. The *de novo* classification route is generally less burdensome than the PMA approval process.

Devices deemed by the FDA to pose the greatest risk, such as life-sustaining, life-supporting, or implantable devices, or those deemed not substantially equivalent to a legally marketed predicate device, are placed in class III. Class III devices typically require PMA approval. To obtain PMA approval, an applicant must demonstrate the reasonable safety and effectiveness of the device based, in part, on data obtained in clinical studies. 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.

Additionally, modifications that could significantly affect the safety and effectiveness of any FDA cleared or approved products, such as changes to the intended use or technological characteristics of the products, will require new 510(k) clearances or PMAs for those distributed in the U.S., or similar foreign marketing authorizations for those distributed outside of the U.S., or require the manufacturer to recall or cease marketing the modified devices until these clearances or approvals are obtained. In particular, even after approval of a PMA, a new PMA or PMA supplement may be required in the event of a modification to the device, its labeling or its manufacturing process. Supplements to a PMA may require the submission of the same type of information required for an original PMA, except that the supplement is generally limited to that information needed to support the proposed change from the product covered by the original PMA.

If we decide to expand our products in the future to include clinical or diagnostic products that are regulated by FDA as medical devices, we will 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. Obtaining the requisite regulatory approvals, including the FDA quality system inspections that are required for PMA approval, can be expensive and time consuming. The regulatory approval process for such products may be significantly delayed, may be significantly more expensive than anticipated, and may conclude without such products being approved by the FDA. Without timely regulatory clearance or approval, we will not be able to launch or successfully commercialize any diagnostic or clinical medical devices that we may develop in the future.

If regulated as a medical device, after a medical device is placed on the market, numerous regulatory requirements apply, including but not limited to the quality manufacturing requirements set forth in the QSRs, labeling regulations, the FDA's general prohibition against promoting products for unapproved or "off label" uses, registration and listing, the Medical Device Reporting regulation, and the Reports of Corrections and Removals regulation. The FDA can enforce pre- and post-market requirements by unannounced inspection, market surveillance and other means. If the FDA finds a violation, it can institute a wide variety of enforcement actions, ranging from an untitled regulatory letter or a warning letter, to more severe sanctions such as fines, injunctions and civil penalties; recall or seizure of products; operating restrictions, partial suspension or total shutdown of production; refusing requests for 510(k) clearance or PMA approval of new products; withdrawing 510(k) clearance or PMA approvals already granted; and criminal prosecution.

#### **Products Labeled and Marketed for Research Use Only**

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

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

As discussed above, although our products are currently labeled and sold 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.

In the future, certain of our products or related applications could become subject to regulation as medical devices by the FDA. For example, if we wish to label and expand product lines to address the diagnosis of disease or for use for a clinical purpose, regulation by governmental authorities in the United States and other countries will become an increasingly significant factor in development, testing, production, labeling, promotion, and marketing. Products that we may develop in the diagnostic, clinical, and healthcare markets, depending on their intended use, may be regulated as medical devices or in vitro diagnostic products (IVDs) by the FDA and comparable agencies in other countries. In the United States, distribution or marketing of medical devices will require us to comply with pre-market and post-market controls imposed by the FDA, unless an exemption applies, and we would be required to obtain either prior 510(k) clearance or prior premarket approval from the FDA before commercializing such medical device.

#### Laboratory Developed Tests (LDTs)

In some cases, our customers may use our RUO products in their own LDTs or in other FDA-regulated products for clinical diagnostic use, which can also increase our liability. LDTs are developed, validated and used within a single laboratory. In the past, the FDA generally exercised enforcement discretion for LDTs and did not require clearance or approval prior to marketing. On October 3, 2014, FDA issued two draft guidances that proposed to actively regulate LDTs using a risk-based approach, which would have required 510(k)s or PMAs for certain "moderate" or "high" risk devices. However, in late November 2016, FDA announced that it would not finalize the 2014 draft LDT guidance. More recently, the FDA has issued warning letters to genomics labs for illegally marketing certain genetic tests without prior FDA clearance or approval, noting that the FDA has not created a legal "carve-out" for LDTs and retains discretion to take action when appropriate, such as when certain genomic tests raise significant public health concerns. As manufacturers develop more complex genetic tests and diagnostic software, the FDA may increase its regulation of LDTs.

In August 2020, the HHS announced rescission of guidance and other informal issuances of the FDA regarding premarket review of LDT absent notice-and-comment rulemaking, stating that, absent notice-and-comment rulemaking, those seeking approval or clearance of, or an emergency use authorization, for an LDT may nonetheless voluntarily submit a premarket approval application, premarket notification or an Emergency Use Authorization request, respectively, but are not required to do so. In November 2021, HHS under the Biden administration issued a statement that withdrew the August 2020 policy announcement, stating that HHS does not have a policy on LDTs that is separate from FDA's longstanding approach. Legislative and administrative proposals to amend the FDA's oversight of LDTs have been introduced in recent years, including the Verifying Accurate Leading-edge IVCT Development Act of 2021 (VALID Act). In September 2022, Congress passed the FDA user fee reauthorization legislation without substantive FDA policy riders, including the VALID Act, but Congress may revisit the policy riders and enact other FDA programmatic reforms in the future. It is unclear how future legislation by federal and state governments and FDA regulation will impact the industry, including our business and that of our customers. Any restrictions or heightened regulatory requirements on LDTs, IVDs, or RUO products by the FDA, HHS, Congress, or state regulatory authorities may decrease the demand for our products, increase our compliance costs, and negatively impact our business and profitability. We will continue to monitor and assess the impact of changing regulatory landscape on our business.

#### International Medical Device Regulation

To the extent we decide to seek regulatory marketing authorization for certain of our products in countries outside of the United States, we or our partners, or collaborators, will need to obtain regulatory marketing authorization for such products for the intended

use in the jurisdiction where such products will be marketed. Regulatory clearance or approval in one jurisdiction does not mean that we will be successful in obtaining regulatory marketing authorization in other jurisdictions where we conduct business.

Sales of such medical products outside the United States will likely be subject to foreign regulatory requirements, which can vary greatly from country to country, as well as FDA regulation on export of medical devices. The European Commission has adopted numerous directives and standards that address regulation of the design, manufacture, labeling, clinical studies and post-market vigilance for medical devices. Under the centralized authorization procedure, devices that comply with the requirements of a relevant directive will be entitled to bear the CE conformity marking, indicating that the device conforms to the essential requirements of the applicable directives and, accordingly, can be marketed throughout the European Union and European Economic Area member states. The European Medical Device Regulation (MDR), which replaces Europe's Medical Device Directive (MDD), come into application on May 26, 2021. Additionally, the In Vitro Diagnostic Regulation (IVDR 2017/746), which addresses several weaknesses of the In Vitro Diagnostic Directive (IVDD 98/79/EC), went into application on May 26, 2022. Recently, European Parliament voted in favor of amendment to extend the transition timelines for MDR and IVDR for certain device manufacturers. Compliance with these and other regulations outside of the United States will increase our compliance costs and exposure to liability.

#### **Other Government Regulations**

In the United States, various federal and state regulators, including governmental agencies like the Consumer Financial Protection Bureau and the Federal Trade Commission, have adopted, or are considering adopting, laws and regulations concerning personal information and data security. Certain state laws may be more stringent or broader in scope, or offer greater individual rights, with respect to personal information than federal, international or other state laws, and such laws may differ from each other, all of which may complicate compliance efforts. For example, the CCPA, which increases privacy rights for California residents and imposes obligations on companies that process their personal information, came into effect on January 1, 2020. Among other things, the CCPA requires covered companies to provide new disclosures to California consumers and provide such consumers new data protection and privacy rights, including the ability to opt-out of certain sales of personal information. The CCPA provides for civil penalties for violations, as well as a private right of action for certain data breaches that result in the loss of personal information. This private right of action may increase the likelihood of, and risks associated with, data breach litigation. In addition, laws in all 50 U.S. states require businesses to provide notice to consumers whose personal information has been disclosed as a result of a data breach. State laws are changing rapidly and there is discussion in the U.S. Congress of a new comprehensive federal data privacy law to which we would become subject if it is enacted.

Although we take measures to protect sensitive data from unauthorized access, use or disclosure, our information technology and infrastructure may be vulnerable to attacks by hackers or viruses or breached due to employee error, malfeasance or other malicious or inadvertent disruptions. Any such breach or interruption could compromise our networks and the information stored there could be accessed by unauthorized parties, manipulated, publicly disclosed, lost or stolen. Any such access, breach or other loss of information could result in legal claims or proceedings, and liability under federal or state laws that protect the privacy of personal information, such as the Health Insurance Portability and Accountability Act of 1996 (HIPAA), the Health Information Technology for Economic and Clinical Health Act, and regulatory penalties. Notice of breaches must be made to affected individuals, the Secretary of the Department of HHS, and for extensive breaches, notice may need to be made to the media or State Attorneys General. Such a notice could harm our reputation and our ability to compete.

In the future, to the extent we develop any clinical or diagnostic medical devices, our operations in the United States and abroad will be subject to various healthcare laws and enforcement by the applicable government agencies. Such laws include, without limitation, federal and state anti-kickback or anti-referral laws; healthcare fraud and abuse laws; false claims laws; federal and state privacy and security laws, such as HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 (HITECH), CCPA, and CPRA; Physician Payments Sunshine Act and related state transparency and manufacturer reporting laws; marketing compliance and advertising laws; and other laws and regulations applicable to medical device manufacturers. If we expand our business outside of the United States, we would be subject to additional laws and regulations in countries where we conduct business, including but not limited to the GDPR. These laws may impact our operations directly, or indirectly through our contractors, agents, or customers, and may impact, among other things, our sales and marketing strategy.

If our operations are found to be in violation of any of the federal, state, and foreign laws described above or any other current or future fraud and abuse or other healthcare laws and regulations that apply to us, we may be subject to significant penalties, including significant criminal, civil, and administrative penalties, damages, fines, imprisonment for individuals, exclusion from participation in government programs, such as Medicare and Medicaid, and we could be required to curtail or cease our operations. Any of the foregoing consequences could seriously harm our business and our financial results.

Given the evolving nature of our industry, legislative bodies or regulatory authorities may adopt additional regulation or expand existing regulation to include our products and services. 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 authorization for our products and services, if required. These regulations and restrictions may materially and adversely affect our business, financial condition, and results of operations.

## Facilities

Our principal facilities are located at 10431 and 10421 Wateridge Circle in San Diego, California and function as our worldwide headquarters. The facilities total approximately 49,077 square feet at 10421 Wateridge Circle and approximately 17,146 square feet at 10431 Wateridge Circle and are leased from BioMed Realty beginning in September 2021 and continuing for 123 months after the lease commencement date. We are entitled to one option to extend the lease term for an additional five years after the expiry of the original 123 month term. The facilities contain infrastructure for reagent manufacturing and for research and development of new products, as well as for supporting supply chain, logistics and limited office space for administrative and commercial functions. The facilities also include wet labs for both reagent manufacturing and research and development on both floors as well as specialized labs for instrument engineering to support the development of new instruments. A designated instrument services lab space supports our current installed base customers.

In connection with the EtonBio Inc., (Eton) acquisition in November 2021, we assumed a lease of office and laboratory space located at 10179 Huennekens Street, San Diego, California. We have recently entered into an amendment under which we occupy approximately 3,500 square feet. The lease term as amended expires in June 2023.

In connection with the Eton acquisition in November 2021, we assumed a lease of office and laboratory space located at 10717 Sorrento Valley Road, San Diego, California. The facility is approximately 8,000 square feet and was leased from Sorrento Realty LLC. The lease term expires in November 2024 and has an option to extend the term for an additional three years at the then current fair market value rental rate for comparable office and laboratory space.

In connection with the Eton acquisition in November 2021, we assumed a lease of office and laboratory space located at 400 Park Offices Drive, Durham County, North Carolina. The facility is approximately 3,000 square feet. and was leased from Frontier Hub, LLC. The lease term expires in October 2023.

In connection with the Eton acquisition in November 2021, we assumed a lease office and laboratory space located at 56 Roland Street, Boston, Massachusetts. The facility is approximately 4,300 square feet and was leased from Paradigm Direct Roland. The lease term expired in June 2022, and we currently occupy the space on a month-to-month basis.

In connection with the Eton acquisition in November 2021, we assumed a lease of office and laboratory space located at 1075 Morris Avenue, Union, New Jersey. The facility is approximately 1,200 square feet and was leased from Institute for Life Sciences Entrepreneurship. The lease term expired in November 2022, and we currently occupy the space on a month-to-month basis.

#### **Employees and Human Capital**

As of December 31, 2022, we had 209 full-time and 20 part-time employees in the United States and 14 full-time employees located internationally. Our team includes: 61 in commercial sales, marketing, and support, 118 in manufacturing and operations, 19 in research and development, 18 in engineering, and 27 in general and administrative functions. None of our employees is represented by a labor union or covered by a collective bargaining agreement. We consider our relationship with our employees to be good.

#### **Corporate Information and History**

We were formed in Delaware as a corporation on March 24, 2011 under the name Synthetic Genomics Solutions, Inc., as a wholly owned subsidiary of Synthetic Genomics, Inc. On February 26, 2013, we changed our name to SGI-DNA, Inc., and on March 31, 2020 we changed our name to Codex DNA, Inc. We subsequently changed our name to Telesis Bio Inc. on November 7, 2022. Our principal executive offices are located at 10431 Wateridge Circle, Suite 150, San Diego, CA 92121. Our telephone number at that address is (858) 228-4115. Our website address is www.telesisbio.com. Information contained on our website is not incorporated by reference into this Annual Report and should not be considered part of this Annual Report.

#### Implications of Being an Emerging Growth Company

We are an "emerging growth company" as defined in the Jumpstart Our Business Startups Act of 2012, as amended, or the JOBS Act. We will remain an emerging growth company until the earliest to occur of: the last day of the fiscal year in which we have more than \$1.235 billion in annual revenue; the date we qualify as a "large accelerated filer," with at least \$700 million of equity

securities held by non-affiliates; the issuance, in any three-year period, by us of more than \$1.0 billion in non-convertible debt securities; and the last day of the fiscal year ending after the fifth anniversary of our initial public offering.

An emerging growth company may take advantage of reduced reporting requirements that are otherwise applicable to public companies. These provisions include, but are not limited to:

- not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002, as amended;
- reduced disclosure obligations regarding executive compensation in our periodic reports, proxy statements and registration statements; and
- exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved.

In addition, the JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards, delaying the adoption of these accounting standards until they would apply to private companies. We have elected to use this extended transition period to enable us to comply with new or revised accounting standards that have different effective dates for public and private companies until the earlier of the date we (i) are no longer an emerging growth company or (ii) affirmatively and irrevocably opt out of the extended transition period provided in the JOBS Act. As a result, our consolidated financial statements may not be comparable to companies that comply with the new or revised accounting standards as of public company effective dates.

To the extent that we continue to qualify as a "smaller reporting company," as such term is defined in Rule 12b-2 under the Securities Exchange Act of 1934, after we cease to qualify as an emerging growth company, we will continue to be permitted to make certain reduced disclosures in our periodic reports and other documents that we file with the SEC.

#### **Available Information**

We make our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, and amendments to those reports, available free of charge at our website as soon as reasonably practicable after they have been filed with the SEC. Our website address is http://telesisbio.com. Information on our website is not part of this report. The SEC maintains a website that contains the materials we file with the SEC at www.sec.gov.

#### **ITEM 1A. RISK FACTORS**

Investing in our common stock involves a high degree of risk. You should carefully consider the risks described below, as well as the other information in this Annual Report, including our consolidated financial statements and the related notes and the section titled "Management's Discussion and Analysis of Financial Condition and Results of Operations" in this Annual Report, before deciding whether to invest in our common stock. The occurrence of any of the events or developments described below could harm our business, financial condition, results of operations and prospects. In such an event, the market price of our common stock could decline, and you may lose all or part of your investment. Additional risks and uncertainties not presently known to us or that we currently deem immaterial also may impair our business operations and the market price of our common stock.

#### **Summary Risk Factor**

- We are an early-stage multi-omic and synthetic biology technology company with a history of net losses, which we expect to continue, and we may not be able to generate meaningful revenues or achieve and sustain profitability in the future;
- we have a limited operating history, which may make it difficult to evaluate the prospects for our future viability and predict our future performance;
- our operating results may fluctuate significantly in the future, which makes our future operating results difficult to predict and could cause our operating results to fall below expectations or any guidance we may provide;
- we will likely need to raise additional capital to fund our operations, which may be unavailable to us or may cause dilution or place significant restrictions on our ability to operate as a going concern on acceptable terms or at all;
- our independent registered public accounting firm's report contains an explanatory paragraph that expresses substantial doubt about our ability to continue as a "going concern.";
- adverse developments affecting the financial services industry, including events or concerns involving liquidity, defaults or non-performance by financial institutions, could adversely affect our business, financial condition or results of operations;
- we may not be able to achieve or maintain satisfactory pricing and margins for our products;
- if we fail to timely introduce compelling new products, our revenues and our prospects could be harmed;
- the size of the markets for our products may be smaller than estimated, and new market opportunities may not develop as quickly as we expect, or at all, thus limiting our ability to successfully meet our anticipated revenue projections;
- we have limited experience in sales and marketing of our products;
- we plan to begin manufacturing certain of our BioXp products in-house in 2023. We have limited experience manufacturing our products and if we directly or indirectly encounter problems manufacturing our products, our business and financial results could suffer;
- we currently rely on a single contract manufacture to manufacture and supply our instruments and single source suppliers for certain components of our instruments and raw materials. If this manufacturer or these suppliers should fail or not perform satisfactorily, our ability to commercialize and supply our products would be adversely affected; and
- if we are unable to obtain and maintain sufficient intellectual property protection for our products and technology, or if the scope of the intellectual property protection obtained is not sufficiently broad, our competitors could develop and commercialize products similar or identical to ours, and our ability to successfully commercialize our products and build a strong brand identity may be impaired.

#### **Risks Related to Our Business**

# We are an early-stage multi-omic and synthetic biology technology company with a history of net losses, which we expect to continue, and we may not be able to generate meaningful revenues or achieve and sustain profitability in the future.

We are an early-stage multi-omic and synthetic biology technology company, and we have incurred significant losses since separating from Synthetic Genomics, Inc. (SGI) and beginning to operate as a stand-alone entity in March 2019, and expect to continue incurring losses in the future. We incurred a net loss of \$48.5 million for the year ended December 31, 2022. As of December 31, 2022, we had an accumulated deficit of \$113.7 million. These losses and accumulated deficit were primarily due to the substantial investments we have made to develop, commercialize and market our technology and products. Over the next several years, we expect to continue to devote a significant portion of our resources towards the continued development and

commercialization of our synthetic biology products. These efforts may prove more costly than we currently anticipate. In addition, as a public company, we will incur significant legal, accounting, administrative, insurance and other expenses that we did not incur as a private company. Accordingly, we cannot assure you that we will achieve profitability in the future or that, if we do become profitable, we will remain profitable.

# We have a limited operating history, which may make it difficult to evaluate the prospects for our future viability and predict our future performance.

Our prospects must be considered in light of the uncertainties, risks, expenses, and difficulties frequently encountered by companies in their early stages of operations. For example, our management team has had a limited time working together and many of our key employees are new to our company. Predictions about our future success or viability are highly uncertain and may not be as accurate as they could be if we had a longer operating history or a longer history of successfully developing and commercializing products.

In addition, as a business with a limited operating history, we may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown obstacles. We have encountered in the past, and will encounter in the future, risks and uncertainties frequently experienced by growing companies with limited operating histories in emerging and rapidly changing industries. If our assumptions regarding these risks and uncertainties, which we use to plan and operate our business, are incorrect or change, or if we do not address these risks successfully, our results of operations could differ materially from our expectations, and our business, financial condition and results of operations could be adversely affected.

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

Our quarterly and annual operating results may fluctuate significantly, which makes it difficult for us to predict our future operating results. These fluctuations may occur due to a variety of factors, many of which are outside of our control, including, but not limited to:

- the level of demand for our commercialized products, which may vary significantly from period to period;
- our ability to drive adoption of our products in our target markets and our ability to expand into any future target markets, including internationally;
- the prices at which we will be able to sell our products;
- the volume and mix of our sales between our BioXp systems, BioXp kits, benchtop reagents and other products, or changes in the manufacturing or sales costs related to our products;
- the length of time of the sales cycle for purchases of, or royalties on, our products, including lead time needed to procure critical raw materials from suppliers and finished goods from our third-party contract suppliers and manufacturers;
- the extent to which we succeed in developing, commercializing and supporting new products;
- our ability to obtain necessary export licenses for our products in certain countries and territories;
- potential shortages, or increases in costs, of our product components or raw materials for existing and new products, or other disruptions to our supply chain;
- the timing and cost of, and level of investment in, research and development and commercialization activities relating to our products, which may change from time to time;
- our ability to successfully manage relationships with customers, third-party distributors and suppliers of our products;
- the timing and amount of expenditures that we may incur to develop, commercialize or acquire additional products and technologies;
- changes in governmental funding sources;
- cyclical changes to the research and development budgets within the pharmaceutical, biotechnology and industrial segments of synthetic biology;
- seasonal spending patterns of our customers;
- the expenses needed to attract and retain skilled personnel;
- future accounting pronouncements or changes in our accounting policies;

- the outcome of any litigation or governmental investigations involving us, our industry or both;
- higher than anticipated service, replacement and warranty costs;
- the costs associated with being a public company;
- changes in the regulatory environment;
- the impact of the COVID-19 pandemic on the economy, investment in synthetic biology and research industries, our business operations, and resources and operations of our customers, suppliers, and distributors; and
- general industry, economic and market conditions and other factors, including factors unrelated to our operating
  performance or the operating performance of our competitors.

The cumulative effects of the factors discussed above could result in large fluctuations and unpredictability in our quarterly and annual operating results. As a result, comparing our operating results on a period-to-period basis may not be meaningful. Investors should not rely on our past results as an indication of our future performance.

This variability and unpredictability could also result in our failing to meet the expectations of industry or financial analysts or investors for any period of time. If our operating results fall below the expectations of analysts or investors or below any guidance we may provide, or if the guidance we provide is below the expectations of analysts or investors, it could cause the market price of our common stock to decline.

# We will likely need to raise additional capital to fund our operations, which may be unavailable to us or may cause dilution or place significant restrictions on our ability to operate as a going concern on acceptable terms or at all.

If our available cash resources and anticipated cash flow from operations are insufficient to satisfy our liquidity requirements, including because of lower demand for our products or the realization of other risks described herein, we will be required to raise additional capital prior to such time through issuances of equity or convertible debt securities, or seek debt financing or other form of third-party funding.

We will likely seek to raise additional capital in the future to expand our business, to pursue strategic investments, to take advantage of financing opportunities or for other reasons, including:

- increasing our sales and marketing and other commercialization efforts to drive market adoption of our products;
- funding development and marketing efforts of our current or any future products;
- expanding our technologies into additional markets;
- acquiring, licensing or investing in technologies and other intellectual property rights;
- acquiring or investing in complementary businesses or assets; and
- financing capital expenditures and general and administrative expenses.

Our present and future funding requirements will depend on many factors, including:

- our rate of progress in increasing penetration of our target markets with current and new products, and the cost of the sales and marketing activities associated with establishing adoption of our products;
- our rate of progress in, and cost of research and development activities associated with, products in research and development; and
- the effect of competing technological and market developments.

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

The various ways we could raise additional capital carry potential risks. If we raise funds by issuing equity securities, dilution to our stockholders would result. If we raise funds by issuing debt securities, those debt securities would have rights, preferences and privileges senior to those of holders of our common stock. The terms of debt securities issued or borrowings pursuant to a credit agreement could impose significant restrictions on our operations. If we raise funds through collaborations or licensing arrangements,

we might be required to relinquish significant rights to our technologies or products or grant licenses on terms that are not favorable to us.

If we raised funds through the sale of assets, we may sell intellectual property, product lines or other parts of our business. Divestitures involve risks, including difficulties in the separation of operations, services, products and personnel, the diversion of management's attention from other business concerns, the disruption of our business, the potential loss of key employees and the retention of uncertain environmental or other contingent liabilities related to the divested assets. In addition, divestitures may result in significant asset impairment charges, including those related to goodwill and other intangible assets, and the loss of revenue which could have a material adverse effect on our financial condition and results of operations. In addition, we may not realize the expected value from the divested assets and may need to raise additional capital to replace the revenue generated from any assets that are divested. We can provide no assurance that such capital will be available or available on terms that are acceptable to us. We cannot assure you that we will be successful in managing these or any other significant risks that we encounter in selling assets, and any divestiture we undertake could materially and adversely affect our business, financial condition, results of operations and cash flows, and may also result in a diversion of management attention, operational difficulties and losses.

### Our independent registered public accounting firm's report contains an explanatory paragraph that expresses substantial doubt about our ability to continue as a "going concern."

As of December 31, 2022, we had \$43.8 million of cash, cash equivalents, and short-term investments. This raises substantial doubt about our ability to continue as a going concern within one year after the date that the financial statements are issued, and we will likely need to raise additional capital in the near term in order to fund our operations through and beyond the first quarter of 2024 and to continue as a going concern thereafter. See Part II, Item 8, Financial Statements and Supplementary Data, Note 1 of this Annual Report on Form 10-K for additional information on our assessment of our ability to continue as a going concern. Uncertainty regarding our ability to continue as a going concern could also have a material and adverse impact on the price of our common stock, which could negatively impact our ability to raise sufficient funds for our operations and continue as a going concern. In addition, cash forecasts and capital requirements are subject to change as a result of a variety of risks and uncertainties. Developments in and expenses associated with our commercialization activities and other research and development activities may consume capital resources to fund our operations, as well as any other operational or business projection we have disclosed, or may disclose, may not be achieved.

### Adverse developments affecting the financial services industry, including events or concerns involving liquidity, defaults or nonperformance by financial institutions, could adversely affect our business, financial condition or results of operations.

Actual events involving limited liquidity, defaults, non-performance or other adverse developments that affect financial institutions or the financial services industry generally, or concerns or rumors about any events of these kinds or other similar risks, have in the past and may in the future adversely affect our liquidity. For example, on March 10, 2023, the Federal Deposit Insurance Corporation (FDIC) announced that Silicon Valley Bank had been closed by the California Department of Financial Protection and Innovation. At that time, some of our cash and cash equivalents were held at Silicon Valley Bank and our access to such funds was limited until the United States Department of the Treasury announced in a joint statement with the Federal Reserve and FDIC that depositors of Silicon Valley Bank will have access to all of their money starting March 13, 2023. While we have regained access to our funds at Silicon Valley Bank and are evaluating our banking relationships, our access to funding sources and other credit arrangements in amounts adequate to finance or capitalize our current and projected future business operations could be significantly impaired by events such as liquidity constraints or failures, disruptions or instability in the financial services industry or financial markets, or concerns or negative expectations about the prospects for companies in the financial services industry. These factors may also adversely affect our ability to access our cash and cash equivalents at affected financial institutions.

In addition, investor concerns regarding the U.S. or international financial systems could result in less favorable commercial financing terms, including higher interest rates or costs and tighter financial and operating covenants, or systemic limitations on access to credit and liquidity sources, thereby making it more difficult for us to acquire financing on terms favorable to us, or at all. Any decline in available funding or access to our cash and liquidity resources could, among other things, adversely impact our ability to meet our operating expenses, financial obligations or fulfill our other obligations, result in breaches of our contractual obligations or result in violations of federal or state wage and hour laws. Any of these impacts, or any other impacts resulting from the factors described above or other related or similar factors not described above, could have material adverse impacts on our liquidity and our business, financial condition or results of operations.

#### We may not be able to achieve or maintain satisfactory pricing and margins for our products.

Our industry has a history of price competition, and we can give no assurance that we will be able to achieve satisfactory prices for our products or maintain prices at the levels we have historically achieved. If we are forced to lower the price we charge for our

products, our gross margins will decrease, which will adversely affect our ability to invest in and grow our business. We believe that we will continue to be subject to significant pricing pressure, which may limit our ability to maintain or increase our prices.

Our cost of goods is dependent upon the pricing we are able to negotiate with our suppliers of raw materials, instruments and components. In particular, we have experienced price increases for certain raw materials, such as oligonucleotides, and expect these raw materials to continue to be in high demand. We have also experienced price increases for certain raw materials directly as a result of supply chain issues associated with the COVID-19 pandemic and we are uncertain how long those constraints could continue to impact our raw material pricing. We do not have long term supply contracts for any of our raw materials. If our costs increase and we are unable to offset such increases with a proportionate increase in our prices, our margins would erode, which would harm our business and results of operations.

#### If we fail to timely introduce compelling new products, our revenues and our prospects could be harmed.

Our ability to attract new customers and increase revenue from existing customers will depend in large part on our ability to timely introduce compelling new products and pursue new market opportunities that develop as a result of technological and scientific advances. The success of any enhancement to our existing commercialized products or introduction of new products depends on several factors, including timely completion and delivery, cost-effective development and manufacturing, competitive pricing, adequate quality testing, integration with existing technologies, appropriately timed and staged introduction and overall market acceptance. We have experienced supply chain delays and increases in raw material cost for several of our products during development, including the BioXp 9600 system that we launched in 2022. If we continue to experience these delays and increases in cost, introduction of the BioXp 9600 or other new, planned products could be delayed. Moreover, any other new product that we develop may not be introduced in a timely or cost-effective manner, may contain defects, errors, vulnerabilities or bugs, or may not achieve the market acceptance necessary to generate significant revenue.

The typical development cycle of new multi-omic and synthetic biology products can be lengthy and complicated, and may require new scientific discoveries or advancements, considerable resources and complex technology and engineering. Such developments may involve external suppliers and service providers, making the management of development projects complex and subject to risks and uncertainties regarding timing, timely delivery of required components or services and satisfactory technical performance of such components or assembled products. If we do not achieve the required technical specifications or successfully manage new product development processes, or if development work is not performed according to schedule, then the development of such new technologies or products may be adversely impacted.

In addition, there is extensive competition in our industry, which 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 maintain a competitive position, including technologically superior and less expensive products compared to those of our competitors. Technological development by others may result in our technologies, as well as products developed using our technologies, becoming obsolete. If we are unable to successfully develop new products, compete with alternative products, or otherwise gain and maintain market acceptance, our business, results of operations and financial condition could be harmed.

### Our Credit, Security and Guarantee Agreements (2022 Loan Agreements) with MidCap Financial Trust contains restrictive covenants that limit our operations

Pursuant to the terms of our Term Loan and Revolver Loan (the Loans) with MidCap Financial Trust (MidCap), we have borrowed \$20.0 million and may become eligible to borrow up to an additional \$20.0 million upon achievement of certain events. If we are not in compliance with the financial covenants of the 2022 Loan Agreements, it is unlikely that MidCap will offer to extend the additional \$20.0 million of debt financing. The 2022 Loan Agreements with MidCap contain various restrictive covenants and other restrictions, including, among other things:

- a minimum revenue covenant;
- on our ability to transfer all or part of our business or property, except for inventory in the ordinary course of business, surplus or obsolete equipment, permitted liens, transfers of cash permitted by the agreement or certain other transfers;
- on our ability to change our business or move our offices;
- on our ability to liquidate or dissolve or merge or consolidate with another entity, or acquire another entity;
- on our ability to incur debt or encumber our assets; and
- on our ability to pay dividends or make investments, other than permitted investments.

These restrictions may restrict our current and future operations, particularly our ability to respond to certain changes in our business or industry or take future actions. See the section titled "Management's Discussion and Analysis of Financial Condition and Results of Operations—Liquidity and Capital Resources" for additional information.

Our ability to meet these restrictive covenants can be impacted by events beyond our control. The Loan Agreements provide that our breach or failure to satisfy certain covenants constitutes an event of default. Upon the occurrence of an event of default, our lenders could elect to declare all amounts outstanding under the Loan Agreements to be immediately due and payable. If the outstanding debt under the Loan Agreements was to be accelerated, we may not have sufficient cash on hand to repay it, which would have an immediate adverse effect on our business and operating results. This could potentially cause us to cease operations and result in a complete loss of your investment in our common stock.

### We depend on our key personnel and other highly qualified personnel, and if we are unable to recruit, train and retain our personnel, we may not achieve our goals.

Our future success depends upon our ability to recruit, train, retain and motivate key personnel. Our senior management team, including Todd R. Nelson, Ph.D., our President and Chief Executive Officer; Daniel Gibson, Ph.D., our Chief Technology Officer; Eric Esser, our Chief Operating Officer and Decky Goodrich, our Senior Vice President, Commercial Operations, is critical to our vision, strategic direction, product development and commercialization efforts. We have entered into at-will employment agreements with each of Dr. Nelson, Dr. Gibson, Mr. Esser and Mr. Goodrich, and such agreements may be terminated by either party at any time without cause. The departure of one or more of our executives officers, senior management team members or other key employees could be disruptive to our business unless we are able to hire qualified successors. We do not maintain "key man" life insurance on our senior management team.

Our continued growth depends, in part, on attracting, retaining and motivating qualified personnel, including highly trained sales personnel with the necessary scientific background and ability to understand our systems at a technical level to effectively identify and sell to potential new customers. New hires require significant training and, in most cases, take significant time before they achieve full productivity. Our failure to successfully integrate these key personnel into our business could adversely affect our business. In addition, competition for qualified personnel is intense, particularly in the San Diego area, where our operations are headquartered. We compete for qualified scientific and information technology personnel with other life science and information technology companies as well as academic institutions and research institutions.

We do not maintain fixed-term employment contracts with any of our employees. As a result, our employees could leave our company with little or no prior notice and would be free to work for a competitor. Due to the complex and technical nature of our products and technology and the dynamic market in which we compete, any failure to attract, train, retain and motivate qualified personnel could materially harm our business, results of operations, financial condition and prospects.

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

Our anticipated growth will place significant strains on our management, operational and manufacturing systems and processes, sales and marketing team, financial systems and internal controls and other aspects of our business. As of December 31, 2022, we had 209 full-time and 20 part-time employees in the United States and 14 full-time employees located internationally. We expect that we will need to hire additional accounting, finance and other personnel in connection to our efforts to comply with the requirements of being a public company. Now that we are a public company, our management and other personnel are required to devote a substantial amount of time towards maintaining compliance with these requirements and effectively manage these growth activities. We may face challenges integrating, developing and motivating our rapidly growing employee base. To effectively manage our growth, we must continue to improve our operational and manufacturing systems and processes, our financial systems and internal controls and other aspects of our business and continue to effectively expand, train and manage our personnel. Our ability to successfully manage our expected growth is uncertain given the fact that we have only been in operation as a stand-alone company since March 2019. As our organization continues to grow, we will be required to implement more complex organizational management structures, and we may find it increasingly difficult to maintain the benefits of our corporate culture, including our ability to quickly develop and launch new and innovative products. If we do not successfully manage our anticipated growth, our business, results of operations, financial condition and prospects will be harmed.

### A significant portion of our revenue in the near term will be generated from the sale of our current products.

While we anticipate that a substantial contributor to our growth will come from new product introductions, we expect that we will generate in the near term, a significant portion of our revenue from the sale of our BioXp systems and the increased sale of BioXp kits and benchtop reagents to our current customers. There can be no assurance that our current customers will increase their BioXp kit and benchtop reagent purchases. There can also be no assurance that we will be able to design other products that will meet the

expectations of our customers or that any of our future products will become commercially viable. As technologies change in the future for synthetic biology research tools, we will be expected to upgrade or adapt our products in order to maintain the latest technology.

While concentrating our research and development and commercialization efforts on our multi-omics and synthetic biology solutions, we may forego other opportunities that may provide greater revenue or be more profitable. If our research and product development efforts do not result in additional commercially viable products within the anticipated timelines, or at all, our business and results of operations will be adversely affected. Any delay or failure by us to develop and release our new products or product enhancements would have a substantial adverse effect on our business and results of operations.

### Rapidly changing technology in multi-omics and synthetic biology could make the products we are developing obsolete unless we continue to develop and manufacture new and improved products and pursue new market opportunities.

Our industry is characterized by rapid and significant technological changes, frequent new product introductions and enhancements and evolving industry standards. The preferences and needs of our customers may change over time. Our future success will depend on our ability to continually improve the products we are developing, 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 developed by us may not be accepted in the markets served by the new products. Our inability to gain market acceptance of new products could harm our future operating results. Our future success also depends on our ability to resolve manufacturing issues that may arise as we commence production of these complex products. 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.

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

During 2021, we announced the acquisition of EtonBio, Inc. We may in the future seek to acquire or invest in other businesses, applications or technologies that we believe could complement or expand our current or future products, enhance our technical capabilities or otherwise offer growth opportunities. Any acquisitions may divert the attention of management and cause us to incur various costs and expenses in identifying, investigating and pursuing suitable acquisitions, whether or not they are consummated. We may not be able to identify desirable acquisition targets or be successful in entering into an agreement with any particular target or obtain the expected benefits of any acquisition or investment.

To date, the growth of our operations has been mostly organic, and we have limited experience in acquiring and integrating other businesses or technologies. We may not be able to successfully integrate acquired personnel, operations and technologies, or effectively manage the combined business following an acquisition, including the EtonBio, Inc. acquisition. Acquisitions could also result in dilutive issuances of equity securities, the use of our available cash, or the incurrence of debt, which could harm our operating results. In addition, if an acquired business fails to meet our expectations, our operating results, business and financial condition may suffer.

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

We rely, and will continue to rely, on multiple information technology systems to operate the systems that allow our company to function, including cloud-based and on-premises information technology systems. We rely extensively on information technology systems to facilitate our principal company activities, including to operate the cloud-based platform on which the services offered to our customers rely. In addition, we also use information technology systems for a variety of key business functions, including to keep financial records, facilitate our research and development initiatives, manage our manufacturing operations, maintain quality control, fulfill customer orders, maintain corporate records, communicate with staff and external parties, and operate other critical functions.

Like all companies that rely on information technology systems, our information technology systems and those of our vendors and partners are potentially vulnerable to failures of confidentiality, integrity, and availability. Such failures could include, for example, malicious intrusion, corruption of data, and disruptive events, including but not limited to natural disasters and catastrophes. Such failures, if they occur, could compromise company, vendor or partner systems and employee, company, vendor, or partner data. A wide range of cyber attacks, including cyber intrusions, denial of service, and other malicious internet-based activity, such as social engineering and phishing scams, continue to increase. Cloud-based platform providers of services have been and are expected to continue to be targeted by a variety of threat actors, including sophisticated nation-state and nation-state-supported actors. Such threat actors use attack methods that change frequently, are increasingly complex and sophisticated, including social engineering and phishing scams, and can originate from a wide variety of sources, including insider threats or external actors. In addition to traditional computer "hackers," malicious code, such as viruses and worms, employee theft or misuse, denial-of-service attacks and sophisticated nation-state and nation-state supported actors now engage in attacks, including advanced persistent threat intrusions. In addition, we have not finalized our information technology and data security policies and procedures and therefore, our information technology systems may be more susceptible to such failures and attacks than if such security policies and procedures were finalized. Despite our efforts to create security barriers to such threats, it is virtually impossible for us to entirely mitigate these risks and there is no guarantee that our efforts are or will be adequate to safeguard against all such threats. Moreover, despite our current and future efforts, it is possible that we may not be able to anticipate, detect, appropriately react and respond to, or implement effective preventative measures against, all cybersecurity incidents. Such cybersecurity incidents can be difficult to detect and any delay in identifying such incidents may lead to increased harm and legal exposure of the type described below.

If our security measures, or those of our vendors and partners, are compromised for any reason, including negligence, error, or malfeasance, our principal company activities could cease to function, or be significantly degraded, until such cybersecurity incidents are remediated. Further, our business could be harmed, our reputation could be damaged, and we could become subject to regulatory inquiries or litigation, all of which could result in significant liability. In addition, if we were to experience a prolonged system disruption in our information technology systems or those of certain of our vendors and partners, it could negatively impact our ability to serve our customers, which could adversely impact our business, financial condition, results of operations and prospects. If operations at our facilities were disrupted and could not be promptly restored, such disruption could cause a material disruption in our business, financial condition, results of operations and prospects. Moreover, there could be public announcements regarding any cybersecurity incidents and, if securities analysts or investors perceive these announcements to be negative, it could, among other things, have a material adverse effect on our business, reputation, financial condition, results of operations and prospects.

Our information technology systems, and those of our vendors and partners, are potentially vulnerable to cybersecurity incidents such as data security breaches, which could lead to the loss and exposure of information, including personal, sensitive, and confidential data, to unauthorized persons, resulting in a data security breach. Any such data security breaches could, among other things, lead to the loss of trade secrets or other intellectual property, or could lead to the exposure of personal information, including sensitive personal information, of our employees, customers and others, any of which could have a material adverse effect on our business, reputation, financial condition, results of operations and prospects. In addition, any such data security breaches could result in legal claims or proceedings, regulatory inquiries, investigations, or actions, and other types of liability under laws that protect the privacy and security of personal information, including federal, state and foreign data protection, privacy, data security, and consumer protection regulations, violations of which could result in significant penalties and fines. Additionally, the introduction and passage of new privacy laws, including but not limited to the California Privacy Rights Act (CPRA), which went into effect on January 1,2023 and modifies the California Consumer Privacy Act (CCPA), potentially resulting in further uncertainty and may require us to incur additional costs and expenses in an effort to comply. The CPRA restricts use of certain categories of sensitive personal information that we may handle, establish restrictions on the retention of personal information, expand the types of data breaches subject to the private right of action, and establish the California Privacy Protection Agency to implement and enforce the new law and impose administrative fines. Additional compliance investment and potential business process changes will likely be required. Similar laws have been proposed in other states and at the federal level, reflecting a trend toward more stringent data privacy and security legislation in the United States. For example, on March 2, 2021, Virginia enacted the Virginia Consumer Data Protection Act, or CDPA, which took effect on January 1, 2023, on June 8, 2021, Colorado enacted the Colorado Privacy Act, or CPA, which takes effect on July 1, 2023, and on March 24, 2022, Utah enacted the Utah Consumer Privacy Act, or UCPA, which takes effect on December 31, 2023; and on May 10, 2022, Connecticut enacted the Connecticut Data Privacy Act, or CTDPA, which takes effect on July 1, 2023. The CPA, CDPA, UCPA, and CTDPA share similarities with and differences from the CPRA and legislation proposed in other states. Aspects of these state privacy statutes remain unclear, resulting in further uncertainty and potentially requiring us to modify our data practices and policies and to incur substantial additional costs and expenses in an effort to comply.

In addition, U.S. and international laws and regulations that have been applied to protect user privacy (including laws regarding unfair and deceptive practices in the U.S. and GDPR in the EU) may be subject to evolving interpretations or applications. This area of law is continuing to evolve and is subject to significant uncertainty, which may require us to incur additional costs and expenses in order to comply. Furthermore, responding to a legal claim or proceeding or a regulatory inquiry, investigation, or action, regardless of its merit, could be costly, divert management's attention and harm our reputation.

The cost of protecting against, investigating, mitigating and responding to cybersecurity incidents and data security breaches, and complying with applicable breach notification obligations to individuals, regulators, vendors, partners, and others can be significant. As threats related to cybersecurity incidents and data security breaches continue to evolve, we may be required to expend significant additional resources to continue to modify or enhance our protective measures or to detect, appropriately react to, and respond to such cybersecurity incidents and data security breaches. The inability to implement, maintain and upgrade adequate

safeguards could have a material adverse effect on our business, financial condition, results of operations and prospects. Should such disruptions occur, our current insurance policies may not be adequate to compensate us for the potential costs and other losses arising from such disruptions, failures, or security breaches and it is possible that an insurer could deny coverage on any future claim. In addition, such insurance may not be available to us in the future on economically reasonable terms or at all. The successful assertion of one or more large claims against us that exceed available insurance coverage, or the occurrence of changes in our insurance policies, including premium increases or the imposition of large deductible or co-insurance requirements, could have a material adverse effect on our business, financial condition, results of operations and prospects.

### A customer may unintentionally misuse our products or a bad actor may intentionally use our products with intent to create harm and, in either case, third parties may seek to hold us liable for the resulting harm.

All orders for our products that we receive are processed through a security filter. We verify that the shipping addresses of our customers are valid, screen the customer versus known agent lists and comply in all material respects with the know your customer rules. Despite these precautions it is possible that one of our customers may unintentionally misuse our products or a bad actor may attempt to misuse our products to create harm. If misuse of our products were to occur, the terms and conditions of our invoices may be insufficient to protect us from liability. Any indemnification that our customers are required to provide to us may be insufficient to cover the costs and damages resulting from the misuse of our products. Further, any product liability insurance we may obtain could specifically exclude bad acts of our customers from coverage or coverage limits may be insufficient to protect us from the amount of the liability we could incur. Any unintentional or intentional misuse of our products could result in liability or require us to expend costs to defend ourselves, may not be covered by insurance and may have a material and adverse effect on our business or results of operations.

### Risks Related to Supply, Manufacturing and Distribution of Our Products

## We plan to begin manufacturing certain of our BioXp products in-house in 2023. We have limited experience manufacturing our products and if we directly or indirectly encounter problems manufacturing our products, our business and financial results could suffer.

We have historically relied on a single contract manufacturer for our BioXp instruments. We plan to begin manufacturing all of our BioXp 9600 systems in-house in mid-2023 and our BioXp 3250 systems by late 2023. Manufacturing our instruments is a highly exacting and complex process. Problems can arise during manufacturing for a variety of reasons, including equipment malfunction, failure to follow specific protocols and procedures, problems with raw materials or components, cyber-attacks, natural disasters and environmental factors, and if not discovered before the product is released to market, such problems could adversely affect our ability to achieve our sales goals and could result in adverse impacts to our business and financial condition. In addition, if we are unable to properly manufacture our BioXp systems, finding an alternative manufacturer on a timely basis to replace lost production capacity may not be possible and we would therefore be unable to supply a sufficient quantity of instruments to meet demand.

Additionally, we have historically relied on external vendors to supply the oligonucleotides we use as raw material in our BioXp kit products. We plan to begin manufacturing oligonucleotides in our own manufacturing facility in 2023 and expect to scale our internal manufacturing operation to supply the majority of this raw material internally. We have limited experience manufacturing oligonucleotides and it is a highly complex process that requires specialized equipment and techniques. Problems may arise that could affect both our ability to produce sufficient volume or achieve sufficient quality of oligonucleotides. Some raw material quality issues may be difficult to detect prior to assembly into our products. This transition requires that we technically achieve our manufacturing startup milestones as well as navigate the wind-down of external supply. Should we fail to achieve our goals in manufacturing, or fail to properly manage the wind-down of external supply, our ability to supply kits would be adversely affected.

## We currently rely on a single contract manufacturer to manufacture and supply our instruments and single source suppliers for certain components of our instruments and raw materials. If this manufacturer or these suppliers should fail or not perform satisfactorily, our ability to commercialize and supply our products would be adversely affected.

While we intend to begin manufacturing of our BioXp systems internally during 2023, we do not currently operate facilities for manufacturing our BioXp systems. We rely on third parties for the production and packaging of our instruments. Until we transition manufacturing of our BioXp products in-house during 2023, we will continue to rely on a single contract manufacturer, D&K Engineering, Inc. (D&K), located in San Diego, to manufacture and supply the BioXp systems. Since our contract with D&K does not commit it to carry inventory or make available any particular quantities of instruments outside of accepted purchase orders, D&K may give other customers' needs higher priority than ours, and we may not be able to obtain adequate supplies in a timely manner or on commercially reasonable terms. We do not have a long-term supply agreement with D&K. Instead, we typically issue purchase orders for our BioXp systems on a six-month rolling basis. Our purchase orders with D&K are terminable without cause upon sixty days' notice in writing to the other party.

Our reliance on a third party for the manufacture of our instruments increases the risk that we will not have sufficient quantities of our instruments or will not be able to obtain such quantities at an acceptable cost or quality, which could delay, prevent or impair commercialization of our instruments. In the event it becomes necessary to utilize a different contract manufacturer for our BioXp systems, we would experience additional costs, delays and difficulties as a result of having to identify and enter into an agreement with a new manufacturer. We would also have to prepare such new manufacturer to meet the technical and logistical requirements associated with manufacturing our instruments, and our business could suffer as a result.

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

We also rely on third parties for certain components of our BioXp kits and benchtop reagents, including the nucleotides we use in our BioXp kits, which are primarily sourced from Integrated DNA Technologies, Inc. (IDT), a division of Danaher Corporation. In the past, supply issues with IDT caused us to rely on an alternative supplier for these components and raw materials. We cannot guarantee that we will be able to source these materials at similar quantities and on similar terms if our preferred suppliers were to become unable or unwilling to fulfill our requirements.

Our reliance on third party manufacturers subjects us to risks associated with their businesses and operations. This dependence on others may harm our ability to develop and commercialize our products on a timely and competitive basis. Any such failure may result in decreased product sales and lower product revenue, which would harm our business. For example, even if we have agreements with third parties, they may not perform their obligations to us and they may be unable or unwilling to establish or increase production capacity commensurate with our needs. Disputes may also arise between us and our suppliers that result in the delay or termination of commercialization or that result in costly litigation or arbitration that diverts management's attention and resources. Also, third party manufacturers are subject to their own operational and financial risks that are outside of our control, and potentially their control also, that may cause them to suffer liquidity or operational problems and that could interfere with their business operations. For example, our suppliers have also been impacted by the COVID-19 pandemic and some of our raw materials and components originate in China. We have also experienced supply delays for critical hardware, instrumentation and supplies that we use for product development, as these other components and supplies are otherwise diverted to COVID-19-related testing and other uses.

## We have limited experience producing and supplying our products. We may be unable to consistently manufacture or source our products to the necessary specifications or in quantities necessary to meet demand on a timely basis and at acceptable performance and cost levels.

Our BioXp systems, BioXp kits and benchtop reagents comprise an integrated solution with many different components that work together. As such, a quality defect in a single component can compromise the performance of the entire system. In order to successfully generate revenue from this product line, we need to supply our customers with products that meet their expectations for quality and functionality in accordance with established specifications on a timely basis. Our instruments are manufactured using complex processes, sophisticated equipment and strict adherence to specifications and quality systems procedures. Given the complexity of this instrumentation, individual units may occasionally require additional installation and service prior to becoming available for customer use. We have experienced quality issues with certain of our mRNA BioXp kits in the past and if we have additional issues with this product or future products, our business could be harmed.

As we continue to scale commercially and develop new products, and as our products incorporate increasingly sophisticated technology, it will become more difficult to ensure our products are produced in the necessary quantities while maintaining quality. There is no assurance that we or our third-party manufacturers will be able to continue to manufacture our products so that our technology consistently achieves the product specifications and produces results with acceptable quality. In addition, our BioXp kits and benchtop reagents have a limited shelf life, after which their performance is not ensured and many of our products must be shipped and stored at controlled temperatures. Shipment of BioXp kits and benchtop reagents that exceed their shelf life or shipment of defective products to customers may result in recalls and warranty replacements, which would increase our costs and may damage our reputation, and depending upon current inventory levels and the availability and lead time for additional inventory, could lead to availability issues. Any future design issues, unforeseen manufacturing problems, such as contamination of our or our manufacturers' facilities, equipment malfunctions, aging components, quality issues with components and materials sourced from third-party suppliers, or failures to strictly follow procedures or meet specifications, may have a material adverse effect on our brand, business, reputation, results of operations and financial condition and could result in us or our third-party manufacturers losing International

Organization for Standardization (ISO) or quality management certifications. If our third-party manufacturers fail to maintain ISO quality management certifications, our customers might choose not to purchase products from us.

In addition, as we scale our commercial operations, we will also need to make corresponding improvements to other operational functions, such as our customer support, service and billing systems, compliance programs and internal quality assurance programs. We cannot assure you that any increases in scale, related improvements and quality assurance will be successfully implemented or that appropriate personnel will be available. As we develop additional products, we may need to bring new equipment on-line, implement new systems, technology, controls and procedures and hire personnel with different qualifications.

An inability to manufacture products and components that consistently meet specifications, in necessary quantities, at commercially acceptable costs and without significant delays, may have a material adverse effect on our business, results of operations, financial condition and prospects.

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

Certain disruptions in supply of, and changes in the competitive environment for, components and raw materials integral to the manufacturing of our products may adversely affect our profitability. We use a broad range of materials and supplies in our products. A significant disruption in the supply of these materials could decrease production and shipping levels, materially increase our operating costs and materially and adversely affect our revenues and profit margins. Shortages of materials or interruptions in transportation systems, labor strikes, work stoppages, war, acts of terrorism or other interruptions to or difficulties in the employment of labor or transportation in the markets in which we purchase materials, components and supplies for the production of our products, in each case, may adversely affect our ability to maintain production of our products and achieve profitability. Unforeseen discontinuation or unavailability of certain components, such as enzymes or nucleotides, each of which we currently primarily source from single supplier, could cause backorders as we modify our product specifications to accommodate replacement components. If we were to experience a significant or prolonged shortage of critical components from any of our suppliers and could not procure the components from other sources, we would be unable to manufacture our products and ship them to our customers in a timely fashion, or at all, which would adversely affect our sales, margins and customer relations.

### Our products could have defects or errors, giving rise to claims against us, adversely affecting market adoption and negatively impacting our business, financial condition, and results of operations.

Our products utilize novel and complex technology related to writing synthetic DNA and mRNA and may develop or contain undetected defects or errors. We cannot assure you that material performance problems, defects, or errors will not arise, and as we commercialize our products, these risks may increase. We provide warranties at the point of sale that our products will meet performance expectations and will be free from defects. We also provide extended warranties at an additional cost to the customer. The costs incurred in correcting any defects or errors may be substantial and could adversely affect our operating margins.

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

If our products contain defects, we may experience:

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

#### If we become subject to product liability claims, we may be required to pay damages out of our cash reserves.

Our business exposes us to potential product liability claims that are inherent in the production, marketing and sale of biotechnological and genetic products. We do not currently have product liability insurance and any product liability claim, or recall of one of our products, would have to be paid out of our cash reserves.

### Shipping is a critical part of our business. Any changes in our shipping arrangements or damages or losses sustained during shipping could adversely affect our business, financial condition, results of operations and prospects.

We currently rely on commercial carriers for our shipping. If we are not able to negotiate acceptable pricing and other terms with these carriers, or if they experience performance problems or other difficulties, it could negatively impact our operating results and our customers' experience. If a product is damaged in transit, it may result in a substantial delay in the fulfillment of the customer's order, and depending on the type and extent of the damage and whether the incident is covered by insurance, it may result in a substantial financial loss to us. If our products are not delivered in a timely fashion or are damaged or lost during the delivery process, our customers could become dissatisfied and cease using our products or services, which would adversely affect our business, financial condition, results of operations and prospects.

Our business depends on our ability to quickly and reliably deliver our products and in particular, our BioXp kits and benchtop reagents, to our customers. Certain of these products are perishable and must be kept below certain temperatures and, therefore, we ship these products on dry ice and only ship such products on certain days of the week to reach customers without spoilage. Disruptions in the delivery of these products, whether due to labor disruptions, bad weather, natural disasters, terrorist acts or threats or for other reasons could result in our customers receiving products that are not fit for use, and if used, could result in inaccurate results or ruined experiments. While we work with customers to replace any products that are impacted by delivery disruptions, our reputation and our business may be adversely impacted even if we replace products free of charge. In addition, if we are unable to continue to obtain expedited delivery services on commercially reasonable terms, our operating results may be adversely affected.

In addition, should our commercial carriers encounter difficulties in delivering our products to customers, particularly at the end of any financial quarter, it could adversely impact our ability to recognize revenue for those products in that period and accordingly adversely affect our financial results for that period.

#### **Risks Related to Our Sales, Marketing and Customer Support**

#### We have limited experience in sales and marketing of our products.

We have limited experience in sales and marketing our products. Our ability to achieve profitability depends on our being able to attract customers for our products. To meet our sales objectives, we must expand our sales, marketing, distribution and customer service and support capabilities with personnel with the appropriate technical expertise. In undertaking expansion efforts, we will face a number of risks relating to:

- our ability to attract, retain and manage the sales, marketing and customer service and support personnel necessary to commercialize and gain market acceptance for our technology;
- the time and cost of maintaining specialized sales, marketing and customer service and support personnel; and
- the relative success of our sales, marketing and customer service and support personnel.

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

## A substantial proportion of our sales are through distributors, and we do not control their efforts to sell our products. If our relationships with these third-party distributors deteriorate, or if these third-party distributors fail to sell our products or engage in activities that harm our reputation, our financial results may be negatively affected.

Our current sales model includes direct sales in North America and parts of Europe, and relationships with third party distributors in other parts of Europe and various countries in the Middle East, Africa and Asia Pacific regions. We believe that our reliance on distributors improves the economics of our business, as we do not carry the high fixed costs of a direct sales force in many of the countries in which our products are sold. If we are unable to maintain or enter into such distribution arrangements on acceptable terms, or at all, we may not be able to successfully commercialize our products in certain countries.

Furthermore, distributors can choose the level of effort that they apply to selling our products relative to others in their portfolio. The selection, training, and compensation of distributors' sales personnel are within their control rather than our own and may vary significantly in quality from distributor to distributor. They may experience their own financial difficulties, or distribution relationships may be terminated or allowed to expire, which could increase the cost of or impede commercialization of our products in applicable countries. Disputes may also arise between us and our distributors that result in the delay or termination of commercialization or that result in costly litigation or arbitration that diverts management's attention and resources. Distributors may not properly maintain or defend our intellectual property rights or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our proprietary information or expose us to potential litigation. Distributors could move forward with competing products developed either independently or in collaboration with others, including our competitors.

In addition, although our contract terms require our distributors to comply with all applicable laws regarding the sale of our products, including regulatory labelling, protection of personal data, U.S. export regulations and the U.S. Foreign Corrupt Practices Act (FCPA), we may not be able to ensure proper compliance. If our distributors fail to effectively market and sell our products in full compliance with applicable laws and regulations, our results of operations and business may suffer.

### The size of the markets for our products may be smaller than estimated, and new market opportunities may not develop as quickly as we expect, or at all, thus limiting our ability to successfully meet our anticipated revenue projections.

The market for synthetic biology technologies and products is evolving, making it difficult to predict with any accuracy the size of the markets for our current and future products, including our BioXp systems, BioXp kits and benchtop reagents. Our estimates of the total addressable market for our current and future products are based on a number of internal and third-party estimates and assumptions. In particular, our estimates are based on our expectations that researchers in the market for certain synthetic biology research tools and technologies will view our products as competitive alternatives to, or better options than, existing tools and technologies. We also expect researchers will recognize the ability of our products to complement, enhance and enable new applications of their current tools and technologies. Underlying each of these expectations are a number of estimates and assumptions that may be incorrect, including the assumptions that government or other sources of funding will continue to be available to synthetic biology researchers at times and in amounts necessary to allow them to purchase our products and that researchers have an unmet need for performing synthetic biology applications. As a result, the sizes of the annual total addressable market for new markets and new products are even more difficult to predict. The synthetic biology market may develop more slowly or differently than we expect. While we believe our assumptions and the data underlying our estimates of the total addressable market for our products are reasonable, these assumptions and estimates may not be correct and the conditions supporting our assumptions or estimates. As a result, our estimates of the total addressable market for our products are estimates of the total addressable market for our estimates. As a result, our estimates of the total addressable market for our products are

The future growth of the market for our current and future products depends on many factors beyond our control. For example, in 2020, 11% of our revenue was from products specifically targeting research and development efforts related to COVID-19 vaccines and therapeutic products. As effective COVID-19 vaccines or treatments were developed, approved and rolled out to protect against and treat the COVID-19 virus, demand for these products declined, the size of our market opportunity for such products was impacted and our revenue was affected as a result. In 2022, our revenue from COVID-19 related products was 1% of total revenue.

We expect that our products will be subject to the market forces and adoption curves common to other new technologies. The market for synthetic biology technologies and products is in its early stages of development. Sales of new products into new market opportunities may take years to develop and mature and we cannot be certain that these market opportunities will develop as we expect. If the markets for our current and future products are smaller than estimated or do not develop as we expect, our growth may be limited and our business, financial condition and operational results of operations could be adversely affected.

#### Our success depends on broad scientific and market acceptance of our products, which we may fail to achieve.

Our ability to achieve and maintain scientific and commercial market acceptance of our products will depend on a number of factors. If widespread adoption of our products takes longer than anticipated, we will continue to experience operating losses.

The success of life sciences products is due, in large part, to recognition and acceptance by the scientific community, their adoption of these products in the applicable field of research and the growth, prevalence and costs of competing products. Such recognition and acceptance of our products may not occur in the near term, or at all. New synthetic biology technology, including our own, may not be adopted until the consistency and accuracy of such technology has been proven.

Other factors in achieving commercial market acceptance of our products include:

our ability to market and increase awareness of the capabilities of our products;

- our customers' willingness to adopt new products and workflows;
- whether early adopters and key opinion leaders (KOLs) publish research involving the use of our products;
- our products' ease-of-use and whether it reliably provides advantages over alternative technologies;
- the rate of adoption of our products and services by academic institutions, laboratories, biopharmaceutical companies and others;
- the prices we charge for our products;
- our ability to develop new products and workflows;
- whether competitors commercialize products that perform similar functions as our products; and
- the impact of our investments in product innovation and commercial growth.

We cannot assure you that we will be successful in addressing each of these criteria or other criteria that might affect the market acceptance of any products we commercialize. If we are unsuccessful in achieving and maintaining scientific and market acceptance of our products, our business, financial condition and results of operations would be adversely affected.

### The synthetic biology technology market is highly competitive. If we fail to compete effectively, our business and results of operation will suffer.

We face significant competition in the synthetic biology technology market. We currently compete with synthetic biology technology companies and the companies that are supplying components, products and services that serve customers engaged in synthetic biology research. These companies include Thermo Fisher Scientific Inc.; Danaher Corporation; Azenta; GenScript Biotech Corporation; DNA Script SAS; Integrated DNA Technologies, Inc.; Molecular Assemblies, Inc.; Nuclera Nucleics Ltd; Nutcracker Therapeutics, Inc.; Twist Bioscience Corporation; Aldevron, LLC; TriLink BioTechnologies, Inc.; Evonetix Ltd.; Eurofins,; Synthego; Illumnina; and Roche.

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

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

We cannot assure investors that our products will compete favorably or that we will be successful in the face of increasing competition from products and technologies introduced by our existing or future competitors or companies entering our markets. In addition, we cannot assure investors that our competitors do not have or will not develop products or technologies that currently or in the future will enable them to produce competitive products with greater capabilities or at lower costs than ours. Any failure to compete effectively could materially and adversely affect our business, financial condition and operating results.

### Our revenue, results of operations and cash flows would be adversely affected by the loss of a significant customer.

We have derived, and we may continue to derive, a significant portion of our revenues from a limited number of large customers. We estimate that our twenty largest customers accounted for 47% and 54% of our revenue for the years ended December 31, 2021 and December 31, 2022, respectively. The loss of key customers, or the reduction in the amount of product ordered by them may adversely affect our revenue, results of operations, cash flows and reputation in the marketplace. One customer, Pfizer, Inc., accounted for 24% of our revenue for the year ended December 31, 2022, based on a Research and License Agreement.

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

We generally do not have long-term contracts with our customers requiring them to purchase any specified quantities of products from us. Without such contracts, our customers are not obligated to order our products. 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. If many of our customers were to substantially reduce their purchase volume or cease ordering products from us, this could materially and adversely affect our financial performance.

## Our business will depend significantly on research and development spending by the pharmaceutical, biotechnology and industrial agricultural customers, as well as academic institutions and other research institutions. Any reduction in spending could limit demand for our products and adversely affect our business, results of operations, financial condition and prospects.

We expect that substantially all of our sales revenue in the near term will be generated from sales to pharmaceutical, biotechnology and industrial agricultural customers, as well as academic institutions and other research institutions. Much of these customers' funding is dependent on annual research and development budgets and in the case of academic and other research institutions will be, in turn, provided by various state, federal and international government agencies. As a result, the demand for our products will depend upon the research and development budgets of these customers, which are impacted by factors beyond our control, such as:

- research and development budgets within the pharmaceutical, biotechnology, agricultural and other industries;
- government funding of research and development;
- changes to programs that provide funding to research laboratories and institutions, including changes in the amount of funds allocated to different areas of research or changes that have the effect of increasing the length of the funding process;
- macroeconomic conditions and the political climate;
- potential changes in the regulatory environment;
- differences in budgetary cycles, especially government- or grant-funded customers, whose cycles often coincide with government fiscal year ends;
- market-driven pressures to consolidate operations and reduce costs; and
- scientific and market acceptance of relatively new synthetic biology products.

In addition, various state, federal and international agencies that provide grants and other funding may be subject to stringent budgetary constraints that could result in spending reductions, reduced grant making, reduced allocations or budget cutbacks, which could jeopardize the ability of funding organizations or the organizations to whom they provide funding, to purchase our products. For example, congressional appropriations to the National Institutes of Health (NIH), have generally increased year-over-year for the last 19 years, and reached a new high in 2020, but the NIH also experiences occasional year-over-year decreases in appropriations, including as recently as 2013. In addition, funding for life science research has increased more slowly during the past several years compared to previous years and has actually declined in some countries. There is no guarantee that NIH appropriations will not decrease in the future, and a decrease may be more likely under the current administration, whose annual budget proposals have repeatedly decreased NIH appropriations. A decrease in the amount of, or delay in the approval of, appropriations to NIH or other similar United States or international organizations, such as the Medical Research Council in the United Kingdom, could result in fewer grants benefiting synthetic biology research. These reductions or delays could also result in a decrease in the aggregate amount of grants awarded for synthetic biology research or the redirection of existing funding to other projects or priorities, any of which in turn could cause our customers and potential customers to reduce or delay purchases of our products. Our operating results may fluctuate substantially due to any such reductions and delays. Any decrease in our customers' budgets or expenditures, or in the size, scope or frequency of their capital or operating expenditures, could materially and adversely affect our business, results of operations, financial condition and prospects.

#### Our success depends on our ability to service and support our products directly or in collaboration with our strategic partners.

To the extent that we or our strategic partners fail to maintain a high quality level of service and support for our products, there is a risk that the perceived quality of our products will be diminished in the marketplace. Likewise, we may fail to provide the level, quantity or quality of service expected by the marketplace. This could result in slower adoption rates and lower than anticipated utilization of our products, which could have a material adverse effect on our business, financial condition and results of operations.

### **Risks Related to the COVID-19 Pandemic and Other Natural Disasters**

### Unfavorable U.S. or global economic conditions, including inflation, as a result of the COVID-19 pandemic, or otherwise, could adversely affect our ability to raise capital and our business, results of operations and financial condition.

While the potential economic impact brought by, and the duration of, the COVID-19 pandemic is difficult to assess or predict, the COVID-19 pandemic has resulted in, and may continue to result in, extreme volatility and disruptions in the capital and credit markets in general and has negatively impacted our stock price since becoming a public company in 2021. Should this impact continue, our ability to raise additional capital through equity, equity-linked or debt financings, will be reduced, which could negatively impact our short-term and long-term liquidity and our ability to operate in accordance with our operating plan, or at all. Additionally, our results of operations could be adversely affected by general conditions in the global economy, including inflation, and financial markets. The capital markets or general economic conditions may be adversely affected by geopolitical risks, hostilities, terrorist attacks or wars, including the current war between Russia and Ukraine. A severe or prolonged economic downturn could result in a variety of risks to our business, including weakened demand for our products and our ability to raise additional capital when needed on favorable terms, if at all. A weak or declining economy could strain our customers' budgets or cause delays in their payments to us. Any of the foregoing could harm our business. We cannot anticipate all of the ways in which the current economic climate and financial market conditions could adversely impact our ability to raise capital, business, results of operations and financial condition.

### The COVID-19 pandemic and efforts to reduce its spread have adversely impacted our business and operations.

The COVID-19 pandemic had an adverse impact on our operations, particularly as a result of preventive and precautionary measures that we, other businesses and governments took as a result of the pandemic. Governmental mandates related to COVID-19 impacted and may continue to impact the availability and cost of materials, which disrupts or delays our receipt of components and supplies from the third parties we rely on to, among other things, manufacture our BioXp systems, BioXp kits and benchtop reagents or source and timely receive parts and components from third parties. Moreover, the COVID-19 pandemic had a significant impact on our ability to retain employees and forced us to fill positions more frequently than we have had to do so in the past. We cannot assure you that in the future we will be able to fill these positions quickly. To the extent that any governmental authority imposes additional regulatory requirements or changes existing laws, regulations and policies that apply to our business and operations, such as additional workplace safety measures, our product development plans may be delayed, and we may incur further costs in bringing our business and operations into compliance with changing or new laws, regulations and policies. Recently, President Biden announced that the administration intends to end the COVID-19 national and public health emergencies on May 11, 2023. The full impact of the termination of the public health emergencies on FDA and other regulatory policies and operations is unclear.

## If our facilities or our third-party manufacturers' facilities become unavailable or inoperable, our research and development program and commercialization of our products could be adversely impacted and manufacturing of our products could be interrupted.

Our San Diego, California, facilities house our corporate, research and development and quality assurance teams and will house our manufacturing operations beginning in 2023. Currently, our instruments are manufactured at our third-party manufacturer's facilities in San Diego, and our BioXp kits and benchtop reagents are manufactured at various locations in the United States and internationally, including our San Diego facilities. We do not have a second or back-up facility to use if our San Diego facilities become inoperable.

Our facilities in San Diego and those of our third-party manufacturers are vulnerable to natural disasters, public health crises, including the impact of the COVID-19 pandemic, and catastrophic events. For example, our San Diego facilities are located near earthquake fault zones and are vulnerable to damage from earthquakes as well as other types of disasters, including fires, floods, power loss, communications failures and similar events. If any disaster, public health crisis or catastrophic event were to occur, our ability to operate our business would be seriously, or potentially completely, impaired. If our facilities or our third-party manufacturer's facilities become unavailable for any reason, we cannot provide assurances that we will be able to secure alternative manufacturing facilities with the necessary capabilities and equipment on acceptable terms, if at all. We may encounter particular difficulties in replacing our San Diego facilities given the specialized equipment housed within it. The inability to manufacture our products, combined with our limited inventory of finished products, may result in the loss of future customers or harm our reputation, and we may be unable to re-establish relationships with those customers in the future.

If our research and development program or commercialization program were disrupted by a disaster or catastrophe, the launch of new products, including our workflow automation and reagent solutions, and the timing of improvements to our products could be significantly delayed and could adversely impact our ability to compete with other available products and solutions. If our or our third-party manufacturer's capabilities are impaired, we may not be able to manufacture and ship our products in a timely manner, which would adversely impact our business. Although we possess insurance for damage to our property and the disruption of our business,

this insurance may not be sufficient to cover all our potential losses and may not continue to be available to us on acceptable terms, or at all.

### **Risks Related to Doing Business Internationally**

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

We estimate that during the fiscal years ended December 31, 2021 and December 31, 2022, approximately 30% and 14%, 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, unexpected changes in legislative or regulatory requirements of foreign countries into which we sell our products, difficulties in obtaining export licenses for our products 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 international business could expose us to business, regulatory, political, operational, financial, and economic risks associated with doing business outside of the United States.

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

- required compliance with existing and changing foreign regulatory requirements and laws that are or may be applicable to
  our business in the future, such as the European Union's General Data Protection Regulation (GDPR), and other data
  privacy requirements, labor and employment regulations, anti-competition regulations, the U.K. Bribery Act of 2010 and
  other anti-corruption laws;
- required compliance with U.S. laws such as the FCPA, and other U.S. federal laws and regulations, including those established by the Office of Foreign Asset Control;
- export requirements and import or trade restrictions;
- laws and business practices favoring local companies;
- foreign currency exchange fluctuations, longer payment cycles and difficulties in enforcing agreements and collecting accounts receivables through certain foreign legal systems;
- hyperinflation or economic or political instability in foreign countries, including the outbreak of war in the Ukraine;
- changes in social, economic, and political conditions or in laws, regulations and policies governing foreign trade, manufacturing, research and development, and investment, including as a result of the separation of the United Kingdom from the European Union, commonly referred to as Brexit;
- the imposition of inconsistent laws or regulations;
- changes in or interpretations of foreign law that may adversely affect our ability to sell our products, perform services or repatriate profits to the United States;
- potentially adverse tax consequences, tariffs, customs charges, bureaucratic requirements and other trade barriers;
- difficulties and costs of staffing and managing foreign operations; and
- difficulties protecting, maintaining, enforcing or procuring intellectual property rights.

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

#### We may be subject to fines or other penalties for potential past violations of U.S. export control and economic sanctions laws.

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 Control.

In late 2021, following a voluntary internal review of our compliance with U.S. export control and sanctions laws, we became aware that certain of our products had been sold indirectly into embargoed countries via our distributors and resellers, potentially in violation of U.S. export control and economic sanctions laws. These laws restrict or prohibit the sale of certain products, including our BioXp systems, into certain countries, including Russia. In the past, we may have exported products prior to receiving these required authorizations. We believe that these potential violations were inadvertent and occurred because we and certain of our resellers did not have sufficient compliance procedures in place to prevent the transactions at issue. As a result, we were unable to preclude certain of our channel partners and resellers from selling our solutions into countries subject to a U.S. embargo until late 2021. Commencing in late 2021, we took a series of corrective actions intended to remediate the effect of any unauthorized past actions, including actions to permanently stop supporting the use of our BioXp systems in sanctioned countries.

### We are subject to various U.S. and international anti-corruption laws and other anti-bribery and anti-money laundering laws and regulations.

We are subject to the FCPA, the U.S. domestic bribery statute contained in 18 U.S.C. § 201, the U.S. Travel Act, and other anticorruption, anti-bribery, and anti-money laundering laws in the jurisdictions where we do business, both domestic and abroad. Anticorruption and anti-bribery laws have been enforced aggressively in recent years and are interpreted broadly. These laws generally prohibit companies, their employees, business partners, third-party intermediaries, representatives, and agents from authorizing, offering, or providing, directly or indirectly, improper payments or benefits to government officials or commercial parties to obtain or retain business, direct business to any person, or gain any improper advantage. We sometimes leverage third parties to conduct our business abroad. We and our employees, business partners, third-party intermediaries, representatives, and agents may have direct or indirect interactions with officials and employees of government agencies or state-owned or affiliated entities and we may be held liable for their corrupt or other illegal activities even if we do not explicitly authorize those activities. We cannot assure you that our employees and agents will not take actions that violate applicable law, for which we may be ultimately held responsible. These laws also require that we keep accurate books and records and maintain internal accounting controls and compliance procedures designed to prevent any such actions. While we have policies and procedures to address compliance with these laws, we cannot assure you that our employees, business partners, third-party intermediaries, representatives, and agents will not take actions that violate our policies or applicable law, for which we may be ultimately held responsible. Our exposure for violating these laws increases as our international presence expands and as we increase sales and operations in foreign jurisdictions.

Any violation of the FCPA or other applicable anti-bribery, anti-corruption, and anti-money laundering laws could result in whistleblower complaints, adverse media coverage, investigations, loss of export privileges, severe criminal or civil sanctions, settlements, prosecution, enforcement actions, fines, damages, or suspension or debarment from government contracts, all of which may have an adverse effect on our reputation, business, stock price, financial condition, prospects, and results of operations. In addition, responding to any investigation or action will likely result in a materially significant diversion of management's attention and resources and significant defense costs and other professional fees.

### **Risks Related to Our Regulatory Environment**

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

Our products are currently labeled and promoted, and are, and in the near-future will be, sold primarily to academic and research institutions and research companies as research use only (RUO) products. They are not currently designed, or intended to be used, for clinical diagnostic tests or as medical devices. If we elect to label and market our products for use as, or in the performance of, clinical diagnostics in the United States, thereby subjecting them to FDA regulations as medical devices, we would be required to obtain premarket 510(k) clearance or premarket approval from the FDA, unless an exception applies.

We may in the future register with the FDA as a medical device manufacturer and list some of our products with the FDA pursuant to an FDA Class I listing for general purpose laboratory equipment. While this regulatory classification is exempt from

certain FDA requirements, such as the need to submit a premarket notification commonly known as a 510(k), and some of the requirements of the FDA's Quality System Regulations (QSRs), we would be subject to ongoing FDA "general controls," which include compliance with FDA regulations for labeling, inspections by the FDA, complaint evaluation, corrections and removals reporting, promotional restrictions, reporting adverse events or malfunctions for our products, and general prohibitions against misbranding and adulteration.

In addition, we may in the future submit 510(k) premarket notifications to the FDA to obtain FDA clearance of certain of our products. It is possible, in the event we elect to submit 510(k) applications for any of our products, that the FDA would take the position that a more burdensome premarket application, such as a premarket approval application or a de novo application, is required for those same products. If such applications were required, greater time and investment would be required to obtain FDA approval. Even if the FDA agreed that a 510(k) was appropriate, FDA clearance can be expensive and time consuming. Notwithstanding the effort and expense, FDA clearance or approval could be denied for some or all of our products for which we choose to market as a medical device or a clinical diagnostic device. There can be no assurance that future products for which we may seek premarket clearance or approval will be approved or cleared by FDA or a comparable foreign regulatory authority on a timely basis, if at all, nor can there be assurance that labeling claims will be consistent with our anticipated claims or adequate to support continued adoption of such products. Compliance with FDA or comparable foreign regulatory authority regulations would require substantial costs, and subject us to heightened scrutiny by regulators and substantial penalties for failure to comply with such requirements or the inability to market our products. The lengthy and unpredictable premarket clearance or approval process, as well as the unpredictability of the results of any required clinical studies, may result in our failing to obtain regulatory clearance or approval to market such products, which would significantly harm our business, results of operations, reputation, and prospects.

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

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

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

We do not currently expect our workflow automation and reagent solutions to be subject to the clearance or approval of the FDA, as it is not intended to be used for the diagnosis, treatment or prevention of disease. However, as we expand our product line and the applications and uses of our current or products into new fields, certain of our future products could become subject to regulation by the FDA, or comparable international agencies, including requirements for regulatory clearance or approval of such products before they can be marketed. Also, even if our products are labeled, promoted and intended as RUO, the FDA or comparable agencies of other countries could disagree with our conclusion that our products are intended for research use only or deem our sales, marketing and promotional efforts as being inconsistent with RUO products. For example, our customers may independently elect to use our RUO labeled products in their own laboratory developed tests (LDTs) for clinical diagnostic use, which could subject our products to government regulation, and the regulatory clearance or approval and maintenance process for such products may be uncertain, expensive, and time-consuming. Regulatory requirements related to marketing, selling and distribution of RUO products could change or be uncertain, even if clinical uses of our RUO products by our customers were done without our consent. If the FDA or other

regulatory authorities assert that any of our RUO products are subject to regulatory clearance or approval, our business, financial condition, or results of operations could be adversely affected.

The FDA has historically exercised enforcement discretion in not enforcing the medical device regulations against laboratories offering LDTs. However, on October 3, 2014, the FDA issued two draft guidance documents that set forth the FDA's proposed risk-based framework for regulating LDTs, which are designed, manufactured and used within a single laboratory. The draft guidance documents provide the anticipated details through which the FDA would propose to establish an LDT oversight framework, including premarket review for higher-risk LDTs, such as those that have the same intended use as FDA-approved or cleared companion diagnostic tests currently on the market. In January 2017, the FDA announced that it would not issue final guidance on the oversight of LDTs and manufacturers of products used for LDTs, but would seek further public discussion on an appropriate oversight approach, and give Congress an opportunity to develop a legislative solution.

As manufacturers develop more complex diagnostic tests and diagnostic software, the FDA may increase its regulation of LDTs. Any future legislative or administrative rule making or oversight of LDTs, if and when finalized, may impact the sales of our products and how customers use our products, and may require us to change our business model in order to maintain compliance with these laws. We cannot predict how these various efforts will be resolved, how Congress or the FDA will regulate LDTs in the future, or how that regulatory system will impact our business. Changes to the current regulatory framework, including the imposition of additional or new regulations, including regulation of our products, could arise at any time during the development or marketing of our products, which may negatively affect our ability to obtain or maintain FDA or comparable regulatory approval of our products, if required. Further, sales of devices for diagnostic purposes may subject us to additional healthcare regulation and enforcement by the applicable government agencies. Such laws include, without limitation, state and federal anti-kickback or anti-referral laws, healthcare fraud and abuse laws, false claims laws, privacy and security laws, Physician Payments Sunshine Act and related transparency and manufacturer reporting laws, and other laws and regulations applicable to medical device manufacturers.

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

As part of the United States' efforts to combat COVID-19 and consistent with Executive Orders 13771 and 13924, the Department of Health and Human Services (HHS) announced rescission of guidance and other informal issuances of the FDA regarding premarket review of LDT absent notice-and-comment rulemaking, stating that, absent notice-and-comment rulemaking, those seeking approval or clearance of, or an emergency use authorization, for an LDT may nonetheless voluntarily submit a premarket approval application, premarket notification or an Emergency Use Authorization request, respectively, but are not required to do so. In November 2021, HHS under the Biden administration issued a statement that withdrew the August 2020 policy announcement, stating that HHS does not have a policy on LDTs that is separate from FDA's longstanding approach. Legislative and administrative proposals to amend the FDA's oversight of LDTs have been introduced in recent years, including the VALID Act. In September 2022, Congress passed the FDA user fee reauthorization legislation without substantive FDA policy riders, including the VALID Act, but Congress may revisit the policy riders and enact other FDA programmatic reforms in the future. It is unclear how future legislation by federal and state governments and FDA regulation will impact the industry, including our business and that of our customers. Any restrictions on LDTs by the FDA, HHS, Congress or state regulatory authorities may decrease the demand for our products. Additionally, compliance with additional regulatory burdens could be time consuming and costly for us, our partners and customers. The adoption of new restrictions on RUO products, whether by the FDA or Congress, could adversely affect demand for our products. Further, we could be required to obtain premarket clearance or approval before we can sell our products to certain customers.

### 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 and research and development processes 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 or have a material effect on our operations and research and development programs. If we do not comply with applicable regulations, we may be subject to fines and penalties.

In addition, accidental injury or contamination from these materials or wastes could interrupt our commercialization efforts, research and development programs and business operations, as well as cause 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 may not be able to maintain insurance on acceptable terms, if at all.

## We could inadvertently 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, impediments to our business and reputational damage.

The Federal Select Agent Program (FSAP) involves rules administered by the Centers for Disease Control and Prevention 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 biosecurity program under which we follow biosafety and biosecurity best practices and avoid DNA synthesis activities that implicate FSAP rules; however, we could inadvertently fail to comply with FSAP or other biosecurity rules. In addition, authorities could promulgate new biosecurity requirements that restrict 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.

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

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

We are in a continuing process of clarifying evolving compliance requirements and updating our compliance measures. We currently have in place policies and procedures related to the storage, collection and processing of information, and are in the process of conducting internal and external data privacy reviews, to evaluate and advance our compliance with all applicable data protection laws and regulations. We do not currently have policies and procedures in place for assessing our third-party vendors' compliance with applicable data protection laws and regulations. All of these evolving compliance and operational requirements impose significant costs, such as costs related to organizational changes, implementing additional protection technologies, training employees and engaging consultants, which are likely to increase over time. In addition, such requirements may require us to modify our data

processing practices and policies, distract management or divert resources from other initiatives and projects, all of which could have a material adverse effect on our business, financial condition, results of operations and prospects. Any failure or perceived failure by us or our third-party vendors, collaborators, contractors and consultants to comply with any applicable federal, state or similar foreign laws and regulations relating to data privacy and security, or could result in damage to our reputation, as well as proceedings or litigation by governmental agencies or other third parties, including class action privacy litigation in certain jurisdictions, which would subject us to significant fines, sanctions, awards, penalties or judgments, all of which could have a material adverse effect on our business, financial condition, results of operations and prospects.

### **Risks Related to Our Intellectual Property**

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

We rely on patent protection as well as trademark, copyright, trade secret and other intellectual property rights protection and contractual restrictions to protect our proprietary products and technologies. Each of these types of measures provides limited protection and may not adequately protect our rights or permit us to gain or keep any competitive advantage. If we fail to obtain, maintain and protect our intellectual property, third parties may be able to compete more effectively against us. In addition, we may incur substantial litigation costs in our attempts to enforce our right in, defend against challenges to, or recover or restrict use of our intellectual property.

To the extent our intellectual property offers inadequate protection, or is found to be invalid or unenforceable, we would be exposed to a greater risk of direct competition. If our intellectual property does not adequately cover competitors' products, our competitive position could be adversely affected, as could our business, financial condition, results of operations and prospects. Both the patent application process and the process of managing patent and other intellectual property disputes can be time-consuming and expensive.

Our success depends in large part on our ability to obtain and maintain protection of the intellectual property, particularly patents we may own solely or jointly with, or license from, third parties, in the United States and in other countries of interest, with respect to our products and technologies. However, obtaining and enforcing patents is costly, time-consuming and complex. We may not be able to file and prosecute all necessary or desirable patent applications, or maintain, enforce and license any patents that may issue from such patent applications, at a reasonable cost or in a timely manner or in all jurisdictions. It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. Moreover, we may not develop additional proprietary products, methods and technologies that are patentable. We may not have the right to control the preparation, filing and prosecution of patent applications, or to maintain the rights to patents licensed from or to third parties; such patents and applications may not be prosecuted and enforced by such third parties in our best interests.

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

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

Changes in either the patent laws or interpretation of the patent laws in the United States or in other jurisdictions could increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents. The U.S. Congress has recently passed legislation implementing significant changes to U.S. patent law.

Various courts including the U.S. Supreme Court have rendered decisions that impact the patentability and patent eligibility of inventions or discoveries relating to synthetic biology technology, including by narrowing the scope and strength of patent protection in some instances. In light of these developments and depending on actions by the U.S. Congress, the federal courts and the United States Patent and Trademark office (the USPTO), the laws and regulations governing patents could be interpreted and applied, or could change, in unpredictable ways that may have a material adverse effect on our ability to obtain new patents and to defend and enforce our existing patents and patents that we might obtain in the future.

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

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

Filing, prosecuting and defending patents on our products in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States can be less extensive than those in the United States.

The laws of some foreign countries do not protect intellectual property rights to the same extent as the laws of the United States. We may encounter difficulties in protecting and defending such rights in foreign jurisdictions. Consequently, we may not be able to prevent third parties from practicing our inventions in competition with us in some or all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors and other third parties may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and technologies and may also export infringing products to territories where we do have patent protection but where enforcement may not be as strong as in the United States. Our patents or other intellectual property rights may not be effective or sufficient to prevent such third-party products from competing with our products. 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 certain kinds of third 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.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of many other countries do not favor the enforcement of patents and other intellectual property protection, which could make it difficult for us to gain any meaningful competitive advantage from our patents or other intellectual property rights. The legal systems in certain countries may also favor state-sponsored or domestic companies over foreign companies, even though we may have patents and other intellectual property protection in these countries. The absence of harmonized intellectual property protection laws makes it difficult to ensure consistent treatment and enforcement of patent, trade secret, and other intellectual property rights on a worldwide basis. As a result, it is possible that we will not be able to enforce our rights against third parties that misappropriate our proprietary technology or otherwise violate our intellectual property rights in any given country around the world.

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, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing, and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate, or that are initiated against us, and any damages or other remedies awarded to us may not be commercially meaningful. In addition, changes in the law and legal decisions by courts in foreign countries may affect our ability to obtain adequate protection for our products, services and other technologies and the enforcement of intellectual property. 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. Any of the foregoing events could have a material adverse effect on our business, financial condition, results of operations and prospects.

### Issued patents covering our products could be found invalid or unenforceable if challenged.

Our owned and licensed patents and patent applications may be subject to validity, enforceability and priority disputes. The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability. Some of our patents or patent applications

(including licensed patents and patent applications) may be challenged in opposition, interference or derivation, ex parte reexamination, inter partes review, post-grant review or other similar proceedings. Any successful third-party challenge to our patents in this or any other proceeding could result in the unenforceability or invalidity of such patents, which may lead to increased competition to our business, which could have a material adverse effect on our business, financial condition, results of operations and prospects. In addition, if we initiate legal proceedings against a third party to enforce a patent covering our products, the defendant could counterclaim that the patent we are asserting in the proceeding is invalid or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity or unenforceability are commonplace. There are numerous grounds upon which a third party can assert invalidity or unenforceability of a patent. Third parties may also raise similar claims before administrative bodies in the United States or abroad, outside the context of litigation per se. Such proceedings could result in revocation of or amendment to our patents in such a way that they no longer protect our products. The outcome following legal assertions of invalidity and unenforceability during patent litigation is unpredictable. If a defendant or other third party were to prevail on a legal assertion of invalidity or unenforceability, we would lose at least part, and perhaps all, of the patent protection on certain aspects of our products and technologies, which could have a material adverse effect on our business, financial condition, results of operations and prospects. In addition, if the breadth or strength of protection provided by our patents and patent applications is threatened, regardless of the outcome, it could dissuade companies from collaborating with us to license intellectual property or to develop or commercialize current or future products.

We may not be aware of all third-party intellectual property rights potentially relevant to our products, technology and services. Publications of discoveries in the scientific literature lag behind the discoveries, and patent applications in the United States and other jurisdictions are typically not published until approximately 18 months after the earliest effective filing date or, in some cases, not until such patent applications issue as patents. We might not have been the first to make the inventions claimed in each of our pending patent applications, we may have to participate in interference or derivation proceedings in the U.S. or analogous proceedings in non-U.S. jurisdictions, which could result in substantial cost to us and the loss of valuable patent protection. No assurance can be given that other patent applications will not have priority over our patent applications. In addition, changes to the patent laws of the United States allow for various post-grant proceedings that have not been extensively tested, and their outcome is therefore uncertain. Furthermore, if third parties bring these proceedings against our patents, regardless of the merit of such proceedings and regardless of whether we are successful, we could experience significant costs and our management may be distracted. Any of the foregoing events could have a material adverse effect on our business, financial condition, results of operations and prospects.

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

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

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

Monitoring unauthorized disclosure is difficult, and we cannot guarantee that the steps we have taken to prevent such disclosure are adequate. If we were to enforce a claim that a third party had wrongfully obtained and was using our trade secrets, it could be expensive and time-consuming, it could distract our personnel, and the outcome would be unpredictable. In addition, courts outside the United States may be less effective in protecting trade secrets.

We also seek to preserve the integrity and confidentiality of our confidential proprietary information by maintaining physical security of our premises and physical and electronic security of our information technology systems, but it is possible that these security measures could be breached. If any of our confidential proprietary information were to be lawfully obtained or independently

developed by a competitor or other third party, absent patent protection, we would have no right to prevent such competitor from using that technology or information to compete with us, which could harm our competitive position. Competitors or third parties could purchase our products and attempt to replicate the competitive advantages we derive from our development efforts with their own competitive technologies that fall outside the scope of our intellectual property rights. They might also independently develop our technologies without reference to our trade secrets. If any of our trade secrets were to be disclosed to or independently discovered by a competitor or other third party, it could materially and adversely affect our business, financial condition, results of operations and prospects.

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

We may be subject to claims that former employees, collaborators or other third parties have an interest in our owned or inlicensed patents, trade secrets or other intellectual property as an inventor or co-inventor. For example, we may have inventorship or ownership disputes arising from conflicting obligations of employees, consultants or others who are involved in developing our products. In addition, counterparties to our consulting, sponsored research, software development and other agreements may assert that they have an ownership interest in intellectual property developed under such arrangements. In particular, certain software development agreements pursuant to which third parties have developed parts of our proprietary software may not include provisions that expressly assign to us ownership of all intellectual property developed for us by such third parties. Furthermore, certain of our sponsored research agreements pursuant to which we provide research services for third parties do not assign to us all intellectual property developed under such agreements. As such, we may not have the right to use all such developed intellectual property under such agreements, we may be required to obtain licenses from third parties and such licenses may not be available on commercially reasonable terms or at all, or they may be non-exclusive. If we are unable to obtain such licenses and such licenses are necessary for the development, manufacture and commercialization of our products and technologies, we may need to cease the development, manufacture and commercialization of our products and technologies. Litigation may be necessary to defend against these and other claims challenging inventorship or ownership of our owned or in-licensed patents, trade secrets or other intellectual property. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights. In such an event, we may be required to obtain licenses from third parties and such licenses may not be available on commercially reasonable terms or at all, or they may be non-exclusive. If we are unable to obtain and maintain such licenses, we may need to cease the development, manufacture and commercialization of the relevant products and technologies. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees, and certain customers or partners may defer engaging with us until the particular dispute is resolved. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

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

The registered or unregistered trademarks or trade names that we use may be challenged, infringed, circumvented, declared generic, opposed, invalidated, cancelled or determined to be infringing on or dilutive of other marks. As a consequence, we may not be able to protect, register or maintain our rights in these trademarks and trade names.

Third parties may have prior rights in, or have filed, and may in the future file, for registration of, trademarks similar or identical to our trademarks in certain markets of interest that may block our ability to use or to register, or that may limit the scope of protection afforded to, our trademarks and trade names in such markets, thereby impeding our ability to protect, register, maintain or enforce our trademarks and trade names in all markets of interest and to build brand identity and possibly leading to litigation risks and market confusion.

If a third party succeeds in registering or developing common law rights in trademarks similar or identical to our trademarks that predate our rights, and if we are not successful in overcoming any objection from the USPTO or such third party based on or in challenging such rights and defending against challenges to our trademarks, we may not be able to use such trademarks to develop brand recognition of our technologies, products or services.

A third party with prior rights in a similar or identical trademark could challenge our use and registration of our trademarks and trade names by filing a trademark infringement court action or by seeking to block or cancel any registration for our trademarks through an opposition, cancellation, invalidity or other administrative proceeding.

The outcome of any such trademark litigation or other proceeding can be uncertain. If we are unable to successfully defend against any such challenge, in addition to not being able to secure or maintain a registration for our trademark, we may be required, including by court order, to cease all further use of such trademark. Moreover, in the case of a trademark infringement action, a court may require us to issue corrective advertising or to take other steps as the court may deem necessary to remove or reduce the risk of consumer confusion, including changing our company name and rebranding our products. Any of these actions could take time, would

be expensive and could lead to a loss of brand recognition or customer confusion as a result. The court may also order us to pay damages (actual damages demonstrated at trial and a disgorgement of our profits), including treble damages and attorneys' fees if the court finds that we willfully infringed such third party trademark. Regardless of success, any such litigation or other proceeding may take substantial time and effort and result in substantial cost, and may divert our efforts and attention from other aspects of our business and could have a material adverse effect on our business, financial condition and results of operations.

Further, we have and may in the future enter into agreements with owners of such third party trade names or trademarks to avoid potential trademark litigation, which may limit our ability to use, register or enforce our trade names or trademarks in certain fields of business or in certain markets or which may place certain other restrictions on the use of our trademarks and trade names that could limit our ability to build a strong brand identity. If we are unable to establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively, and our business, financial condition, results of operations and prospects may be adversely affected.

### Patent terms may be inadequate to protect our competitive position on our workflow automation and reagent solutions for an adequate amount of time.

Patents have a limited lifespan. In the United States, if all maintenance fees are timely paid, the basic term of a utility patent is 20 years from its earliest effective non-provisional filing date. In the United States, the basic term of a patent may be lengthened by patent term adjustment, which compensates the patentee for certain administrative delays by the USPTO in examining and granting a patent, and it may be shortened by filing a terminal disclaimer over an earlier expiring patent. Even if a patent covering our products is obtained, once the patent life has expired, we would no longer be able to use the patent to exclude others from making or selling competitive products. If one of our products requires extended development, testing or regulatory review, patent protection for the product might expire soon after or even before the product is commercialized. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours, which could have a material adverse effect on our business, financial condition and results of operations.

## We may become involved in lawsuits to defend against third-party claims of infringement, misappropriation or other violations of intellectual property or to protect or enforce our intellectual property, any of which could be expensive, time consuming and unsuccessful, and may prevent or delay our development and commercialization efforts.

Our commercial success depends in part on our ability and the ability of future collaborators to develop, manufacture, market and sell our product and use our products and technologies without infringing, misappropriating or otherwise violating the intellectual property rights of third parties. There is a substantial amount of litigation involving patents and other intellectual property rights in the synthetic biology technology sector, as well as other proceedings for challenging patents, including interference, derivation, *inter partes* review, post grant review, reexamination proceedings, and pre- and post-grant oppositions. We may be exposed to, or threatened with, future litigation by third parties having patent or other intellectual property rights alleging that our products, manufacturing methods, software or technologies infringe, misappropriate or otherwise violate their intellectual property rights. Numerous issued patents and pending patent applications that are owned by third parties exist in the fields in which we are developing our products and technologies. It is not always clear to industry participants, including us, the claim scope that may issue from pending patent applications owned by third parties or which patents cover various types of products, technologies or their methods of use or manufacture. Because of the large number of patents issued and patent applications filed in our fields, there may be a risk that third parties, including our competitors, may allege that they have patent rights encompassing our products, technologies or methods and that we are employing their proprietary technology without authorization.

If third parties, including our competitors, believe that our products or technologies infringe, misappropriate or otherwise violate their intellectual property, such third parties may seek to enforce their intellectual property, including patents against us by filing an intellectual property-related lawsuit, including a patent infringement lawsuit, against us. Even if we believe third-party intellectual property claims are without merit, there is no assurance that a court would find in our favor on questions of misappropriation, infringement, validity, enforceability, or priority. If any third parties were to assert patents against us and we are unable to successfully defend against any such assertion, we may be required, including by court order, to cease the development and commercialization of the infringing products or technology and we may be required to redesign such products and technologies so they do not infringe such patents, which may not be possible or may require substantial monetary expenditures and time. We could also be required to pay damages, which could be significant, including treble damages and attorneys' fees if we are found to have willfully infringed such patents. We could also be required to obtain a license to such patents in order to continue the development and commercialization of the infringing product or technology; however such a license may not be available on commercially reasonable terms or at all, including because certain of these patents are held by or may be licensed to our competitors. Even if such license were available, it may require substantial payments or cross-licenses under our intellectual property rights, and it may only be available on a nonexclusive basis, in which case third parties, including our competitors, could use the same licensed intellectual property robust.

with us. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operation or prospects.

We may choose to challenge, including in connection with any allegation of patent infringement by a third party, the validity or enforceability of any third-party patent that we believe may have applicability in our field, and any other third-party patent that may be asserted against us. Such challenges may be brought either in court or by requesting that the USPTO, European Patent Office (EPO), or other patent offices' review the patent claims, such as in an *ex-parte* reexamination, *inter partes* review, post-grant review proceeding or opposition proceeding. However, there can be no assurance that any such challenge by us will be successful. Even if such proceedings are successful, these proceedings are expensive and may consume our time or other resources, distract our management and technical personnel, and the costs of the proceedings could be substantial.

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

Litigation proceedings may be necessary for us to enforce our patent and other intellectual property rights. In any such proceedings, a court may refuse to stop the other party from using the technology at issue on the grounds that our owned and inlicensed patents do not cover the technology in question. Further, in such proceedings, the defendant could counterclaim that our intellectual property is invalid or unenforceable and the court may agree, in which case we could lose valuable intellectual property rights, which could allow third parties to commercialize technology or products similar to ours and compete directly with us, without payment to us, or could require us to obtain license rights from the prevailing party in order to be able to manufacture or commercialize our products without infringing such party's intellectual property rights, and if we unable to obtain such a license, we may be required to cease commercialization of our products and technologies, any of which could have a material adverse effect on our business, financial condition, results of operations and prospects. The outcome in any such proceedings is unpredictable.

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

## Obtaining and maintaining our patent protection depends on compliance with various required procedures, document submissions, fee payments and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

Various official fees, including renewal fees, must be paid to the respective patent authorities to apply for, prosecute, and maintain patent applications. The USPTO and other patent authorities also variously require compliance with a number of procedural and substantive provisions under local law and practice during and sometimes after the patent application process. In many cases, an inadvertent lapse in paying a fee or fulfilling another requirement can be cured by payment of a late fee or by other means in accordance with the applicable rules. However, there are situations in which non-compliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, our competitors may be able to enter the market without infringing our patents and this circumstance would have a material adverse effect on our business, financial condition, results of operations and prospects.

## We may be subject to claims that our employees, consultants or independent contractors have wrongfully used or disclosed confidential information of third parties or that our employees have wrongfully used or disclosed alleged trade secrets of their former employers.

We have employed and expect to employ individuals who were previously employed at universities or at other companies, including our competitors or potential competitors. Although we try to ensure that our employees, consultants, advisors and independent contractors do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that our employees, advisors, consultants or independent contractors have inadvertently or otherwise used or disclosed intellectual property, including trade secrets or other proprietary information, of their former employers or other third parties, or to claims that we have improperly used or obtained such trade secrets. Litigation may be necessary to defend against these claims. If we fail in defending such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights and face increased competition to our business. Any such litigation or the threat thereof may adversely affect our ability to hire employees or contract with advisors, contractors and consultants. A loss of key research personnel work product could hamper or prevent our ability to commercialize potential products, which could harm our business. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management. This type of litigation or proceeding could substantially increase our operating losses and reduce our resources available for development activities. Some of our competitors may be able to sustain the costs of this type of litigation or proceedings more effectively than we can because of their substantially greater financial resources.

In addition, while it is our policy to require our employees and contractors who may be involved in the conception or development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who, in fact, conceives or develops intellectual property that we regard as our own. The assignment of intellectual property rights may not be self-executing, or the assignment agreements may be breached, and we may be forced to bring claims against third parties, or defend claims that they may bring against us, to determine the ownership of what we regard as our intellectual property. Furthermore, individuals executing agreements with us may have pre-existing or competing obligations to a third party, such as an academic institution, and thus an agreement with us may be disputed or ineffective in perfecting ownership of inventions developed by that individual, which could have a material adverse effect on our business, financial condition, results of operations, and prospects.

Furthermore, we may in the future be subject to claims by former employees, consultants or other third parties asserting an ownership right in our owned or licensed patents or patent applications. An adverse determination in any such proceeding may result in loss of exclusivity or freedom to operate or in patent claims being narrowed, invalidated or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar technology, without payment to us, or could limit the duration of the overall patent protection covering our technology and products. Such challenges may also result in our inability to develop, manufacture or commercialize our products without infringing third-party patent rights. Any of the foregoing could harm our business, financial condition, results of operations and prospects.

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

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

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

### Intellectual property rights do not necessarily address all potential threats.

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations, and may not adequately protect our business or permit us to maintain our competitive advantage. For example:

- others may be able to make products that are similar to products and technologies we may develop or utilize similar technology that are not covered by the claims of the patents that we own or license now or in the future;
- we might not have been the first to make the inventions covered by the issued patent or pending patent application that we license or may own in the future;
- we might not have been the first to file patent applications covering certain of our or their inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing, misappropriating or otherwise violating our owned or licensed intellectual property rights;
- it is possible that our pending licensed patent applications or those that we may own in the future will not lead to issued patents;
- issued patents that we hold rights to may be held invalid or unenforceable as a result of legal challenges by our competitors;
- our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- we may not develop additional proprietary technologies that are patentable;
- the patents of others may harm our business; and
- we may choose not to file a patent for certain trade secrets or know-how, and a third party may subsequently file a patent covering such intellectual property.

Should any of these events occur, they could materially adversely affect our business, financial condition, results of operations and prospects.

### **Risks Related to Ownership of Our Common Stock**

### The market price of our common stock has been volatile and may continue to be volatile in the future, which could result in substantial losses for investors purchasing our common stock in the market.

The market price of our common stock has been highly volatile since our initial public offering may continue to be volatile. As a result, you may not be able to sell your common stock at or above the price at which you purchased the stock. Some of the factors that may cause the market price of our common stock to continue fluctuating include, but are not limited to:

- actual or anticipated fluctuations in our operating results, including fluctuations in our quarterly and annual results;
- operating expenses being more than anticipated;
- supply chain and production disruption due to our moving primary manufacturing facilities to a new location;
- the failure or discontinuation of any of our product development and research programs;
- changes in the structure or funding of research at academic and research laboratories and institutions, including changes that would affect their ability to purchase our products;
- the success of existing or new competitive businesses or technologies;
- announcements about new research programs or products of our competitors;
- developments or disputes concerning patent applications, issued patents or other proprietary rights;
- the recruitment or departure of key personnel;
- litigation and governmental investigations involving us, our industry or both;
- regulatory or legal developments in the United States and other countries;
- variations in market conditions in the synthetic biology technology sector;
- investor perceptions of us or our industry;

- changes in estimates or recommendations by securities analysts, if any, that cover our common stock or companies that are perceived to be similar to us;
- whether our financial results meet the expectations of securities analysts or investors;
- the level of expenses related to any of our research and development programs or products;
- actual or anticipated changes in our estimates as to our financial results or development timelines;
- variations in our financial results or those of companies that are perceived to be similar to us;
- the announcement or expectation of additional financing efforts;
- sales of our common stock by us or sales of our common stock by our insiders or other stockholders;
- general economic, industry and market conditions, including deteriorating market conditions due to investor concerns regarding inflation and the outbreak of war in the Ukraine; and
- the pandemics, natural disasters or major catastrophic events.

Recently, stock markets in general, and the market for life sciences technology companies in particular, have experienced significant price and volume fluctuations that have often been unrelated or disproportionate to changes in the operating performance of the companies whose stock is experiencing those price and volume fluctuations. Broad market and industry factors may seriously affect the market price of our common stock, regardless of our actual operating performance. Following periods of such volatility in the market price of a company's securities, securities class action litigation has often been brought against that company. Because of the potential volatility of our stock price, we may become the target of securities litigation in the future. Securities litigation could result in substantial costs and divert management's attention and resources from our business.

### If securities analysts do not continue to publish research or reports about our business or if they publish negative evaluations of our common stock, the price of our common stock could decline.

The trading market for our common stock relies in part on the research and reports that industry or securities analysts publish about us or our business. We do not currently have and may never obtain extensive research coverage by industry or securities analysts. If more analysts do not commence coverage of us, the trading price of our common stock could decrease. If one or more of the analysts covering our business downgrade their evaluations of our common stock, the price of our common stock could decline. If one or more of these analysts cease to cover our common stock, we could lose visibility in the market for our common stock, which in turn could cause the price of our common stock to decline.

### Our directors, officers and principal stockholders have significant voting power and may take actions that may not be in the best interests of our other stockholders.

As of December 31, 2022, our directors, officers and stockholders holding 5% or more of our outstanding common stock and their affiliates beneficially owned over 66% of our outstanding common stock in the aggregate, assuming the exercise of all options and warrants held by such persons. As a result, these stockholders, if they act together, will be able to exert significant influence over the management and affairs of our company and most matters requiring stockholder approval, including the election of directors and approval of significant corporate transactions. This concentration of ownership may have the effect of delaying or preventing a change in control, might adversely affect the market price of our common stock and may not be in the best interests of our other stockholders.

### Sales of a substantial number of shares of our common stock by our existing stockholders could cause the price of our common stock to decline.

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

Holders of an aggregate of 15,079,329 shares of our common stock have rights, subject to conditions, to require us to file registration statements with the SEC covering their shares or to include their shares in registration statements that we may file for ourselves or other stockholders. We also have registered all shares of common stock that we may issue under our equity compensation and employee stock purchase plans, making them freely tradeable in the public market upon issuance and, if applicable, vesting, subject to volume limitations applicable to affiliates. Sales of common stock in the public market as restrictions end or pursuant to registration rights may make it more difficult for us to sell equity securities in the future at a time and at a price that we deem appropriate. These sales also could cause the trading price of our common stock to fall and make it more difficult for you to sell shares of our common stock.

#### We do not expect to pay any dividends for the foreseeable future. Investors may never obtain a return on their investment.

You should not rely on an investment in our common stock to provide dividend income. We do not anticipate that we will pay any dividends to holders of our common stock in the foreseeable future. Instead, we plan to retain any earnings to maintain and expand our existing operations, fund our research and development programs and continue to invest in our commercial infrastructure. In addition, our current credit facility with MidCap contains, and any future credit facility or financing we obtain may contain, terms prohibiting or limiting the amount of dividends that may be declared or paid on our common stock. Accordingly, investors must rely on sales of their common stock after price appreciation, which may never occur, as the only way to realize any return on their investment. As a result, investors seeking cash dividends should not purchase our common stock.

# Our amended and restated bylaws designate a state or federal court located within the State of Delaware as the exclusive forum for substantially all disputes between us and our stockholders, and also provide that the federal district courts will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act, each of which could limit our stockholders' ability to choose the judicial forum for disputes with us or our directors, officers, stockholders, or employees.

Our amended and restated certificate of incorporation specifies that, unless we consent in writing to the selection of an alternative forum, the sole and exclusive forum for (a) any derivative action or proceeding brought on our behalf, (b) any action asserting a claim of breach of a fiduciary duty owed by any of our current or former directors, stockholders, officers, or other employees to us or our stockholders, (c) any action or proceeding asserting a claim arising pursuant to, or seeking to enforce any right, obligation or remedy under, any provision of the Delaware General Corporation Law, our amended and restated certificate of incorporation, or our amended and restated bylaws, (d) any action or proceeding as to which the Delaware General Corporation Law confers jurisdiction on the Court of Chancery of the State of Delaware, or (e) any action or proceeding asserting a claim that is governed by the internal affairs doctrine shall be the Court of Chancery of the State of Delaware (or, if the Court of Chancery does not have jurisdiction, another state court in Delaware or, if no state court in Delaware has jurisdiction, the federal district court for the District of Delaware) and any appellate court therefrom, in all cases subject to the court having jurisdiction over the claims at issue and the indispensable parties; provided that the exclusive forum provision will not apply to suits brought to enforce any liability or duty created by the Exchange Act.

Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all such Securities Act actions. Accordingly, both state and federal courts have jurisdiction to entertain such claims. To prevent having to litigate claims in multiple jurisdictions and the threat of inconsistent or contrary rulings by different courts, among other considerations, our amended and restated bylaws also provide that the federal district courts of the United States of America will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act.

Any person or entity purchasing or otherwise acquiring or holding or owning (or continuing to hold or own) any interest in any of our securities shall be deemed to have notice of and consented to the foregoing bylaw provisions. Although we believe these exclusive forum provisions benefit us by providing increased consistency in the application of Delaware law and federal securities laws in the types of lawsuits to which each applies, the exclusive forum provisions may limit a stockholder's ability to bring a claim in a judicial forum of its choosing for disputes with us or any of our directors, officers, stockholders, or other employees, which may discourage lawsuits with respect to such claims against us and our current and former directors, officers, stockholders, or other employees. Our stockholders will not be deemed to have waived our compliance with the federal securities laws and the rules and regulations thereunder as a result of our exclusive forum provisions. Further, in the event a court finds either exclusive forum provision contained in our amended and restated bylaws to be unenforceable or inapplicable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could harm our results of operations.

## Delaware law and provisions in our amended and restated certificate of incorporation and amended and restated bylaws might discourage, delay or prevent a change in control of our company or changes in our management and, therefore, depress the trading price of our common stock.

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

 our board of directors is classified into three classes of directors with staggered three-year terms and directors will only be able to be removed from office for cause by the affirmative vote of holders of at least a majority of the voting power of our then outstanding capital stock;

- certain amendments to our amended and restated certificate of incorporation will require the approval of a majority of our board of directors and stockholders holding two-thirds of the voting power of our then outstanding capital stock;
- stockholder-proposed amendments to our amended and restated bylaws will require the approval of a majority of the stockholders entitled to vote, except certain provisions would require the affirmative vote of stockholders holding twothirds of the voting power of our then outstanding capital stock;
- our stockholders will only be able to take action at a meeting of stockholders and will not be able to take action by written consent for any matter;
- vacancies on our board of directors will be able to be filled only by our board of directors and not by stockholders;
- only the chair of the board of directors, chief executive officer, president or a majority of the board of directors are authorized to call a special meeting of stockholders;
- certain litigation against us can only be brought in Delaware;
- our restated certificate of incorporation authorizes undesignated preferred stock, the terms of which may be established and shares of which may be issued, without the approval of the holders of our capital stock; and
- advance notice procedures apply for stockholders to nominate candidates for election as directors or to bring matters before an annual meeting of stockholders.

These anti-takeover defenses could discourage, delay, or prevent a transaction involving a change in control of our company. These provisions could also discourage proxy contests and make it more difficult for stockholders to elect directors of their choosing and to cause us to take other corporate actions they desire, any of which, under certain circumstances, could limit the opportunity for our stockholders to receive a premium for their shares of our capital stock and could also affect the price that some investors are willing to pay for our common stock.

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

As of December 31, 2022, we had U.S. federal and state net operating loss carryforwards (NOLs) of \$96 million and \$70 million, respectively. The federal NOLs of \$1.3 million, generated before January 1, 2018, will begin to expire in 2034, but can be used to offset up to 100% of taxable income. Amounts generated after December 31, 2017 will carryforward indefinitely, but will be subject to a 80% taxable income limitation beginning in tax years after December 31, 2020, as provided by the Coronavirus Aid, Relief, and Economic Security Act (CARES Act). State NOLs, if not utilized, will begin to expire in 2029. We may use these NOLs to offset against taxable income for U.S. federal and state income tax purposes. Additionally, Section 382 of the Internal Revenue Code of 1986, as amended (the Code), may limit the NOLs we may use in any year for U.S. federal income tax purposes in the event of certain changes in ownership of our company. A Section 382 "ownership change" generally occurs if one or more stockholders or groups of stockholders who own at least 5% of a company's stock increase their ownership by more than 50 percentage points over their lowest ownership percentage within a rolling three-year period. Similar rules may apply under state tax laws. We have not conducted a 382 study to determine whether the use of our NOLs is impaired. We may have previously undergone an "ownership change." In addition, future issuances or sales of our stock, including certain transactions involving our stock that are outside of our control, could result in future "ownership changes." "Ownership changes" that have occurred in the past or that may occur in the future could result in the imposition of an annual limit on the amount of pre-ownership change NOLs and other tax attributes we can use to reduce our taxable income, potentially increasing and accelerating our liability for income taxes, and also potentially causing those tax attributes to expire unused. States may impose other limitations on the use of our NOLs. Any limitation on using NOLs could, depending on the extent of such limitation and the NOLs previously used, result in our retaining less cash after payment of U.S. federal and state income taxes during any year in which we have taxable income, rather than losses, than we would be entitled to retain if such NOLs were available as an offset against such income for U.S. federal and state income tax reporting purposes, which could adversely impact our operating results.

### We are an "emerging growth company" and a "smaller reporting company" and the reduced disclosure requirements applicable to emerging growth companies and smaller reporting companies may make our common stock less attractive to investors.

We are an "emerging growth company," as defined in the JOBS Act. For so long as we remain an emerging growth company, we are permitted by SEC rules and plan to rely on exemptions from certain disclosure requirements that are applicable to other SEC registered public companies that are not emerging growth companies. These exemptions include not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes Oxley Act, not being required to comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements, reduced disclosure obligations regarding executive compensation and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and

stockholder approval of any golden parachute payments not previously approved. As a result, the information we provide stockholders will be different than the information that is available with respect to other public companies. To the extent that we continue to qualify as a "smaller reporting company," as such term is defined in Rule 12b-2 under the Exchange Act, after we cease to qualify as an emerging growth company, we will continue to be permitted to make certain reduced disclosures in our periodic reports and other documents that we file with the SEC. We cannot predict whether investors will find our common stock less attractive if we rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile.

In addition, the JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards. This allows an emerging growth company to delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have elected to avail ourselves of this exemption from new or revised accounting standards and, therefore, we will not be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies. As a result, our financial statements may not be comparable to companies that comply with new or revised accounting pronouncements as of public company effective dates.

### We incur significantly increased costs and management resources as a result of operating as a public company, and our management is required to devote substantial time to new compliance initiatives.

As a public company, we incur significant legal, accounting, compliance and other expenses that we did not incur as a private company and these expenses may increase even more after we are no longer an "emerging growth company." Our management and other personnel need to devote a substantial amount of time and incur significant expense in connection with compliance initiatives. As a public company, we also bear all of the internal and external costs of preparing and distributing periodic public reports in compliance with our obligations under the securities laws.

In addition, regulations and standards relating to corporate governance and public disclosure, including the Sarbanes Oxley Act, and the related rules and regulations implemented by the SEC and Nasdaq, have increased legal and financial compliance costs and will make some compliance activities more time-consuming. We intend to invest resources to comply with evolving laws, regulations and standards, and this investment will result in increased general and administrative expenses and may divert management's time and attention from our other business activities. If our efforts to comply with new laws, regulations and standards differ from the activities intended by regulatory or governing bodies due to ambiguities related to practice, regulatory authorities may initiate legal proceedings against us, and our business may be harmed. In the future, it may be more expensive or more difficult for us to obtain director and officer liability insurance as a public company, and we may be required to accept reduced coverage or incur substantially higher costs to obtain coverage.

These factors could also make it more difficult for us to attract and retain qualified members of our board of directors, particularly to serve on our audit committee and compensation committee, and qualified executive officers.

#### We may be subject to securities litigation, which is expensive and could divert management attention.

The market price of our common stock has been and may continue to be volatile. The stock market in general, and the Nasdaq Stock Market and life sciences technology companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. In the past, companies that have experienced volatility in the market price of their stock have been 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 seriously harm our business.

#### Our actual operating results may differ significantly from any guidance that we provide.

From time to time, we may provide 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 would include forward-looking statements, would be based on projections prepared by our management. Neither our registered public accountants nor any other independent expert or outside party would compile or examine the projections. Accordingly, no such person would 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. The principal reason that we would 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 any guidance furnished by us will not materialize or will vary significantly from actual

results. Accordingly, our guidance would be 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.

## If we fail to maintain an effective system of internal control over financial reporting, we may not be able to accurately report our financial results in a timely manner or prevent fraud, which would adversely affect investor confidence in our company and harm our business.

Effective internal controls over financial reporting are necessary for us to provide reliable financial reports and, together with adequate disclosure controls and procedures, are designed to prevent fraud. Any failure to implement required new or improved controls, or difficulties encountered in their implementation, could cause us to fail to meet our reporting obligations in a timely manner, or at all. In addition, any testing by us conducted in connection with Section 404(a) of the Sarbanes Oxley Act or any subsequent testing by our independent registered public accounting firm in connection with Section 404(b) of the Sarbanes Oxley Act, may reveal deficiencies in our internal controls over financial reporting that are deemed to be significant deficiencies or material weaknesses or that may require prospective or retroactive changes to our financial statements or identify other areas for further attention or improvement. Ineffective internal controls could also cause investors to lose confidence in our reported financial information, which could have a negative effect on the trading price of our common stock.

We will be required to disclose material changes made in our internal controls over financing reporting and procedures on a quarterly basis and our management will be required to assess the effectiveness of these controls annually. Beginning with our second Annual Report on Form 10-K, we will be required to make a formal assessment of the effectiveness of our internal control over financial reporting, and once we cease to be an emerging growth company, we will be required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. However, for as long as we are an "emerging growth company" under the JOBS Act, our independent registered public accounting firm will not be required to attest to the effectiveness of our internal controls over financial reporting pursuant to Section 404(b).

To achieve compliance with Section 404(a) within the prescribed period, we will be engaging in a process to document and evaluate our internal control over financial reporting, which is both costly and challenging. In this regard, we will need to continue to dedicate internal resources, potentially engage outside consultants and adopt a plan to assess and document the adequacy of our internal control over financial reporting, continue steps to improve control processes as appropriate, validate through testing that controls are designed and operating effectively and implement a continuous reporting and improvement process for internal control over financial reporting.

We could be an "emerging growth company" for up to five years. An independent assessment of the effectiveness of our internal controls could detect problems that our management's assessment might not identify. Undetected material weaknesses in our internal controls could lead to financial statement restatements and require us to incur the expense of remediation.

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

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the amounts reported in our financial statements and accompanying notes. We base our estimates on historical experience and estimates and on various other assumptions that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets, liabilities, equity, revenue and expenses that are not readily apparent from other sources. For example, in connection with the implementation of the new revenue accounting standard related to product sales, management makes judgments and assumptions based on our interpretation of the new standard. The new revenue standard is principle-based and interpretation, industry practice and guidance may evolve as we apply the new standard. If our assumptions underlying our estimates and judgements relating to our critical accounting policies change or if actual circumstances differ from our assumptions, estimates or judgements, our operating results may be adversely affected and could fall below our publicly announced guidance or the expectations of securities analysts and investors, resulting in a decline in the market price of our common stock.

### Item 1B. Unresolved Staff Comments

None.

#### **Item 2. Properties**

Our principal facilities are located at 10421 and 10431 Wateridge Circle in San Diego, California and function as our worldwide headquarters. The facilities comprise approximately 66,223 square feet across the two buildings and are leased from BioMed Realty. The Wateridge lease provides for a 10 year and 3 month term beginning at the lease commencement date and we are entitled to one option to extend the lease term for an additional five years. The buildings contain infrastructure for reagent and equipment manufacturing and for research and development of new products, as well as for supporting supply chain, logistics and limited office space for administrative and commercial functions. The facilities includes wet labs for both reagent manufacturing and research and development on both floors as well as specialized labs for instrument engineering to support the development of new instruments. A designated instrument services lab space supports our current instrument installed base customers.

In connection with the EtonBio Inc., (Eton) acquisition in November 2021, we assumed a lease of office and laboratory space located at 10179 Huennekens Street, San Diego, California. The facility is approximately 8,600 square feet and was leased from Oberlin Realty LLC. The lease term, as amended, expires June 2023.

In connection with the Eton acquisition in November 2021, we assumed a lease of office and laboratory space located at 10717 Sorrento Valley Road, San Diego, California. The facility is approximately 8,000 square feet and was leased from Sorrento Realty LLC. The lease term expires in November 2024 and has an option to extend the term for an additional three years at the then current fair market value rental rate for comparable office and laboratory space.

In connection with the Eton acquisition in November 2021, we assumed a lease of office and laboratory space located at 400 Park Offices Drive, Durham County, North Carolina. The facility is approximately 3,000 square feet. and was leased from Frontier Hub, LLC. The lease term expires in October 2023.

In connection with the Eton acquisition in November 2021, we assumed a lease office and laboratory space located at 56 Roland Street, Boston, Massachusetts. The facility is approximately 4,300 square feet and was leased from Paradigm Direct Roland. We lease this facility on a month-to-month basis.

In connection with the Eton acquisition in November 2021, we assumed a lease of office and laboratory space located at 1075 Morris Avenue, Union, New Jersey. The facility is approximately 1,200 square feet and was leased from Institute for Life Sciences Entrepreneurship. We lease this facility on a month-to-month basis.

#### **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**

Our common stock trades under the symbol "TBIO" on the Nasdaq Global Select Market and has been publicly traded since June 18, 2021. Prior to this time, there was no public market for our common stock.

As of January 6, 2023, there were approximately 212 holders of record of shares of our common stock. This number does not include stockholders for whom shares are held in "nominee" or "street" name.

### **Dividend Policy**

We have never declared or paid any cash dividends on our capital stock. We currently intend to retain any future earnings to fund the development and expansion of our business, and therefore we do not anticipate paying cash dividends on our common stock in the foreseeable future. Any future determination to pay dividends will be at the discretion of our board of directors and will depend on our results of operations, financial condition, capital requirements, contractual restrictions and other factors deemed relevant by our board of directors.

#### **Unregistered Sales of Equity Securities**

None.

### Securities Authorized for Issuance Under Equity Compensation Plans

The information required by Item 5 of Form 10-K regarding equity compensation plans will be set forth in the Proxy Statement and is incorporated herein by reference.

### Purchases of Equity Securities by the Issuer and Affiliated Purchasers

We did not purchase any of our registered equity securities during the period covered by this Annual Report.

Item 6. Reserved.

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

Unless the context otherwise requires, all references in this section to the "Company," "we," "us, or "our" refer to the business of Telesis Bio Inc. and its subsidiaries.

You should read the following discussion and analysis of our financial condition and results of operations together with our consolidated financial statements and the related notes and other financial information included elsewhere in this Annual Report. Some of the information contained in this discussion and analysis or set forth elsewhere in this Annual Report, including information with respect to our plans, strategy for our business and beliefs, includes forward-looking statements that involve risks and uncertainties. As a result of many factors, such as those set forth under the "Risk Factors" and "Special Note Regarding Forward-Looking Statements" sections and elsewhere in this Annual Report, our actual results may differ materially from those anticipated in these forward-looking statements.

### Overview

We are a leader in automated multi-omic and synthetic biology solutions focused on providing applications to enable researchers to rapidly, accurately and reproducibly build or "write" high-quality synthetic DNA and mRNA that is ready to use in many downstream synthetic biology enabled markets. Our synthetic biology solution addresses the bottlenecks across the multi-step process of building DNA and mRNA, as well as the significant limitations of existing solutions that prevent the rapid building of virtually error-free DNA and mRNA at a useable scale. A key part of our solution are our BioXp systems, end-to-end automated workstations that fit on the benchtop and are broadly accessible due to their ease-of-use and hands-free automation. We believe our BioXp systems can democratize synthetic biology by simplifying the process of building DNA and mRNA, thereby accelerating the discovery, development and production of novel high-value products, including antibody-based biologics, mRNA-based vaccines and therapeutics and precision medicines.

Our on-market and our planned solutions are comprised of the following:

- BioXp 3250 system: which we believe is the first commercially available push-button, walkaway, end-to-end automated workstation that empowers researchers to go from a digital DNA sequence to endpoint-ready synthetic DNA in as few as 8 hours and mRNA in less than 24 hours, exclusive of shipment time;
- BioXp 9600 system: a walkaway, high throughput end-to-end automated workstation that empowers researchers to go
  from a digital DNA sequence to endpoint-ready DNA in as few as 8 hours and mRNA in less than 24 hours, exclusive of
  shipment time, with onboard NGS preparation;
- *BioXp DBC*: will be our first entry into delivering on demand enzymatic DNA synthesis with design to endpoint-ready synthetic RNA in as few as 24hours;
- *BioXp portal*: a user-friendly online portal that offers an intuitive guided workflow and design tools for building new DNA sequences and assembling them into vector(s) of choice;
- BioXp De Novo kits: will contain all the necessary building blocks and reagents, including our proprietary Gibson Assembly branded reagents, for specific synthetic biology workflow applications to go from in-silico design to end-point product such as DNA or mRNA;
- BioXp Select kits: offer customers the ability to use non Telesis Bio DNA while using the BioXp to perform synthetic biology workflow applications such as cloning, mRNA generation and cell free amplification;
- BioXp Next Generation Sequencing kits: will contain all the necessary reagents to go from DNA or RNA to a sequencer ready library;
- *BioXp DBC kits:* will contain all the necessary building blocks to go from a stock DNA kit to CRISPR guides in a single run; and
- Benchtop reagents: contain all the reagents necessary to proceed with a specific synthetic biology workflow on the benchtop using products generated on the BioXp system.
- Short Oligo Ligation Assembly (SOLA) enzymatic DNA synthesis (EDS): is a sustainable, scalable, and cost-effective approach designed to significantly reduce timelines for constructing synthetic DNA, RNA, and proteins compared to traditional chemical synthesis, paving the way for more efficient and effective development of mRNA-based vaccines, diagnostics, therapeutics, and personalized medicines.

We were incorporated in the state of Delaware in March 2011, as Synthetic Genomics Solution, Inc., a wholly owned subsidiary of Synthetic Genomics, Inc. (SGI). We changed our name to SGI-DNA, Inc. (SGI-DNA) in February 2013. On March 8, 2019, SGI

sold SGI-DNA to GATTACA Mining, LLC (GATTACA) by entering into a stock purchase agreement to sell all of our outstanding common and preferred stock in exchange for a \$10.0 million non-recourse promissory note (the Purchase Note). Subsequently, we focused our efforts on launching new synthetic biology products and expanding our distribution and marketing efforts on our existing research using only products. We changed our name to Codex DNA, Inc. in March 2020 and then to Telesis Bio Inc. in November 2022.

We commercially launched our current synthetic biology solution in September 2019, which now includes the BioXp 3250 and BioXp 9600 systems, BioXp kits with associated cloud-based application scripts, and benchtop reagent kits. Since the introduction of our solution through December 31, 2022, we have placed over 200 BioXp systems globally. We target customers in the fields of personalized medicine, biologics drug discovery, vaccine development, genome editing and cell and gene therapy. As of December 31, 2022, our customer base was composed of over 450 customers and included 15 of the 25 largest biopharmaceutical companies in the world ranked by 2020 revenue, excluding affiliates of those companies. Our customer base also includes leading academic research institutions, government institutions, CROs and synthetic biology companies.

Our BioXp system placements in 2022 represent the following markets and customer segments:

- Areas of focus: 35% cell and gene therapy, 31% biologics, 14% vaccine development, 10% genome editing and 10% other.
- Research area: 25% genetic/rare disease, 24% infectious disease, 12% immuno-oncology and 39% other.
- Application: 12% cell engineering, 19% protein engineering, 18% vaccines, 51% antibody engineering, 12% nucleic acid engineering and 10% other.
- *Customer type*: 54% biotechnology and pharmaceutical development, 25% academic institutions, 3% contract research and 18% other.

We estimate that our 2022 product sales mix statistics were as follows:

- Sales mix: 61% BioXp systems, 27% BioXp kits, 9% services and 3% benchtop reagents.
- *Geographic mix*: 72% North America, 14% Europe/Middle East/Africa and 14% Asia Pacific.
- Distribution mix: 82% direct sales and 18% distributors.

Since our inception as a stand-alone company on March 8, 2019, we have devoted substantially all of our efforts to raising capital, organizing, and staffing our company, commercializing existing products and developing new products. On June 18, 2021, we completed our initial public offering (IPO) of 7,666,664 shares of common stock, including the exercise in full by the underwriters of their option to purchase up to 999,999 additional shares of common stock, for aggregate gross proceeds of \$122.7 million. We received \$112.5 million in net proceeds after deducting underwriting discounts and commissions and other offering expenses payable by us. Prior to our IPO, we had funded our operations with proceeds from the issuance of convertible notes and convertible preferred stock, payments received from royalties and product sales, and proceeds from borrowings under our credit facilities. Prior to our IPO, we had received gross proceeds of \$40.0 million through borrowings under our loan and security agreements with Oxford Finance LLC (the 2019 Loan Agreement) and Silicon Valley Bank (the 2021 Loan Agreement). Subsequent to our IPO, we also received \$20.0 million through borrowing under our credit, security and guaranty agreements with MidCap Financial Trust and MidCap Funding IV Trust (the 2022 Loan Agreements), \$15.0 million of which was used to repay the loans from Silicon Valley Bank.

We have incurred significant operating losses since our inception. During the years ended December 31, 2022 and 2021, our revenue was \$27.4 million and \$11.0 million, respectively. As of December 31, 2022, we had cash and cash equivalents of \$30.6 million and short-term investments of \$13.2 million. Our ability to generate product revenue sufficient to achieve profitability will depend on the successful development and commercialization of our products. We reported net losses of \$48.5 million and \$39.0 million for the years ended December 31, 2022 and 2021, respectively. As of December 31, 2022, we had an accumulated deficit of \$113.7 million.

We expect that our cash, cash equivalents and short-term investments of \$43.8 million as of December 31, 2022 will not be sufficient to fund our operating expenses for at least twelve months from the date our financial statements were issued. Refer to additional discussion related to going concern considerations in "Liquidity and Capital Resources" and "Going Concern" below.

#### Acquisition

On November 18, 2021, we entered into a Share Purchase Agreement, with the stockholders of EtonBio Inc. (Eton), a California corporation, pursuant to which we agreed to purchase all of the outstanding shares of capital stock of Eton. The total purchase price was approximately \$14.1 million, which was funded with our existing cash on hand.

Eton is a San Diego-based biotech company specializing in synthetic biology products and services, including DNA sequencing and oligo synthesis, for the global academic research, pharmaceutical, and biotechnology industries. Eton also markets DNA prep services and products such as antibodies, peptides, and metabolism assay kits.

### **Components of Results of Operations**

#### Revenue

Revenue consists of product sales, services, collaboration revenue, and royalties and other revenue. Net product sales primarily consist of sales of our BioXp systems, BioXp kits, and benchtop reagents. Service revenue primarily consists of DNA sequencing and preparation services. Royalties and other revenue consist of fees charged for the license of non-exclusive rights of our patents to third parties and grant revenue received from government entities as reimbursement of expenses related to the development and use of synthetic biology tools to develop solutions to address various areas of concern. The grants typically require the performance of specific activities and timely reporting of results.

Historically, revenue growth has come from BioXp systems and BioXp kits. Growth in BioXp systems sales has come from investments in direct and indirect distribution channels and new product introductions. Growth in BioXp kit sales has come from the growth of the installed base of BioXp systems and new application kits. As we continue to expand our revenue opportunities, we launched our collaboration research program which works with government entities to develop solutions to specific areas of concern.

### Collaboration and License Agreement with Pfizer

In December 2021, we entered into a Research Collaboration and License Agreement (Pfizer Agreement) with Pfizer Inc. (Pfizer), pursuant to which we agreed to collaborate with Pfizer to further develop our novel enzymatic DNA synthesis technology for Pfizer's use in its research and development of mRNA-based vaccines and biotherapies. The financial terms of the deal include an upfront payment from Pfizer to us, along with success-based technical milestone payments that could be earned in the near term. We are also eligible to receive additional milestone payments based on the achievement of specified development, regulatory and commercialization goals associated with any products developed from the application of our technology developed and licensed under the agreement.

We granted Pfizer a non-exclusive, worldwide license to use our enzymatic DNA synthesis technology for purposes of researching, developing, manufacturing and commercializing pharmaceutical and biopharmaceutical products and a limited-time option to convert such license to exclusive for specific applications. If Pfizer exercises its option for these application(s) within the applicable period, then the license to Pfizer will become exclusive for products for such application(s); provided that Pfizer may later convert the particular application back to non-exclusive.

Under the Pfizer Agreement, Pfizer made an upfront payment to us of \$8.0 million at the time of execution and a milestone payment of \$2.5 million in 2022 as a result of successful completion of our first technical milestone. If we meet certain technical milestones defined in the Pfizer Agreement, we will be eligible to receive an additional \$7.5 million in near-term milestone payments.

In addition to the upfront payment and technical milestone payments, Pfizer has agreed to make milestone payments to us upon the products meeting certain clinical milestones, with each product (other than exclusive products) being eligible for milestone payments up to \$20 million if it were to meet the applicable clinical milestones and the first exclusive product in each exclusive field being eligible for milestone payments up to \$55 million if it were to meet the applicable clinical milestones. Pfizer has also agreed to pay us up to \$60 million in sales milestones for products (other than exclusive products) if aggregate net sales of such products meet certain thresholds and up to \$180 million in sales milestones for exclusive products if aggregate net sales of the exclusive products meet certain thresholds. Provided the Pfizer Agreement remains in place, Pfizer will also pay escalating royalties from a low to midfraction of one percent of net sales of all products. Pfizer's obligations to pay royalties with respect to a product within a country will expire after specific criteria including such product no longer being covered by patent rights licensed to Pfizer by us in such country. Royalty payments are subject to reduction after the introduction of a biosimilar product in such country by a third party.

## Cost of Revenue

Cost of revenue primarily consists of material and labor costs, freight and indirect overhead costs associated with sales of our BioXp instruments, BioXp kits, benchtop reagents, services and collaboration research programs. Cost of revenue also includes period costs related to certain inventory adjustment charges, and unabsorbed manufacturing and overhead costs, as well as any write-offs of inventory that fail to meet specification or are otherwise no longer suitable for commercial manufacture. Cost of revenue is expected to increase as revenue increases.

## **Research and Development Expenses**

Research and development expenses include pre-production costs related to the design, development and improvement of our products and technologies, including employee compensation, benefits and related costs of sustaining our engineering teams, project material costs, third party fees paid to consultants, prototype development expenses, legal costs related to intellectual property, patent fees, and other costs incurred in the product design and development process. We expense research and development costs as incurred. Non-refundable advance payments that we make for goods or services to be received in the future are recorded as prepaid expenses. The prepaid amounts are expensed as the related goods are delivered or the services are performed, or when it is no longer expected that the goods will be delivered or the services rendered.

We expect that our research and development expenses will decrease, both in the near term and subsequently, as we shift our focus to the sales and marketing of our developed products. At this time, we cannot accurately estimate or know the nature, timing and costs of the efforts that will be necessary to complete the development of any of our future products. The successful development and commercialization of our future products is highly uncertain. This is due to the numerous risks and uncertainties associated with product development and commercialization, including but not limited to the following:

- we can never be certain that we can solve any technical challenge;
- if such solution can be found, we can never be certain of the timing of such a solution;
- once we find a technical solution, we cannot be certain that the solution will be commercially feasible; and
- any solution may not be desired by our customers.

These uncertainties with respect to the development of any of our future products could significantly impact the costs and timing associated with the development of these products.

### Sales and Marketing Expenses

Sales and marketing expenses include employee compensation and benefits for sales, marketing, customer service, corporate development personnel and related administrative expenses. In addition, sales and marketing expenses also include costs for international employees and facility overhead based on headcount. We anticipate that our sales and marketing expenses will increase in the future as we increase our headcount to support increasing sales and continued expansion of our international operations. Sales and marketing costs are expensed as incurred.

### General and Administrative Expenses

General and administrative expenses consist primarily of salaries and related costs for personnel in executive, finance, IT, and administrative functions. General and administrative expenses also include legal fees relating to corporate matters; professional fees for accounting, auditing, tax and administrative consulting services; insurance costs, administrative travel expenses, other operating costs; and facility costs not otherwise included in research and development or sales and marketing expenses.

We anticipate that our general and administrative expenses will stay constant in the near term and increase subsequently as we increase our administrative headcount to support our continued commercialization activities. We also anticipate that we will continue to incur significant accounting, audit, legal, regulatory, compliance and director and officer insurance costs as well as investor and public relations expenses associated with operating as a publicly traded company. General and administrative expenses are expensed as incurred.

### Other Income (Expense)

#### Interest Expense,Net

Interest expense, net primarily consists of cash and non-cash interest on our term loan facilities and our finance leases and of interest income earned on our cash equivalents and investment balances.

### Change in Fair Value of Derivative Liabilities

Change in fair value of derivative liabilities consists of the change in fair value of our SGI participation right liability, warrant liabilities, contingent put option liability, and success fee contingent liability. We classify derivative liabilities as a liability on our consolidated balance sheets that we remeasure to fair value at each reporting date. We recognize changes in the fair value of the derivative liabilities as a component of other income (expense) in our consolidated statements of operations and comprehensive loss. In connection with our IPO in June 2021, the participation right was extinguished and the warrants underlying our warrant liability were exercised. The success fee contingent liability was paid in full in July 2021. The contingent put option liability related to the 2021 Loan Agreement was extinguished in August 2022 in connection with the paydown and termination of the corresponding term loan. Upon entering into the 2022 Term Loan Agreements, we bifurcated a contingent put option derivative liability related to the acceleration clause triggered upon an event of default. At December 31, 2022, the contingent put option liability is listed as a derivative liability on our consolidated balance sheet.

### Other Income (Expense),Net

Other expense, net consists primarily of gains and losses on the disposal of fixed assets, losses on the write off of intangible assets, and the loss on extinguishment of debt.

### Income Taxes

Since our inception, we have not recorded any income tax benefits for the NOLs we have incurred in each year or for our earned research and development tax credits generated in each period, as we believe, based upon the weight of available evidence, that it is more likely than not that all of our NOLs and tax credit carryforwards will not be realized. As of December 31, 2022 and 2021, we had federal NOL carryforwards of \$95.9 million and \$62.1 million, respectively and state NOL carryforwards of \$70.1 million and \$38.5 million, respectively. The federal NOL carryforwards of \$1.3 million generated before January 1, 2018 will begin to expire in 2034, but can be used to offset up to 100% of taxable income.

Amounts generated after December 31, 2017 will carryforward indefinitely, but will be subject to 80% taxable income limitation beginning in tax years after December 31, 2020, as provided by the CARES Act. We have recorded a full valuation allowance against our net deferred tax assets at each balance sheet date.

On March 27, 2020, the CARES Act was passed by the U.S. Congress and signed into United States law. The CARES Act, among other things, includes certain provisions for individuals and corporations; however, these benefits did not impact our income tax provisions in the years presented given the existence of the full valuation allowance.

# **Results of Operations**

# Comparison of the Years Ended December 31, 2022 and 2021

The following table summarizes our results of operations for the years ended December 31, 2022 and 2021:

		For the Ye Decem		
	_	2022	2021	Change
	_		(in thousands)	
Revenue				
Product revenue	\$	10,913	\$ 6,818	\$ 4,095
Service revenue		7,121	1,644	5,477
Collaboration revenue		6,650	160	6,490
Royalties and other revenue		2,751	2,421	330
Total revenue		27,435	11,043	16,392
Cost of revenue		11,840	6,744	5,096
Gross profit	_	15,595	4,299	11,296
Operating expenses:				
Research and development		23,460	14,466	8,994
Sales and marketing		16,489	10,958	5,531
General and administrative		22,131	14,249	7,882
Total operating expenses		62,080	39,673	22,407
Loss from operations		(46,485)	(35,374)	(11,111)
Other expense, net:				
Interest expense, net		(1,217)	(1,369)	152
Change in fair value of derivative liabilities		8	(1,521)	1,529
Loss on extinguishment of debt		(727)	(618)	(109)
Other expense, net		(26)	(62)	36
Total other expense, net	_	(1,962)	(3,570)	1,608
Loss before provision for income taxes		(48,447)	(38,944)	(9,503)
Provision for income taxes		(24)	(14)	(10)
Net loss	\$	(48,471)	\$ (38,958)	\$ (9,513)

#### Revenue

Revenue for the year ended December 31, 2022 was \$27.4 million, compared to \$11.0 million for the year ended December 31, 2021. The increase of \$16.4 million was primarily driven by an increase in collaboration revenue of \$6.5 million, an increase in service revenue of \$5.5 million, and an increase in BioXp product revenue of \$4.1 million. Collaboration revenue increases were driven by our Pfizer contract, which began in December 2021 and increased by \$6.5 million. Service revenue increases were driven by a DNA sequencing and services revenue increase of \$5.4 million, attributable to the Eton acquisition in 2021. Product sales of new 9600 BioXp instrument and 3250 BioXp instruments increased revenue by \$3.2 million, and reagent product sales increased revenue by \$0.9 million due to an increase base of installed instrument.

#### Cost of Revenue

Cost of revenue for the year ended December 31, 2022 was \$11.8 million, compared to \$6.7 million for the year ended December 31, 2021. The increase of \$5.1 million was primarily driven by increase of cost attributable to 2021 acquisition of Eton of \$3.4 million and increased volume of revenue and higher raw material costs, shipping associated with our instrument sales of \$1.1 million, and our reagent product sales of \$0.6 million. Our gross margin percentage was 57% and 39% of total revenues for the years ended December 31, 2022 and 2021, respectively. The favorable change in gross margin percentage was mainly due to increase in revenue from collaboration research programs, an increase in volume of product sold, and change in the mix of products sold during the current year.

#### Research and Development Expenses

Research and development expenses for the year ended December 31, 2022 were \$23.5 million, compared to \$14.5 million for the year ended December 31, 2021. The increase of \$9.0 million was primarily due to higher personnel expenses, professional services, and facility related and other costs. Personnel expenses increased \$6.7 million as we continued to increase our headcount related to our ongoing product development efforts, as well as costs associated with our Eton acquisition. Professional service expenses increased by \$1.6 million related to cost for research and development activities as part of our product development efforts. This increase was partially offset by a decrease in legal expense for patents and IP. Facility related and other costs increased \$0.7 million and were mainly due to higher allocation due to the increase of headcount over the prior year in research and development.

#### Sales and Marketing Expenses

Sales and marketing expenses for the year ended December 31, 2022 were \$16.5 million compared to \$11.0 million for the year ended December 31, 2021, an increase of \$5.5 million. Higher personnel expenses accounted for \$5.0 million of the increase and was due to increased headcount as we build out our European and US sales and marketing teams to support increased revenue, a \$0.3 million increase in professional services due to increased marketing activities, and an increase of \$0.2 million primarily due to increase of travel expenses.

#### General and Administrative Expenses

General and administrative expenses for the year ended December 31, 2022 were \$22.1 million, compared to \$14.2 million for the year ended December 31, 2021. The increase of \$7.9 million was primarily due to increases in personnel expenses, facility related and other costs and professional service. Personnel expenses increased \$6.1 million due to higher headcount including additions to our executive leadership team, and employee stock-based compensation expenses. Facility related and other costs increased \$1.3 million due to higher insurance costs related to being a publicly traded company, taxes, and other general expenses in support our increased headcounts. Professional service increased \$0.5 million due to higher utilization of consultants for IT, audit, accounting and legal services.

#### Other Income (Expense), Net

Other income (expense), net for the year ended December 31, 2022 was a net expense of \$2.0 million, compared to a net expense of \$3.6 million for the year ended December 31, 2021. The decrease of \$1.6 million was primarily due to the absence of a \$1.5 million charge on the change in fair value of our derivative liabilities due to the completion of the IPO in June 2021 and the termination of the participation right liability, preferred stock warrant liability and the success fee contingent liability. Interest and other expenses decreased \$0.1 million related to lower interest expenses and loss on extinguishment of debt.

## Liquidity and Capital Resources

## Sources of Liquidity

Since our inception, we have incurred significant operating losses. On June 18, 2021, we completed our IPO of 7,666,664 shares of common stock, including the exercise in full by the underwriters of their option to purchase up to 999,999 additional shares of common stock, for aggregate gross proceeds of \$122.7 million. We received \$112.5 million in net proceeds after deducting underwriting discounts and commissions and other offering expenses payable by us. Prior to our IPO, we had funded our operations with proceeds from the issuance of convertible notes and convertible preferred stock, payments received from royalties and product sales, and proceeds from borrowings under our credit facilities. Prior to our IPO, we had received gross proceeds of \$32.8 million from sales of our convertible preferred stock, \$6.8 million from the issuance of our convertible notes and gross proceeds of \$40.0 million through borrowings under our loan and security agreements with Oxford Finance LLC (the 2019 Loan Agreement) and Silicon Valley Bank (the 2021 Loan Agreement). After completion of our IPO, we received \$20 million under our credit, security and guaranty agreements with MidCap Financial Trust and MidCap Funding IV Trust (The 2022 Loan Agreements), \$15 million of which was used to repay the debt under the 2021 Loan Agreement. As of December 31, 2022, we had cash and cash equivalents of \$30.6 million and short-term investments of \$13.2 million.

We will continue to incur significant expenses and expect to incur losses for the foreseeable future. We also expect that our expenses and capital expenditures will increase substantially in connection with our ongoing activities, particularly as we:

- seek to develop new products and services and hire additional research, development and engineering personnel;
- expand our distribution and marketing infrastructure to further commercialize current and future products and support our growing customer base;
- add operational, financial, and administrative systems and personnel to support growing sales; and
- maintain, expand, enforce, defend and protect our intellectual property portfolio and provide reimbursement of third-party expenses related to our patent portfolio.

These matters raise substantial doubt about our ability to continue as a going concern within one year from the date of filing this Annual Report. The accompanying consolidated financial statements have been prepared under the assumption we will continue to operate as a going concern, which contemplates the realization of assets and the settlement of liabilities in the normal course of business. The consolidated financial statements do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts of liabilities that may result from uncertainty related to our ability to continue as a going concern.

Until such time as we can generate significant revenue from product sales, if ever, we expect to finance our operations through a combination of equity offerings, debt financings, or other capital sources, including collaborations with other companies, and other strategic transactions. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interest of our stockholders will be or could be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our stockholders. Debt financing and equity offerings, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise funds through collaborations, or other similar arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or grant licenses on terms that may not be favorable to us and/or may reduce the value of our stock. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market our product candidates even if we would otherwise prefer to develop and market such product candidates ourselves.

The field of synthetic biology is rapidly developing and subject to numerous risks and uncertainties associated with new technologies and novel products. Consequently, we are unable to accurately predict the timing or amount of increased product sales or expenses or when, or if, we will be able to achieve or maintain profitability. Even if we are able to continue to generate significant product sales, we may not become profitable. If we fail to become profitable or are unable to sustain profitability on a continuing basis, then we may be unable to continue our operations at planned levels and be forced to reduce or terminate our operations.

### Cash Flows

### Comparison of the Years Ended December 31, 2022 and 2021

The following table summarizes our consolidated cash flows for the years ended December 31, 2022 and 2021:

	For	For the Years Ended December 31,					
		2022 2021					
		(in thou	isands)	1			
Net cash used in operating activities	\$	(38,715)	\$	(36,698)			
Net cash used in investing activities		(18,007)		(15,040)			
Net cash provided by financing activities		4,510		121,081			
Net change in cash, cash equivalents, and restricted cash	\$	(52,212)	\$	69,343			

#### **Operating** Activities

During the year ended December 31, 2022, we used \$38.7 million of cash in operations, primarily resulting from our net loss of \$48.5 million, partially offset by non-cash charges of \$7.6 million and changes in our operating assets and liabilities of \$2.1 million. Non-cash charges consisted primarily of \$3.7 million in stock-based compensation, depreciation and amortization expense of \$2.2 million, amortization of our right-of-use operating lease asset of \$1.2 million, and the loss on debt extinguishment of \$0.7 million. Net changes in our operating assets and liabilities consisted primarily of a \$3.7 million increase in deferred revenue and a \$1.2 million increase in accounts payable, accrued payroll and accrued liabilities, partially offset by a \$2.2 million increase in accounts receivable and changes in operating lease liabilities of \$1.4 million.

During the year ended December 31, 2021, we used \$36.7 million of cash in operations, primarily resulting from our net loss of \$39.0 million and net cash used in changes in our operating assets and liabilities of \$3.0 million, partially offset by non-cash charges of \$5.3 million. Net changes in our operating assets and liabilities consisted primarily of a \$3.9 million increase in deposits, prepaid expenses and other current assets, a \$1.5 million increase in inventories, a \$0.8 million increase in lease liabilities, a \$0.7 million increase in accounts receivable, and a \$0.5 million increase in deferred revenue, partially offset by a \$4.4 million increase in accounts payable, accrued payroll and accrued liabilities. Non-cash charges consisted primarily of the change in fair value of derivative liabilities of \$1.5 million, stock-based compensation expense of \$1.1 million, depreciation and amortization expense of \$0.9 million, amortization of lease right-of-use assets of \$0.7 million, loss on the extinguishment of debt of \$0.6 million, and amortization of the debt discount of \$0.5 million.

#### Investing Activities

During the year ended December 31, 2022, net cash used in investing activities was \$18.0 million, consisting primarily of \$77.4 million of purchases of short-term investments and \$4.5 million of purchases of property and equipment, partially offset by \$64.4 million of maturities of short-term investments.

During the year ended December 31, 2021, net cash used in investing activities was \$15.0 million, consisting of the Eton business acquisition, net of cash acquired of \$13.2 million and \$1.8 million related to purchases of property and equipment.

#### Financing Activities

During the year ended December 31, 2022, net cash provided by financing activities was \$4.5 million, consisting primarily of borrowings of \$19.8 million from the issuance of debt under the 2022 Term Loan Agreement and \$0.6 million received from the exercise of stock options and issuance of common shares pursuant to the ESPP, partially offset by \$15.7 million related to the repayment and extinguishment of debt from the 2021 Loan Agreement.

During the year ended December 31, 2021, net cash provided by financing activities was \$121.1 million, consisting primarily of net proceeds from our IPO of \$112.5 million and from borrowings of \$14.9 million from the issuance of debt under the 2021 Loan Agreement, partially offset by \$6.1 million related to the repayment and extinguishment of debt from the 2019 Loan Agreement and \$0.2 million in principal payments on leased equipment and other.

#### 2021 Loan Agreement

On March 4, 2021, we entered into a Loan and Security Agreement with Silicon Valley Bank (SVB) as the lender (the 2021 Loan Agreement). Under the 2021 Loan Agreement, on March 5, 2021, we borrowed a \$15.0 million senior secured term loan, the proceeds of which were used to repay all of our existing obligations under the 2019 Loan Agreement, with the remaining proceeds available for our working capital and general corporate purposes. Under the 2021 Loan Agreement, we had the option to elect to obtain a second term loan from SVB in a principal amount up to but not exceeding \$5.0 million, provided certain revenue milestones are achieved. The 2021 Loan Agreement was terminated in August 2022 and was fully repaid.

In connection with the 2021 Loan Agreement, we issued to SVB a warrant to purchase a number of shares of preferred stock (the Preferred Warrant). The Preferred Warrant was exercisable into the number of preferred shares equal to approximately \$0.2 million divided by the applicable warrant price. The Preferred Warrant was initially exercisable for Series A-1 convertible preferred stock at an exercise price of \$3.61 per share. The Preferred Warrant also provided for the grant of additional shares upon the disbursement of an advance under the 2021 Loan Agreement. Such additional shares would be equal to 1.5% of the principal amount of the advance divided by the warrant price. The Preferred Warrant is exercisable at the original purchase price of the Series A-1 convertible preferred stock in which the warrant would have been exercisable into converted into common stock, the warrant holder gained the right to exercise the warrant for such number of shares of common stock into which the preferred shares would have converted into had they been exercised prior to the conversion. The Preferred Warrant may be exercised at any time, in whole or in part. Unless previously exercised, the Preferred Warrant will expire on March 4, 2031. The Preferred Warrant was exercised in June 2021 in exchange for 51,409 shares of common stock.

The term loans bore interest at a per annum rate equal to the greater of (a) 4.0% above the prime rate and (b) 7.25%. The loans was secured by substantially all of our assets, other than our intellectual property. We agreed not to encumber our intellectual property assets, except as permitted by the 2021 Loan Agreement.

A final payment (the Final Payment) equal to \$0.4 million was due at the earlier of the maturity date, acceleration of the loans, or a voluntary or mandatory prepayment of the loans. The Final Payment was being accrued through interest expense using the effective interest method.

The 2021 Loan Agreement also included customary indemnification obligations and customary events of default, including, among other things, payment defaults, breaches of covenants following any applicable cure period, material misrepresentations, a failure of the loans or the lender's security interest in the collateral to have the priority as required under the 2021 Loan Agreement, a material adverse change as defined in the 2021 Loan Agreement (including without limitation as a result of a government approval having been revoked, rescinded, suspended, modified or not renewed), certain material judgments and attachments, and events relating to bankruptcy or insolvency. The 2021 Loan Agreement also contains a cross default provision under which, if a third party (under any agreement) has a right to accelerate indebtedness greater than \$0.5 million, we would be in default of the 2021 Loan Agreement. During the continuance of an event of default, SVB may apply a default interest rate of an additional 5% to the outstanding loan balances, and SVB may declare all outstanding obligations immediately due and payable and may exercise other rights and remedies as set forth in the 2021 Loan Agreement and related loan documents. Acceleration would result in the payment of all outstanding loans, any default interest charged by the lender, all expenses of the lender and the Final Payment. The 2021 Loan Agreement was repaid in full and terminated in August 2022.

### 2022 Loan Agreements

On August 9, 2022, the we entered into (i) a Credit, Security and Guaranty Agreement (Term Loan) (the 2022 Term Loan Agreement), with MidCap Financial Trust, and (ii) a Credit, Security and Guaranty Agreement (Revolving Loan) (the 2022 Revolving Loan Agreement, and together with the 2022 Term Loan Agreement, the 2022 Loan Agreements), with MidCap Funding IV Trust.

The 2022 Term Loan Agreement provides for a secured term loan facility in an aggregate principal amount of up to \$30.0 million, comprised of (i) a tranche one term loan of up to \$20.0 million (Tranche One), (ii) a tranche two term loan of up to \$5.0 million (Tranche Two), and (iii) a tranche three term loan of up to \$5.0 million (Tranche Three). The 2022 Revolving Loan Agreement provides for a secured revolving loan facility in an aggregate principal amount of up to \$10.0 million, subject to a borrowing base equal to percentages of eligible accounts receivable and inventory as determined in accordance with the Revolving Credit Agreement. The term loans and revolving loans mature on August 1, 2027.

Tranche One was fully funded on August 9, 2022, to pay transaction fees incurred in connection with the 2022 Loan Agreements and to repay in full our borrowings under the existing loan facility under the 2021 Loan Agreement with Silicon Valley Bank, with the remaining amount to be used for general corporate purposes. Subject to certain terms and conditions of the 2022 Term Loan Agreement, Tranche Two is available between January 1, 2023, and September 30, 2023, following our achievement of

specified milestones relating to minimum net revenues and minimum net cash proceeds from equity financing. Subject to certain terms and conditions of the 2022 Term Loan Agreement, Tranche Three is available between September 30, 2024, and March 31, 2025. The proceeds of Tranche Two and Tranche Three may be used for working capital and general corporate purposes.

The term loans bear interest at a floating rate based on an adjusted term secured overnight financing rate (SOFR) plus 0.1% (subject to a floor of 1.50%) for a one-month interest period, plus a margin of 5.75%. Interest on the term loans is payable monthly in arrears on the first day of each month and at maturity. For the year ended December 31, 2022, the effective interest rate on outstanding borrowings was approximately 12.16%. Following an initial interest-only period, beginning on August 1, 2025, the outstanding principal amount of the term loans is repayable in twenty-four equal monthly principal payments, with all remaining outstanding principal, together with all accrued and unpaid interest, due at maturity. The term loans may be voluntarily prepaid in full, but not in part, at any time and are also subject to mandatory prepayments with the net proceeds of certain dispositions and casualty events, subject to specified thresholds and reinvestment rights. Prepayments are subject to prepayment premiums of 3.00%, 2.00%, and 1.00% of the amount prepaid for prepayments made during years one, two, and three of the term, respectively. Once repaid, the term loans may not be reborrowed. We are also obligated to pay an exit fee equal to 4.5% of the outstanding principal amount of the term loans borrowed and other customary fees for a credit facility of this size and type. The exit fee is being accrued through interest expense using the effective interest method.

We may borrow, repay and reborrow the revolving loans until August 1, 2027, at which time the revolving commitments will terminate and all outstanding revolving loans, together with all accrued and unpaid interest, must be repaid. The proceeds of the revolving loans may be used for working capital needs and general corporate purposes. As of December 31, 2022, no revolving loans were outstanding under the 2022 Revolving Loan Agreement.

The revolving loans bear interest at a floating rated based on an adjusted term SOFR (subject to a floor of 1.50%) for a onemonth interest period, plus a margin of 3.00%. Interest on the revolving loans is payable monthly in arrears on the first day of each month and at maturity. We are obligated to pay an unused line fee equal to 0.50% per annum on the unused portion of the available revolving commitments, a fee for failure to maintain a minimum balance under the 2022 Revolving Loan Agreement, and other customary fees for a credit facility of this size and type.

Our obligations and any future guarantors are secured by liens on substantially all of the our assets.

The 2022 Loan Agreements require us to comply with (i) a minimum net revenue covenant and (ii) a minimum cash covenant, which requires certain unrestricted cash to be greater than or equal to \$7.0 million at all times.

The 2022 Loan Agreements contain customary affirmative and negative covenants, including covenants limiting the ability of us and our subsidiaries, among other things, to incur debt, grant liens, make distributions, enter certain restrictive agreements, pay or modify subordinated debt, dispose of assets, make investments and acquisitions, enter into certain transactions with affiliates, and undergo certain fundamental changes, in each case, subject to limitations and exceptions set forth in the 2022 Loan Agreements.

The 2022 Loan Agreements contain customary events of default that include, among other things, certain payment defaults, cross defaults to certain other contracts and indebtedness, covenant defaults, inaccuracy of representations and warranties, bankruptcy and insolvency defaults, judgment defaults, change of control defaults, defaults related to the failure to remain registered with the Securities and Exchange Commission and listed for trading on the Nasdaq Stock Market, and a material adverse change default.

Upon the occurrence and during the continuance of an event of default under the 2022 Loan Agreements, the respective administrative agent, if requested by the respective lenders, may, among other things, (i) suspend or terminate commitments, as well as obligations of the relevant administrative agent and lenders, (ii) declare all outstanding obligations under the applicable agreement (including principal and accrued and unpaid interest) immediately due and payable, and (iii) exercise the other rights and remedies provided for under the applicable agreement. The 2022 Loan Agreements provide that, under certain circumstances, a default interest rate will apply on all obligations under such agreement during the existence of an event of default, at a per annum rate equal to 2.0% above the applicable interest rate.

We bifurcated a derivative liability related to the acceleration clause triggered upon an event of default (contingent put option) under the 2022 Term Loan Agreement. The contingent put option liability is classified as a component of derivative liabilities on the consolidated balance sheet. The estimated fair value of the contingent put option liability was determined by using a risk-neutral valuation model wherein the fair value of the underlying debt facility is estimated, both with and without the presence of the default provisions, holding all other assumptions constant.

### Funding Requirements

We expect our expenses to continue to be significant in connection with our ongoing activities, particularly with respect to research and development efforts related to our future products and our efforts to expand sales of current products and to commercialize future products. In addition, we expect to continue to incur costs associated with operating as a public company. The timing and amount of our operating and capital expenditures will depend largely on:

- the cost of developing new products that are commercially viable; and
- the costs of marketing and selling our products globally.

Until such time, if ever, as we can generate substantial product revenue, we expect to finance our operations through a combination of equity offerings, debt financings, collaborations, strategic alliances and marketing, distribution or licensing arrangements. If we are unable to raise additional funds through equity or debt financings or other arrangements when needed, we may be required to delay, limit, reduce or terminate our research, product development or future commercialization efforts, or grant rights to develop and market products that we would otherwise prefer to develop and market ourselves. Our ability to continue as a going concern is dependent upon the ability to raise additional capital. There can be no assurance that such capital will be available in sufficient amounts or on terms acceptable to the Company. These factors raise substantial doubt about our ability to continue as a going concern. Based upon our current plans, we believe there currently is insufficient financial resources to fund our operations for at least twelve months from the filing date of this Annual Report. See Note 1 to our consolidated financial statements included elsewhere in this Annual Report for additional information.

### **Contractual Obligations and Commitments**

The following table summarizes our commitments to settle contractual obligations at December 31, 2022:

			Payn	nent	s Due by P	erio	bd		
	 Total	Le	ess than 1 Year		1 to 3 Years		4 to 5 Years	-	re than Years
				(in	thousands)	)			
Operating lease commitments <sup>(1)</sup>	\$ 2,075	\$	769	\$	656	\$	650	\$	
Finance lease commitments <sup>(2)</sup>	96		64		32				_
Debt obligations <sup>(3)</sup>	28,235		2,022		8,147		18,066		
Total	\$ 30,406	\$	2,855	\$	8,835	\$	18,716	\$	

- (1) Consists of payments due for our leases of office and laboratory space in San Diego, California and Durham County, North Carolina that expire between in February 2023 and November 2027. Payments under signed leases that have not commenced yet are not included.
- (2) Consists of payments due for our leases of equipment that expire in October 2025.
- (3) Consists of the contractually required principal and interest payable under the 2022 Term Loan Agreement. For purposes of this table, the interest due under the 2022 Term Loan Agreement was calculated using an assumed interest rate of 9.97% per annum, which was the interest rate in effect as of December 31, 2022 and assumes no borrowings under Tranche Two.

### **Off-Balance Sheet Arrangements**

We did not have during the periods presented, and we do not currently have any, off-balance sheet arrangements, as defined in the rules and regulations of the SEC.

### **Going Concern**

As of December 31, 2022, we had approximately \$43.8 million in cash, cash equivalents and short-term investments. In accordance with ASU No. 2014-15 Presentation of Financial Statements – Going Concern (subtopic 205-40), our management evaluates whether there are conditions or events, considered in the aggregate, that raise substantial doubt about our ability to continue as a going concern within one year after the date that our consolidated financial statements are issued. Based on our evaluation, substantial doubt exists regarding our ability to continue as a going concern for a period of one year from the issuance of our consolidated financial statements.

Cash used in our operating activities is heavily influenced by the timing and structure of new corporate collaborations and BioXP system revenue. While one feature of our business strategy is seeking new corporate collaborations, assuming no new

collaborations and no milestone payments from our existing collaborations, we anticipate that cash used in operating activities will increase in the near term. See the table of contractual obligations and commitments above.

Presently, we do not have sufficient cash resources to fund our planned operations, existing debt and contractual commitments and planned capital expenditures through at least the next twelve months from issuance of these financial statements. We may consume available resources more rapidly than currently anticipated, resulting in the need for additional funding. We expect to incur continuing losses and negative cash flows from operations for the foreseeable future.

Depending on whether we enter into additional collaborative agreements in the near term and the extent to which we earn revenues from our collaborative agreements and product sales, we may decide to raise additional capital through a variety of sources in the short-term and in the long-term, including:

- the public equity markets;
- private equity financings;
- collaborative arrangements; and/or
- public or private debt.

There can be no assurance that we will enter into additional collaborative agreements or maintain existing collaborative agreements, will earn collaborative revenues or that additional capital will be available on favorable terms, if at all. If adequate funds are not available, we may be required to significantly reduce or re-focus our operations or to obtain funds through arrangements that may require us to relinquish rights to certain of our products, technologies or potential markets, either of which could have a material adverse effect on our business, financial condition and results of operations. To the extent that additional capital is raised through the sale of equity or convertible debt securities, the issuance of such securities would result in ownership dilution to our existing stockholders (assuming convertible debt securities were converted into shares). These factors raise substantial doubt regarding our ability to continue as a going concern. Our inability to obtain required funding in the near future or our inability to obtain funding on favorable terms will have a material adverse effect on our operations and strategic development plan for future growth. If we cannot successfully raise additional capital and implement our strategic development plan, our liquidity, financial condition and business prospects will be materially and adversely affected, and we may have to cease operations.

As a result of our recurring losses from operations, negative cash flows from operating activities and need to raise additional capital, our independent registered public accounting firm included an explanatory paragraph in its report on our audited consolidated financial statements for the year ended December 31, 2022 expressing substantial doubt as to our ability to continue as a going concern.

#### **Critical Accounting Policies and Significant Judgments and Estimates**

Our consolidated financial statements are prepared in accordance with U.S. GAAP. The preparation of our consolidated financial statements and related disclosures requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, costs and expenses, and the disclosure of contingent assets and liabilities in our consolidated financial statements. We base our estimates on historical experience, known trends and events, and various other factors that we believe are 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 apparent from other sources. We evaluate our estimates and assumptions on an ongoing basis. Our actual results may differ from these estimates under different assumptions or conditions.

While our significant accounting policies are described in more detail in Note 2 to our audited consolidated financial statements included elsewhere in this Annual Report, we believe that the following accounting policies are those most critical to the judgments and estimates used in the preparation of our consolidated financial statements.

#### **Revenue Recognition**

To date, our revenues have consisted primarily of payments received related to product sales and royalty agreements. We adopted the provisions of ASU 2014-09, Revenue from Contracts with Customers (Topic 606), (ASC 606), at inception. Under ASC 606, we recognize revenue when our customers obtain control of the goods, warranty services are delivered or royalties are earned.

Revenue for our product sales is recognized upon delivery to the customer. Revenue related to extended product warranty arrangements is deferred and recognized over time, as services are delivered. To determine the appropriate amount of revenue to be recognized for arrangements determined to be within the scope of ASC 606, we perform the following five steps: (i) identification of the promised goods or services in the contract; (ii) determination of whether the promised goods or services are performance obligations including whether they are distinct in the context of the contract; (iii) measurement of the transaction price, including the

assessment of the constraint on variable consideration; (iv) allocation of the transaction price to the performance obligations; and (v) recognition of revenue when, or as we satisfy each performance obligation. As part of the accounting for arrangements under ASC 606, we must use significant judgment to determine: (a) the performance obligations based on the determination under step (ii) above; (b) the transaction price under step (iii) above; and (c) the standalone selling price for each performance obligation identified in the contract for the allocation of transaction price in step (iv) above. We also use judgment to determine whether milestones or other variable consideration, except for royalties and sales-based milestones, should be included in the transaction price as described below. The transaction price is allocated to each performance obligation based on the relative stand-alone selling price of each performance obligations under the contract, and we recognize revenue based on those amounts when, or as, the performance obligations under the contract are satisfied.

The standalone selling price is the price at which an entity would sell a promised good or service separately to a customer. Management estimates the standalone selling price of each of the identified performance obligations in our customer contracts, maximizing the use of observable inputs. Because we have not sold the same goods or services in our contracts separately to any customers on a standalone basis and there are no similar observable transactions in the marketplace, we estimate the standalone selling price of each performance obligation in our customer arrangements based on our estimate of costs to be incurred to fulfil our obligations associated with the performance, plus a reasonable margin.

We determined that our only contract liability under ASC 606 is deferred revenue. Amounts received prior to revenue recognition are recorded as deferred revenue in the consolidated balance sheets. Amounts expected to be recognized as revenue within the 12 months following the consolidated balance sheet date are classified as deferred revenue, current in the consolidated balance sheets. Amounts not expected to be recognized as revenue within the 12 months following the consolidated balance sheet date are classified as deferred revenue, current in the consolidated balance sheets are classified as deferred revenue, net of current portion in the consolidated balance sheets. Amounts are recorded as accounts receivable when our right to consideration is unconditional.

### Product Revenue, Net

We recognize revenue on product sales to customers when the transfer of control happens, which generally occurs upon shipment. We recognize revenue on installation and training when the service has been rendered. We include a standard one year warranty with our product sales. These standard warranties are accounted for at the time product revenues are recognized. We also offer extended warranty for an additional fee. Revenue related to extended warranty is recognized on a straight-line basis over the term. Product revenues are recorded net of variable consideration, including discounts.

### Product Returns

We generally do not accept product returns and have received an insignificant amount of returns to date.

#### Service Revenue

We recognize service revenue at a point in time when the service has been rendered and control of promised goods and services are transferred to a customer.

#### Collaboration Revenue

Research collaboration agreements are recognized as the research services are performed.

#### Royalties and Other Revenue

Royalties and other revenue consist of fees charged for the license of non-exclusive rights of our patents to third parties, research collaboration agreements and grant revenue received from government entities as reimbursement of expenses related to the development and use of synthetic biology tools to develop solutions to address various areas of concern. The royalties revenue is recognized at the same time as the third parties record the revenue associated with the use of the license. The grant revenue from the contracts is recognized as the services are performed or ratably over the milestone period and typically require the performance of specific activities and timely reporting of results. Associated expenses are recognized when incurred. Revenue and related expenses are presented gross in the consolidated statements of operations and comprehensive loss.

#### Inventories

Inventories are stated at the lower of cost or net realizable value. Cost is computed using standard cost, which approximates actual cost on a first-in, first-out basis. Net realizable value is evaluated by considering obsolescence, excess levels of inventory,

deterioration and other factors. Adjustments to reduce the cost of inventory to its net realizable value, if required, are made for estimated excess, obsolescence or impaired inventory. Excess and obsolete inventory is charged to cost of revenue and a new, lowercost basis for that inventory is established and subsequent changes in facts and circumstances do not result in the restoration or increase in that newly established cost basis.

#### Goodwill

We test goodwill for impairment on an annual basis, or more frequently if events or changes in circumstances indicate that the asset might be impaired. Our goodwill impairment tests are performed at the enterprise level as we have concluded that we have one reporting unit and that our chief operating decision maker is our chief executive officer. The fair value of the reporting unit was substantially in excess of the carrying value of the reporting unit at each date impairment was tested and consequently we have not recorded any impairment of goodwill.

#### Acquired Intangible Assets

Acquired intangible assets consist of rights to technologies and trade names. We engaged third party valuation specialists to assist us with the initial measurement of the fair value of acquired intangible assets. Acquired intangible assets, other than goodwill, are amortized over their estimated useful lives based upon the estimated economic value derived from the related intangible assets.

#### **Business** Acquisitions

We account for acquisitions using the acquisition method of accounting. The fair value of purchase consideration is allocated to the tangible and intangible assets acquired, and liabilities assumed, based on their estimated fair values. The excess of the fair value of purchase consideration over the values of the identifiable assets acquired and liabilities assumed is recorded as goodwill. When determining the fair values of assets acquired and liabilities assumed, management makes significant estimates and assumptions, especially with respect to intangible assets.

Significant estimates in valuing certain identifiable assets include, but are not limited to, the selection of valuation methodologies, future expected cash flows, discount rates, and useful lives. Our estimates of fair value are based upon assumptions believed to be reasonable, but which are inherently uncertain and unpredictable and, as a result, actual results may differ from estimates. Acquisition costs, such as legal and consulting fees, are expensed as incurred and are included in general and administrative expenses in the consolidated statements of operations and comprehensive loss. During the measurement period, which is up to one year from the acquisition date, we may record adjustments to the assets acquired and liabilities assumed, with the corresponding offset to goodwill. Upon the conclusion of the measurement period, any subsequent adjustments are recorded in the consolidated statements of operations and comprehensive loss.

#### Stock-Based Compensation

We measure all stock-based awards granted to employees and directors based on their fair value on the date of the grant using the Black-Scholes option-pricing model for options. Compensation expense for those awards is recognized over the requisite service period, which is generally the vesting period of the respective award for the employees and directors.

For stock-based awards granted to non-employees, the measurement date for non-employee awards is the date of the grant. The compensation expense for non-employees is recognized in the same manner as if we had paid cash in exchange for the goods or services, which is generally the vesting period of the award.

We use the straight-line method to record the expense of awards with service-based vesting conditions. As inputs, the Black-Scholes option-pricing model uses the fair value of our common stock and assumptions we make for the volatility of our common stock, the expected term of our common stock options, the risk-free interest rate for a period that approximates the expected term of our common stock options, our expected dividend yield, and an expected forfeiture rate.

#### **Recently Issued Accounting Pronouncements**

A description of recently issued accounting pronouncements that may potentially impact our financial position and results of operations is disclosed in Note 2 to our consolidated financial statements appearing in this Annual Report.

#### **Emerging Growth Company Status**

In April 2012, the JOBS Act was enacted. Section 107 of the JOBS Act provides that an "emerging growth company," or an EGC, can take advantage of the extended transition period provided in Section 7(a)(2)(B) of the Securities Act for complying with

new or revised accounting standards. Thus, an EGC can delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have elected to use the extended transition period for new or revised accounting standards during the period in which we remain an emerging growth company; however, we may adopt certain new or revised accounting standards early.

We will remain an emerging growth company until the earliest to occur of: (i) the last day of the fiscal year in which we have more than \$1.235 billion in annual revenue; (ii) the date we qualify as a "large accelerated filer," with at least \$700.0 million of equity securities held by non-affiliates; (iii) the date on which we have issued more than \$1.0 billion in non-convertible debt securities during the prior three-year period; and (iv) the last day of the fiscal year ending after the fifth anniversary of our initial public offering.

## Item 7A. Quantitative and Qualitative Disclosures about Market Risk

We are a smaller reporting company as defined by Item 10 of Regulation S-K and are not required to provide the information otherwise required under this Item.

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## INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

	Page
Report of Independent Registered Public Accounting Firm (PCAOB ID 100) for the Years Ended December 31, 2022 and 2021	F-2
Consolidated Balance Sheets as of December 31, 2022 and 2021	F-3
Consolidated Statements of Operations and Comprehensive Loss for the Years Ended December 31, 2022 and 2021	F-4
Consolidated Statements of Convertible Preferred Stock and Stockholders' Equity for the Years Ended December 31, 2022 and 2021	F-5
Consolidated Statements of Cash Flows for the Years Ended December 31, 2022 and 2021	F-6
Notes to Consolidated Financial Statements	F-7

### **Report of Independent Registered Public Accounting Firm**

To the Stockholders and Board of Directors Telesis Bio Inc.

## **Opinion on the Consolidated Financial Statements**

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

## **Going Concern**

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

## **Basis for Opinion**

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

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

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

/s/ WithumSmith+Brown, PC

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

San Francisco, California March 22, 2023

PCAOB ID Number 100

## Telesis Bio Inc. Consolidated Balance Sheets (In thousands, except share and per share data)

	December 31,			l,
	2022			2021
Assets				
Current assets:				
Cash and cash equivalents	\$	30,419	\$	82,806
Restricted cash		175		
Short-term investments		13,159		
Accounts receivable, net of allowance for bad debts of \$343 and \$0 at December 31,				
2022 and 2021, respectively		5,851		3,665
Inventory		2,200		2,368
Prepaid expenses and other current assets		3,288		4,345
Total current assets		55,092		93,184
Property and equipment, net		6,861		3,456
Right-of-use assets		1,660		2,281
Other long-term assets		981		609
Goodwill		14,886		14,330
Other intangible assets, net		1,882		2,397
Total Assets	\$	81,362	\$	116,257
Liabilities and stockholders' equity				
Current liabilities:				
Accounts payable	\$	1,295	\$	2,499
Accrued employee expenses		5,858		3,849
Finance lease liability, current portion		59		81
Operating lease liability, current portion		578		1,156
Deferred revenue, current portion		3,958		205
Notes payable, current portion		—		603
Other accrued liabilities		1,377		1,005
Other current liabilities		373		335
Total current liabilities		13,498		9,733
Finance lease liability, net of current portion		30		
Operating lease liability, net of current portion		1,111		1,394
Notes payable, net of discount and current portion		19,649		14,088
Derivative liabilities		367		108
Deferred revenue, net of current portion		142		150
Total liabilities		34,797		25,473
Commitments and contingencies (Note 11)				
Stockholders' equity				
Preferred stock, \$0.0001 par value; 5,000,000 and 0 shares authorized at December 31,				
2022 and 2021, respectively. No shares issued and outstanding		—		—
Common stock, \$0.0001 par value; 100,000,000 shares authorized at December 31, 2022				
and 2021; 29,647,091 and 29,318,578 shares issued and outstanding at December 31,				
2022 and 2021, respectively		5		5
Additional paid-in capital		160,304		156,049
Accumulated other comprehensive loss		(3)		
Accumulated deficit		(113,741)	_	(65,270)
Total stockholders' equity		46,565		90,784
Total liabilities and stockholders' equity	\$	81,362	\$	116,257

## Telesis Bio Inc. Consolidated Statements of Operations and Comprehensive Loss (in thousands, except share and per share data)

	For the Years Ended December 31,			
		2022		2021
Revenue:	-			
Product revenue	\$	10,913	\$	6,818
Service revenue		7,121		1,644
Collaboration revenue		6,650		160
Royalties and other revenue		2,751		2,421
Total revenue		27,435		11,043
Cost of revenue		11,840		6,744
Gross profit		15,595		4,299
Operating expenses:				
Research and development		23,460		14,466
Sales and marketing		16,489		10,958
General and administrative		22,131		14,249
Total operating expenses		62,080		39,673
Loss from operations		(46,485)		(35,374)
Other expense, net:				
Interest expense, net		(1,217)		(1,369)
Change in fair value of derivative liabilities		8		(1,521)
Loss on extinguishment of debt		(727)		(618)
Other expense, net		(26)		(62)
Total other expense, net		(1,962)		(3,570)
Loss before provision for income taxes		(48,447)		(38,944)
Provision for income taxes		(24)		(14)
Net loss	\$	(48,471)	\$	(38,958)
Other comprehensive loss:				
Unrealized loss on available-for-sale short-term investments		(3)		
Total comprehensive loss	\$	(48,474)	\$	(38,958)
Net loss attributable to common stockholders	\$	(48,471)	\$	(38,958)
Net loss per share attributable to common stockholders—basic and diluted	\$	(1.65)	\$	(2.14)
Weighted average common stock outstanding—basic and diluted		29,463,361		18,222,495

## Telesis Bio Inc. Consolidated Statements of Convertible Preferred Stock and Stockholders' Equity (in thousands, except share data)

	Convertible I Stock		Commo	n Stock	Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Loss	Total Stockholders' Equity
	Shares	Amount	Shares	Amount				
Balance at December 31, 2020	15,079,329	\$ 38,914	5,023,957	\$ 2	\$ 851	\$ (26,312)	\$	\$ (25,459)
Issuance of shares of common stock upon initial public offering, net of issuance costs								
of \$8,587	_	_	7,666,664	1	112,483	_	_	112,484
Conversion of shares of convertible preferred stock into an equivalent number								
of shares of common stock	(15,079,329)	(38,914)	15,079,329	2	38,912		—	38,914
Issuance of warrant and conversion into								
shares of common stock	_	_	1,252,468	_	2,770	_		2,770
Payment of offering costs			—		(226)		—	(226)
Issuance of Common Stock upon exercise								
of stock options	_		296,160	_	173		_	173
Stock-based compensation expense			_	—	1,086		—	1,086
Net loss						(38,958)		(38,958)
Balance at December 31, 2021		<u>\$                                    </u>	29,318,578	<u>\$5</u>	\$ 156,049	<u>\$ (65,270)</u>	<u>\$                                    </u>	<u>\$ 90,784</u>
Issuance of Common Stock upon exercise								
of stock options	_	_	90,678	_	98	_	_	98
Issuance of Common Stock related to								
ESPP			237,835	_	482		_	482
Stock-based compensation expense	_		—	_	3,727	_	_	3,727
Unrealized loss on available- for-sale								
short-term investments	_		—	_			(3)	(3)
Payment of financing costs	_		—		(52)		_	(52)
Net loss						(48,471)		(48,471)
Balance at December 31, 2022		<u>\$                                    </u>	29,647,091	<u>\$5</u>	\$ 160,304	<u>\$ (113,741</u> )	<u>\$ (3</u> )	\$ 46,565

## Telesis Bio Inc. Consolidated Statements of Cash Flows (in thousands)

Zash Flows From Operating Activities:         Z022         Z021           Net loss         \$ (48,471)         \$ (38,958)           Adjustments to reconcile net loss to net cash used in operating activities:         1,156         450           Depreciation         1,156         450           Amortization of intangible assets         2         27           Loss on disposal of assets         1,204         666           Amortization of pub option liability
Net loss\$(48,471)\$(38,958)Adjustments to reconcile net loss to net cash used in operating activities:1,156450Deprecitation1,156450Amortization of intangible assets515458Amortization of discount4824480Loss on disposal of assets227Loss on disposal of assets1,204666Change in fair value of put option liability-1.854Change in fair value of put option liability-282Non-cash interest on finance leases-(420)Changes in fair value of put option liability-282Non-cash interest on finance leases-(420)Accretion of discount on short-term investments(179)-Changes in assets and liabilities:-(2,186)(735)Accounts receivable(2,186)(735)(36,698)Accounts receivable-(1,444)(766)Accounts repaid expenses and other current assets685(3,916)Accounts repaid expenses and other current assets(38,715)(36,698)Cash Flows From Investing Activities-(13,186)Purchase of acquired business, net of cash acquired-(13,186)Purchase of short-term investments(556)-Purchase of short-term investments(556)-Purchase of short-term investments(15,000)(15,000)Cash Flows From Inacting Activities:-(13,186)Purchase of short-term investments(14,424)
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Amortization of intangible assets         515         458           Amortization of debt discount         482         480           Loss on debt extinguishment         727         618           Stock-based compensation         3,727         1,086           Amortization of lease right-of-use assets         1,204         666           Change in fair value of warrant liability         —         1,854           Change in fair value of put option liability         —         480           Change in fair value of put option liability         —         420           Change in fair value of success fee liability         —         420           Non-cash interest on finance leases         —         (90           Accretion of discount on short-term investments         (179)         —           Accounts receivable         (2,186)         (7355           Inventories         1668         (1,464)           Deposits, prepaid expenses and other current assets         685         (3,916           Accounts payable, accrued payroll and accrued liabilities         1,163         4,394           Deferred revenue         3,744         (542           Operating lease liabilities         (1,444)         (776           Purchase of acquired business, net of cash acquired
Amortization of debt discount $482$ $480$ Loss on disposal of assets227Loss on debt extinguishment727618Stock-based compensation3,7271,086Amortization of lease right-of-use assets1,204666Change in fair value of warrant liability—1,884Change in fair value of put option liability
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Net proceeds from issuance of shares of common stock in initial public offering — 112,484
Payments of offering costs (52)
Proceeds from the exercise of common stock options 98 173
Proceeds from the issuance of common stock related to ESPP 482 —
Net Change In Cash, Cash Equivalents, and Restricted Cash (52,212) 69,343
Cash, cash equivalents, and restricted cash at beginning of year 82,806 13,463
Cash, cash equivalents, and restricted cash at end of year\$ 30,594\$ 82,806
Supplemental Disclosure Of Cash Flow Information:
Cash paid for interest         \$ 1,379         \$ 825
Purchases of property and equipment included in accounts payable and accrued expenses \$ 148 \$ 684
Issuance of preferred stock warrant in connection with term loan \$ \$ 322
Extinguishment of put option derivative liability in connection with term loan \$ (112) \$ (51)
Issuance of put option derivative liability in connection with term loan \$ 379 \$ 303
Conversion of shares of convertible preferred stock into common stock \$ \$ 38,914
Conversion of warrant into shares of common stock \$ \$ 2,770
Right-of-use-assets obtained in exchange for operating lease liabilities\$583\$1,904
Right-of-use-assets obtained in exchange for finance lease liabilities \$ 87 \$ —
Right-of-use asset derecognized upon lease modification\$-\$2,047

### Telesis Bio Inc. NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (In thousands, except share and per share data, unless otherwise specified)

## 1. ORGANIZATION AND OPERATIONS

#### **Business**

Telesis Bio Inc. (the Company) was incorporated in the state of Delaware in March 2011, as Synthetic Genomics Solution, Inc., a wholly owned subsidiary of Synthetic Genomics, Inc. (SGI). The Company changed its name to SGI-DNA, Inc. (SGI-DNA) in February 2013, to Codex DNA, Inc. in March 2020, and then to Telesis Bio Inc. in November 2022. SGI-DNA Limited, a United Kingdom company focused on sales and marketing activities, is a wholly owned subsidiary of Telesis Bio Inc. The Company manufactures and sells laboratory equipment, specifically synthetic biology instruments, reagents and associated products and related services, primarily to pharmaceutical and academic laboratories worldwide.

On March 8, 2019, SGI sold SGI-DNA to GATTACA Mining, LLC (Purchaser or GATTACA) by entering into a stock purchase agreement to sell all of the Company's outstanding common and preferred stock in exchange for a \$10 million non-recourse promissory note. Both the Company and Purchaser are co-borrowers of the promissory note. As this transaction was a change in control transaction in accordance with generally accepted accounting principles in the United States (U.S. GAAP), the Company elected to apply push-down accounting and recognized a step up in the basis of the assets acquired and liabilities assumed in the acquisition.

On June 10, 2021, the Company's Board of Directors and stockholders approved a 3-for-1 reverse stock split of the Company's issued and outstanding common stock and outstanding shares of convertible preferred stock, which was effected on June 11, 2021. The reverse stock split also applied to all outstanding securities or rights convertible into, or exchangeable or exercisable for, common stock or convertible preferred stock. Accordingly, all shares, stock options, warrants and per share information presented in the accompanying consolidated financial statements and notes thereto have been retroactively adjusted to reflect the reverse stock split. There was no change in the par value and authorized number of shares of the Company's common stock or preferred stock.

On June 18, 2021, the Company completed an initial public offering (IPO) of 7,666,664 shares of its common stock, including the exercise in full by the underwriters of their option to purchase up to 999,999 additional shares of common stock, for aggregate gross proceeds of \$122.7 million. The Company's shares began trading on the Nasdaq Global Select Market under the ticker symbol "DNAY" on June 18, 2021. The Company has since changed its ticker symbol to "TBIO" in connection with its name change to Telesis Bio, Inc. The Company received \$112.5 million in net proceeds after deducting underwriting discounts and commissions and other offering expenses payable by the Company. Upon closing of the IPO, all outstanding convertible preferred stock converted into 15,079,329 shares of common stock and SGI's outstanding warrants were automatically exercised into 1,201,059 shares of common stock.

On November 18, 2021, the Company entered into a Share Purchase Agreement, with the stockholders of EtonBio Inc., a California corporation ("Eton"), pursuant to which, the Company agreed to purchase all of the outstanding shares of capital stock of Eton (see Note 6). The total purchase price was approximately \$14.1 million, which was funded with the Company's existing cash on hand. Eton is a San Diego-based biotech company specializing in synthetic biology products and services, including DNA sequencing and oligo synthesis, for the global academic research, pharmaceutical, and biotechnology industries. Eton also markets DNA prep services and products such as antibodies, peptides, and metabolism assay kits.

Since its inception, the Company has devoted substantially all of its efforts to raising capital, commercializing its current products, and developing new product offerings. The Company is subject to a number of risks similar to those of other companies conducting high-risk, early-stage research and development of products. Principal among these risks are a dependence on key individuals and intellectual property, competition from other products and companies, and the technical risks associated with the successful research, development and manufacturing of its products. The Company's success is dependent upon its ability to continue to raise additional capital in order to fund ongoing research and development, commercialize its products, generate revenue, meet its obligations, and, ultimately, become profitable.

Products currently under development will require significant additional research and development efforts. These efforts require significant amounts of additional capital, adequate personnel and infrastructure.

### **Going Concern**

Under Accounting Standards Update ("ASU") No. 2014-15, Presentation of Financial Statements-Going Concern (Subtopic 205-40), the Company has the responsibility to evaluate whether conditions and/or events raise substantial doubt about its ability to meet its future financial obligations as they become due within one year after the date that the financial statements are issued. The Company has incurred losses and negative cash flows from operations in each year since its inception. As of December 31, 2022, the Company had an accumulated deficit of \$113.7 million. From its inception through December 31, 2022, the Company has received \$112.5 million in net proceeds upon completion of its IPO. Prior to the IPO, the Company had funded operations with proceeds from the issuance of convertible notes and convertible preferred stock, payments received from royalties and product sales, and proceeds from borrowings under credit facilities. The Company has also received \$8.0 million in upfront payments and \$2.5 million in milestone payments under its collaboration with Pfizer Inc. (Note 16). Until such time, if ever, as the Company can generate substantial product revenue and/or collaboration revenue and achieve sustained profitability, the Company expects to finance its cash needs through a combination of equity offerings, drawing on existing credit facilities, collaborations, strategic alliances, licensing arrangements and other sources of funding. However, the existing credit facilities may not be available if certain financial covenants are not achieved. Although the Company is actively pursuing new financing opportunities, it may not be able to raise cash on terms acceptable to the Company or at all. There can be no assurance that the Company will be successful in obtaining additional funding. Financings, if available, may be on terms that are dilutive to shareholders, and the prices at which new investors would be willing to purchase the Company's securities may be lower than the current price of ordinary shares. The holders of new securities may also receive rights, preferences or privileges that are senior to those of existing holders of ordinary shares. If additional financing is not available or is not available on acceptable terms, the Company could be forced to delay, limit, reduce or terminate product development or future commercialization efforts or grant rights to develop and market products or product candidates that the Company would otherwise prefer to develop and market itself. These factors raise substantial doubt about the Company's ability to continue as a going concern. Based upon the Company's current level of expenditures, management believes there currently is insufficient financial resources to fund the Company's operations for at least twelve months from the filing date of this Annual Report. The accompanying consolidated financial statements have been prepared on a going concern basis, which contemplates the realization of assets and satisfaction of liabilities in the ordinary course of business. The consolidated financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might result from the outcome of this uncertainty.

## 2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

### **Basis of Presentation and Principles of Consolidation**

The Company has prepared the accompanying consolidated financial statements in accordance with U.S. GAAP and included the accounts of the Company and its wholly owned subsidiaries after the elimination of all significant intercompany accounts and transactions.

#### Use of Estimates

The preparation of consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, disclosure of contingent assets and liabilities at the date of the consolidated financial statements, and the reported amounts of revenues and expenses during the reporting periods presented. Key estimates in the consolidated financial statements include the Company's ability to continue as a going concern, revenue recognition, impairment assessment for goodwill and intangible assets, allowance for doubtful accounts, estimated useful lives of property and equipment, valuation of inventory, accrued expenses, valuation of deferred income tax assets, valuation of derivative liabilities, share-based compensation, accrued warranty and valuation of acquired businesses are subject to significant estimation. Actual results could differ from those estimates.

### **Reclassifications**

Certain prior year amounts have been reclassified to conform to the current presentation. The Company reclassified an aggregate of \$0.1 million of field services and technical support costs from the research and development line to the sales and marketing and general administrative lines on the consolidated statement of operations and comprehensive loss for the year ended December 31, 2021. The Company believes these costs are better reflected in sales and marketing. The reclassification had no impact on net loss for the year ended December 31, 2021.

#### Concentrations of Credit Risk and Significant Customers

Financial instruments that potentially subject the Company to concentrations of credit risk consist of cash, cash equivalents, and accounts receivable.

The Company's accounts receivable are derived from revenue earned from customers. The Company does not require collateral on accounts receivable. The Company maintains reserves for estimated potential credit losses. For the year ended December 31, 2022, one customer accounted for 10% of the Company's accounts receivable balance and one customer accounted for 24% of the Company's revenue. For the year ended December 31, 2021, one customer accounted for 11% of the Company's accounts receivable balance and one customer accounted for 14% of the Company's revenue.

The Company has significant cash balances at accredited financial institutions which throughout the year regularly exceed the federally insured limit of \$250,000. Any loss incurred or a lack of access to such funds could have a significant adverse impact on the Company's financial condition, results of operations, and cash flows.

### Cash and Cash Equivalents

Cash and cash equivalents consist of cash deposited with banks and money market funds. The Company considers all highly liquid investments with an original maturity of 90 days or less at the date of purchase to be cash equivalents. The Company's cash equivalents as of December 31, 2022, are funds held in a money market accounts and are measured at fair value on a recurring basis.

### Short-term Investments

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

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

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

			Decem	ber (	31, 2022		
	An	nortized Cost	 ealized Fains		Unrealized Losses	Fa	ir Value
Assets							
Commercial paper	\$	1,737	\$ 	\$		\$	1,737
U.S. Government agencies		11,425	1		(4)		11,422
Total	\$	13,162	\$ 1	\$	(4)	\$	13,159

As of December 31, 2022, all short-term investments held by the Company had remaining contractual maturities of one year or less.

### **Restricted Cash**

In accordance with ASU 2016-18, Statement of Cash Flows (Topic 230): Restricted Cash, the Company explains the change during the period in the total of cash, cash equivalents and restricted cash, and includes restricted cash with cash and cash equivalents when reconciling the beginning-of-period and end-of-period total amounts shown on the consolidated statements of cash flows.

The following table provides a reconciliation of cash, cash equivalents, and restricted cash reported within the consolidated balance sheet dates that comprise the total of the same such amounts shown in the consolidated statements of cash flows for all years presented herein (in thousands):

	December 31,				
	2022 2021			2021	
Cash and cash equivalents	\$	30,419	\$	82,806	
Restricted cash		175			
Total cash, cash equivalents, and restricted cash as shown in the consolidated					
statements of cash flows	\$	30,594	\$	82,806	

### Accounts Receivable

Accounts receivable is comprised of amounts due from third-party payors recorded at the invoice amount and does not bear interest. The Company reports accounts receivable net of estimated contractual adjustments and any allowance for doubtful accounts. The Company reviews accounts receivable on an ongoing basis to determine collectability. The Company maintains an allowance for doubtful accounts based on its assessment of the collectability of the amounts owed to the Company by its customers. The Company considers the following in determining the level of allowance required: its customer's payment history, the age of the receivable, the credit quality of its customers, the general financial condition of its customer base and other factors that may affect the customers' ability to pay. The Company writes off accounts against the allowance for doubtful accounts when they are deemed to be uncollectible. Net accounts receivable amounted to \$5.9 million and \$3.7 million as of December 31, 2022 and 2021, respectively. Net accounts receivable include an allowance for doubtful accounts of \$0.3 million and \$0, as of December 31, 2022 and 2021 respectively, for those accounts deemed uncollectible by the Company.

#### Inventory

Inventory, which primarily consists of raw materials, labor and overhead related to work in process and sub-assemblies are stated at the lower of cost or net realizable value. Cost is computed using standard cost, which approximates actual cost on a first-in, first-out basis. Net realizable value is evaluated by considering obsolescence, excessive levels of inventory, deterioration and other factors. Adjustments to reduce the cost of inventory to its net realizable value, if required, are made for estimated excess, obsolescence or impaired inventory. Excess and obsolete inventory is charged to cost of revenue and a new, lower-cost basis for that inventory is established and subsequent changes in facts and circumstances do not result in the restoration of amounts previously written off.

## **Property and Equipment**

Property and equipment are recorded at cost, net of accumulated depreciation and amortization. The Company depreciates property and equipment using the straight-line method over estimated useful lives ranging from three to five years. Leasehold improvements and equipment held under capital leases are amortized on a straight-line basis over the shorter of the lease term or the estimated life of the asset.

Upon the sale or retirement of assets, the cost and related accumulated depreciation and amortization are removed from the balance sheet and the resulting gain or loss is reflected in other expense, net in the consolidated statements of operations and comprehensive loss. Maintenance and repairs are charged to the general and administrative expenses in the consolidated statements of operations and comprehensive loss as incurred.

### Intangible Assets

The Company has intangible assets and goodwill recorded in connection with its acquisition in March 2019, as well as from the Eton acquisition. Intangible assets are recognized apart from goodwill if they arise from contractual or other legal rights or if they are separable. An asset is considered separable if (a) it is capable of being separated from the acquired entity and sold, transferred, licensed, rented or exchanged, or (b) it can be conveyed in combination with a related asset or liability. Those assets that do not meet either criterion are included in goodwill for financial reporting purposes.

Intangible assets are amortized over their estimated useful lives based upon the estimated economic value derived from the related intangible asset. Intangible assets are reviewed for impairment whenever events or changes in circumstances, such as service discontinuance, technological obsolescence, or significant decreases in the Company's market capitalization indicate that the carrying amount of the asset may not be recoverable. When such events occur, the Company compares the carrying amount of the asset to the undiscounted expected future cash flows related to the asset. If this comparison indicates that an impairment is present, the amount of the impairment is calculated as the difference between the carrying amount and the fair value of the asset. There was no impairment recorded for the years ended December 31, 2022 and 2021.

#### Goodwill

The Company recognizes the excess of the purchase price over the fair value of identifiable net assets acquired as goodwill. Goodwill is not amortized but is tested for impairment annually or more frequently if events or changes in circumstances indicate that the carrying amount of the goodwill may not be recoverable. The Company's goodwill impairment tests are performed at the enterprise level given the Company's single reporting unit.

The Company's goodwill impairment analysis first assesses qualitative factors to determine whether events or circumstances existed that would lead the Company to conclude it is more likely than not that the fair value of the reporting unit is below its carrying amount. If the Company determines that it is more likely than not that the fair value of the reporting unit is below the carrying amount, a quantitative goodwill assessment is required. In the quantitative evaluation, the fair value of the reporting unit is determined and compared to the carrying value. If the fair value is greater than the carrying value, then the carrying value is deemed to be recoverable and no further action is required. If the fair value estimate is less than the carrying value, goodwill is considered impaired for the amount by which the carrying value exceeds the reporting unit's fair value and a charge would be recognized as impairment of goodwill in the consolidated statements of operations and comprehensive loss. There was no impairment of goodwill recorded for the years ended December 31, 2022 and 2021.

### Accounting for Long-Lived Assets

The Company reviews its long-lived assets for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Recoverability of an asset to be held and used is measured by a comparison of the carrying amount of an asset or asset group to the future undiscounted cash flows expected to be generated by the asset or asset group. No such impairments have been identified for the years ended December 31, 2022 and 2021.

#### Leases

ASC Topic 842, "Leases" ("ASC 842"), requires lessees to recognize most leases on the balance sheet with a corresponding right-to-use asset ("ROU asset"). ROU 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. The assets and lease liabilities are recognized at the lease commencement date based on the estimated present value of fixed lease payments over the lease term. ROU assets are evaluated for impairment using the long-lived assets impairment guidance.

Leases will be classified as financing or operating, which will drive the expense recognition pattern. The Company elects to exclude short-term leases if and when the Company has them.

The Company leases office and laboratory space, all of which are operating leases (see Note 7). Most leases include the option to renew and the exercise of the renewal options is at the Company's sole discretion. Options to renew a lease are not included in the Company's assessment unless there is reasonable certainty that the Company will renew. In addition, the Company's lease agreements generally do not contain any residual value guarantees or restrictive covenants.

The interest rate implicit in lease contracts is typically not readily determinable. As a result, the Company utilizes its incremental borrowing rate, which reflects the fixed rate at which the Company could borrow on a collateralized basis the amount of the lease payments in the same currency, for a similar term, in a similar economic environment.

For real estate leases, the Company has elected the practical expedient under ASC 842 to account for the lease and non-lease components together for existing classes of underlying assets and allocates the contract consideration to the lease component only. This practical expedient is not elected for manufacturing facilities and equipment embedded in product supply arrangements.

#### **Business Combinations**

The Company accounts for acquisitions using the acquisition method of accounting. The fair value of purchase consideration is allocated to the tangible and intangible assets acquired, and liabilities assumed, based on their estimated fair values. The excess of the fair value of purchase consideration over the fair values of the identifiable assets acquired and liabilities assumed is recorded as goodwill. When determining the fair values of assets acquired and liabilities assumed, management makes significant estimates and assumptions, especially with respect to intangible assets.

Significant estimates in valuing certain identifiable assets include, but are not limited to, the selection of valuation methodologies, future expected cash flows, discount rates, and useful lives. Management's estimates of fair value are based upon assumptions believed to be reasonable, but which are inherently uncertain and unpredictable and, as a result, actual results may differ from estimates. Acquisition costs, such as legal and consulting fees, are expensed as incurred and are included in general and administrative expenses in the consolidated statements of operations and comprehensive loss. During the measurement period, which is up to one year from the acquisition date, the Company may record adjustments to the assets acquired and liabilities assumed, with the corresponding offset to goodwill. Upon the conclusion of the measurement period, any subsequent adjustments are recorded in the consolidated statements of operations.

## **Deferred Offering Costs**

The Company capitalizes within other current assets certain legal, consulting and other third-party fees that are directly related to the Company's in-process equity financings, until such financings are consummated. After consummation of the equity financing, these costs are recorded as a reduction of the proceeds received as a result of the offering. Should a planned equity financing be abandoned, terminated, or significantly delayed, the deferred offering costs are immediately written off to operating expenses. There were \$0 and \$0.9 million of offering costs capitalized during the years ended December 31, 2022 and 2021, respectively.

### **Deferred Financing Costs**

The Company capitalizes certain legal and other third-party fees that are directly associated with obtaining access to capital under credit facilities. Deferred financing costs incurred in connection with obtaining access to capital under credit facilities are recorded as a reduction to the carrying amount of the debt and amortized to interest expense using the effective interest method over the repayment term.

### Income Taxes

The Company is a C Corporation for federal income tax purposes. The Company was not profitable during the years ended December 31, 2022 and 2021. Accordingly, no provision for federal income taxes has been presented in the accompanying consolidated statements of operations and comprehensive loss.

The Company accounts for income taxes under the asset and liability method. Under this method, deferred tax assets and liabilities are recognized for the future tax consequences attributed to differences between financial statement carrying amounts of existing assets and liabilities and their respective tax bases, including operating losses and tax credit carryforwards, if applicable. Deferred tax assets and liabilities are measured using the enacted tax rates expected to apply to taxable income in the years in which the differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in the tax rates is recognized in income in the period that includes the enactment date.

A valuation allowance may be established for carryforwards and other deferred tax assets when it is more likely than not that such deferred tax assets will not be realized. Based on its facts, the Company considered all available evidence, both positive and negative, including historical levels of taxable income, expectations, and risks associated with estimates of future taxable income, and ongoing prudent and feasible tax planning strategies in assessing the need for a valuation allowance. The Company recorded a valuation allowance against the deferred tax asset as the Company believes it is more likely than not that the deferred asset will not be utilized.

The Company recognizes the effect of income tax positions only if those positions are more likely than not to be sustained upon examination, including resolution of any related appeals or litigation processes. A tax position that meets the more likely than not

recognition threshold is measured at the largest amount of benefit that is greater than 50% likely of being realized upon ultimate settlement with a taxing authority. Changes in recognition or measurement are reflected in the period in which the change in judgment occurs. The Company records interest related to unrecognized tax benefits in interest and penalties in general and administrative expenses. The Company has determined that it has an uncertain tax position as it relates to its state research and development credits for the years ended December 31, 2022 and 2021 (see Note 11).

### Share-Based Compensation

For share-based awards granted to employees and directors, the Company estimates the grant-date fair value using the Black-Scholes option-pricing model. Compensation expense for these awards is recognized net of the estimated forfeiture rate, over the requisite service period, which is generally the vesting period of the respective award.

For share-based awards granted to non-employees, the Company adopted Accounting Standards Update No. (ASU) 2018-07, Compensation—Stock Compensation (Topic 718) (ASU 2018-07) at inception, as discussed below, in which the measurement date for non-employee awards is the date of grant. The compensation expense for non-employees is recognized in the same manner as if the Company had paid cash in exchange for the goods or services, which is generally the vesting period of the award. The Company applies an estimated forfeiture rate to share-based compensation.

The Company classifies share-based compensation expense in its consolidated statements of operations and comprehensive loss in the same manner in which the award recipient's payroll costs are classified or in which the award recipient's service payments are classified.

#### **Revenue Recognition**

The Company recognizes revenues in accordance with Financial Accounting Standards Board (FASB) ASU 2014-09, Revenue from Contracts with Customers (Topic 606) (ASC 606). To date, revenues have consisted primarily of payments received related to product sales, services and royalty agreements. Under ASC 606, the Company recognizes revenue when customers obtain control of promised goods or services, in an amount that reflects the consideration which the Company expects to receive in exchange for those goods or services.

Revenue for product sales is recognized upon delivery to the customer. Revenue related to extended product warranty arrangements is deferred and recognized over time as services are delivered. To determine the appropriate amount of revenue to be recognized for arrangements determined to be within the scope of ASC 606, the Company performs the following five steps: (i) identification of the promised goods or services in the contract; (ii) determination of whether the promised goods or services are performance obligations including whether they are distinct in the context of the contract; (iii) measurement of the transaction price, including the assessment of the constraint on variable consideration; (iv) allocation of the transaction price to the performance obligations; and (v) recognition of revenue when, or as the Company satisfies each performance obligation. As part of the accounting for arrangements under ASC 606, management must use its significant judgment to determine: (a) the performance obligations based on the determination under step (ii) above; (b) the transaction price under step (iii) above; and (c) the standalone selling price for each performance obligation identified in the contract for the allocation of transaction price in step (iv) above. Management also uses its judgment to determine whether milestones or other variable consideration, except for royalties and sales-based milestones, should be included in the transaction price as described below. The transaction price is allocated to each performance obligation based on the relative stand-alone selling price of each performance obligation in the contract, and revenue is recognized based on those amounts when, or as, the performance obligations under the contract are satisfied.

The standalone selling price is the price at which an entity would sell a promised good or service separately to a customer. Management estimates the standalone selling price of each of the identified performance obligations in customer contracts, maximizing the use of observable inputs. Because the Company has not sold the same goods or services in the contracts separately to any customers on a standalone basis and there are no similar observable transactions in the marketplace, the Company estimates the standalone selling price of each performance obligation in customer arrangements based on estimated costs to be incurred to fulfil obligations associated with the performance, plus a reasonable margin.

Amounts received prior to revenue recognition are recorded as deferred revenue in the consolidated balance sheets. Amounts expected to be recognized as revenue within the twelve months following the balance sheet date are classified as deferred revenue, current portion in the consolidated balance sheets. Amounts not expected to be recognized as revenue within the twelve months following the balance sheet date are classified as other long-term liabilities in the consolidated balance sheets. Amounts are recorded as accounts receivable when the right to consideration is unconditional.

### Product Revenue, Net

The Company recognizes revenue on product sales to customers when the transfer of control happens, which generally occurs upon shipment. The Company recognizes revenue on installation and training when the service has been rendered. The Company includes a standard one year warranty with its product sales. These standard warranties are accounted for at the time product revenues are recognized. The Company also offers extended warranty for an additional fee. Revenue related to extended warranty is recognized on a straight-line basis over the term. Product revenues are recorded net of variable consideration, including discounts.

### Product Returns

The Company does not generally offer customers the ability to return product and has received an immaterial amount of returns to date.

### Service Revenue

The Company recognizes service revenue at a point in time when the service has been rendered and control of promised goods and services are transferred to a customer.

### Collaboration Revenue

Research collaboration agreements are recognized as the research services are performed. See Note 16 for additional description of collaboration revenue.

### Royalties and Other Revenue

Royalties and other revenue consist of fees charged for the license of non-exclusive rights of the Company's patents to third parties and grant revenue received from government entities as reimbursement of expenses related to the development and use of synthetic biology tools to develop solutions to address various areas of concern. The royalties and other revenue are recognized at the same time as the third parties record the revenue associated with the use of the license. The grant revenue from the contracts is recognized as the services are performed or ratably over the milestone period and typically require the performance of specific activities and timely reporting of results. Associated expenses are recognized when incurred. Revenue and related expenses are presented gross in the consolidated statements of operations and comprehensive loss.

#### Warranties

The Company provides warranty coverage on its systems. Warranty coverage includes providing labor and parts necessary to repair the systems during the warranty period. The standard warranty coverage is twelve months for system sales. In addition, customers may pay for enhanced warranty service or to extend the warranty period to 24 months. Warranty revenue is deferred and recognized over the warranty period as a part of product sales in the consolidated statements of operations and comprehensive loss. The Company charges warranty expenses to cost of revenue in the period the expense is incurred. The changes in deferred revenue for warranties during the years ended December 31, 2022 and 2021 are summarized as follows (in thousands):

Balance at December 31, 2020	\$ 257
Warranty revenue deferred	487
Warranty revenue recognized	(389)
Balance at December 31, 2021	355
Warranty revenue deferred	615
Warranty revenue recognized	(571)
Balance at December 31, 2022	\$ 399

The deferred revenue for warranties at December 31, 2022 and 2021 are summarized as follows (in thousands):

		December 31,				
	202	2		2021		
Deferred warranty revenue, current portion	\$	257	\$	205		
Deferred warranty revenue, net of current portion		142		150		
Total deferred warranty revenue	\$	399	\$	355		

#### Shipping and Handling Costs

Shipping and handling costs are included as a component of cost of revenue in the consolidated statements of operations and comprehensive loss.

#### Fair Value of Assets and Liabilities

In accordance with ASC 820, fair value is defined as the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. When determining fair value, the Company considers the principal or most advantageous market in which the Company would transact, and considers assumptions that market participants would use when pricing the asset or liability. The fair value hierarchy distinguishes between (1) market participant assumptions developed based on market data obtained from independent sources (observable inputs) and (2) an entity's own assumptions about market participant assumptions developed based on the best information available in the circumstances (unobservable inputs).

The fair value hierarchy consists of three broad levels, which gives the highest priority to unadjusted quoted prices in active markets for identical assets or liabilities (Level 1) and the lowest priority to unobservable inputs (Level 3). The three levels of the fair value hierarchy as described below:

Level 1-Quoted prices (unadjusted) in active markets for identical assets or liabilities.

Level 2–Directly or indirectly observable inputs as of the reporting date through correlation with market data, including quoted prices for similar assets and liabilities in active markets and quoted prices in markets that are not active. Level 2 also includes assets and liabilities that are valued using models or other pricing methodologies that do not require significant judgment since the input assumption used in the models, such as interest rates and volatility factors, are corroborated by readily observable data from actively quoted markets substantially the full term of the financial instrument.

Level 3–Unobservable inputs that are supported by little or no market data and require the use of significant management judgment. These values are generally determined using pricing models for which the assumptions utilize management's estimates of market participant assumptions.

The Company's contingent put liability is carried at fair value, determined according to Level 3 inputs in the fair value hierarchy described above (see Note 3). The carrying value of the Company's prepaid expenses and other current assets, accounts payable and accrued expenses approximate their fair value principally because of the short-term maturities of these instruments.

#### **Research and Development**

Research and development costs, including direct and allocated expenses, are expensed in the period incurred. Research and development costs include payroll and personnel expense, consulting costs, external contract research and development costs, raw materials and allocated overhead such as depreciation and amortization, rent and utilities. Advance payments for goods and services to be used in future research and development activities are recorded as prepaid expenses and are expensed over the service period as the services are provided or when the goods are consumed.

### Advertising

The Company expenses the cost of advertising, including promotional expenses, as incurred. Advertising and promotional expenses for the years ended December 31, 2022 and 2021 were \$1.0 million and \$0.9 million, respectively.

### Comprehensive Income (Loss)

Comprehensive income (loss) includes net loss as well as other changes in stockholders' equity that result from transactions and economic events other than those with stockholders. Other comprehensive loss consists of unrealized gains and losses on investments.

#### Net Loss per Share

The Company follows the two-class method when computing net loss per share as the Company has issued shares that meet the definition of participating securities. The two-class method determines net loss per share for each class of common and participating securities according to dividends declared or accumulated and participation rights in undistributed earnings. The two-class method requires income available to common stockholders for the period to be allocated between common and participating securities based upon their respective rights to receive dividends as if all income for the period had been distributed.

Basic net loss per share attributable to common stockholders is computed by dividing net loss attributable to common stockholders by the weighted-average number of shares of common stock outstanding for the period. Diluted net loss per share attributable to common stockholders is computed by adjusting net loss attributable to common stockholders to reallocate undistributed earnings based on the potential impact of dilutive securities. Diluted net loss per share attributable to common stockholders is computed by dividing the diluted net loss attributable to common stockholders by the weighted-average number of shares of common stockholders by the weighted-average number of shares of common stock outstanding for the period, including potential dilutive shares of common stock assuming the dilutive effect of common stock equivalents. For purposes of this calculation, outstanding stock options, unvested restricted common stock, and convertible preferred stock are considered potential dilutive common stock and are excluded from the computation of diluted net loss per share attributable to common stockholders if their effect is anti-dilutive.

The Company's convertible preferred stock contractually entitles the holders of such shares to participate in dividends but do not contractually require the holders of such shares to participate in losses of the Company. Accordingly, in periods in which the Company reports a net loss, such losses are not allocated to such participating securities. In periods in which the Company reports a net loss attributable to common stockholders, diluted net loss per share attributable to common stockholders, since dilutive shares of common stockholders for the years ended December 31, 2022 and 2021.

#### **Segments Information**

Operating segments are defined as components of an entity for which separate financial information is available and that is regularly reviewed by the chief operating decision maker (CODM), in deciding how to allocate resources to an individual segment and in assessing performance. The Company's CODM is its chief executive officer. The Company has determined it operates in one segment.

#### **Recently Adopted Accounting Pronouncements**

In November 2021, the FASB issued ASU No. 2021-10, Disclosures by Business Entities about Government Assistance. The ASU codifies new requirements to disclose information about the nature of certain government assistance received, the accounting policy used to account for the transactions, the location in the financial statements where such transactions were recorded and significant terms and conditions associated with such transactions. The guidance is effective for annual periods beginning after December 15, 2021. The Company adopted this standard on January 1, 2022. The adoption of ASU 2021-10 did not have a material impact on our consolidated financial statements.

In August 2020, the FASB issued ASU 2020-06, Debt – Debt with Conversion and Other (Subtopic 470-20) and Derivatives and Hedging – Contracts in Entity's Own Equity (Subtopic 815-40). This update simplifies the accounting for convertible debt instruments by removing certain accounting separation models as well as the accounting for debt instruments with embedded conversion features that are not required to be accounted for as derivative instruments. The update also updates and improves the consistency of earnings per share calculations for convertible instruments. The amendments in this ASU are effective for fiscal years beginning after December 15, 2021, including interim periods within those fiscal years. The Company adopted this standard on January 1, 2022. The adoption of ASU 2020-06 did not have any impact on our consolidated financial statements or overall EPS calculation.

### **Recent Accounting Pronouncements Not Yet Adopted**

In June 2016, the FASB issued ASU 2016-13, Financial Instruments-Credit Losses: Measurement of Credit Losses on Financial Instruments (Topic 326) (ASU 2016-13). ASU 2016-13 requires measurement and recognition of expected credit losses for financial assets. In April 2019, the FASB issued clarification to ASU 2016-13 within ASU No. 2019-04, Codification Improvements to Topic 326, Financial Instruments-Credit Losses, Topic 815, Derivatives and Hedging, and Topic 825, Financial Instruments. This update is effective for entities other than public business entities, including emerging growth companies that elected to defer compliance with new or revised financial accounting standards until a company that is not an issuer is required to comply with such standards, for annual reporting periods beginning after December 15, 2022. The Company does not expect the adoption of ASU 2016-13 to have a material impact on its consolidated financial statements and related disclosures.

In December 2019, the FASB issued ASU 2019-12, Simplifying the Accounting for Income Taxes (ASU 2019-12). ASU 2019-12 eliminates certain exceptions related to the approach for intra-period tax allocation, the methodology for calculating income taxes in an interim period and the recognition of deferred tax liabilities for outside basis differences. It also clarifies and simplifies other aspects of the accounting for income taxes. This update is effective for entities other than public business entities, including emerging growth companies that elected to defer compliance with new or revised financial accounting standards until a company that is not an issuer is required to comply with such standards, for annual reporting periods beginning after December 15, 2021, and interim periods within annual periods beginning after December 15, 2022. The Company does not expect the adoption of ASU 2019-12 to have a material impact on its consolidated financial statements and related disclosures.

In October 2021, the FASB issued ASU 2021-08, Business Combinations (Topic 805): Accounting for Contract Assets and Contract Liabilities from Contracts with Customers. The ASU requires entities to apply Topic 606 to recognize and measure contract assets and contract liabilities in a business combination. The amendments improve comparability after the business combination by providing consistent recognition and measurement guidance for revenue contracts with customers acquired in a business combination and revenue contracts with customers not acquired in a business combination. The ASU is effective for fiscal years, including interim periods within those fiscal years, beginning after December 15, 2022. Entities should apply the amendments prospectively and early adoption is permitted. The Company does not expect the adoption of ASU 2021-08 to have a material impact on its consolidated financial statements and related disclosures.

## **3. FAIR VALUE MEASUREMENT**

The following table summarizes the fair values of the Company's derivative liabilities on the consolidated balance sheets which comprise money market funds, commercial paper, U.S. government agencies, and the contingent put liability (in thousands):

		Fair value measurements as of December 31, 2022				2022		
	Ī	evel 1	L	evel 2	L	evel 3		Total
Assets								
Money market funds	\$	26,784	\$		\$		\$	26,784
Commercial paper				1,737				1,737
U.S. government agencies				11,422				11,422
Total	\$	26,784	\$	13,159	\$		\$	39,943
Liabilities								
Contingent put option liability	\$		\$		\$	367	\$	367
Total	\$		\$		\$	367	\$	367

	Fair valu	Fair value measurements as of December 31, 2021			
	Level 1	Level 2	Level 3	Total	
Assets					
Money market funds	\$ 79,893	\$	\$	\$ 79,893	
Total	\$ 79,893	\$	\$	\$ 79,893	
Liabilities					
Contingent put option liability	\$	\$	\$ 108	\$ 108	
Total	\$	\$	\$ 108	\$ 108	

During the year ended December 31, 2022, there were no transfers between Level 1, Level 2 and Level 3.

#### Participation Right Liability

The participation right liability consists of the fair value of 3% of the securities sold in a future equity financing round and was originated from the participation right that was given to SGI in conjunction with the Company acquisition (see Note 1). The fair value of the participation right liability was based on significant inputs not observable in the market, which represent a Level 3 measurement within the fair value hierarchy.

The quantitative elements associated with the Company's Level 3 inputs impacting the fair value measurement of the participation right liability include management's expectation of amounts to be raised and the probability of success in obtaining the funds. The participation right liability was extinguished pursuant to the Company's IPO.

### **Preferred Stock Warrants**

The preferred stock warrant liability consists of the fair value of warrants to purchase Series A-1 Preferred Stock issued in conjunction with the Series A-1 financing in December 2019 with SGI and the 2021 Loan Agreement (See Note 8) and was based on significant inputs not observable in the market, which represent a Level 3 measurement within the fair value hierarchy. Upon the closing of the IPO, SGI's outstanding preferred stock warrants were automatically exercised into 119,315 shares of common stock. Subsequent to the closing of the IPO, all outstanding warrants issued pursuant to the 2021 Loan Agreement were exercised into 51,409 shares of common stock. As of December 31, 2021, there were no outstanding preferred stock warrants.

#### Success Fee Contingent Liability

The success fee contingent liability consists of the fair value of contingent obligation to pay the lender a success fee of \$0.8 million upon a Liquidity Event under the 2019 Loan Agreement. Due to the Company's IPO, the fair value of the success fee contingent liability was classified as a Level 1 input due to the use of an observable market quote in an active market. The success fee was paid in full in July 2021, and the liability was extinguished.

### **Contingent Put Option Liability**

The contingent put option liability consists of the fair value of the contingent interest feature and acceleration clause (contingent put option) under the 2019 Loan Agreement, 2021 Loan Agreement and the 2022 Term Loan Agreement (see Note 8). The fair value of the contingent put option liability was based on significant inputs not observable in the market, which represent a Level 3 measurement within the fair value hierarchy. The Company's valuation of the contingent put option liability utilized a risk-neutral valuation model wherein the fair value of the underlying debt facility is estimated, both with and without the presence of the default provisions, holding all other assumptions constant. The Company assesses these assumptions and estimates each reporting period as additional information impacting the assumptions are obtained. Changes in the fair value of the consolidated statements of operations and comprehensive loss. The significant inputs not observable in the market consist of the adjusted market rate of debt and the probability of default. As of December 31, 2022 and 2021, the adjusted market rate of debt was 12.58% and 4.24%, respectively, and the probability of default was 63% and 21%, respectively. A significant change in those inputs could cause a significant change in valuation.

The following table provides a roll-forward of the aggregate fair value of the Company's derivative liabilities for which fair value is determined using Level 3 inputs (in thousands):

	ntingent Put ion Liability
Fair value at December 31, 2020	\$ 51
Extinguishment of liability	(51)
Issuance of liability	303
Change in fair value	(195)
Fair value at December 31, 2021	 108
Change in fair value	(8)
Extinguishment of liability	(112)
Issuance of liability	379
Fair value at December 31, 2022	\$ 367

For the years ended December 31, 2022 and 2021, the Company recorded a change in fair value of derivative liabilities included in other income of \$8,000 and other expense of \$1.5 million, respectively.

### **4. INVENTORY**

Inventories include material, labor and overhead and are stated at the lower of cost (first-in, first-out method) or net realizable value. The components of inventory are as follows as of December 31, 2022 and 2021 (in thousands):

	December 31,		
	 2022		
Raw materials	\$ 1,044	\$	962
Work in process and sub-assemblies	647		896
Finished goods	509		510
Total	\$ 2,200	\$	2,368

# 5. PROPERTY AND EQUIPMENT

Property and equipment consisted of the following on December 31, 2022 and 2021 (in thousands):

		December 31,		
	202	2022		2021
Machinery and equipment	\$	5,647	\$	2,589
Furniture and fixtures		64		
Computer hardware and software		1,531		29
Leasehold improvements		58		95
Construction in progress		1,501		1,536
Total		8,801		4,249
Less: Accumulated depreciation and amortization		(1,940)		(793)
Total property and equipment, net	\$	6,861	\$	3,456

Depreciation expense for the years ended December 31, 2022 and 2021 was \$1.2 million and \$0.5 million, respectively.

### 6. GOODWILL AND OTHER INTANGIBLE ASSETS

## Goodwill

In 2019, SGI sold SGI-DNA to GATTACA Mining, LLC. As part of the transaction, the Company acquired its intangible assets with resulting goodwill. The goodwill carries a fair value of approximately \$3.5 million. Due to the recent decline in global economic and labor market conditions caused by the global outbreak of the COVID-19 pandemic, the Company considered the effects on its goodwill and determined that there was no significant impact that would cause the goodwill to be impaired. There were no other events or circumstances that have changed since the last annual assessment that could reduce the fair value of the Company's reporting segment below its carrying values.

In connection with the Eton acquisition in November 2021, the excess of the purchase price over the fair value of the net identifiable tangible and intangible assets acquired has been assigned to goodwill at a fair value of \$11.4 million.

For the years ended December 31, 2022 and 2021, the Company did not record any impairment of goodwill.

## **Other Intangible Assets**

Other intangible assets acquired in the sale of SGI-DNA to GATTACA Mining, LLC include the rights to technology and the SGI-DNA trade name. The technology was valued at approximately \$3.2 million with a seven year useful life.

Other intangible assets acquired in the Eton acquisition include the Eton trade name, customer relationships and noncompetition agreements. The trade name was valued at \$0.1 million with a three year useful life, the customer relationships at \$0.4 million with a 15 year useful life and the non-competition agreements at approximately \$30,000 with a three year useful life.

Other intangible assets, net consists of the following (in thousands):

	 December 31, 2022				
	s Carrying Value		cumulated nortization	Net	Carrying Value
Intellectual property	\$ 3,150	\$	(1,725)	\$	1,425
Trade name	80		(30)		50
Customer relationships	420		(32)		388
Non-competition agreements	30		(11)		19
Total	\$ 3,680	\$	(1,798)	\$	1,882

	December 31, 2021			
	Gross Carrying Value		Net Carrying Value	
Intellectual property	\$ 3,150	(1,275)	\$	1,875
Trade name	80	(3)		77
Customer relationships	420	(4)		416
Non-competition agreements	30	(1)		29
Total	\$ 3,680	(1,283)	\$	2,397

Amortization expense for each of the years ended December 31, 2022 and 2021, was approximately \$0.5 million.

The following table summarizes the estimated future amortization expense of the intangible assets (in thousands):

Years ending December 31:	Amortization of Intangible Assets
2023	\$ 514
2024	510
2025	478
2026	103
2027	28
Thereafter	249
Total	\$ 1,882

### 7. LEASES

As of December 31, 2022, the Company had four outstanding leases for office and laboratory space and equipment. The leases have remaining terms between two and 59 months. The Company has also entered into certain short-term leases with a term of less than one year. These leases are not included within the Company's right-of-use assets or lease liabilities due to the Company's election of the practical expedient recognition exemption for short-term leases.

#### **Corporate Headquarters**

In September 2021, the Company entered into the Wateridge Pointe lease for future office and laboratory space and concurrently signed a second amendment to the operating lease agreement for its corporate headquarters located at 9535 Waples Street, San Diego, California (the Second Amendment). Under the Second Amendment, the lease at 9535 Waples Street will terminate upon the occupancy of office and laboratory space at 10421 and 10431 Wateridge Circle, San Diego, California, which will occur subsequent to the renovation and build-out of the spaces. The Wateridge Pointe lease provides for a tenant improvement (TI) allowance for the renovation and build-out of the spaces up to \$185.00 per square foot, or approximately \$12.3 million, with an additional allowance of up to \$10.00 per square foot, or approximately \$0.7 million if properly requested by the Company. The lessor is solely responsible for the management and payment of the tenant improvements and these expenses will be recorded as lessor improvements per ASC 842 guidance. Rent for the Wateridge Pointe lease provides for a 10 year and 3 month term and the Company is entitled to one option to extend the lease term for an additional five years. Occupancy of 10421 and 10431 Wateridge Circle and the corresponding termination of the lease at 9535 Waples Street are expected to occur in the first quarter of 2023.

Upon the execution of the Second Amendment, which was deemed to be a lease modification, the Company re-evaluated the assumptions made at the original lease commencement date. The Company determined the Second Amendment consists of a single contract under ASC 842. Accordingly, the Company bifurcated the components of the modified lease. Upon execution of the Second Amendment the Company adjusted the right-of-use asset and lease liability for the reduced term of the 9535 Waples Street lease component. In addition the Company will record a right-of-use asset and lease liability on the commencement date of the 10421 and 10431 Wateridge Circle lease components.

### Equipment

The Company entered into finance lease agreements for equipment in November 2017 (the 2017 Equipment Lease), January 2018 (the 2018 Equipment Lease), in March 2019 (the 2019 Equipment Lease), and in November 2022 (the 2022 Equipment Lease). The terms of the leases commenced when the equipment was delivered and placed into use which occurred in the same months and years as above, respectively, and accordingly the related right-of-use assets and lease liabilities were recognized on the consolidated balance sheets at their respective commencement dates. The 2017 Equipment Lease expired in October 2022, the 2018 Equipment Lease in December 2022, and the 2019 Equipment Lease expired in April 2021. The 2022 Equipment Lease expires in October 2025.

## Summary of Lease Cost

The components of lease cost under ASC 842 are as follows (in thousands):

	December 31,			51,
		2022		2021
Lease costs				
Finance lease cost:				
Payment of finance lease liability	\$	79	\$	81
Interest on lease liabilities		3		9
Operating lease costs		1,366		920
Variable lease cost		706		475
Short term lease cost		915		236
Total lease cost	\$	3,069	\$	1,721

Supplemental disclosure of cash flow information related to leases are as follows (in thousands):

	December 31,			
		2022		2021
Cash paid for amounts included in the measurement of lease liabilities:				
Operating cash flows from operating leases	\$	1,606	\$	1,031
Operating cash flows from finance leases	\$	3	\$	9
Financing cash flows from finance leases	\$	79	\$	81

The weighted-average remaining lease term and discount rate were as follows:

	December	31,
	2022	2021
Weighted-average remaining lease term		
Finance leases	2.8 years	1.0 years
Operating leases	3.9 years	3.9 years
Weighted-average discount rate		-
Finance leases	10.0%	7.7%
Operating leases	8.5%	8.5%

The following table summarizes the minimum lease payments of the Company's operating and finance lease liabilities as of December 31, 2022 (in thousands):

Year Ending December 31,	Operating	Finance	
2023	\$ 769	\$	65
2024	323		32
2025	333		
2026	343		
2027	307		
Thereafter			
Total future minimum lease payments	2,075		97
Less: imputed interest	(386)		(8)
Present value of operating lease liability	\$ 1,689	\$	89
Less: current portion of lease liability	(578)		(59)
Non-current portion of lease liability	1,111		30

The table above excludes an estimated \$45.1 million of legally binding minimum lease payments to be made over a period of approximately 10 years for the lease at 10421 and 10431 Wateridge Circle, San Diego, California that has been executed but not yet commenced as of December 31, 2022. Commencement of the lease at 10421 and 10431 Wateridge Circle is expected to occur in the first quarter of 2023.

## 8. NOTES PAYABLE

## Loan and Security Agreement

As of December 31, 2022 and 2021, the loans payable on the consolidated balance sheets pertains to the Credit, Security and Guaranty Agreement with MidCap Financial Trust and the Loan and Security Agreement with Silicon Valley Bank and consists of the following (in thousands):

	Dece	ember 31,
	2022	2021
Principal amount of loans payable	\$ 20,000	0 \$ 15,000
Less: Current portion of loans payable		(603)
Loans payable, net of current portion	20,000	14,397
Accrued Interest	172	2 94
Final debt payment liability	90	) 400
Debt discount and financing costs, net of accretion	(1,42)	3) (803)
Loans payable, net of discount and current portion	<u>\$ 19,64</u>	9 \$ 14,088

## 2021 Loan Agreement

On March 4, 2021, the Company entered into a Loan and Security Agreement with Silicon Valley Bank (SVB) as the lender (the 2021 Loan Agreement). The 2021 Loan Agreement was terminated in August 2022, and was fully repaid. Under the 2021 Loan Agreement, the Company borrowed a \$15.0 million senior secured term loan, the proceeds of which were used to repay all existing obligations under the Company's previously outstanding loan agreement with Oxford Finance LLC, with the remaining proceeds available for working capital and general corporate purposes. Under the 2021 Loan Agreement, the Company had the option to elect to obtain a second term loan from SVB in a principal amount up to but not exceeding \$5.0 million, provided certain revenue milestones are achieved.

In connection with the 2021 Loan Agreement, the Company issued to SVB a warrant to purchase a number of shares of preferred stock (the Preferred Warrant). The Preferred Warrant was exercisable into the number of preferred shares equal to approximately \$0.2 million divided by the applicable warrant price. The Preferred Warrant also provides for the grant of additional shares upon the disbursement of an advance under the 2021 Loan Agreement. Such additional shares would be equal to 1.5% of the principal amount of the advance divided by the warrant price. The Preferred Warrant was exercisable at the original purchase price of

the Series A-1 convertible preferred stock. When the Series A-1 convertible preferred stock, in which the warrant would have been exercisable into, was converted into common stock, the warrant holder gained the right to exercise the warrant for such number of shares of common stock into which the preferred shares would have converted into had they been exercised prior to the conversion. The Preferred Warrant was exercised in June 2021 in exchange for 51,409 shares of common stock.

The term loan bore interest at a per annum rate equal to the greater of (a) 4.0% above the prime rate and (b) 7.25%. The loan was secured by substantially all of the Company's assets, other than intellectual property. The Company agreed not to encumber its intellectual property assets, except as permitted by the 2021 Loan Agreement.

A final payment (the Final Payment) equal to \$0.4 million was due at the earlier of the maturity date, acceleration of the loans, or a voluntary or mandatory prepayment of the loan. The Final Payment was accrued through interest expense using the effective interest method.

The Company bifurcated a compound derivative liability related to the contingent interest feature and acceleration clause (contingent put option) under the 2021 Loan Agreement. The contingent put option liability was valued and separately accounted for in the Company's consolidated financial statements. The contingent put option liability was extinguished when the 2021 Loan Agreement was terminated in August 2022 and the loan fully repaid (Note 3) in connection with the Company entering into the 2022 Term Loan Agreement discussed below.

The Company recorded a \$0.7 million loss on debt extinguishment in connection with the termination of the 2021 Loan Agreement in August 2022.

#### 2022 Loan Agreements

On August 9, 2022, the Company entered into (i) a Credit, Security and Guaranty Agreement (the 2022 Term Loan Agreement), with Company and MidCap Financial Trust, and (ii) a Credit, Security and Guaranty Agreement (Revolving Loan) (the 2022 Revolving Loan Agreement, and together with the 2022 Term Loan Agreement, the 2022 Loan Agreements), with MidCap Funding IV Trust.

The 2022 Term Loan Agreement provides for a secured term loan facility in an aggregate principal amount of up to \$30.0 million, comprised of (i) a tranche one term loan of up to \$20.0 million (Tranche One), (ii) a tranche two term loan of up to \$5.0 million (Tranche Two), and (iii) a tranche three term loan of up to \$5.0 million (Tranche Three). The 2022 Revolving Loan Agreement provides for a secured revolving loan facility in an aggregate principal amount of up to \$10.0 million the (Revolving Loan), subject to a borrowing base equal to percentages of eligible accounts receivable and inventory as determined in accordance with the 2022 Revolving Credit Agreement. The Term Loans and Revolving Loans mature on August 1, 2027.

Tranche One was fully funded on August 9, 2022 to pay transaction fees incurred in connection with the 2022 Loan Agreements and to repay in full the Company's borrowings under its existing loan facility under the 2021 Loan Agreement with Silicon Valley Bank, with the remaining amount to be used be for general corporate purposes. Subject to certain terms and conditions of the 2022 Term Loan Agreement, Tranche Two is available between January 1, 2023, and September 30, 2023, following the Company's achievement of specified milestones relating to minimum net revenues and minimum net cash proceeds from equity financing. Subject to certain terms and conditions of the 2022 Term Loan Agreement, Tranche Three is available between September 30, 2024, and March 31, 2025. The proceeds of Tranche Two and Tranche Three may be used for working capital and general corporate purposes.

The Term Loan bears interest at a floating rate based on an adjusted term secured overnight financing rate (SOFR) plus 0.1% (subject to a floor of 1.50%) for a one-month interest period, plus a margin of 5.75%. Interest on the Term Loans is payable monthly in arrears on the first day of each month and at maturity. For the year ended December 31, 2022, the effective interest rate on outstanding borrowings was approximately 12.16%.

Following an initial interest-only period, beginning on August 1, 2025, the outstanding principal amount of the term loans is repayable in twenty-four equal monthly principal payments, with all remaining outstanding principal, together with all accrued and unpaid interest, due at maturity. The Term Loans may be voluntarily prepaid in full, but not in part, at any time and are also subject to mandatory prepayments with the net proceeds of certain dispositions and casualty events, subject to specified thresholds and reinvestment rights. Prepayments are subject to prepayment premiums of 3.00%, 2.00%, and 1.00% of the amount prepaid for prepayments made during years one, two, and three of the term, respectively. Once repaid, the term loans may not be reborrowed. The Company is also obligated to pay an exit fee equal to 4.5% of the outstanding principal amount of the term loans borrowed and other customary fees for a credit facility of this size and type. The exit fee is being accrued through interest expense using the effective interest method.

The Company may borrow, repay and reborrow the Revolving Loans until August 1, 2027, at which time the revolving commitments will terminate and all outstanding revolving loans, together with all accrued and unpaid interest, must be repaid. The proceeds of the Revolving Loans may be used for working capital needs and general corporate purposes. As of December 31, 2022, no amount of Revolving Loans was outstanding under the 2022 Revolving Loan Agreement.

The revolving loans bear interest at a floating rated based on an adjusted term SOFR (subject to a floor of 1.50%) for a onemonth interest period, plus a margin of 3.00%. Interest on the Revolving Loans is payable monthly in arrears on the first day of each month and at maturity. The Company is obligated to pay an unused line fee equal to 0.50% per annum on the unused portion of the available revolving commitments, a fee for failure to maintain a minimum balance under the 2022 Revolving Loan Agreement, and other customary fees for a credit facility of this size and type.

The obligations of the Company and any future guarantors under the 2022 Loan Agreements are secured by liens on substantially all of the Company's assets.

The 2022 Loan Agreements require the Borrowers to comply with (i) a minimum net revenue covenant and (ii) a minimum cash covenant, which requires certain unrestricted cash to be greater than or equal to \$7.0 million at all times.

The 2022 Loan Agreements contain customary affirmative and negative covenants, including covenants limiting the ability of the Company and its subsidiaries, among other things, to incur debt, grant liens, make distributions, enter certain restrictive agreements, pay or modify subordinated debt, dispose of assets, make investments and acquisitions, enter into certain transactions

with affiliates, and undergo certain fundamental changes, in each case, subject to limitations and exceptions set forth in the 2022 Loan Agreements.

The 2022 Loan Agreements contain customary events of default that include, among other things, certain payment defaults, cross defaults to certain other contracts and indebtedness, covenant defaults, inaccuracy of representations and warranties, bankruptcy and insolvency defaults, judgment defaults, change of control defaults, defaults related to the failure to remain registered with the Securities and Exchange Commission and listed for trading on the Nasdaq Stock Market, and a material adverse change default.

Upon the occurrence and during the continuance of an event of default under the 2022 Loan Agreements, the respective administrative agent, if requested by the respective lenders, may, among other things, (i) suspend or terminate commitments, as well as obligations of the relevant administrative agent and lenders, (ii) declare all outstanding obligations under the applicable agreement (including principal and accrued and unpaid interest) immediately due and payable, and (iii) exercise the other rights and remedies provided for under the applicable agreement. The 2022 Loan Agreements provide that, under certain circumstances, a default interest rate will apply on all obligations under such agreement during the existence of an event of default, at a per annum rate equal to 2.0% above the applicable interest rate.

The Company bifurcated a derivative liability related to the acceleration clause triggered upon an event of default (contingent put option) under the 2022 Term Loan Agreement. The contingent put option liability is classified as a component of derivative liabilities on the consolidated balance sheet. As of December 31, 2022, the estimated fair value of the contingent put option liability was \$0.4 million, which was determined by using a risk-neutral valuation model wherein the fair value of the underlying debt facility is estimated, both with and without the presence of the default provisions, holding all other assumptions constant (Note 3).

As of December 31, 2022, the estimated future principal payments due were as follows:

	December 31,	2022
Estimated future principal payments due		
2023	\$	
2024		
2025		4,167
2026		10,000
2027		5,833
Total	\$	20,000

## 9. STOCKHOLDERS' EQUITY

On June 18, 2021, the Company completed its IPO of 7,666,664 shares of its common stock, including the exercise in full by the underwriters of their option to purchase up to 999,999 additional shares of common stock, for aggregate gross proceeds of \$122.7 million. The Company's common stock began trading on the Nasdaq Global Select Market under the ticker symbol "DNAY" on June 18, 2021. The Company has since changed its ticker symbol to "TBIO" in connection with its name change to Telesis Bio Inc. The Company received \$112.5 million in net proceeds after deducting underwriting discounts and commissions and other offering expenses payable by the Company. Upon closing of the IPO, all outstanding convertible preferred stock converted into 15,079,329 shares of common stock and SGI's outstanding warrants were automatically exercised into 1,201,059 shares of common stock. Subsequent to the closing of the IPO, all outstanding warrants issued pursuant to the 2021 Loan Agreement were exercised into 51,409 shares of common stock.

## **10. STOCK-BASED COMPENSATION**

For the years ended December 31, 2022 and 2021, the Company recorded stock-based compensation expense of approximately \$3.7 million and \$1.1 million, respectively. No income tax benefit was recognized in the accompanying consolidated statements of operations and comprehensive loss for the Company's equity incentive plan.

The Company's Board of Directors approved the adoption of the SGI-DNA, Inc. 2019 Stock Plan (the 2019 Plan) in March 2019. The 2019 Plan permitted the Company to grant up to 5,544,187 shares for options and restricted stock units of the Company's common stock. On March 3, 2021, the Company's Board of Directors and stockholders approved the termination of the 2019 Plan and the adoption of the 2021 Equity Incentive Plan (the 2021 Plan). 6,000,000 shares of common stock were reserved for issuance under the 2021 Plan.

In June 2021, the Company established the 2021 Stock Incentive Plan (the 2021 SIP). The 2021 SIP became effective on the effective date of the IPO, at which time the Company ceased granting awards under the 2021 Plan. The 2021 SIP allows the Company's compensation committee to grant equity-based awards to the Company's employees, directors and consultants. A total of 3,500,000 shares of common stock were initially reserved for issuance under the 2021 SIP, plus the number of shares (not to exceed 2,459,970 shares) consisting of (i) the shares of common stock that were available for the issuance of awards under the 2021 Plan at the time the 2021 SIP became effective, which ceased to be available for future issuance under the 2021 Plan at such time and (ii) any shares subject to outstanding options or other share awards that were granted under the 2019 Plan and the 2021 Plan that terminate or expire prior to exercise or settlement; are forfeited because of the failure to vest; or are reacquired or withheld (or not issued) to satisfy a tax withholding obligation or the purchase or exercise price. In addition, the number of shares reserved and available for issuance under the 2021 SIP automatically increases each January 1, beginning on January 1, 2022 and each January 1 thereafter by the lesser of 5,250,000 shares or 5% of the outstanding number of shares of common stock on the immediately preceding December 31, or such lesser number of shares as determined by the Company's Board of Directors. As of December 31, 2022, the number of shares of common stock reserved for issuance under the 2021 SIP was 2,517,179.

Stock option activity under the 2019 Plan, the 2021 Plan and the 2021 SIP for the year ended December 31, 2022 is as follows:

	Number of options	Weighted average exercise price	Weighted average remaining contractual term (in years)	ir va	gregate trinsic alue (in busands)
Balances at December 31, 2021	2,550,984	\$ 6.09	9.1	\$	12,417
Options granted	2,749,952	5.73			
Options exercised	(90,678)	1.08			
Options cancelled	(721,703)	6.99			
Balances at December 31, 2022	4,488,555	\$ 2.11	8.9	\$	252
Vested and expected to vest at December 31, 2022	3,747,773	\$ 2.09	8.8	\$	232
Exercisable at December 31, 2022	895,270	\$ 2.64	8.0	\$	139

There were 2,749,952 options granted during the year ended December 31, 2022. The weighted average grant date calculated fair value of options granted during the year ended December 31, 2022 was \$3.28 per share.

The calculated value of option grants during the years ended on December 31, 2022 and 2021 were estimated using the Black-Scholes option pricing model with the following weighted average assumptions:

	For the Years Ended	December 31,
	2022	2021
Risk free interest rate	2.4%	1.2%
Expected dividend yield	<u> </u>	%
Expected term (in years)	5.1 years	6.4 years
Forfeiture rate	20.0%	29.2%
Expected volatility	54.5%	39.9%

In December 2022, the Company's Board of Directors approved a one-time repricing of stock option awards that had been granted to date under the 2021 Plan and the 2021 SIP. The repricing modification took effect on December 13, 2022, while awards held by certain executives were modified on December 19, 2022. The repricing impacted all stock option holders with outstanding shares on the respective repricing dates. The original exercise prices of the repriced stock options ranged from \$1.59 to \$11.75 per share for 4,261,402 options originally granted from March 2021 through November 2022. The option exercise price was reduced to between \$1.15 and \$1.26 per share. In addition to the repricing, the vesting of all unvested awards held by certain executives will be suspended for three months following the December 19, 2022 date of modification, and will restart pursuant to the original applicable vesting schedule on March 19, 2023. There were no changes to the number of shares or the expiration date of the repriced stock options. Incremental stock-based compensation expense resulting from the repricing was \$0.8 million, of which \$0.3 million was recognized on the date of modification and \$0.5 million will be recognized prospectively over the remaining term of the stock option awards.

The Company has granted restricted stock units with vesting based conditions. Unvested shares of restricted common stock may not be sold or transferred by the holder. They are legally issued and outstanding. These restrictions lapse accordingly to the time-based vesting of each award.

A summary of the restricted stock unit activity during the year ended December 31, 2022 is as follows:

	Restricted Stock Units	Weighted- Average Grant Date Fair Value
Unvested at December 31, 2021	_	\$ _
Granted	310,901	6.88
Cancelled	(38,300)	10.20
Unvested at December 31, 2022	272,601	\$ 6.41

No restricted stock units vested during the year ended December 31, 2022.

Effective in connection with the IPO, the Company established the 2021 Employee Stock Purchase Plan (the ESPP). The maximum number of shares of common stock that may be issued under the ESPP was initially 350,000. Additionally, the number of shares reserved and available for issuance under the ESPP automatically increases each January 1, beginning on January 1, 2022 and each January 1 thereafter, by the lesser of (i) 1,050,000 shares of common stock, (ii) 1.0% of the total number of shares of common stock outstanding on December 31 of the preceding calendar year, or (iii) such smaller number of shares of common stock as the Company's Board of Directors may designate. As of December 31, 2022, the number of shares of common stock that may be issued under the ESPP is 405,350.

As of December 31, 2022, 237,835 shares of common stock have been issued under the ESPP.

The Company recorded stock-based compensation expense in the following award type categories included within the consolidated statements of operations and comprehensive loss as follows (in thousands):

	For t	For the Years Ended December 31,			
	20	22		2021	
Stock options	\$	2,954	\$	1,047	
Restricted stock units		349			
Employee stock purchase plan		424		39	
Total	\$	3,727	\$	1,086	

The Company recorded stock-based compensation expense in the following expense categories of its consolidated statements of operations and comprehensive loss as follows (in thousands):

	For	For the Years Ended December 31,			
		2022		2021	
Research and development	\$	582	\$	29	
Sales and marketing		425		100	
General and administrative		2,720		957	
Total	\$	3,727	\$	1,086	

As of December 31, 2022, total unrecognized stock-based compensation expense related to unvested stock-based awards was \$7.8 million, which is expected to be recognized over a weighted average period of 4.9 years.

## **11. INCOME TAXES**

The domestic and foreign components of pre-tax loss for the years ended December 31, 2022 and 2021, were as follows (in thousands):

	For the Years End	ed December 31,
	2022	2021
Domestic	\$ (48,556)	\$ (39,026)
Foreign	109	81
Total	<u>\$ (48,447</u> )	\$ (38,945)

The Company had no current or deferred federal and state income tax expense or benefit for the years ended December 31, 2022 and 2021, because the Company generated net operating losses, and currently management does not believe it is more likely than not that the net operating losses will be realized. The Company's non-U.S. tax obligation is primarily for business activities conducted through the United Kingdom subsidiary for which taxes were determined to be immaterial and accordingly, such amounts were excluded from the following tables.

A reconciliation of the U.S. federal statutory income tax rate to the Company's effective income tax rate is as follows:

	For the Years Ended	For the Years Ended December 31,		
	2022	2021		
Federal statutory income (benefit) tax rate	(21.0)%	(21.0)%		
State income taxes, net of federal benefit		(3.7)		
Change in valuation allowance	20.6	23.7		
Permanent items	0.8	1.2		
Tax credits	(0.4)	(0.2)		
Effective income tax rate	%	%		

The components of our deferred tax assets and liabilities on December 31, 2022 and 2021, consisted of (in thousands):

	For	For the Years Ended December 31,		
		2022 202		2021
Deferred tax assets:				
Net operating loss carryforwards	\$	24,847	\$	15,555
Research and development tax credit carryforwards		1,202		915
Stock based compensation		669		168
Capitalized research and development costs		981		
Accruals and other		2,420		666
		30,119		17,304
Valuation Allowance		(29,447)		(16,749)
Total deferred tax assets		672		555
Deferred tax liabilities:				
Fixed assets		(93)		(62)
Intangibles		(579)		(493)
Total deferred tax liabilities		(672)		(555)
Net deferred tax assets	\$		\$	

The Company has evaluated the positive and negative evidence bearing upon its ability to realize its deferred tax assets, which are composed principally of net operating loss carryforwards. Management has considered the Company's history of cumulative net losses incurred since inception and has concluded that it is more likely than not that the Company will not realize the benefits of its federal and state net deferred tax assets. Accordingly, a full valuation allowance has been established against the net deferred tax assets as of December 31, 2022 and 2021. The Company reevaluates the positive and negative evidence at each reporting period.

The changes in the valuation allowance for deferred tax assets during the years ended December 31, 2022 and 2021, related primarily to the increases in net operating loss carryforwards, research and development tax credits generated and accruals.

The valuation allowance increased by \$12.7 million and \$9.2 million during the years ended December 31, 2022 and 2021, respectively.

On March 27, 2020, the U.S. enacted the Coronavirus Aid, Relief, and Economic Security Act (the CARES Act). On December 21, 2020, the U.S. Congress passed the Consolidation Appropriations Act, 2021 (the CAA Act). The tax provisions under the CARES Act and CAA Act, do not have a material impact on the financial statements for the years ended December 31, 2022 and 2021 given the existence of the full valuation allowance.

For the tax years beginning on or after January 1, 2022, the Tax Cuts and Jobs Act of 2017 ("TCJA") eliminates the option to currently deduct research and development expenses and requires taxpayers to capitalize and amortize them over five years for research activities performed in the United States and 15 years for research activities performed outside the United States pursuant to IRC Section 174. Although Congress is considering legislation that would repeal or defer this capitalization and amortization requirement, it is not certain that this provision will be repealed or otherwise modified. If the requirement is not repealed or replaced, it will decrease our tax deduction for research and development expense in future years.

On June 29, 2020 California Assembly Bill 85 (AB 85) was signed into law, which suspends the use of California net operating losses and limits the use of California research tax credits for tax years beginning in 2020 and before 2023. The Company does not expect the suspension of net operating losses and the restriction of research tax credits to have a significant impact on the financial statements.

As of December 31, 2022 and 2021, the Company had U.S. federal net operating loss carryforwards of \$95.9 million and \$62.1 million, respectively. The federal net operating loss carryforwards of \$1.3 million, generated before January 1, 2018, will begin to expire in 2034 and the other \$94.6 million will carryforward indefinitely but are subject to an 80% taxable income limitation. The Company also had federal research and development tax credit carryforwards of approximately \$1.0 million which will begin to expire in 2039, if not utilized.

As of December 31, 2022 and 2021, the Company had state net operating loss carryforwards of \$70.1 million and \$38.5 million, respectively. The state net operating loss carryforwards of \$70.1 million will begin to expire in 2029.

The Company also had California research and development tax credit carryforwards of approximately \$0.6 million which do not expire.

The utilization of net operating losses and tax credit carryforwards may be subject to an annual limitation as a result of ownership changes that have occurred previously or may occur in the future. Under Sections 382 and 383 of the Internal Revenue Code (the Code), a corporation that undergoes an ownership change may be subject to limitations on its ability to utilize its pre-change net operating losses and other tax attributes otherwise available to offset future taxable income or tax liability. An ownership change is defined as a cumulative change of 50% or more in the ownership positions of certain stockholders during a rolling 3-year period. The Company has not completed a formal study to determine if any ownership changes within the meaning of Code Section 382 and 383 have occurred. If such ownership change has occurred, the Company's ability to use its net operating losses or tax credit carryforwards may be restricted, which could require the Company to pay federal or state income taxes earlier than would be required if such limitations were not in effect.

The Company recognizes the financial statements benefit of a tax position only after determining that the relevant tax authority would more likely than not sustain the position following an audit. For tax positions meeting the more likely than not threshold, the amount recognized in the financial statements is the largest benefit that has a greater than 50% likelihood of being realized upon ultimate settlement with the relevant tax authority. The Company's policy is to record interest associated with uncertain tax positions as interest expense and related penalties in general and administrative expenses.

The following table shows the changes in the gross amount of unrecognized tax benefits as of December 31, 2022 and 2021, (in thousands):

Balance as of December 31, 2020	\$ 316
Increase of unrecognized tax benefits taken in prior years	(36)
Increase of unrecognized tax benefits taken in current year	58
Balance as of December 31, 2021	338
Increase of unrecognized tax benefits taken in current year	105
Balance as of December 31, 2022	\$ 443

If the Company is able to recognize these uncertain tax positions, the unrecognized tax benefits would not impact the effective tax rate if the Company applies a full valuation allowance against the deferred tax assets, as provided in the Company's current policy.

The Company had not incurred any material tax interest or penalties as of December 31, 2022. The Company does not anticipate any significant change within 12 months of this reporting date of its uncertain tax positions. The Company is subject to taxation in the United States and various state jurisdictions, and the United Kingdom. There are no ongoing examinations by taxing authorities at this time. The Company's tax years 2014 through 2022 will remain open for examination by the federal and state authorities for three and four years, respectively, from the date of utilization of any net operating loss credits. The Company's 2021 and 2022 tax years will remain open for examination by the United Kingdom tax authority for one year from the filing deadline.

## **12. COMMITMENTS AND CONTINGENCIES**

#### Litigation

The Company may become involved in various claims, suits, and legal proceedings from time to time in the ordinary course of its business. The Company accrues a liability when it believes that it is both probable and the amount of loss can be reasonably estimated. While the outcome of such claims, lawsuits or other proceedings cannot be predicted with certainty, management expects that any liability, to the extent not provided for by insurance or otherwise, will not have a material adverse effect on the Company's consolidated financial position or results of operations.

#### **Codexis Trademark Litigation**

In May 2020 Codexis, Inc. (Codexis) filed a complaint against the Company relating to its CODEX DNA name based on Codexis' rights in the CODEX and CODEXIS mark in the U.S. District Court, Northern District of California for federal and common law trademark infringement and unfair competition/false designation (the Complaint). Codexis seeks injunctive relief, including that the Company cease all use of the term CODEX and any other trademark confusingly similar to the marks CODEX and CODEXIS and not apply for registration of or register the CODEX mark or any other mark confusingly similar to the CODEX or CODEXIS marks, transfer to Codexis all domain names and social media accounts/user names that include the term "codex" and pay damages (consisting of Codexis' actual damages, a disgorgement of the Company's profits and punitive damages as permitted by California common law) as well as attorneys' fees and costs. In April 2022, Codexis and the Company reached a mutually agreeable resolution to the Codexis trademark litigation.

#### Eurofins Pharma Non-Competition/Non-Solicitation Litigation

In October 2018, Eurofins Pharma US Holdings II, Inc. (EPUSH II) and Eurofins DiscoverX Corporation (Eurofins DiscoverX) (collectively, Plaintiffs) filed a complaint against Todd R. Nelson, the Company and Synthetic Genomics, Inc. (the Company's former parent company, and together with Dr. Nelson and SGI-DNA, the Defendants) to enforce non-competition and non-solicitation provisions of an agreement.

The complaint, filed in the Superior Court of California, County of San Diego, charged Dr. Nelson with breach of contract, the Company with tortious interference, and both with unfair competition. The complaint sought permanent injunctive relief, monetary damages and other equitable relief (including restitution) against the Defendants. On April 9, 2021, the Defendants filed a motion for summary judgment, or in the alternative, summary adjudication, with regard to all causes of action. A hearing on this motion was held on June 25, 2021, at which time the court granted the motion in summary judgment on behalf of SGI-DNA and Dr. Nelson on three of the four claims. The court directed the parties back to mediation on the remaining claim but there was no resolution. On June 22, 2022, at the conclusion of a bench trial, the court ruled in favor of the Company and Dr. Nelson on the remaining claim.

#### Leases

The Company's non-cancelable lease commitments are described in Note 7.

## **13. NET LOSS PER SHARE**

## Net loss per share

Basic and diluted net loss per share attributable to common stockholders was calculated as follows (in thousands, except share and per share amounts:):

	For the Years Ended December 31,	
	2022	2021
Numerator:		
Net loss	\$ (48,471)	\$ (38,958)
Net loss attributable to common stockholders	\$ (48,471)	\$ (38,958)
Denominator:		
Weighted average common stock outstanding - basic and diluted	29,463,361	18,222,495
Net loss per share attributable to common stockholders - basic and diluted	\$ (1.65)	\$ (2.14)

The Company's potential dilutive securities have been excluded from the computation of diluted net loss per share as the effect would be to reduce the net loss per share. Therefore, the weighted-average number of shares of common stock outstanding used to calculate both basic and diluted net loss per share attributable to common stockholders is the same. The Company excluded the following potential shares of common stock from the computation of diluted net loss per share attributable to common stockholders for the periods indicated because including them would have had an anti-dilutive effect:

	For the Years End	For the Years Ended December 31,		
	2022	2021		
Stock options to purchase common stock	4,488,555	2,550,984		
Restricted stock units that vest into common stock	272,601	_		
Shares issuable under employee stock purchase plan	118,520			
Total	4,879,676	2,550,984		

## **14. RETIREMENT PLAN**

The Company has a retirement saving plan (the 401(k) Plan) that allows participating employees to defer a portion of their annual compensation on a pretax basis. The Company made no contributions to the 401(k) Plan for the years ended December 31, 2022 and 2021.

#### **15. ACQUISITION**

On November 18, 2021, the Company entered into a Share Purchase Agreement, with the stockholders of EtonBio Inc., a California corporation ("Eton"), pursuant to which, the Company agreed to purchase all of the outstanding shares of capital stock of Eton. The total purchase price was approximately \$14.1 million, of which \$13.6 million was funded with the Company's existing cash on hand on the acquisition date and the remaining \$0.5 million paid in 2022 after a tax election was made. Eton is a San Diego-based biotech company specializing in synthetic biology prollucts and services, including DNA sequencing and oligo synthesis, for the global academic research, pharmaceutical, and biotechnology industries. Eton also markets DNA prep services and products such as antibodies, peptides, and metabolism assay kits. The Eton acquisition has been accounted for as a business combination in accordance with ASC 805.

The assets acquired and liabilities assumed in connection with the Eton acquisition were recorded at their fair values on the date of acquisition as follows (in thousands):

Cash	\$ 393
Accounts receivable	664
Inventory	305
Other current assets	79
Right-of-use assets	1,904
Property and equipment, net	1,388
Other long-term assets	28
Goodwill	11,389
Intangible assets	530
Accounts payable, accrued employee expenses and other accrued liabilities	(389)
Deferred revenue, current portion	(252)
Operating lease liability, current portion	(427)
Operating lease liability, net of current portion	(1,477)
Total purchase consideration	14,135
Less: Acquired cash	 (393)
Purchase of Eton, net of cash acquired	\$ 13,742

The excess of the purchase price over the fair values of the net identifiable tangible and intangible assets acquired has been assigned to goodwill. Goodwill represents the future benefits as a result of the acquisition that will enhance the services available to both new and existing customers and increase the Company's competitive position.

The following table sets forth the amounts allocated to the intangible assets identified and the estimated useful lives of those intangible assets as of the date of acquisition (in thousands):

	 Fair value	Useful life (in years)
Trade name	\$ 80	3
Customer relationships	420	15
Non-competition agreements	30	3
Total intangible assets acquired	\$ 530	

The intangible assets acquired are expected to be amortized over their useful lives on a straight-line basis.

As part of the Eton acquisition, the Company incurred acquisition-related costs of \$0.3 million which were recorded in general and administrative expenses in the consolidated statements of operations and comprehensive loss.

As of the date of the Eton acquisition, the Company's consolidated statements of operations and comprehensive loss includes the results of the acquired Eton business unit. For the year ended December 31, 2021, revenue of \$0.5 million and net loss of \$0.2 million have been included in the Company's consolidated statement of operations and comprehensive loss.

The unaudited supplemental pro forma financial results below for the year ended December 31, 2021, combine the consolidated results of the Company and the Eton business unit, giving effect to the Eton acquisition as if it had been completed on January 1, 2021. This unaudited supplemental pro forma financial information is presented for informational purposes only and is not indicative of future operations or results had the acquisition been completed as of January 1, 2021, or any other date (in thousands).

	 Year Ended December 31,	
Pro forma revenue	\$ <b>2021</b> 17,094	
Pro forma net loss	\$ (38,228)	

The unaudited pro forma financial information in the table above summarizes the combined results of our operations and the Eton business unit, on a pro forma basis, as though we had acquired the Eton business unit on January 1, 2021. The unaudited pro forma financial information for all periods presented also includes the effects of business combination accounting resulting from the acquisition, amortization expense from acquired intangibles assets, and reversal of the acquisition-related expenses in the period incurred and recognition of the acquisition-related expenses in the prior period.

## **16. COLLABORATION**

In December 2021, the Company entered into a Research Collaboration and License Agreement (Pfizer Agreement) with Pfizer Inc. (Pfizer), pursuant to which we agreed to collaborate with Pfizer to further develop our novel enzymatic DNA synthesis technology for Pfizer's use in its research and development of mRNA-based vaccines and biotherapies. The financial terms of the deal include an upfront payment from Pfizer to the Company, along with success-based technical milestone payments that could be earned in the near term. The Company is also eligible to receive additional milestone payments based on the achievement of specified development, regulatory and commercialization goals associated with any products developed from the application of the Company's technology developed and licensed under the agreement.

The Company granted Pfizer a non-exclusive, worldwide license to use the Company's enzymatic DNA synthesis technology for purposes of researching, developing, manufacturing and commercializing pharmaceutical and biopharmaceutical products and a limited-time option to convert such license to exclusive for specific applications. If Pfizer exercises its option for these application(s) within the applicable period, then the license to Pfizer will become exclusive for products for such application(s); provided that Pfizer may later convert the particular application back to non-exclusive.

Under the Pfizer Agreement, Pfizer made an upfront payment to us of \$8.0 million and if the Company meets certain technical milestones, the Company will be eligible to receive an additional \$10.0 million in near-term milestone payments associated with the Research Plan.

In addition to the upfront payment and technical milestone payments, Pfizer has agreed to make milestone payments to the Company upon the products meeting certain clinical milestones, with each product (other than exclusive products) being eligible for milestone payments up to \$20.0 million if it were to meet the applicable clinical milestones and the first exclusive product in each exclusive field being eligible for milestone payments up to \$55.0 million if it were to meet the applicable clinical milestones. Pfizer has also agreed to pay the Company up to \$60.0 million in sales milestones for products (other than exclusive products) if aggregate net sales of such products meet certain thresholds and up to \$180.0 million in sales milestones for exclusive products if aggregate net sales of the exclusive products meet certain thresholds. Provided the Pfizer Agreement remains in place, Pfizer will also pay escalating royalties from a low to mid-fraction of one percent of net sales of all products. Pfizer's obligations to pay royalties with respect to a product within a country will expire after specific criteria including such product no longer being covered by patent rights licensed to Pfizer by the Company in such country. Royalty payments are subject to reduction after the introduction of a biosimilar product in such country by a third party.

The Company assessed the collaboration and license agreement in accordance with ASC 606, Revenue from Contracts with Customers, and concluded that Pfizer is a customer based on the agreement structure. The Company identified a single combined performance obligation under the arrangement for the performance under the research plan, technology transfer between the parties, participation in the Joint Research Committee, research licenses exchanged by the parties and the non-exclusive commercial license. In addition, the Company identified a material right for the option granted to Pfizer to extend the research term by an additional year. The \$8.0 million upfront payment represents the transaction price at inception.

The Company determined that the \$8.0 million upfront payment represents the entirety of the consideration to be included in the transaction price as of the outset of the arrangement. The potential milestone payments that the Company may have been eligible to receive were initially excluded from the transaction price at the outset of the arrangement because (i) all technical and development milestone payments did not meet the criteria for inclusion using the most-likely amount method and (ii) the Company recognizes as revenue sales-based milestones and royalties when the related sales occur. As of December 31, 2022 the Company achieved its first technical milestone associated with the Research Plan and recognized \$2.5 million in revenue associated with the milestone achievement. No other milestones or royalties have been deemed likely to be achieved or have been achieved.

In accordance with ASC 606, the Company allocated the transaction price, comprising the upfront payment of \$8.0 million, based on the standalone selling price of the combined performance obligation and the material right. Based on Management's analysis, the material right was allocated \$0.3 million of the transaction price, while the combined performance obligation was allocated \$7.7 million of the transaction price.

The \$7.7 million of revenue allocated to the combined performance obligation is being recognized using the input method based on time elapsed as compared to the research term of 24 months, and the \$0.3 million of revenue allocated to the material right was to be recognized over the third year of services performed under the research plan in the event the option to extend the research plan is exercised, or when the option expires in the event the option to extend the research plan was not exercised. During 2022, the option expired unexercised, and the \$0.3 million was recognized.

During the year ended December 31, 2022, the Company recognized \$6.6 million of revenue related to the Pfizer Agreement. As of December 31, 2022, aggregate deferred revenue related to the Pfizer Agreement was \$3.7 million, all of which was classified as current.

## **17. RELATED PARTY TRANSACTIONS**

During the years ended December 31, 2022 and 2021, the Company made payments to related parties of approximately \$0.5 million and \$0.3 million, respectively for payments to board members and services relating to intellectual property matters, including patent filings and patent prosecution.

## **18. SUBSEQUENT EVENTS**

The Company has evaluated subsequent events through March 22, 2023, the date these consolidated financial statements were issued.

## Silicon Valley Bank Closure

On March 10, 2023, the Federal Deposit Insurance Corporation (FDIC) announced that it has closed and taken control of Silicon Valley Bank (SVB). On March 13, 2023, pursuant to a joint statement released by the U.S. Department of the Treasury, the U.S. Federal Reserve, and the FDIC, the U.S. government reassured that all depositors will be fully protected. In light of the situation, the Company is in the process of moving all cash and other deposits previously held at SVB to larger financial institutions. The Company does not currently anticipate any disruption to its ongoing operations.

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

None.

## Item 9A. Controls and Procedures.

TBD

## Item 9B. Other Information

None.

## Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections.

None.

#### Part III

#### Item 10. Directors, Executive Officers and Corporate Governance

We have adopted a written code of business conduct and ethics that applies to our directors, officers and employees, including our principal executive officer, principal financial officer, principal accounting officer or controller or, persons performing similar functions. The code of business conduct and ethics is available on our website at http://telesisbio.com. We intend to disclose future amendments to such code, or any waivers of its requirements, applicable to any principal executive officer, principal financial officer, principal accounting officer or controller or persons performing similar functions, or our directors on our website identified above or in a Current Report on Form 8-K. Information contained on the website is not incorporated by reference into this Annual Report.

The remaining information required under this item is incorporated herein by reference to our definitive proxy statement (Proxy Statement) pursuant to Regulation 14A under the Securities Exchange Act of 1934, as amended, which Proxy Statement is expected to be filed with Securities and Exchange Commission not later than 120 days after the close of our fiscal year ended December 31, 2022.

#### Item 11. Executive Compensation

The information required by this item will be set forth in the Proxy Statement and is incorporated herein by reference.

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

The information required by this item will be set forth in the Proxy Statement and is incorporated herein by reference.

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

The information required by this item will be set forth in the Proxy Statement and is incorporated herein by reference.

## Item 14. Principal Accounting Fees and Services

The information required by this item will be set forth in the Proxy Statement and is incorporated herein by reference.

## Part IV

## Item 15. Exhibits, Financial Statement Schedules

The following documents are filed as part of this Annual Report:

- 1. Financial Statements: The financial statements filed as part of this Annual Report are included in Part II, Item 8 of this Annual Report.
- 2. Financial Statement Schedules: Financial statement schedules have been omitted in this Annual Report because they are not applicable, not required under the instructions or the information requested is set forth in the financial statements or related notes thereto.
- 3. Exhibits: The list of exhibits filed with this Annual Report is set forth in the Exhibit Index preceding the signature page and is incorporated herein by reference or filed with this Annual Report, in each case as indicated therein (numbered in accordance with Item 601 of Regulation S-K).

Exhibit Number	Description	Form	File No.	Exhibit	Filing Date
2.1	Share Purchase Agreement among Telesis Bio, Inc. and the stockholders of Eton Bioscience Inc. dated November 9, 2021	8-K	001-40497	2.1	11/9/21
3.1	Amended and Restated Certificate of Incorporation of the Registrant.	S-1	333-256644	3.2	5/28/21
3.2	Amended and Restated Bylaws of the Registrant.	S-1	333-256644	3.4	5/28/21
4.1	Amended and Restated Investors' Rights Agreement by and among the Registrant and certain of its stockholders, dated December 19, 2019.	S-1	333-256644	4.1	5/28/21
4.2	Specimen common stock certificate of the Registrant.	S-1/A	333-256644	4.2	6/14/21
4.3	Warrant to Purchase Stock issued to Silicon Valley Bank, dated as of March 4, 2021.	S-1	333-256644	4.3	5/28/21
4.4	Description of the Registrant's securities registered pursuant to section 12 of the securities exchange act of 1934.	10-K	001-40497	4.4	3/23/22
10.1+	Form of Indemnification Agreement between the Registrant and each of its directors and executive officers.	S-1	333-256644	10.1	5/28/21
10.2+	2019 Stock Plan, as amended, and forms of agreement thereunder.	S-1	333-256644	10.2	5/28/21
10.3+	2021 Equity Incentive Plan, as amended, and forms of agreement thereunder.	S-1	333-256644	10.3+	5/28/21
10.4+	2021 Stock Incentive Plan and forms of agreements thereunder.	S-1/A	333-256644	10.4+	6/14/21
10.5+	2021 Employee Stock Purchase Plan and forms of agreements thereunder.	S-1	333-256644	10.5+	5/28/21
10.6+	Confirmatory Employment Letter between the Registrant and Todd Nelson dated May 19, 2021.	S-1	333-256644	10.6+	5/28/21
10.7+	Confirmatory Employment Letter between the Registrant and Jennifer McNealey dated May 19, 2021.	S-1	333-256644	10.7+	5/28/21
10.8+	Confirmatory Employment Letter between the Registrant and Daniel Gibson dated May 19, 2021.	S-1	333-256644	10.8+	5/28/21
10.9+	Confirmatory Employment Letter between the Registrant and Timothy Cloutier dated May 19, 2021.	S-1	333-256644	10.9+	5/28/21
10.10+	Confirmatory Employment Letter between the Registrant and Brent Hunter dated May 19, 2021.	S-1	333-256644	10.10+	5/28/21

10.11+	Executive Incentive Compensation Plan.	S-1	333-256644	10.11+	5/28/21
10.12+	Form of Change in Control Severance Agreement.	S-1	333-256644	10.12+	5/28/21
10.13+	Outside Director Compensation Policy.	S-1	333-256644	10.13+	5/28/21
10.14	Office Lease, dated April 4, 2019, between the Registrant and BMR-Waples LP, as amended.	S-1	333-256644	10.14+	5/28/21
10.15#	Supply Agreement, dated October 26, 2015, between the Registrant and Integrated DNA Technologies, Inc., as amended.	S-1	333-256644	10.15+	5/28/21
10.16#	Loan and Security Agreement, dated March 4, 2021, between the Registrant and Silicon Valley Bank.	S-1	333-256644	10.16+	5/28/21
10.17#	Confidential Settlement Agreement between the Registrant and New England Biolabs, Inc. dated September 20, 2017.	S-1/A	333-256644	10.17#	6/14/21
10.18	Separation and General Release Agreement	10 <b>-</b> Q	001-40497	10.2	11/10/21
10.19	Second Amendment to Loan and Security Agreement by and between Registrant and Silicon Valley Bank, dated November 8, 2021	8-K	001-40497	10.1#	11/08/21
10.20#	Research Collaboration and License Agreement by and between Registrant and Pfizer Inc. dated December 20, 2021	10-K	001-40497	10.21#	3/23/22
21.1	Subsidiaries of the Registrant	S-1	333-256644	21.1	5/28/21
23.1	Consents of Independent Registered Public Accounting Firms.				
31.1†	Certification of Principal Executive Officer and Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				
32.1†	Certification of Principal Executive Officer and Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.				
101.INS	Inline XBRL Instance Document				
101.SCH	Inline XBRL Taxonomy Extension Schema Document				
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document				
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document				
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document				
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document				
104	Cover Page Interactive Data File (formatted as Inline XBRL and				

contained in Exhibit 101)

+ Indicates management contract or compensatory plan.

<sup>#</sup> Portions of the exhibit have been omitted as the Registrant has determined that (i) the omitted information is not material; and (ii) the Registrant customarily and actually treats the omitted information as private or confidential.

<sup>&</sup>lt;sup>†</sup> The certifications attached as Exhibit 31.1, 31.2 and 32.1 that accompany this Annual Report, are deemed furnished and not filed with the Securities and Exchange Commission and are not to be incorporated by reference into any filing of the Registrant under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, whether made before or after the date of this Annual Report, irrespective of any general incorporation language contained in such filing.

## Item 16. Form 10-K Summary

None.

## SIGNATURES

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

Date: March 22, 2023

## **TELESIS BIO, INC.**

By: /s/ Todd R. Nelson

Todd R. Nelson 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 in the capacities and on the dates indicated.

Signature	Title	Date
/s/ Todd R. Nelson Todd R. Nelson	President, Chief Executive Officer and Director (Principal Executive Officer and Principal Accounting Officer)	March 22, 2023
/s/ Andrea L. Jackson Andrea L. Jackson	- Director	March 22, 2023
/s/ Jami D. Nachtsheim Jami D. Nachtsheim	- Director	March 22, 2023
/s/ Annette Tumolo Annette Tumolo	- Director	March 22, 2023
/s/ William F. Snider William F. Snider	- Director	March 22, 2023
/s/ Christine A. Tsingos Christine A. Tsingos	- Director	March 22, 2023
/s/ Frank R. Witney Frank R. Witney	- Chair of the Board of Directors	March 22, 2023

# UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington D.C. 20549

# **FORM 10-K/A**

#### Amendment No. 2

ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITY EXCHANGE ACT OF 1934 For the fiscal year ended December 31, 2022 Commission File Number 001-40497

### **TELESIS BIO INC.**

(Exact name of registrant as specified in its charter)

Delaware (State or other jurisdiction of incorporation or organization)

> 10431 Wateridge Circle, Suite 150, San Diego, CA 92121 (Address of principal executive offices) (858) 228-4115 (Registrant's telephone number, including area code)

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock (\$0.001 par value)	TBIO	Nasdaq Global Select Market
Secur	ities registered pursuant to Section 12(g) of the Act: N	one

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 Section 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  $\boxtimes$  No  $\square$ 

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  $\boxtimes$  No  $\square$ Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	Accelerated filer	
Non-accelerated filer	Smaller reporting company	$\mathbf{X}$
	Emerging growth company	$\boxtimes$

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. Yes  $\boxtimes$  No  $\square$ 

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

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

Indicate by check mark whether registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes 🗆 No 🗵

Auditor Firm:	Auditor Firm ID:	Auditor Firm Location:		
WithumSmith+Brown, PC	100	San Francisco, CA		
The aggregate market value of voting stock held by non-affiliates of the Registrant on June 30, 2022, based on the closing price of \$1.80 for shares of the Registrant's				
common stock as reported by the Nasdag Global Select Market, was approximately \$16.8 million. In determining the market value of non-affiliate common stock				

common stock as reported by the Nasdaq Global Select Market, was approximately \$16.8 million. In determining the market value of non-affiliate common stock The number of shares of Registrant's common stock issued and outstanding as of April 24, 2023 was 29,698,496.

45-1216839 (I.R.S. Employer Identification No.)

## EXPLANATORY NOTE

This Amendment No. 2 (this "Amendment") on Form 10-K/A amends Telesis Bio Inc.'s (the "Company," "Telesis," "we," "us" or "our") Annual Report on Form 10-K for the year ended December 31, 2022 filed with the Securities and Exchange Commission (the "SEC") on March 22, 2023 (the "Original 10-K"). We are filing this Amendment to amend and restate in its entirety Part II, Item 9A of the Original 10-K to provide our management's report on the Company's internal control over financial reporting and correct other inadvertent omissions required to be included pursuant to Items 307 and 308 of Regulation S-K.

Pursuant to the SEC rules, Part IV, Item 15 has also been amended to contain the currently dated certificates from the Company's principal executive officer and principal financial officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002. The certificates of the Company's principal executive office and principal financial officer are attached to this Amendment as Exhibit 31.3.

Except for the changes to Part II, Item 9A and the filing of related certifications added to the list of Exhibits in Part IV, this Amendment makes no changes to the Original 10-K. Unless otherwise stated, this Amendment does not reflect events occurring after the filing of the Original 10-K or modify disclosures affected by subsequent events. Terms used but not otherwise defined in the Amendment have such meaning as ascribed to them in the Original 10-K.

## Item 9A. Controls and Procedures

## **Evaluation of Disclosure Controls and Procedures**

Under the supervision and with the participation of our management, including our Principal Executive Officer (PEO), and Principal Financial Officer (PFO), we evaluated the effectiveness of the design and operation of our disclosure controls and procedures pursuant to Rule 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the Exchange Act) as of the end of the period covered by this report. Our disclosure controls and procedures are designed to ensure that information required to be disclosed in the reports we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to our management, including the PEO and PFO, to allow timely decisions regarding required disclosures. Any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objective and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on that evaluation, our PEO and PFO have concluded, as of December 31, 2022, our disclosure controls and procedures were effective to provide reasonable assurance 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 SEC's rules and forms, and that such information is accumulated and communicated to our management, including our PEO and PFO, have concluded 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 SEC's rules and forms, and that such information is accumulated and communicated to our management, including our PEO and PFO, as appropriate, to allow timely decisions regarding required disclosures.

## Management's Annual Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act). Our internal control system is designed to provide reasonable assurance regarding the preparation and fair presentation of externally-reported consolidated financial statements in accordance with generally accepted accounting principles in the United States (U.S. GAAP). As discussed above, internal control systems, no matter how well designed, have inherent limitations and can provide only reasonable assurance that their objectives have been met.

As of December 31, 2022, our management conducted an evaluation, under the supervision and with the participation of our PEO and PFO, of the effectiveness of our internal control over financial reporting based upon the framework in the *Internal Control -Integrated Framework* (2013), issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based upon that evaluation, our PEO and PFO concluded that our internal control over financial reporting was effective as of December 31, 2022.

We are a smaller reporting company, and therefore our independent registered public accounting firm has not issued a report on the effectiveness of internal control over financial reporting.

## **Inherent Limitations on Effectiveness of Controls**

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

## **Changes in Internal Control over Financial Reporting**

There have been no changes in our internal control over financial reporting that occurred during the year ended December 31, 2022 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

# PART IV

# Item 15. Exhibits and Financial Statement Schedules

(a)(3) Exhibits.

The following is a list of exhibits filed as part of this Amendment.

Exhibit Number	Description	Form	File No.	Exhibit	Filing Date
31.3*	Certification of Principal Executive Officer, Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101)				
* Filed herewith.					

## 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.

Date: May 17, 2023

## **TELESIS BIO, INC.**

By: /s/ Todd R. Nelson

Todd R. Nelson 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 in the capacities and on the dates indicated.

Signature	Title	Date	
/s/ Todd R. Nelson Todd R. Nelson	Chief Executive Officer and Director (Principal Executive Officer, Principal Financial Officer and Principal Accounting Officer)	May 17, 2023	
/s/ Andrea L. Jackson	Director	May 17, 2023	
Andrea L. Jackson			
/s/ Jami D. Nachtsheim	Director	May 17, 2023	
Jami D. Nachtsheim			
/s/ Annette Tumolo	Director	May 17, 2023	
Annette Tumolo			
/s/ William F. Snider	Director	May 17, 2023	
William F. Snider			
/s/ Christine A. Tsingos	Director	May 17, 2023	
Christine A. Tsingos			
/s/ Frank R. Witney	Chair of the Board of Directors	May 17, 2023	
Frank R. Witney			

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