

## MaxCyte, Inc. 2023 Annual Report

#### **MAXCYTE 2023 ANNUAL REPORT**

#### Dear Stockholders,

This is the third annual report of MaxCyte following the listing of our common stock on the Nasdaq Global Select Market in July 2021.

This year marks our 25<sup>th</sup> year anniversary. We can proudly say we have dedicated the last twenty-five years building our clinical cell engineering expertise and are the pioneers of non-viral gene editing. My promise to you and all our customers is that we will continue to work each day to ensure the ExPERT platform remains the premier cell engineering technology in our industry. Our platform supports the development of a growing portfolio of advanced cell-based therapeutics, including CASEGEVY, the first non-viral engineered cell therapy product approved by the FDA, developed by our SPL client CRISPR Therapeutics and Vertex Pharmaceuticals. 2023 was a monumental year for MaxCyte, in being the first and only electroporation platform to support a non-viral engineered therapy through FDA approval; however, we believe this is just the first of many potential approvals by MaxCyte SPL clients over the coming years.

MaxCyte's performance in 2023 was challenged by headwinds faced in our industry. Early-stage customers in cell therapy and drug discovery had limited access to capital, and some clinical customers adjusted their spending and extended project timelines, impacting our core business performance. Despite this, non-viral cell therapy market trends and development advancements towards novel approaches, new indications, and more complex engineering, continued to bode well for our platform. These industry trends all drive demand for MaxCyte's electroporation technology. While a challenging operating environment may persist into 2024, we expect the non-viral cell therapy opportunity and regulatory backdrop for cell therapies to continue to improve and we remain confident in our ability to grow our business over the long term.

Our strategy remains focused on expanding our SPLs, and in 2023 we grew our SPL clients across diverse cell types, disease indications and geographic regions. We now have a total of 27 SPLs including our four most recent SPLs announced in 2024, which include Be Biopharma, Wugen, Imugene, and Lion TCR. Across our SPL portfolio, programs continue to make exciting progress with several entering and/or progressing through the clinic. Overall, our global customer base is expanding across all stages of development and across a growing number of diseases. We now have an instrument installed base of 683 at the end of 2023, compared to just 616 instruments at the end of 2022.

Since our IPO, MaxCyte has strategically invested to support the growth opportunity ahead of us. Notably, we have made investments to ensure that we have the strongest manufacturing, regulatory, and quality capabilities to support our customers throughout development and commercialization. We have added to our teams across the organization in order to scale the business, and we have made targeted product development enhancements. We believe these investments have positioned MaxCyte to better capture the substantial growth opportunity in our industry.

In 2024, we will be measured in our investments, and focus on areas that we believe will deliver significant returns to our customers and MaxCyte in the long-term. The key areas of investment may include improvements to our best in-class electroporation systems, building additional application knowhow, building capabilities to work with customers earlier in the continuum of development, and expanding into new applications for EP. We believe these are the right investments to drive continued business momentum across our customer base, and position us well over the long-term.

Importantly, we enter 2024 with significant confidence in the value that our ExPERT platform provides to the industry, as well as the strength of our SPLs and pipeline opportunities. We are honoured to support our customers, and believe we remain the platform of choice for non-viral cell engineering technology, supporting critical programs through development to commercialization. The cell and gene therapy industry is in the early innings of significant global opportunity to deliver therapies to patients and we remain very optimistic about the medium-to-longer term growth opportunities for MaxCyte.

Thank you for your continued support of MaxCyte.

Mar Men

**Maher Masoud** 

Chief Executive Officer

# UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

## **FORM 10-K**

(Mark one)

<b>△</b> A	ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934									
		For the fiscal year ended December 31, or	2023							
□ T	RANSITION REPORT PURSUA	NT TO SECTION 13 OR 15(d) OF THE  For the transition period from to  Commission file number: 001-40674	SECURITIES EXCHANGE ACT OF 1934							
		MaxCyte, Inc. (Exact name of registrant as specified in its char	er)							
(5	<b>Delaware</b> State or other jurisdiction of incorporation o	r organization)	52-2210438 (I.R.S. Employer Identification No.)							
		9713 Key West Avenue, Suite 400 Rockville, Maryland 20850 (Address of principal executive offices and zip co	ode)							
	Registrant's telephone number, including area code: (301) 944-1700									
		Securities registered pursuant to Section 12(b) of the	e Act:							
	Title of each class	Trading Symbol(s)	Name of each exchange on which registered							
Cc	ommon stock, par value \$0.01 per share	MXCT	The Nasdaq Stock Market LLC							
Indicate by ch Indicate by ch	neck mark if the registrant is not required to neck mark whether the registrant (1) has file									
-		ted electronically every Interactive Data File require for for such shorter period that the registrant was rec	d to be submitted pursuant to Rule 405 of Regulation S-T (§ uired to submit such files). Yes $\boxtimes$ No $\square$							
			d filer, a smaller reporting company, or an emerging growth d "emerging growth company" in Rule 12b-2 of the Exchange							
Large acceler Smaller repor		□ Accelerated filer ⊠ Emerging growth company	<ul><li>□ Non-accelerated filer</li><li>☑</li></ul>							
	g growth company, indicate by check mark unting standards provided pursuant to Secti	_	ransition period for complying with any new or revised							
	_		nent of the effectiveness of its internal control over financial nting firm that prepared or issued its audit report. $\Box$							
	re registered pursuant to Section 12(b) of th an error to previously issued financial stater	· · · · · · · · · · · · · · · · · · ·	statements of the registrant included in the filing reflect the							
-	neck mark whether any of those error correct ecutive officers during the relevant recover		sis of incentive-based compensation received by any of the							

As of March 5, 2024, the registrant had 104,128,650 shares of common stock, \$0.01 par value per share, issued and outstanding.

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

#### DOCUMENTS INCORPORATED BY REFERENCE

that date, was approximately \$467.5 million.

Portions of the registrant's definitive proxy statement relating to the 2024 annual meeting of stockholders, which the registrant intends to file with the Securities and Exchange Commission not later than 120 days after the registrant's fiscal year ended December 31, 2023, are incorporated by reference into Part III of this Annual Report on Form 10-K.

The aggregate market value of the registrant's voting and non-voting common stock held by non-affiliates as of June 30, 2023, the last business day of the registrant's most recently completed second fiscal quarter, based on the closing sale price of the registrant's common stock of \$4.59, as reported by the Nasdaq Global Select Market as of

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## **Risk Factors Summary**

Our business is subject to numerous risks that you should carefully consider. These risks are more fully described in the section titled "Risk Factors" included in Item 1A of this Annual Report on Form 10-K. These risks, which could materially and adversely affect our business, financial condition, operating results and prospects include, but are not limited to, the following:

- We are a cell engineering and life sciences company and have incurred significant losses since our inception, and we expect to incur losses for the foreseeable future. We have limited product offerings approved for commercial sale and may never achieve or maintain profitability.
- We are highly dependent on a limited number of product offerings. Our revenue has been primarily generated from the sale and licensing of our instruments, as well as sales of single-use disposable processing assemblies ("PAs"), which require a substantial sales cycle and are prone to quarterly fluctuations in revenue, as well as revenues earned based upon customer clinical development progress events which are outside of our control and highly variable from period to period. We may never generate a level of revenue that is sufficient to support our operations or achieve profitability.
- Our business is dependent on adoption of our products by organizations such as biopharmaceutical companies
  and academic institutions for their research and development activities focused on cell-based therapeutics. If
  organizations such as biopharmaceutical companies and academic institutions are unwilling to change current
  practices to adopt our products, it may negatively affect our business, financial condition, prospects and results
  of operations.
- We may be unable to compete successfully against our existing or future competitors.
- If we cannot maintain and expand current partnerships and enter into new partnerships, that generate marketed licensed products, our business could be adversely affected.
- The failure of our partners to meet their contractual obligations to us could adversely affect our business.
- Our partners may not achieve projected development, regulatory milestones or other anticipated key events in the expected timelines or at all, or may discontinue some or all of their programs, which could have an adverse impact on our business and could negatively impact our value.
- In recent periods, we have depended on a limited number of partners for our revenue, the loss of any of which could have an adverse impact on our business.
- We may engage in future acquisitions that could disrupt our business, cause dilution to our stockholders or harm our financial condition and operating results.
- We depend on continued supply of high quality components and raw materials for our ExPERT<sup>TM</sup> instruments and PAs from third-party suppliers, and if shortages of these components or raw materials arise, we may be required to pay higher prices for these components or may not be able to secure enough components to build new products to meet customer demand at all.
- We have limited experience manufacturing our PAs and may be unable to successfully and consistently manufacture our PAs in high-quality commercial quantities to meet demand, which could limit our growth.
- Our results of operations may be harmed if we are unable to accurately forecast customer demand for our products and manage our inventory.

- If we are unable to successfully develop new products, adapt to rapid and significant technological change, respond to introductions of new products by competitors, make strategic and operational decisions to prioritize certain markets, technology offerings or partnerships, or develop and capitalize on markets, technologies or partnerships, our business could suffer.
- New product development involves a lengthy and complex process and we may be unable to develop or commercialize products on a timely basis, or at all.
- Our systems are complex in design and may contain defects that are not detected until deployed by our
  customers, which could harm our reputation, increase our costs or reduce our sales. If our products do not
  perform as expected or the reliability of the technology on which our products are based is questioned, our
  operating results, reputation and business may suffer.
- Failure or perceived failure to comply with existing or future laws, regulations, contracts, self-regulatory schemes, standards, and other obligations related to data privacy and security (including security incidents) could harm our business. Compliance or the actual or perceived failure to comply with such obligations could increase the costs of our products, limit their use or adoption, and otherwise negatively affect our operating results and business.
- Our FDA Master File, and equivalent Master and Technical Files in foreign jurisdictions, are an important part of our strategic offering which allows our partners to expedite their cellular therapies into and through clinical development. Delays in filing or obtaining, or our inability to obtain or retain (as applicable in a given jurisdiction), acceptance of such filings in individual countries could negatively impact the progress of our partners if they intend to run clinical trials in such countries, and as a result, could negatively affect our reputation and revenues or require disclosure of confidential information to our partners. Further, changes that we are required to make from time to time, or changes to regulations or negative data or adverse events for our partners, could impact references to our FDA Master File and Master and Technical Files by our partners.
- We may need additional funding and may be unable to raise capital when needed, which could require us to delay, reduce, eliminate or abandon our commercialization efforts or product development programs. If we do raise additional capital through public or private equity or convertible debt offerings, the ownership interest of our existing stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect our stockholders' rights. If we raise additional capital through debt financing (including refinancing our existing debt), we may be subject to covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures, or declaring dividends.
- Our partners may not achieve projected development and regulatory milestones and other anticipated key events in the expected timelines or at all, or may discontinue some or all of their programs, which could have an adverse impact on our business and could cause the price of our common stock to decline.
- Our common stock is traded on two separate stock markets and investors seeking to take advantage of price
  differences between such markets may create unexpected volatility in our share price; in addition, investors may
  not be able to easily move shares for trading between such markets.

## SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K contains forward-looking statements within the meaning of the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1995. These statements about us and our industry involve substantial known and unknown risks, uncertainties, and assumptions, including those described in Item 1A under the heading "Risk Factors" and elsewhere in this report, that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. All statements other than statements of historical facts contained in this report, including statements regarding our future results of operations or financial condition, business strategy and plans and objectives of management for future operations, are forward-looking statements. Forward-looking statements include, but are not limited to, statements about the Company's preliminary results of operations, including fourth quarter and full year 2023 total revenue, core revenue, and SPL program revenue and statements about possible or future results of operations or financial position. In some cases, you can identify forward-looking statements because they contain words such as "anticipate," "believe," "contemplate," "continue," "could," "estimate," "expect," "intend," "may," "plan," "potential," "predict," "project," "should," "target," "will" or "would" or the negative of these words or other similar terms or expressions. These forward-looking statements include, but are not limited to, statements concerning the following:

- our expected future growth and the success of our business model;
- the potential payments we may receive pursuant to our Strategic Platform Licenses ("SPLs");
- the size and growth potential of the markets for our products, and our ability to serve those markets, increase our market share and achieve and maintain industry leadership;
- the market acceptance and demand for our technology and products, including in the cell therapeutics and bioprocessing application markets;
- the expected future growth of our manufacturing capabilities and sales, support and marketing capabilities;
- our ability to expand our customer base and enter into additional SPL partnerships;
- our ability to accurately forecast and manufacture appropriate quantities of our products to meet clinical or commercial demand;
- our expectations regarding development of the cell therapy market, including projected growth in adoption of non-viral delivery approaches and gene editing manipulation technologies;
- our expectation that our partners will have access to capital markets to develop and commercialize their cell therapy programs;
- our ability to maintain our FDA Master File and Master and Technical Files in other countries and expand Master and Technical Files into additional countries;
- our research and development for any future products, including our intention to introduce new instruments and processing assemblies and move into new applications;
- the development, regulatory approval and commercialization of competing products and our ability to compete with the companies that develop and sell such products;
- risks associated with our management transition and our ability to retain and hire senior management and key personnel;

- regulatory developments in the United States and foreign countries;
- our expectations regarding the period during which we qualify as an emerging growth company under the JOBS Act (as defined below);
- our ability to develop and maintain our corporate infrastructure, including our internal controls;
- our financial performance and capital requirements;
- the adequacy of our cash resources and availability of financing on commercially reasonable terms;
- our expectations regarding our ability to obtain and maintain intellectual property protection for our products, as well as our ability to operate our business without infringing the intellectual property rights of others;
- general market and economic conditions that may impact investor confidence in the biopharmaceutical industry and affect the amount of capital such investors provide to our current and potential partners; and
- our use of available capital resources.

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

In addition, statements that "we believe" and similar statements reflect our beliefs and opinions on the relevant subject. These statements are based on information available to us as of the date of this Annual Report on Form 10-K. And while we believe that information provides a reasonable basis for these statements, that information may be limited or incomplete. Our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all relevant information. These statements are inherently uncertain, and investors are cautioned not to unduly rely on these statements.

The forward-looking statements made in this Annual Report on Form 10-K relate only to events as of the date on which the statements are made. We undertake no obligation to update any forward-looking statements made in this Annual Report to reflect events or circumstances after the date of this Annual Report or to reflect new information or the occurrence of unanticipated events, except as required by law. Given these uncertainties, you should not place undue reliance on our forward-looking statements. Our forward-looking statements do not reflect the potential impact of any future acquisitions, mergers, dispositions, or joint ventures.

You should read this Annual Report on Form 10-K and the documents that we file from time to time with the Securities and Exchange Commission (the "SEC") with the understanding that our actual future results, levels of activity, performance and events and circumstances may be materially different from what we expect.

In this Annual Report on Form 10-K, unless the context requires otherwise, all references to "we," "our," "us," "MaxCyte" and the "Company" refer to MaxCyte, Inc.

## **Trademarks**

We have applied for various trademarks that we use in connection with the operation of our business. This Annual Report on Form 10-K includes trademarks, service marks, and trade names owned by us or other companies. All trademarks, service marks, and trade names included in this Annual Report on Form 10-K are the property of their respective owners. Solely for convenience, the trademarks and trade names in this report may be referred to without the ® or TM symbols, but such references should not be construed as any indicator that their respective owners will not assert, to the fullest extent under applicable law, their rights thereto.

#### PART I

#### Item 1. Business

#### Overview

We are a leading commercial cell engineering company focused on providing enabling platform technologies to advance the discovery, development and commercialization of next-generation cell therapeutics including cell and gene therapies and to support innovative cell-based research and development. Over more than two decades, we have developed and commercialized our proprietary Flow Electroporation® technology, which is used by biopharmaceutical companies in the complex engineering of a wide variety of cells.

Electroporation is a method of transfection, or the process of deliberately introducing molecules into cells, that involves applying an electric field in order to temporarily increase the permeability of the cell membrane. This precisely controlled increase in permeability allows the intracellular delivery of molecules, such as genetic material and proteins, that would not normally be able to cross the cell membrane as easily.

With increased knowledge of cell complexity and systems biology in the scientific community, researchers have sought to leverage or repurpose cell functions and/or machinery for research or therapeutic purposes. The ability to engineer living cells by introducing foreign molecules, such as gene editing systems and transgenes, has led to a revolution in biological research and resulted in numerous biological discoveries. Living human cells can also be engineered *ex vivo*, or outside the body, where they are repaired or reprogrammed to fight disease. In this case, the engineered cell itself is the drug.

Cell therapy has emerged as one of the fastest growing and most promising treatment modalities to address a host of human diseases. Recent developments in multiple U.S. Food and Drug Administration (the "FDA") approved cell therapies in generating promising data suggests that they may be able to provide long-lasting amelioration of symptoms or presence of disease has catalyzed tremendous investment—leading to significant growth in cell-based therapies being evaluated for therapeutic applications. The Alliance for Regenerative Medicine ("ARM"), an international advocacy organization, estimates that the regenerative medicine sector, which consists of gene, cell, and tissue-based therapeutic developers raised an aggregate of \$11.7 billion in 2023 and that, as of February 2024, there were more than 1,900 active clinical trials focused on regenerative and advanced medicine, which includes gene therapy, cell-based immuno-oncology, cell therapy and tissue engineering.

Our ExPERT platform, which is based on our Flow Electroporation technology, has been designed to address this rapidly expanding cell therapy market and can be utilized across the continuum of the high-growth cell therapy sector, from discovery and development through commercialization of next-generation, cell-based medicines. The ExPERT family of products includes four instruments, which we call the ATx<sup>TM</sup>, STx<sup>TM</sup>, GTx<sup>TM</sup> and VLx<sup>TM</sup>, as well as a portfolio of proprietary related disposables and consumables. We launched the ExPERT VLx<sup>TM</sup> instrument for very large-scale cell engineering in September 2022. Our disposables and consumables include PAs designed for use with our instruments, as well as accessories supporting PAs such as electroporation buffer solution and software protocols. We have garnered meaningful expertise in cell engineering via our internal research and development efforts as well as our customer-focused commercial approach, which includes a growing application scientist team. The platform is also supported by a robust intellectual property portfolio with more than 150 granted U.S. and foreign patents and more than 95 pending patent applications worldwide.

From leading commercial cell therapy drug and biologic developers and top biopharmaceutical companies to top academic and government research institutions, including the U.S. National Institutes of Health ("NIH"), our customers have extensively validated our technology. We believe the features and performance of our platform have led to sustained customer engagement. Our existing customer base, which includes but is not limited to our 26 SPL partners, ranges from large biopharmaceutical companies, including a majority of the top 25 pharmaceutical companies based on 2022 global revenue, to hundreds of biotechnology companies and academic centers focused on translational research. Our Flow

Electroporation technology is used by one of our SPL partners to engineer the first ex-vivo cell therapy approved by the FDA in December 2023.

## **Our Competitive Strengths**

We believe our industry leadership position and continued growth will be driven by the following competitive strengths:

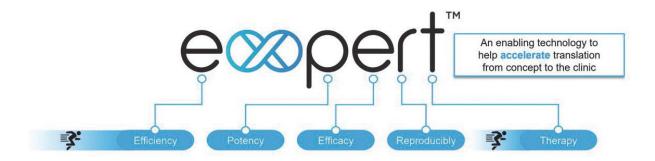
- Proprietary technology platform that can unlock the significant potential of cell-based therapeutics. We built our ExPERT platform to advance the growing demands for non-viral delivery and next-generation cell and gene engineering approaches. Our ExPERT platform enables delivery of almost any molecule into almost any cell type. We believe our ExPERT platform leads the industry in performance, as measured by consistency, efficiency, viability, flexibility and scale. Our ExPERT platform is further supported by a robust intellectual property portfolio.
- Comprehensive, high-performance transfection platform. We believe our ExPERT platform offers a unique value proposition given the flexibility to scale up from research to current good manufacturing practices ("cGMP") manufacturing on a single platform— enabling the engineering of cells ranging from tens of thousands of cells to more than tens of billions of cells in a single transfection run taking 30 minutes or less. Our long-term internal engineering expertise is supplemented by our customer focused approach—with a growing application scientist team working with our customers across increasingly diverse applications.
- Capitalizing on the large and growing next-generation cell therapy market with the ability to take advantage of rising demand for non-viral approaches. We believe we are well positioned to increase our market share within the large and growing next-generation cell therapy market. Since the FDA approved the first engineered CAR-T cell therapies to treat blood-based cancers in 2017, the number of cell therapy candidates being evaluated pre-clinically and clinically has grown significantly. We expect growth to continue given the remaining high unmet medical need in cancer and other chronic conditions and predict increased investments in cell therapy product development across a variety of human diseases. We expect to continue to grow our market share given the high performance of our platform and the ongoing adoption of non-viral delivery methods as the cell and gene therapy industry has trended towards developing advanced cell-based therapies with complex engineering strategies to improve efficacy, reduce time to patient treatment and expand into new indications.
- Innovative partnership business model focused on value creation and shared success. Our SPL partnerships allow us to participate in the value creation of our customers' programs via precommercial milestones and in commercial sales-based payments. We intend to continue to build a portfolio of strategic partnerships with cell therapy developers, which provide us with a growing, diversified source of annual licenses and potential downstream revenue.

In addition to the high performance and flexibility of the ExPERT platform, we believe our partnership model further reduces clinical risk and development timelines for our cell therapy partners. By entering into SPL partnerships with us, for example, our partners gain access to our FDA Master File to support their IND-enabling studies and potentially shortening clinical development. Our FDA Master File, which is a submission to the FDA with confidential detailed information about our products, methods, processes and data, was originally established in 2002 and has been continuously updated as platform improvements have been implemented to support different applications and cell types. The FDA Master File and equivalent Technical Files and Master Files in other countries can be referenced by our partners to support their own regulatory submissions with the goal of accelerating regulatory submissions processes for our partners. To date, our FDA Master File and Technical Files have been referenced by our customers in over 60 clinical trials.

- Recurring revenue model provides high visibility, with drivers of potential long-term upside. Our business model enables us to generate revenue from five sources: sales of instruments, disposables and consumables to new customers; additional sales of instruments, disposables and consumables to our existing installed base; annual instrument license fees from cell therapy customers; potential precommercial milestones under SPL partnerships; and potential commercial sales-based payments under SPL partnerships. We generate recurring revenue from our ExPERT instrumentation licenses, as well as disposables and consumables (or buffer) sales, which provides high visibility into future near-term revenue. In addition to recurring revenue, we have the potential to receive meaningful precommercial and commercial payments under SPL partnerships as our customers achieve success in advancing programs through the clinical stage and into the commercial stage. In aggregate, given our SPLs entered into to-date, we have the potential to receive over \$1.95 billion in precommercial milestone payments, if all of the programs were to be granted regulatory approvals.
- Leadership team and workforce with deep domain knowledge. Our management team combines strong and broad subject matter expertise with a demonstrated history of commercial and operational execution. Moreover, our workforce has deep domain knowledge across a range of scientific, engineering, regulatory and business disciplines. We have supplemented our diverse technical experience by assembling a deep operational team with expertise in manufacturing, legal, sales, marketing, customer service and finance. We believe the team we have assembled with talent from multiple disciplines and a science- and customer-focused culture represents a significant competitive advantage for us. As of December 31, 2023, of our 143 full-time employees, 81 have advanced degrees including 29 with Ph.D. degrees.

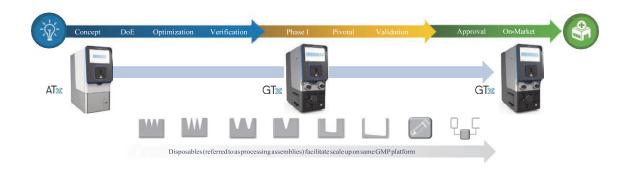
## **Our Technology Platform**

The foundation of our technology platform is our proprietary and patented Flow Electroporation technology, which we have developed and optimized for more than 20 years. Electroporation, or electro-permeabilization, leverages the fundamental properties of cell membranes, the ability to create reversible permeability in the presence of an electric charge, as a universal method to introduce foreign molecules, or transfect, eukaryotic cells, which are cells with a cell membrane and nucleus. Electroporation can be applied to almost any eukaryotic cell type to deliver a broad range of molecules, including DNA, human messenger RNA ("mRNA"), small interfering RNA ("siRNA"), and proteins. Our proprietary Flow Electroporation platform is fully scalable and can support small-scale research and development through large-scale cell engineering for development of commercial therapeutics.



Our technology platform is marketed under the ExPERT brand, the elements of which are depicted in the graphic above. The value of our ExPERT brand starts with Efficiency—with high delivery **Efficiency**, users can achieve **Potency**; with high Potency, users improve their chances of therapeutic **Efficacy**; and if this can be repeated, **Reproducibly** from patient to patient, users can have a successful **Therapy**. By delivering high efficiency at any scale, the ExPERT platform is designed to improve our customers' ability to achieve the required therapeutic index, enabling accelerated, cost-efficient translation of complex cellular therapies from research to clinical development.

Our ExPERT platform consists of four instruments, the ATx, STx, GTx and VLx, which use a broad range of PAs, or disposables, of different volumes to enable scalable electroporation from tens of thousands to billions of cells to facilitate the translation of complex cellular therapies from concept to clinical development, in support of the intended therapeutic commercialization. Our family of instruments and disposables has been designed to support scale-up for cell therapy development, as shown in the picture below.



#### Overview of our ExPERT Platform

Our Flow Electroporation technology was designed to meet the stringent demands of clinical use—namely, the ability to safely and reproducibly modify a broad range of primary human cells with high efficiency, low cytotoxicity, at the scale required to enable the treatment of patients across a diverse range of diseases.

We believe the current ExPERT instrument family represents the next generation of our clinically validated electroporation technology for complex and scalable cellular engineering. By delivering high transfection efficiency with enhanced functionality and ease of use, the ExPERT platform delivers the high-end performance that we believe is essential to enabling the next wave of biological and cellular therapeutics. The combination of the ExPERT instruments, associated disposables and universal electroporation buffer provides researchers, production scientists, and cGMP facilities with a solution to transfect cells with high efficiency, viability and consistency, which are the three attributes that are consistently ranked by our customers as the top requirements when choosing a cellular or gene engineering platform for clinical use. We believe our ExPERT platform is seen as a critical enabling technology by our customers, many of whom are leading cell therapy companies, helping them work towards achieving their program goals and milestones expeditiously. Our instruments are sold or licensed for research or clinical use, while the associated disposables and electroporation buffer are sold to support pre-clinical research and development work and are compatible for integration into cGMP manufacturing environments.

We believe that the following four components of our platform have allowed us to successfully address the increasing complexity of cellular engineering approaches in the industry:

- instrument design;
- electroporation and cell handling protocols;
- PAs (disposables); and
- universal electroporation buffer formulation (consumables).

In addition, we have implemented a global scientific and regulatory support strategy for our customers that is designed to accelerate clinical development and help streamline the regulatory submission process, thereby potentially saving time and reducing cost and development risk.

We believe our ExPERT platform offers a compelling value proposition to our customers due to: (i) the ability to use our technology to deliver almost any molecule into almost any cell type, including hard-to-transfect human primary cells, while maintaining high cell viability and function; (ii) the capacity to introduce larger and more diverse molecules, as well as multiple payloads, which exceeds the capabilities of other intracellular delivery technologies, such as viral vectors; and (iii) the flexibility to scale up from research to cGMP, manufacturing on a single platform—enabling the engineering of cells ranging from tens of thousands of cells to tens of billions of cells in a single transfection run in 30 minutes or less.

We believe our ExPERT intracellular delivery platform provides value across numerous applications in the life sciences market, including research, discovery, development, and manufacturing of next-generation, cell-based therapeutics, as well as in biomanufacturing, such as transient protein production for drug discovery and manufacturing of other proteins, including biological therapeutics, viral vectors and vaccines, and small molecule drug discovery.

Our ExPERT technology platform is being used in the clinic to support the development of next-generation cell therapy approaches to treat human disease. Following the successful clinical development leading to FDA approvals of CAR-T cell therapies in blood-based cancers, developers have focused on improving efficacy, lowering the cost of manufacturing and/or expanding engineered cell therapies into new indications, such as solid tumors, as well as autoimmune and neurogenerative diseases. To address these goals, the ex vivo cell therapy industry has trended towards developing more complex therapies that require sophisticated engineering and gene manipulation as well as the use of different starting cell types.

In addition, we are committed to continued research and development investments in technology and scientific innovation to continue to build out our position as a market leader.

### **Our Industry Background**

As the cell therapy market continues to evolve, developers face both the challenges of more complex approaches, which are being deployed to improve efficacy, reduce time to treat patients and expand the application of cell therapy to additional indications. The use of viral vectors carries several challenges, however, especially given the increase in complexity of these "next-generation" ex vivo cell therapy approaches, such as:

- Viral payload limitations. Many methods of gene manipulation require insertion of relatively large molecules, including proteins such as CAS9 RNP for CRISPR or plasmids. Viral vectors, particularly Adeno-Associated Virus ("AAV"), have fundamental payload capacity limitations, curtailing their utility for complex engineering systems. Additionally, the cell therapy industry has continued to shift to using complex molecules including combinations of proteins and mRNA which cannot be delivered by viral means.
- Concerns around toxicity. Given viruses used in gene therapy by default infect human cells, there continue to be questions around the safety profile associated with viruses. In particular, there are concerns over the potential for random integration of lentiviruses and the widespread presence of neutralizing antibodies against many AAV serotypes used in gene therapies.
- Costs and time to market. Concerns exist regarding viral vector manufacturing capacity and the cost associated with viral development and manufacturing. Additional bottlenecks arise from demand for viral approaches, which has led to subsequent demand for cGMP plasmids. Furthermore, vein-to-vein manufacturing times remain high and efficiencies are needed to deliver cell therapeutic medicines to patients faster.

Novel intracellular delivery approaches are needed to support the increased complexity of the burgeoning cell therapy pipeline. Such characteristics include reducing immunogenicity risk of viral vectors, driving high efficiency of multi-molecule delivery while maintaining high cell viability and potency, reducing the risk of potential genotoxicity of multiplex editing (potential for translocations), delivering a large number of molecules at scale, the ability to deliver to a large number of cell types in a time efficient matter, and manufacturing in a cGMP environment—all at a manageable cost.

The challenges of viral delivery methods and increased complexity of next-generation cell therapies has driven increased adoption of non-viral delivery technologies, such as electroporation. We believe our ExPERT technology is well positioned as a non-viral delivery platform in the cell therapy market. Originally developed in 1999 for the cell therapy market, we have systematically designed and improved the platform to deliver any molecule, into any cell at any scale, with high efficiency and under cGMP conditions. Our ExPERT platform is now the delivery backbone for a number of next-generation cell therapy programs, including one that has received FDA approval and is presently being commercialized.

## **Our Agreements with Customers**

We have a diverse portfolio of clinical partners and licensees that mirror the overall next-generation engineered ex vivo cell therapies. While difficult to predict given uncertainty around regulatory approvals and clinical risk, the first next-generation ex vivo cell therapies using non-viral approaches was approved in the United States in 2023 using our platform.

Our platform's ability to engineer a diversity of cell types (including CAR-T, chimeric antigen receptor Natural Killer cells ("CAR-NK/NK"), T cell receptor cells ("TCR") and stem cells) and cell sources (autologous and allogeneic) enhances our opportunity by potentially providing SPL partnership revenues regardless of which approaches advance in the coming years. Additionally, our instruments and platform have been used in over 60 clinical trials to date for drugs being developed to treat a variety of indications, from hematological malignancies to solid tumors to inherited genetic disorders. We believe that the increasing number of publications highlighting the performance of our platform compared to other electroporation, transfection and transduction approaches will continue to drive acceptance of our products in the cellular engineering market segments.

In addition to sales of our instruments, as part of our business model we enter into the following types of instrument license agreements with our customers:

## Research Licenses

Research licenses are agreements with academic institutions or commercial entities which provide access to the use of our instruments for preclinical research-only purposes, without the rights or ability to produce material for use in the clinic or commercially. Research licenses are granted either (a) as part of the terms and conditions of a sale of an instrument to a cell therapy user, or (b) in a licensing arrangement whereby we retain title to the instrument, while providing the customer with the ability to use the platform for research in exchange for a non-refundable annual payment of typically \$150,000 per instrument per year. We have entered into many research licenses to-date, either as (i) instrument sales, (ii) stand-alone research license agreements, (iii) research and clinical license agreements that do not have associated commercial rights, or (iv) under an SPL partnership, which allows a customer to use the instrument for clinical development and potential commercial sale of a therapeutic product. Research licenses under a stand-alone research license agreement, as well as instruments purchased for research use, could represent opportunities for future SPL partnerships.

## Clinical Licenses

Clinical licenses are agreements with academic institutions or commercial entities that provide access to the use of our instruments for the clinical evaluation and development of a therapeutic product intended for human use. In a clinical license, we retain title to the instrument and provide the customer with the ability to reference our FDA Master File (and international equivalents), use the platform for production of clinical material for human clinical use, as well as access to our application scientist team, all in exchange for an annual payment of typically \$250,000 per instrument per year for commercial customers. Academic clinical licenses can represent opportunities for future SPL partnerships to the extent that commercial entities seek and obtain rights to such programs from the academic institution.

## Strategic Platform Licenses (SPLs)

Given our value proposition in non-viral delivery, we have established strategic relationships in the form of SPL partnerships with a growing number of leading cell therapy developers as they work to bring next-generation cell therapies into and through clinical development and advance those candidates to potential commercialization.

Under these SPL partnerships and other license agreements with our customers, we retain title to the licensed instrument and associated intellectual property, and in exchange for an annual license fee per instrument, we provide our customers with non-exclusive access, for a defined field of use, to our:

- cGMP-compatible platform, which enables early-optimization and scale-up from pre-clinical research into clinical development using our intellectual property portfolio;
- FDA Master File and Technical Files, which may help accelerate and streamline development and reduce regulatory risk in the creation and development of our partners' therapeutic drug candidates;
- experienced team of sales personnel and application scientists who work directly with our customers to solve cell engineering problems; and
- continuous know-how and cell engineering process improvements.

In return, these SPL partnerships provide us with the ability to receive downstream program-related precommercial milestone payments and, in most cases, commercial sales-based payments. In addition, from our SPL partnership customers, we receive annual research fees for certain products and clinical license fees for others as well as payments from sales of our proprietary disposables as recurring revenue streams. Given growth in the cell therapy pipeline and increased investment in the space, we estimate that the number of potential SPL partnerships for us will continue to grow significantly, based on our estimates of growth in the cell therapy pipeline, growth in the number of therapeutic delivery entrants into the market and ongoing shift in the industry to non-viral delivery.

A customer relationship may evolve to an SPL partnership after the customer's drug candidate optimization and verification process nears completion and the clinical process development stage begins. Specifically, if a customer wishes to use our products in the clinical phase of process development, they will need to enter into an agreement establishing an SPL partnership, as a customer must obtain clinical rights to perform clinical process development, including for engineering runs. Customer discussion for an SPL partnership can take place any time during our engagement.

Our SPL customers typically pay an annual license fee per instrument per year for a research license (for preclinical use) or per instrument per year for a clinical license (for clinical or commercial use) or in certain circumstances may purchase an instrument for research use. Partners may also purchase associated single-use disposables and consumables as needed. Our SPL partners also commit to pay precommercial milestone payments for each therapeutic licensed under the agreement and produced using our platform, to be paid as they achieve key precommercial clinical development events (including, for example, Investigational New Drug ("IND") applications and approvals, filing, dosing of an agreed number of patients in a Phase 1 clinical trial, initiating a pivotal clinical trial, and Biologics License applications ("BLA") approvals in specified regions). Almost all of our SPL partnerships also include a commitment to pay us post-approval sales-based payments for commercialized therapeutics.

We view our ability to establish SPL partnerships as a key measure of our success in partnering with leading therapeutic developers, which then supports the performance of our platform.

The following graphic is an example of typical single-product revenues from a representative SPL partnership:



Our SPL partnerships and research and clinical licenses may be terminated at the option of our customers at any time. Annual instrument lease fees are non-refundable and customers may not use our instruments or process assemblies after terminating their agreement with us. We retain title to the leased instrument in each of our licenses. Upon contract termination, our customers would be responsible for any further clinical studies or data development that regulators may require to allow a change in their cell engineering methodology. We have entered into 26 SPL partnerships with commercial cell therapy developers and, to date, none of our SPL partnership licensees has ever terminated their contract with us.

Of the over 160 potential programs allowed under our current SPL partnerships, one is in the commercial stage and 16 are active in clinical development, meaning they have at least an FDA-cleared IND application or foreign equivalent. An IND is a request for authorization from the FDA to administer a therapeutic being investigated in humans in a clinical research setting and to ship such products in interstate commerce for use in investigational clinical trials. An IND must become effective before human clinical trials may begin. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day time period, raises safety concerns or questions about the proposed clinical trial. Clinical trials then involve the administration of the investigational product to human subjects under the supervision of qualified investigators and are conducted under protocols detailing, among other things, the objectives of the study, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated.

Our 26 SPL partnerships have the potential to generate over \$1.95 billion in precommercial milestone payments if all of the licensed programs were to achieve regulatory approvals. In addition, under the SPL partnerships, we typically have the potential to receive significant, sales-based commercial payments for approved products. However, clinical development involves a lengthy and expensive process with uncertain outcomes, including the results of pre-clinical research, as well as clinical trials demonstrating product safety and efficacy, and therefore our customers may not begin or complete clinical development, and may never receive FDA or other regulatory approval for all or any product candidates covered by their SPL partnership agreements with us, in which case we will not receive the full potential precommercial milestone payments or the sales-based commercial payments or royalties contemplated by our SPL agreements.

#### **Our Products**

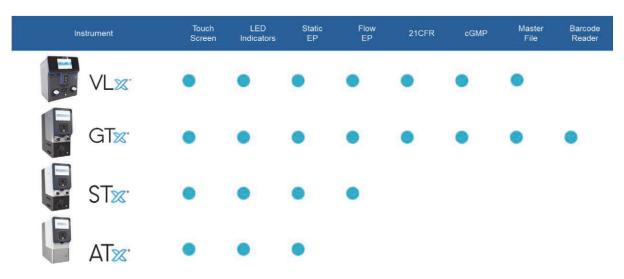
#### **ExPERT Instruments**

The ExPERT instrument family was designed to provide a single unifying technology that can be used from concept to clinic, with both the research and clinical versions of an instrument incorporating the same underlying technology and protocols. Our customers have a choice of four different instrument versions that are standardized on the same technology to deliver equivalent high performance—ATx, STx, GTx and the VLx, as well as a portfolio of proprietary related disposables and consumables. Customers can start with the lower to medium scale research instrument (ATx) and then scale up to the clinical version (GTx) without the need for re-optimization or re-validation. The STx provides the same scale as the GTx but is used for drug discovery applications, such as preclinical monoclonal antibody production, and not for human therapeutic use. VLx provides the capability for large-scall cell engineering and drug discovery applications. The STx is not covered by our FDA Master File or our Technical Files.

We believe these systems will also be supportive of the commercial marketing of our partners' therapeutic products which we enable. Our platform allows our customers to perform their research and process optimization on a research platform and seamlessly scale to a clinically validated, cGMP environment and 21 CFR Part 11 compatible clinical platform. Further, we believe our platform provides an opportunity for our customers to realize significant time and cost savings.

All our instruments have been designed to provide customers with the key features required for a scalable high-performance transfection solution. Each of our ExPERT instruments is benchtop with the same small footprint and has integrated touch screens with an intuitive Graphical User Interface ("GUI"), designed for simple training and operation. To support use in the cGMP suite for clinical manufacturing, our GTx ExPERT software is network capable to enable upload of electronic batch records to a local shared drive and has a software intermediary to facilitate integration and automated data transfer to cloud-based data management solutions. We have integrated hardware and software design solutions, manufactured under cGMP, that are tailored for use in cGMP manufacturing of clinical products for advanced cellular therapies.

The following chart summarizes the features of the four ExPERT instruments:



ExPERT ATx: Research focused, static electroporation for small to medium scale transfection



Our ExPERT ATx static electroporation instrument is a research focused, high performance electroporation platform for small to medium scale transfection. The ATx instrument delivers high efficiency and viability at research scale and can utilize our range of PAs capable of transfecting from 75,000 to 700 million cells. Additionally, our ATx instrument is compatible with all of our static PAs, which can also be used on our GTx instrument, allowing for a seamless transition to our clinical cGMP-compatible platform. The ATx is designed and used by our customers for early design of experiment and process optimization at small scale to minimize cell acquisition and reagent costs. Once optimized for the biological function with smaller numbers of cells, the process can be replicated and scaled before being transferred to the clinical platform (GTx) for eventual manufacturing in the cGMP suite or to the STx platform for drug discovery and bioprocessing applications.

ExPERT STx: Flow Electroporation for protein production and drug development





Our ExPERT STx instrument, which is generally used in the field of protein production and for other drug discovery applications, also incorporates our proprietary Flow Electroporation Technology for high yield transient expression of complex proteins, viral vectors, vaccines, virus like particles ("VLPs") and biologics. Our STx instrument has high efficiency and can rapidly transfect from 75,000 to 20 billion cells. When combined with flexible media strategies, the STx allows for substantial improvement in yields of high-quality, transiently expressed proteins while enabling reduced media costs.

Another key application area for the STx is expression of therapeutic targets for cell-based assays. Traditionally, drug screening has been performed using stable cell lines because conventional transfection technologies, such as lipofection, may induce changes to membrane composition, which does not offer the consistency and scalability that are critical for sensitive, high throughput screens. By enabling high efficiency transfection of multiple plasmids simultaneously into billions of cells, the STx provides drug developers with the ability to express complex, multi-subunit proteins, such as ion channels, in physiologically relevant cells. The high viability of our transfected cells leads to robust assay responses on multiple platforms, including automated electrophysiology and high content screening technologies.

Moreover, precise control over loading efficiency gives assay developers the ability to "dial in" optimal assay windows. By providing applications for cell-based assays, the STx offers a unique opportunity to apply our technology.

ExPERT GTx: Flow Electroporation for large scale transfection in therapeutic applications



The ExPERT GTx incorporates our proprietary Flow Electroporation technology for use in the cGMP manufacturing of cellular therapies with clinical uses. By incorporating the Flow Electroporation technology, larger volumes of up to 20 billion cells can be electroporated within 15 to 20 minutes. With a processing potential that ranges from 75,000 to 20 billion cells on a cGMP, 21 CFR Part 11 compatible system, the GTx represents a platform for clinical electroporation at large scale.

The GTx integrates several design features that are critical for use in a cGMP setting, such as barcode reading capability to maintain positive identification of patient samples, 21 CFR Part 11 compatible software and networking capability for automated uploading of electronic batch records to either a central server or to a cloud-based data management platform. The GTx enables closed sample processing, on a system compatible with integration into cGMP manufacturing environments, and that has an established regulatory path supported by our FDA Master File and Technical Files.

ExPERT VLx: Designed for very large volume cell-engineering



The ExPERT VLx Large-Scale Transfection System is a cGMP compliant instrument specifically designed for very large volume cell-engineering. Using proprietary Flow Electroporation technology, the VLx supports the ability to transfect up to 200 billion cells in less than 30 minutes—10 times the capacity of the STx and GTx. This system is designed for the rapid and large-scale production of recombinant proteins, monoclonal antibodies, viral vectors, vaccines, VLPs and allogeneic cell therapies. We launched the VLx under the ExPERT brand in September 2022 to provide customers with an easy to use, large-scale system that incorporates the benefits of the ExPERT platform for large-scale bioprocessing. As of September 2023, the VLx has an established regulatory path supported by our FDA Master File.

## Disposables—Processing Assemblies (PAs)

Our range of disposable PAs is an important differentiator for us. We are not aware of any other company with the breadth and diversity of supported processing volumes that enable high efficiency electroporation flow, in single-well and multi-well formats, for use in both the research and clinical settings. We view our PA designs as one of the key contributors to the capacities, high efficiency and viability delivered by the ExPERT platform.

We have developed a broad range of PAs that are specially designed to process and electroporate the user's chosen quantity of cells. Each PA contains two electrodes, between which a medical-grade gasket is sandwiched that has a unique well design consistent with the processing volume required and to allow maximum retrieval of cells. Our PAs are capable of electroporating cell volumes from small to large scale, in single and multi-well formats, for both research and

clinical use. Cells are placed into the sample bag in large scale PAs, or into the well or wells in small scale PAs, and the PA is then connected to the instrument for processing. The instrument touch screen allows the operator to select the desired cell protocol that encodes the electroporation parameters, select the type of PA to be used and enter any sample specific information. Once the sample information has been entered, the operator will touch the "Start Processing" icon on the user interface and the sample will be rapidly processed. Larger volumes of cells are accommodated by larger capacity PAs and a set of simple software commands through the intuitive GUI.

Our ExPERT system uses two PA designs — a static cuvette used for smaller cell volumes (from 75,000 cells up to 200 million cells) and a cartridge design that is used for both static and Flow Electroporation for larger cell volumes (700 million up to tens of billions of cells). The Flow Electroporation PA ("Flow PA") allows for processing of cellular volumes ranging from 10 mL to 100 mL and up to tens of billions of cells. The Flow PA consists of bags and associated tubing, made from medical grade materials, that are connected to the electroporation cartridge. Users transfer their cells and loading molecules to the sample bag, and the pump on either the GTx or STx instrument pumps a fixed volume of cells into the cartridge chamber where they are electroporated. Once the electroporation is complete, the cells are pumped to the collection bag and the chamber is filled with the next volume of cells for electroporation. This process is repeated until the entire sample volume is processed. The maximum volume of 100 mL of cells can be processed in approximately 15–20 minutes.

Examples of our two ExPERT PA designs are shown in the pictures below:



ExPERT cuvette design (Static Processing Assembly)



ExPERT Flow Electroporation design (Flow Processing Assembly)

We have conducted extensive end-user research to continue improving the design of the PAs and the range of products available. We launched the ExPERT cuvette in 2020 based on customer feedback, which incorporated a new design to improve handling and ease of use, and we have continued to expand the availability of the ExPERT PA portfolio design. We have also expanded our portfolio of multi-well cuvettes, which reduce manual handling and improve productivity in the lab, with the launch of our R-50x8. The R-50x8 is an 8-well cuvette capable of processing up to 225,000 cells in each well. By enabling eight samples to be processed in the same cuvette, a more efficient process can be achieved by users. We plan to continue to support customers using legacy processing assemblies until they transition to our ExPERT products.

In 2022, we added the R-20K Flow Electroporation Processing Assembly for our STx and GTx platforms, which can process between 5 mL and 20 mL sample volumes, which can accommodate between 200 million and up to 4 billion cells. The R-20K assembly allows clients to develop therapies at small or mid-scale volumes with improved cell recovery in a closed process adaptable format to assist in de-risking their manufacturing process at the electroporation step. To further support our customers' sterile closed process workflows, we also introduced 'Closed Process Electroporation Buffer' products in two volume sizes, 500 mL and 1 Liter, which allow for the addition of our proprietary electroporation buffer to concentrated cell samples before electroporation. At the same time, for our VLx Platform, we introduced the R-1L Flow Electroporation Processing Assembly, which can process in 30 minutes or less between 100 mL and 1 Liter sample volume accommodating up to 200 billion cells in a single run. The R-1L assembly

allows for large volume sample processing that can be adapted to a closed and sterile workflow for continuous endproduct production.

The following matrix shows our full line of currently available PAs and their respective specifications and features, including the ExPERT instruments with which they can be used:

Feature	OC-25x3	R-50x3	R-50x8	OC-100x2	OC-100	OC-400	R-/G-1000	CL-1.1	R-/G-20K	CL-2	R-/G-1L
РА Туре	1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1	-	377-317	100 mm m m m m m m m m m m m m m m m m m	100 mm m m m m m m m m m m m m m m m m m	1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1	400	DLA1	ONE A		20 1-25
Well Type	W	W	шшш	W	u	П					
Volume	15 - 25 µL	45 - 55 µL	45 - 55 μL	50 - 100 μL	50 - 100 μL	200 - 400 μL	0.4 - 1 mL	1 - 3.5 mL	5 – 20 mL	10 - 100 mL	100-1000 mL
# Samples	3	3	8	2	1	1	1	1	1	1	1
Cell Number/Well	7.5x10 <sup>4</sup> - 5x10 <sup>8</sup>	2.25x10 <sup>5</sup> - 1x10 <sup>7</sup>	2.25x10 <sup>6</sup> - 1x10 <sup>7</sup>	2.5x10 <sup>5</sup> - 2x10 <sup>7</sup>	2.5x10 <sup>5</sup> - 2x10 <sup>7</sup>	1x10 <sup>6</sup> - 8x10 <sup>7</sup>	2x10 <sup>8</sup> - 2x10 <sup>8</sup>	5x10 <sup>8</sup> - 7x10 <sup>8</sup>	5x10 <sup>8</sup> - 4x10 <sup>9</sup>	5x10 <sup>7</sup> - 2x10 <sup>10</sup>	5x10 <sup>6</sup> - 2x10 <sup>11</sup>
ATx*	•	•	•	•	•	•	•	•			
GT <b>x</b> °	•	•	•	•	0	•	•	•	•	0	
ST <b></b> ≥×*	•	•	•	•	•	•	•	•	•	•	
VL <sub>X</sub>	•	•		•	•	•	•	•			•

We are committed to strategically investing in improvements in the PA design and range of products to ensure that customers have solutions that address all of their volume and use requirements, in both research and clinical settings, including current development of advancements for PA that support the VLx.

## Supporting Products

Our proprietary electroporation buffer, a balanced salt solution that protects cells during transfection, is formulated for use with all our instrument platforms and PAs. This consumable is used for all cell types, eliminating the need to change buffers as users switch protocols, cell types or scale up. The buffer is made in a cGMP facility, is fully chemically defined and is free of human or animal components, and is tested to meet technical, sterility and endotoxin specifications. This buffer formulation is a key contributing factor, in combination with instrument and PA design features, to the flexibility, high efficiency and viability that can be achieved by customers across the broad range of cell types processed using our platform.

## Sales and Marketing

We follow a direct sales model in North America, the United Kingdom, and Europe, while also selling through third-party distributors in Asia and some regions of Europe. As of December 31, 2023, we had over 36 field sales and application scientists located in the United States, the United Kingdom, and several regions in Europe and Asia. Since the commercial launch of our first Flow Electroporation instrument in 2003, the installed base of our instruments has grown to more than 680 instruments globally.

Our sales force and field application scientists and international partners inform our current and potential customers of current product offerings, new target applications and advances in our technologies and products. As our primary point of contact in the marketplace, our field teams focus on delivering a consistent marketing message and high level of customer support, while also working to help us better understand the evolving market and customer needs. We intend to expand our sales, support, and marketing efforts in regions such as those within the Asia-Pacific region. We currently use distributors in countries in these regions, such as in China and Japan, supplemented by dedicated MaxCyte team

members, and continuously assess the need for direct sales and local support personnel to supplement our distributors' resources. When we expand into a new geography, we generally rely initially on third-party distributors until we are able to recruit a direct sales force, field application scientists and business development resources in the country or region.

Our business model is focused on identifying new applications in cell engineering to enable our customers to develop better medicines and maximize use across our customers' value chains. This is enabled through customer partnerships that allows us to further understand the critical applications for our technology and inform our future developments and market expansion.

## **Research and Development**

Investment in research and development is at the core of our business strategy. Members of our research and development team specialize in many functional areas including molecular biology, cellular biology, physics, gene editing, cell culture, protein manufacturing, process development, mechanical engineering, cell handling processes, electroporation algorithm development and customer technical support.

Our research and development teams are aligned into two teams, applications and instrumentation. The application team is responsible for developing data on key applications, including improving approaches to cell handling and cell culture; designing, developing and enhancing electroporation protocols; developing and enhancing cell engineering applications, and performing product testing and quality assurance activities. The instrumentation engineering team focuses on developing and improving electroporation instruments and PA disposables to meet our partners' wide range of needs from research to commercialization in a GMP environment. The research and development functional teams work together as a core team, following a stage-gate process to develop, qualify and launch new products to market.

Other research and development activities include customer technical support such as cell processing techniques, instrumentation training and application support. Most of our research and development operations are conducted in our Maryland facility.

We have made substantial investments in product and technology development since our inception. Research and development expenses totaled \$23.8 million and \$19.5 million in the years ended December 31, 2023 and 2022, respectively.

We expect our research and development expenses to increase significantly for the foreseeable future as we develop data supporting the use of our products in various applications and continue to enhance our existing products as well as develop new products for our current and new markets.

## **Manufacturing and Supply**

We design and develop our PA disposables and conduct final functional testing in our Maryland facility. PAs are manufactured both in our Maryland facility and at a third-party manufacturer. In addition, we design, develop and manufacture our ExPERT instruments in-house. Our in-house PA manufacturing and design function is certified as ISO 9001 compliant and our manufacturing facility and controlled-access shipping, receiving and storage spaces are located at our current headquarters in Maryland. We relocated our operations, including inventory and manufacturing, to a significantly larger space in a new facility during 2022, as described more fully under Item 2 hereof.

## Instruments

Our range of ExPERT instruments are manufactured, tested and shipped from our Maryland facility. Several custom components of our ExPERT instruments are manufactured by third-party suppliers. The assembly of technology-sensitive components and the final assembly is completed in-house. Presently, our Maryland manufacturing facility can support the production of ExPERT instruments in excess of anticipated demand, and we plan to continue obtaining the space and staffing necessary to meet customer demand for the foreseeable future.

## **Processing Assemblies**

Our PAs are only available for purchase directly from us and our third-party distributors and are designed for use only with our instruments. The PAs are designed, developed, and shipped from our headquarters facility. We outsource supply and manufacturing of key PA components. Final clean-room disposables assembly is performed at our headquarters facility and at a third party. In-house cleanroom PA assembly activities were initiated in 2022 to enhance operational control over quality, expand capacity, enable automation implementation, provide for multiple manufacturing sites and improve other areas of operations. In addition, in-house manufacturing allows research and development teams located in the same facility to more rapidly develop new products and enhancements.

## Supply

For both instrument and PA manufacturing, we regularly assess our supply chain to ensure our ability to respond to customer demand for our products. We have relationships with multiple custom parts manufacturers and electronics suppliers that can provide components for our instruments, including components currently provided by a single source. Approximately 56% of inventory for the year ended December 31, 2023 was purchased from one supplier. Single source suppliers are chosen for their business stability and scalability to minimize risk. If a single source supplier has a part or process that is time-consuming to transfer to another supplier, our approach is to hold enough inventory of that part to allow adequate time for technical transfer and qualification wherever possible. Our ongoing strategy is to maintain adequate levels of inventories at all times and we plan to continue the diversification of our supply chain as we scale. This inventory strategy was designed to minimize supply chain risk and as a result we are currently able to ship on demand and to date have never had a backorder for a product.

## Competition

The life sciences market is highly competitive and dynamic, reflecting rapid technological evolution and continually evolving customer requirements. There are other companies, both established and early-stage, that have or are developing electroporation and other non-viral delivery technologies that could be applicable to both bioprocessing and cell engineering, and who are or may compete directly with our business. These companies include Lonza Group AG, Thermo Fisher Scientific Inc., Miltenyi Biotec, Bio-Rad Laboratories, Inc. and Harvard Biosciences Inc. (BTX), as well as several other smaller companies, including spinouts from academic labs.

Some of these companies may have substantially greater financial and other resources than us, including larger research and development staff or more established sales forces. Other competitors are in the process of developing novel technologies for the life sciences market which may lead to products that rival or replace our products.

For further discussion of the risks we face as a result of competition, see "Risk Factors—Risks Related to Our Business and Growth Strategy—We may be unable to compete successfully against our existing or future competitors."

#### **Intellectual Property**

Our long-standing intellectual property strategy has been to obtain patent protection in relevant jurisdictions over our instruments and related methods, as well as design patents covering the ExPERT system. As part of this strategy, we have focused on obtaining protection for our non-viral delivery platform to the extent possible, particularly in the United States and other key jurisdictions of commercial value. As of March 1, 2024, we have more than 150 granted U.S. and foreign patents, including in Australia, Canada, Japan, China, South Korea, and certain countries in Europe, as well as over 95 pending patent applications worldwide. Our portfolio protects our core technology, the Flow Electroporation® process, the processing assemblies and consumables, control and process elements, and application methods of using our non-viral delivery platform. The protection over our instruments and related methods is estimated to last through at least 2028 and through 2034 for our electroporation applications. Our design protection covering the ExPERT system has the potential to provide protection through at least 2036.

In addition to our granted patents and filed applications, we maintain protection over a number of trade secrets related to our cell processing technology and other core technology areas, including our electroporation protocols, pulsing patterns, proprietary buffer, and other formulations we have developed. Our years of accumulated know-how together with the technical expertise of our employees provide us with a competitive advantage. We use this know-how and technical expertise to optimize, revise and improve our proprietary methods and protocols, such as cell handling and preparation techniques unique to different cells and target molecules, which we confidentially share with our customers.

We maintain the confidentiality of our trade secrets, know-how and proprietary methods and protocols to protect our intellectual property from competitors including through confidentiality provisions in our agreements with our SPL partners and execution of non-disclosure agreements with prospective clients. One key element of this protection is our FDA Master File and Technical Files described in more detail below, which allow us to submit to the regulatory authorities confidential detailed information about our ExPERT system and disposables. The relevant submission can be referenced by our customers or licensees to support their own regulatory filings without the need for us to disclose the confidential information contained in the FDA Master File and Technical Files.

We also seek to protect our brand through the procurement of trademark rights. As of March 1, 2024, we owned 17 registered trademarks in the United States, over 190 registered foreign trademarks, 13 pending U.S. trademark applications, and more than 30 pending foreign trademark applications. This collection includes trademarks for our company name, logos and stylized versions of our ExPERT product line names. In order to supplement the protection of our brand, we maintain registration of several internet domain names.

## **Government Regulation**

The FDA and other federal, state, and local governmental authorities, as well as their foreign equivalents, regulate, among other things, the research, development, testing, manufacturing, safety, effectiveness, clearance, approval, labeling, packaging, quality control, storage, recordkeeping, advertising, promotion, marketing, distribution, post-market monitoring and reporting, as well as import and export of technologies including biological and drug products.

Our biopharmaceutical and life sciences customers are subject to extensive regulations by the FDA and similar federal, state, and local authorities, as well as their foreign equivalents, regarding the conduct of preclinical studies and clinical trials, in the manufacture of product candidates and products for use in humans (i.e., "Good Manufacturing Practice" laws and regulations) and the marketing authorization and commercialization of biological and drug products.

The activities of sponsors, applicants and manufacturers are subject to regulation of those jurisdictions where the research or manufacturing occur, and also jurisdictions for which applications are planned or have been made and the product is intended to be marketed.

Although our products are not intended to treat patients directly, they are used in manufacturing therapeutics by our customers to treat patients. Therefore, our customers will generally assess our products for sufficiency in meeting their regulatory needs, and may impose rigorous quality or other regulatory compliance requirements on us as their supplier through supplier qualification processes and customer contracts.

We have established a quality management system (under ISO 9001:2015 standards) which is designed to respond to customer expectations and needs and support customer adherence to applicable regulatory requirements. The technologies we offer for potential use by customers in a cGMP environment are produced under this ISO 9001:2015 quality management system.

## Master Files and Technical Files to Support Customer Regulatory Submissions

Our core business is focused on developing our proprietary and patented electroporation technology platform, which is used by our customers in research and development applications as well as for manufacture of commercial cell therapies. In order to support our customers' use of our platform in regulatory submissions, we have submitted Master

Files to the FDA, Center for Biologics Evaluation and Research and Master Files and/or Technical Files to comparable regulatory authorities in other jurisdictions, including Canada, Japan, Australia, the United Kingdom and Austria, and provide nonexclusive Letters of Authorization to the Master or Technical Files under contractual agreements with our customers. In this way, the regulatory body may review information on our platform in the context of its utilization by our partners in regulated products, for example, as described in our customers' INDs or BLAs. We continuously update the Master and Technical Files in order to support the regulatory activities of our customers. The FDA allows Master Files, but they do not approve them. Rather, they review them in the context of evaluating the submissions by our customers that reference our files.

## U.S. Healthcare Laws and Reform

In the United States, there are federal and state healthcare laws that constrain the business or financial arrangements and relationships through which our customers who use our platform and we, if we develop research, sell, market and distribute products. Such laws include federal and state anti-kickback laws, false claims laws, transparency laws and health information privacy and security laws. Violations of these laws by our customers who are subject thereto can lead to significant administrative, civil and criminal penalties, including sanctions, damages, disgorgement, monetary fines, possible exclusion from participation in government healthcare programs such as Medicare and Medicaid, imprisonment, additional reporting requirements and/or oversight obligations, contractual damages, reputational harm, diminished profits and future earnings and curtailment or restructuring of operations.

Additionally, in the United States and some foreign jurisdictions there have been, and continue to be, several legislative and regulatory changes and proposed reforms of the healthcare system in an effort to contain costs, improve quality, and expand access to care, including the proposed modification to some of the aforementioned laws. In the United States, there have been and continue to be a number of healthcare-related legislative initiatives that have significantly affected the healthcare industry. These reform initiatives may, among other things, result in modifications to the aforementioned laws and/or the implementation of new laws affecting the healthcare industry. Similarly, a significant trend in the healthcare industry is cost containment. Third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. Our customers and collaborators' ability to commercialize their products successfully, will depend in part on the extent to which coverage and adequate reimbursement for these products will be available from third-party payors. As such, cost containment reform efforts may result in an adverse effect on our operations.

## The Foreign Corrupt Practices Act

The Foreign Corrupt Practices Act ("FCPA"), prohibits any U.S. individual or business from paying, offering, or authorizing payment or offering of anything of value, directly or indirectly, to any foreign official, political party or candidate for the purpose of influencing any act or decision of the foreign entity in order to assist the individual or business in obtaining or retaining business. The FCPA also obligates companies whose securities are listed in the United States to comply with accounting provisions requiring the company to maintain books and records that accurately and fairly reflect all transactions of the corporation, including international subsidiaries, and to devise and maintain an adequate system of internal accounting controls for international operations.

## Data Privacy and Security Laws and Regulations

In the ordinary course of business, we collect, receive, store, process, generate, use, transfer, disclose, make accessible, protect, secure, dispose of, transmit, and share (collectively, process) personal information, such as clinical trial data and other health data. Accordingly, we may be subject to numerous data privacy and security obligations, including federal, state, local, and foreign laws, regulations, guidance, industry standards, external and internal privacy and security policies, contractual requirements and other obligations related to data privacy and security. These frameworks are evolving and may impose potentially conflicting obligations. Such obligations may include, without limitation, the Federal Trade Commission Act, the California Consumer Privacy Act of 2018, as amended by the California Privacy Rights Act of 2020 ("CPRA") (collectively, "CCPA"), the European Union's General Data Protection

Regulation 2016/679 ("EU GDPR"), the EU GDPR as it forms part of United Kingdom law by virtue of section 3 of the European Union (Withdrawal) Act 2018 ("UK GDPR"), the ePrivacy Directive, and wiretapping laws. Further, the federal Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), as amended by the Health Information Technology for Economic and Clinical Health Act ("HITECH"), imposes specific requirements relating to the privacy, security, and transmission of individually identifiable health information. In addition, several states within the United States, such as Virginia, Colorado, Connecticut, and Utah, have enacted comprehensive data privacy laws, and similar laws are being considered at the federal, state, and local levels.

The EU GDPR, UK GDPR, and CCPA are examples of the increasingly stringent and evolving regulatory frameworks related to personal information processing that may increase our compliance obligations and exposure for any noncompliance. European data privacy and security laws (including the EU GDPR and UK GDPR) impose significant and complex compliance obligations on companies that are subject to those laws, notably with respect to the processing of health-related data from European Economic Area ("EEA") or United Kingdom-based individuals. Additionally, the CCPA applies to personal information of consumers, business representative, and employees who are California residents, imposes specific requirements on covered businesses, provides for administrative fines of up to \$7,500 per violation and allows private litigants affected by certain data breaches to recover significant statutory damages. In addition, the CPRA expanded the CCPA's requirements. Furthermore, U.S. federal and state consumer protection laws may require us to publish statements that accurately and fairly describe how we handle personal information and choices individuals may have about the way we handle their personal information.

See the section titled "Risk Factors – Risks Related to Our Regulatory Environment and Our Industry" for additional information about the laws and regulations to which we are or may become subject and about the risks to our business associated with such laws and regulations.

## **Employees and Human Capital**

As of December 31, 2023, we had 143 full-time employees, 81 of whom have advanced degrees, including 29 with Ph.D. degrees.

Our human capital resources objectives include, as applicable, identifying, recruiting, retaining, training, incentivizing and integrating our existing and new employees, advisors and consultants. We have implemented an equity incentive plan, the principal purposes of which are to attract, retain and reward personnel through the granting of equity-based compensation awards in order to increase shareholder value and the success of our company by motivating such individuals to perform to the best of their abilities and achieve our objectives. More information about our equity incentive plan will be available in our proxy statement for the 2024 annual meeting of stockholders.

None of our employees is represented by a labor organization or under any collective-bargaining arrangements. We consider our employee relations to be good.

#### **Corporate Information**

We were incorporated under the laws of the State of Delaware in July 1998 under the name Theramed, Inc. and changed our name to MaxCyte, Inc. in 2001. Our principal executive offices are located at 9713 Key West Avenue, Suite 400, Rockville, Maryland 20850, and our telephone number is (301) 944-1700.

#### **Available Information**

Our website address is www.maxcyte.com. In addition to the information about us and our subsidiaries contained in this Annual Report, information about us can be found on our website. Our website and information included in or linked to our website are not part of this Annual Report.

Our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Exchange Act are available free of charge through our website as soon as reasonably practicable after they are electronically filed with or furnished to the SEC. The SEC maintains an internet site that contains reports, proxy and information statements and other information that we file electronically with the SEC. The address of the SEC's website is www.sec.gov.

#### Item 1A. Risk Factors

You should consider carefully the following risks and other information contained in this Annual Report on Form 10-K, including the section of this report captioned "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our financial statements and related notes. If any of the events contemplated by the following discussion of risks should occur, our business, results of operations, financial condition and growth prospects could suffer significantly. The risks below are not the only ones we face. Additional risks that we currently do not know about or that we currently believe to be immaterial may also impair our business.

## Risks Related to Our Business and Growth Strategy

We are a cell engineering and life sciences company and have incurred significant losses since our inception, and we expect to incur losses for the foreseeable future. We have limited product offerings approved for commercial sale and may never achieve or maintain profitability.

We are a cell engineering and life sciences company focused on advancing the discovery, development and commercialization of next-generation cell-based medicines. The biopharmaceutical development industry, where the majority of our customers operate, is a highly speculative undertaking and involves a substantial degree of risk. We have incurred significant losses since inception and have financed our operations principally through private financings and public offerings of our securities. We have historically relied on sales and licensing of our instruments, as well as sales of our portfolio of single-use disposable PAs for the significant majority of our revenue. We may be unable to sell or license our instruments to new customers and existing customers may cease or reduce their utilization of our instruments or fail to renew licenses of our instruments. Our net losses were \$37.9 million and \$23.6 million for the years ended December 31, 2023 and 2022, respectively. As of December 31, 2023, we had an accumulated deficit of \$175.8 million. Our losses have resulted principally from expenses incurred for research and development for our cell engineering platforms and from sales and marketing costs, manufacturing expenses, management and administrative costs as well as other expenses that we have incurred while building our business infrastructure.

We expect that our expenses and operating losses may continue for the foreseeable future as we expand our research and development efforts, expand the capabilities of our cell engineering platforms and operate as a public company in the United States. We anticipate that our expenses will increase as we:

- continue to advance our *ex vivo* cell engineering platforms and develop new technologies related to our platform;
- acquire and license technologies aligned with our ex vivo cell engineering platforms;
- expand our operational, financial and management systems and increase personnel, including staff to support our research and development, manufacturing and commercialization efforts;
- continue to develop, prosecute and defend our intellectual property portfolio; and
- incur additional legal, accounting and other expenses in operating our business, including the additional costs associated with operating as a public company in the United States.

We have devoted a significant portion of our financial resources and efforts to building our organization, developing our *ex vivo* cell engineering platforms, acquiring technology, building out our manufacturing capabilities, organizing and staffing the company, business planning, establishing our intellectual property portfolio, raising capital, securing license and partnership arrangements with customers and providing general and administrative support for these operations.

To become and remain profitable, we must succeed in realizing meaningful precommercial milestone payments from our current SPLs and potentially secure future commercial partnership, licensing or collaboration arrangements for use of our cell engineering platforms and similar arrangements for cell therapy programs in development that have not yet been partnered. This will require us to be successful in a range of challenging activities, including continuing to develop our technology and products, accessing, developing and advancing manufacturing capacity, advancing our sales and marketing capabilities and commercializing and selling our products. We may never succeed in any or all of these activities and, even if we do, we may never generate a level of revenue that is sufficient to achieve profitability. Even if we do achieve profitability, we may not be able to sustain profitability or meet outside expectations for our financial results, including profitability. If we are unable to achieve or sustain profitability or to meet outside expectations for our financial results, the value of our shares of common stock could be materially adversely affected.

We are highly dependent on a limited number of product offerings. Our revenue has been primarily generated from the sale and licensing of our instruments, as well as sales of single-use disposable PAs, which require a substantial sales cycle and are prone to quarterly fluctuations in revenue, as well as revenues earned based upon customer clinical development progress events which are outside of our control and highly variable from period to period.

Our ExPERT technology platform and family of instruments was commercially launched in April 2019 with a new instrument launched in late 2022. Sales and licensing of ExPERT technology systems and related instruments together accounted for 45% and 51% of our revenue for the years ended December 31, 2023 and 2022, respectively. We expect that, for at least the foreseeable future, sales and licensing of our ExPERT technology systems will continue to account for a substantial portion of our revenue. The sales cycle for our cell engineering instruments is complex and can take up to 12 months or longer to complete.

Material, one-time milestone payments earned as SPL partners achieve clinical progress are also a significant portion of our revenue, although such milestone payments are not in our control, are unpredictable because of the early-stage nature of cell therapy clinical development, and may contribute materially to the volatility of our revenue. As a result of our lengthy and unpredictable sales cycle, we may be prone to quarterly fluctuations in our revenue. Quarterly fluctuations may make it difficult for us to predict our future operating results. Consequently, comparisons of 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.

As a result of variability and unpredictability, we may also fail to meet the expectations of industry or financial analysts or investors for any period. If our revenue or operating results fall short of the expectations of analysts or investors or any guidance we may provide, or if the guidance we provide falls short of the expectations of analysts or investors, the price of our common stock could decline substantially. Such a stock price decline could occur even when we have met or exceeded any previously publicly stated guidance we may have provided.

## We may be unable to successfully execute on our growth strategy.

We intend to grow our business and market opportunity by continuing to invest in technology and scientific innovation, broadening our distribution capabilities to expand our installed base of ExPERT products, pursuing SPLs with target customers, expanding our commercial infrastructure and considering opportunistic investments, partnerships and acquisitions, among other initiatives. Each of these growth strategies will require considerable time and resources, and we may not be successful in executing any or all of these strategies.

One of the components of our growth strategy is to sell our recently launched ExPERT VLx platform for large-scale bioprocessing applications, including viral vector production in suspension cell cultures and rapid production of proteins,

including monoclonal antibodies. The success of the VLx, including new engineering modifications to the platform, may depend in part on the availability, compatibility and capability of appropriate technologies upstream and downstream of electroporation to support potential large-scale applications enabled by the VLx platform, our ability to develop and launch GMP-compliant processing assemblies, and willingness of customers to adopt the VLx for new applications. We expect that additional investment will be needed to build out process development capabilities, manufacturing capacity, new processing assembly design and the addition of large-scale bioprocessing-specific field resources and those investments may not be successful. Further, we could encounter delays and setbacks in implementing engineering modifications necessary for certain large-scale applications, resulting in delayed acceptance by future customers and partners of such a large-scale system. In addition, the sales and implementation cycles of customers for such a large-scale platform may require more time than originally assumed as we may encounter delays in acceptance by potential customers for the VLx platform in large-scale applications, which could negatively impact forecasted revenues.

Another component of our growth strategy is expanding our SPL model, through which we build collaborative relationships with our customers as we facilitate their efforts to bring critical cell-based medicines to market. Even if we are able to enter into additional future SPL arrangements and similar arrangements for future therapeutic products that have not yet been partnered, there can be no assurance that any of the therapeutic products that are being or might be developed by our partners using our technology will continue to advance through clinical development, receive regulatory approvals or be successfully developed into commercially viable products. As a result, we may suffer setbacks in increasing awareness and adoption of our products in addition to the material impact on our financial results as a result of milestones not being realized and leased instruments being returned. Further, setbacks in the clinical trials of our current or future partners, such as serious adverse events, including patient deaths, could significantly impact capital available to customers and our ability to enter into future SPL agreements with new therapeutic product companies.

Our growth strategy also involves expanding our international operations. In addition to risks associated with international operations in general, we will also need to navigate complex foreign regulatory requirements with which we may not be familiar or have experience. To operate successfully, or for our partners to obtain regulatory approval in other countries, we must comply with numerous and varying regulatory requirements imposed by such countries regarding safety, efficacy, manufacturing, clinical trials, commercial sales, pricing and distribution of our products. Although our partners have historically been able to reference our FDA Master File in the United States and our Master and Technical Files in some other countries in the course of clinical development of their therapeutic products, we cannot ensure that we will obtain or establish a regulatory Master or Technical File in other countries. If we fail to establish a regulatory Master or Technical File in any jurisdiction, this could make customers in such jurisdictions less likely to adopt our instruments, and the geographic market for our products could be limited.

We believe there are several opportunities to grow our sales and product line. However, we have limited financial and managerial resources, and we may forgo or delay pursuit of growth opportunities that later prove to have greater value to our business. Our resource allocation decisions may cause us to fail to capitalize on viable opportunities, and we could spend resources on strategies that are not ultimately successful.

Our estimates of market opportunity and forecasts of market growth may prove to be inaccurate, and even if the markets in which we compete are as large as we estimate or achieve their forecasted growth, our business could fail to grow at projected rates, if at all.

Market opportunity estimates and growth forecasts on which we develop our business strategies, including those estimates and forecasts we have generated ourselves, are subject to significant uncertainty and are based on assumptions and estimates that may not prove to be accurate. The variables that go into the calculation of our market opportunity are subject to change over time, and there is no guarantee that any particular number or percentage of customers covered by our market opportunity estimates will purchase our products or generate any particular level of revenue for us at all. Any expansion in our market depends on a number of factors, including the cost and perceived value associated with our products and those of our competitors. Even if the markets in which we compete meet our size estimates and growth forecasts, our business could fail to grow at projected rates, if at all. Our growth is subject to many factors, including our success in implementing our business strategy, which is subject to many risks and uncertainties.

We rely on assumptions, estimates and data to calculate certain of our key metrics, and real or perceived inaccuracies in such metrics may harm our reputation and negatively affect our business.

In addition to our financial results, our management regularly reviews a number of operating and financial metrics, including a breakdown of product and leased revenue into instrument sales, PAs, leased revenue (recurring revenue), product placements, cumulative product placements, revenue by customer market (cell therapy and drug discovery), status or number of installed instruments, SPLs, program licenses (research, clinical and SPL), and potential precommercial milestones, to evaluate our business, measure our performance, identify trends affecting our business, formulate financial projections and make strategic decisions. As both our business and the industry in which we operate evolve, the metrics by which we evaluate our performance may also change. In addition, while the calculation of the metrics we use is based on what we believe to be reasonable estimates, our internal tools are not independently verified by a third party and have a number of limitations and, furthermore, our methodologies for tracking these metrics may change over time.

## Our future success is dependent upon our ability to increase penetration in our existing markets and expand into adjacent markets.

Our customer base includes biopharmaceutical and biotechnology companies and academic institutions focused on cell-based therapeutics. Our success will depend in part upon our ability to increase our market penetration by expanding sales to existing customers and acquiring new customers and partnerships within our existing markets, and our ability to market new products and applications to existing and new customers. Attracting new customers and introducing new products and applications require substantial time and expense. For example, it may be difficult to identify, engage and market to customers who are unfamiliar with our current products. We cannot guarantee that we will be able to further penetrate our existing markets or that these markets will be able to sustain our current and future product and service offerings. Any failure to increase penetration in our existing markets could adversely affect our ability to improve our operating results.

Our success will also depend on our ability to further expand into adjacent markets, such as penetrating non-commercial customer opportunities, including translational academic centers. Our inability to further expand in adjacent markets and attract new customers could adversely affect our ability to improve our operating results.

Due to the significant resources required to enable access in new markets, we must make strategic and operational decisions to prioritize certain markets, technology offerings and partnerships, and there can be no assurance that we will expend our resources successfully or in a way that results in meaningful revenue or capitalizes on potential new markets.

We believe our platform has potential applications across a wide range of markets, and we have targeted certain markets in which we believe we have a higher probability of success or revenue opportunity or for which the path to commercialize products and realizing or achieving revenue is shorter. For example, we believe our products have applications in markets for engineered cell therapies in immuno-oncology and inherited disorders. We seek to continue to prioritize opportunities and allocate our resources among our programs to maintain a balance between advancing near-term opportunities and exploring additional markets for our technology. However, due to the significant resources required for the development of new markets, we must make decisions regarding which markets to pursue and the amount of resources to allocate to each. Our decisions concerning the allocation of research, development, collaboration, management and financial resources toward particular markets or workflows may not lead to the development of any viable product and may divert resources away from other opportunities that may ultimately be better-suited to our business. Similarly, our potential decisions to delay, terminate or collaborate with third parties in respect of certain markets may subsequently also prove to be suboptimal and could cause us to miss out on valuable opportunities. In particular, if we are unable to develop additional relevant products and applications for markets such as cell therapy or large-scale bioprocessing, it could slow or stop our business growth and negatively impact our business, financial condition, results of operations and prospects.

Our business is dependent on adoption of our products by organizations such as biopharmaceutical companies and academic institutions for their research and development activities focused on cell-based therapeutics. If organizations such as biopharmaceutical companies and academic institutions are unwilling to change current practices to adopt our products, it may negatively affect our business, financial condition, prospects and results of operations.

Our primary strategy to grow our revenue is to market our products across key stakeholders in cell-based therapeutics, such as biopharmaceutical companies and academic institutions. Most of our potential customers already use expensive research systems in their laboratories and may be reluctant to replace those systems. While the number of customers using our products has increased in recent years, many biopharmaceutical companies and academic institutions have not yet adopted our products, and such institutions and companies may choose not to adopt our products for a number of reasons, including:

- inability to convince potential customers that our products are an attractive alternative to existing technologies and reluctance of potential customers to replace those existing technologies;
- inadequate recruiting or training of talented sales force and field application scientists in existing and new markets to facilitate outreach and further adoption and awareness of our products;
- lack of experience of potential customers with our products for cell engineering;
- perceived inadequacy of evidence supporting benefits or cost-effectiveness of our products over existing alternatives or negative publicity regarding cell engineering technologies;
- liability risks generally associated with the use of new products and processes;
- time and training required for potential customers to use and validate our products;
- delays in research and development activities involving our products;
- competing products and alternatives; and
- introduction of other novel alternative products for cell engineering.

In addition, our customers may experience a change of control or otherwise consolidate with other biopharmaceutical companies and academic institutions. If, as a result of such change of control, our customers choose or are forced to modify or terminate cell therapy strategies, adopt other products, or otherwise reduce their use of our products, our ability to execute our growth strategy could be impaired, which may negatively affect our business, financial condition, prospects and results of operations.

We believe that educating notable industry key opinion leaders ("KOLs"), and representatives of biopharmaceutical companies and academic institutions about the merits and benefits of our products for Flow Electroporation and cell engineering is one of the key elements of increasing the adoption of our products. If these KOLs, institutions and companies do not adopt our products for any reason, including those listed above, acceptance and adoption of our products may be slowed and our ability to execute our growth strategy may be impaired, which may negatively affect our business, financial condition, prospects and results of operations.

## We may be unable to compete successfully against our existing or future competitors.

We operate in a highly competitive market characterized by rapid technological change, evolving industry standards, changes in customer needs, emerging competition, new product introductions and strong price competition. We currently compete with both established and early-stage life sciences technologies companies that design,

manufacture and market electroporation and other non-viral cell engineering technology based on efficacy, price, ease of use, reimbursement and customer support services.

Our success depends, in part, on our ability to maintain a competitive position in the development of technologies, enhancements and products for use by our customers. Many of the companies developing or marketing competing or alternative products have competitive advantages when compared to us, including:

- greater financial and human resources for product development, sales and marketing;
- greater domestic and international name recognition and more product familiarity among users;
- broader and more established relationships with pharmaceutical companies and academic institutions;
- broader product lines and the ability to offer lower prices or rebates, integrate technologies more successfully
  to offer better workflow solutions, bundle products to offer greater discounts or incentives or offer more
  attractive milestone and partnership terms;
- broader intellectual property protection for their technology and products;
- larger sales forces and broader and more established domestic and international sales and marketing and distribution networks; and
- more experience in conducting research and development, manufacturing and preparing regulatory submissions, both in the United States and in foreign jurisdictions.

We primarily compete against products marketed by Lonza Group AG, Thermo Fisher Scientific Inc., Miltenyi Biotec, Bio-Rad Laboratories, Inc. and Harvard Bioscience, Inc. (BTX), as well as several other smaller companies, including spinouts from academic labs.

In addition to already marketed products, we also face competition from products that are or could be under development and that target the same applications as our products or applications that we may address in the future. Such product candidates may be developed by the above-mentioned entities and others, including life sciences tools companies, biotechnology companies, pharmaceutical companies, private and public research institutions and academic institutions or may come about as the result of consolidation in our industry. Our competitors may develop and patent processes or products earlier than we can and develop more effective and/or less expensive products or technologies that render our technology or products obsolete or non-competitive. Despite the steps we have taken to maintain and protect our intellectual property, competitors may nevertheless attempt to, or succeed in, developing similar electroporation technology, including Flow Electroporation. We also compete with other organizations in recruiting and retaining qualified scientific and management personnel. If our competitors are more successful than us in these matters, we may be unable to compete successfully against our existing or future competitors.

Our business currently depends significantly on research and development spending by biopharmaceutical companies, a reduction in which could limit demand for our products and adversely affect our business and operating results.

A portion of our revenue is derived from sales to biopharmaceutical companies and academic institutions. Much of their funding is, in turn, provided by public and private financings, including investments from venture capital funds and, for public companies, the capital markets. In the near term, we expect that a portion of our revenue will continue to be derived from sales to biopharmaceutical companies and academic institutions. Accordingly, the spending policies and practices of these customers—which have been impacted by market conditions and other factors—could have a significant effect on the demand for our products. In addition, the demand for our products may depend upon the research and development budgets of these customers, which are impacted by factors beyond our control, such as:

- macroeconomic conditions, and the political climate;
- investor confidence in the biopharmaceutical industry and the amount of capital such investors provide to our potential customers;
- reduced pricing of approved therapeutics;
- scientists' and customers' opinions of the utility of new products or services;
- changes in the regulatory environment;
- differences in budgetary cycles;
- competitor product offerings or pricing;
- merger and acquisition activity within the industry;
- market-driven pressures to consolidate operations and reduce costs;
- market acceptance of relatively new technologies, such as ours;
- clinical trial or milestone failures that impact our customers' ability to raise capital; and
- inability to sustain capital requirements or bankruptcy.

In addition, while the majority of our revenues are derived from biopharmaceutical customers, various state, federal and foreign agencies that provide grants and other funding may be subject to stringent budgetary constraints that could result in spending reductions, reduced grant making, reduced allocations or budget cutbacks, which could jeopardize the ability of these customers, or the customers to whom they provide funding, to purchase our products. For example, congressional appropriations to the National Institutes of Health ("NIH") have generally increased year-over-year in recent years, but the NIH also experiences occasional year-over-year decreases in appropriations. There is no guarantee that NIH appropriations will not decrease or cease in the future. A decrease in the amount of, or delay in the approval of, appropriations to NIH or other similar United States or foreign organizations, such as the Medical Research Council in the United Kingdom, could result in fewer grants benefiting life sciences research. These reductions or delays could also result in a decrease in the aggregate amount of grants awarded for life sciences research or the redirection of existing funding to other projects or priorities, any of which in turn could cause our customers and potential customers to reduce or delay purchases or licensing of our products.

Our operating results may fluctuate substantially due to the potential changes in our customers' resources as described above. 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, operating results and financial condition.

## Our current research and development efforts may not produce significant revenue for several years, if at all.

Developing our products is expensive, and the investment in product development may involve a long payback cycle. Our investment in research and development may not result in the data we hope to develop to support marketing of our products or in marketable products or may result in products that take longer to generate revenue, or generate less revenue, than we anticipate. For the years ended December 31, 2023 and 2022, our research and development expenses were \$23.8 million and \$19.5 million, respectively, or approximately 58% and 44%, respectively, of our total revenue. Our future plans include increased significant investments in research and development of product opportunities for expansion of our products and new application areas for our products. We believe that we must continue to dedicate a

significant amount of resources to our research and development efforts to maintain our competitive position. However, we may not receive significant revenue from these investments for several years, if at all.

## Our international operations may raise additional risks, which could have an adverse effect on our operating results.

International customers have typically accounted for a meaningful portion of our revenue. For the year ended December 31, 2023, approximately 21% of our revenue was derived from international customers, with the most significant markets being the United Kingdom, Switzerland, Canada and China. We expect that our international revenue and operations will continue to expand in the future. Our international operations are subject to a variety of risks that we do not face in the United States, including:

- difficulty of increased travel, infrastructure and legal compliance costs associated with developing international revenue;
- difficulties in enforcing contracts, collecting accounts receivable and longer payment cycles, especially in emerging markets;
- general economic conditions in the countries in which we operate;
- additional withholding taxes or other taxes on our foreign income, and tariffs or other restrictions on foreign trade or investment;
- compliance with data privacy and security requirements in foreign jurisdictions in which we operate;
- imposition of, or unexpected adverse changes in, foreign laws or regulatory requirements, many of which differ from those in the United States;
- costs and delays associated with developing products or technology in multiple languages, such as the software embedded in our products;
- compliance with foreign technical standards;
- increased length of time for shipping and acceptance of our products;
- increased exposure to foreign currency exchange rate risk;
- uncertainties related to geopolitical and economic environments;
- reduced protection for intellectual property rights in some countries, particularly in China; and
- political unrest, war, incidents of terrorism, or responses to such events.

In connection with the ongoing armed conflict between Russia and Ukraine, the U.S. government, United Kingdom and European Union countries have imposed enhanced export controls on certain products and sanctions on certain industry sectors and parties in Russia and the regions of Donetsk and Luhansk, as well as enhanced export controls on certain products and industries. These and any additional sanctions and export controls, as well as any counter responses by the governments of Russia or other jurisdictions, could adversely affect, directly or indirectly, the levels of government spending or the global supply chain. Conflicts between Russia and Ukraine, in the Middle East, or elsewhere may directly or indirectly affect our supply chain, which may lead to negative implications on the availability and prices of raw materials, energy prices, and our customers, as well as the global financial markets. Although we do not currently conduct any operations in Russia, Ukraine or the Middle East further escalation of geopolitical tensions could have a broader impact that expands into other markets where we do business or conduct operations, which could adversely affect our business and sales of our products.

As we continue to expand our business globally, our success will depend, in large part, on our ability to anticipate and effectively manage these and other risks associated with our international operations.

Our overall success in international markets depends, in part, on our ability to succeed in differing legal, regulatory, economic, social and political conditions. We may not be successful in developing and implementing policies and strategies that will be effective in managing these risks in each country where we do business. Our failure to manage these risks successfully could harm our international operations, reduce our international sales and increase our costs, thus adversely affecting our business, operating results and financial condition.

#### If we fail to offer high-quality customer service, our business and reputation could suffer.

We differentiate ourselves from our competition through our commitment to an exceptional customer experience. Accordingly, high-quality customer service is important for the growth of our business and any failure to maintain such standards of customer service, or a related market perception, could affect our ability to sell products to existing and prospective customers. The number of our customers has grown significantly and such growth, as well as any future growth, may put additional pressure on our field application scientists and customer service organization. We may be unable to hire qualified staff quickly enough or to the extent necessary to accommodate increases in demand. Providing an exceptional customer experience requires significant time and resources from our customer service team. Therefore, failure to scale our customer service organization adequately may adversely impact our business results and financial condition.

Customers utilize our service teams and online content for help with a variety of topics, including how to use our products efficiently, how to integrate our products into existing workflows, and how to resolve technical, analysis and operational issues if and when they arise. While we have developed significant resources for remote training and customer service, including our virtual product demonstration process, if our customers do not adopt these resources, we may be required to increase the staffing of our customer service team, which could increase our costs. Also, as our business scales, we may need to engage third-party customer service providers, which could increase our costs and negatively impact the quality of the customer experience if such third parties are unable to provide service levels equivalent to ours.

In addition, as we continue to grow our operations and reach a global customer base, we will need to be able to provide efficient customer service that meets our customers' needs globally at scale. In geographies where we sell through distributors, we often rely on those distributors to provide customer service. If these third-party distributors do not provide a high-quality customer experience, our business operations and reputation may suffer.

## If we cannot maintain and expand current partnerships and enter into new partnerships that generate marketed licensed products, our business could be adversely affected.

We do not have our own pipeline of therapeutic candidates, and instead we focus our efforts on the development of our cell engineering offerings, including our ExPERT platform. Our partners then use our instruments and PAs for cell engineering to develop their own therapeutic candidates without our direct involvement. As a result, our success depends on our ability to expand the number and scope of our partnerships. Many factors may impact the success of these partnerships, including our ability to perform our obligations, our partners' satisfaction with our products, competitive offerings of other companies, our partners' ability to successfully develop, secure regulatory approval for and commercialize therapeutic candidates using our products, our partners' internal priorities (including fluctuations in research and developments budgets), our partners' resource allocation decisions and competitive opportunities, disagreements with our partners, the costs required of either party to the partnerships and related financing needs, and operating, legal and other risks in any relevant jurisdiction, as well as severe adverse events in cell therapy trials regardless of association with our partners.

We engage in conversations with companies regarding potential partnerships on an ongoing basis. These conversations may not result in commercial agreement. Even if agreement is reached, the resulting relationship may not be successful, including due to factors beyond our control, such as our partners' inability to successfully develop or

commercialize their therapeutic candidates. In such circumstances, we may not generate any substantial revenues from such a collaboration in the form of milestone payments, royalties or otherwise. Speculation in the industry about our existing or potential partnerships can be a catalyst for adverse speculation about us which can adversely affect our reputation and our business.

Further, our customers are subject to the extensive risks and uncertainties that apply to product candidates in this area including those associated with preclinical and clinical research and development and related regulatory and Institutional Review Board authorization and oversight, manufacturing challenges and compliance standards, the data requirements and review process for seeking marketing authorization, and the potential for safety and efficacy concerns to emerge at any stage of product development and even after approval.

If the quality or delivery of our products does not meet our customers' expectations and needs relative to their regulatory obligations, our reputation could suffer and ultimately our sales and financial results could be negatively impacted.

Our customers operate in highly regulated industries. In the course of conducting our business, our customers will expect us to adequately address any quality issues suspected to be associated with our products, including defects in our engineering, design, manufacturing and delivery processes, as well as defects in third-party components included in our products. The occurrence of defects in our products may increase as we continue to introduce new products and rapidly scale up manufacturing to meet potentially increased customer demand. Although we have established internal procedures designed to reduce the risks of product quality issues that may arise, there can be no assurance that we will be able to eliminate or mitigate occurrences of these issues and associated potential liabilities. In addition, identifying the root cause of quality issues may be difficult, which may increase the time needed to address quality issues as they arise and increase the risk that similar problems could recur. Finding solutions to quality issues can be expensive and we may incur significant costs or lost revenue in connection with, for example, shipment holds, product recalls or other service obligations. In addition, quality issues may impair our relationships with new or existing customers and adversely affect our brand image, and our reputation could suffer, which could adversely affect our business, financial condition, results of operations, cash flows and prospects.

#### The failure of our partners to meet their contractual obligations to us could adversely affect our business.

Our reliance on our partners poses a number of additional risks, including the risk that they may not perform their contractual obligations to our standards, in compliance with applicable legal or contractual requirements, in a timely manner or at all; they may not maintain the confidentiality of our proprietary information; and disagreements or disputes could arise that could cause delays in, or termination of, the research, development or commercialization of therapeutic candidates produced using our instruments and PAs.

In addition, certain of our partners are large, multinational organizations that run many programs concurrently, and we are dependent on their ability to accurately track and make milestone payments to us pursuant to the terms of our agreements with them. Any failure by them to inform us when milestones are reached and make related payments to us could adversely affect our results of operations.

Some of our partners operate in markets subject to political and social risk, corruption, infrastructure problems and natural disasters, and are often subject to country-specific data privacy and data security risk as well as burdensome legal and regulatory requirements. Any of these factors could adversely impact their financial condition and results of operations, which could impair their ability to meet their contractual obligations to us, which may have a material adverse effect on our business, financial condition and results of operations.

Our partners have significant discretion in determining when and whether to make announcements, if any, about the status of their clinical developments and timelines for advancing collaborative programs, and the price of our common stock may decline as a result of announcements of unexpected results or developments.

Our partners have significant discretion in determining when and whether to make announcements about the status of their programs that use our technology, including their preclinical and clinical programs, such as setbacks or terminations, and timelines for advancing therapeutic candidates developed using our platform. We do not plan to disclose, and historically, have not disclosed, the development status and progress of individual therapeutic candidates of our partners. Our partners may wish to report such information more or less frequently than we prefer or may not wish to report such information at all. In addition, if partners choose to announce a collaboration with us or their progress, there is no guarantee that we will concurrently recognize any fees or that such announcement will be indicative of future fees to us, as such fees are not due to us until our partner reaches certain specific activities or clinical progress events, for example IND submissions or start of pivotal trials. The price of our common stock may decline as a result of the public announcement of unexpected results or developments in our partnerships, or as a result of our partners withholding such information.

Our partners may not achieve projected development and regulatory milestones and other anticipated key events in the expected timelines or at all, or may discontinue some or all of their programs, which could have an adverse impact on our business and could cause the price of our common stock to decline.

From time to time, we may make public statements regarding the expected timing of certain milestones and key events, as well as regarding developments and milestones under our partnerships, to the extent that our partners have publicly disclosed such information or permit us to make such disclosures. Certain of our partners have also made public statements regarding their expectations for the development of programs under partnership with us and they and other partners may in the future make additional statements about their goals and expectations for the progress of their programs and/or their partnerships with us. The actual timing of these events and any resultant revenue to us may vary dramatically due to a number of factors such as delays or failures in our or our current and future partners' therapeutic discovery and development programs and the numerous uncertainties inherent in the development of therapeutics. As a result, there can be no assurance that our partners' current and future programs will advance or be completed in the time frames we or they expect, or at all.

In addition, we have very little visibility into, or advance notice of, any changes in our partners' development timelines and expectations, which means that we may not be able to swiftly react and adapt to changed expectations related to the achievement and payment of milestones under our agreements. If our partners fail to achieve one or more of these milestones or other key events as we or they expect, our business could be materially adversely affected and the price of our common stock could decline.

Biopharmaceutical drug, biologics and therapeutics development is inherently uncertain, and it is possible that none of the drug, biologic or therapeutic candidates discovered using our platform that are further developed by our partners will receive marketing approval or become viable commercial products on a timely basis or at all.

We offer our cell engineering platform to partners who are engaged in drug, biologics and therapeutics discovery and development. These partners include large pharmaceutical companies, biotechnology companies of all sizes and non-profit and academic institutions. While we receive early payments generated through sales of our ExPERT instruments and PAs and recurring revenue through the annual licenses of the ExPERT instrument to our partners, we estimate that the vast majority of the economic value of the SPL partnerships that we enter into with our partners is in the downstream payments that are payable if certain milestones are met or approved products are sold. As a result, our future growth is dependent on the ability of our partners to successfully develop and commercialize therapies discovered or produced using our platform. Due to our reliance on our partners, the risks relating to product development, regulatory authorization or approval and commercialization apply to us derivatively through the activities of our partners. There can be no assurance that our partners will successfully develop, secure marketing approvals for and commercialize any drug, biologic or therapeutic candidates discovered or produced with our instruments. As a result, we may not realize the intended benefits of our partnerships. We have entered into 26 SPL partnerships resulting in a growing number of clinical milestone payments and the first licensed program to receive regulatory marketing approval occurred in 2023.

Due to the uncertain, time-consuming and costly clinical development and regulatory approval process, our partners may not successfully develop any drug, biologic or therapeutic candidates with our platform, or our partners may choose to discontinue the development of these candidates for a variety of reasons, including due to safety, risk versus benefit profile, exclusivity, competitive landscape, manufacturing challenges, commercialization potential, production limitations or prioritization of their resources. For product candidates of the type expected to be developed using our technology, there is the potential they could create a safety risk to patients and can also limit product efficacy. It is possible that none of these drug, biologic or therapeutic candidates will ever receive regulatory approval and, even if approved, such candidates may never be successfully commercialized resulting in clinical progress milestones and commercial sales-based payments not being earned.

Regulatory authorities have substantial discretion in the review and approval process and may refuse to accept any application or may decide that our partners' data are insufficient to support progression to further stages of preclinical or clinical development or for marketing approval and require additional preclinical, clinical or other studies. The number and types of preclinical studies and clinical trials that will be required for regulatory approval also varies depending on the product candidate (including cell therapies, for which development is inherently challenging), the disease or condition that the product candidate is designed to address, and the regulations applicable to any particular product candidate. Application of the legal and regulatory standards for approval, and the type and amount of clinical data and data supporting chemistry, manufacturing and control necessary to gain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions. It is possible that any product candidates our partners may seek to develop in the future will never obtain the appropriate, necessary regulatory approvals.

In addition, even if these drug, biologic or the apeutic candidates receive regulatory approval in the United States. our partners may never obtain approval or commercialize them outside of the United States, which would limit their full market potential and therefore may impact our ability to realize their potential downstream value. Furthermore, approved drugs, biologics or therapeutics may not achieve broad market acceptance among physicians, patients, the medical community and third-party payors, in which case revenue generated from their sales could be limited. Third-party payors may opt to implement efficacy-based payment mechanisms over a multi-year period, which could impact potential product sales in any given year. Likewise, our partners have to make decisions about which clinical stage and preclinical drug, biologic and therapeutic candidates to develop and advance, and our partners may not have the resources to invest in all of the drug, biologic or therapeutic candidates that are produced using our platform, or clinical data and other development considerations may not support the advancement of one or more drug candidates developed using our platform. Decision-making about which drug or therapeutic candidates to prioritize involves inherent uncertainty, and our partners' development program decision-making and resource prioritization decisions, which are outside of our control, may adversely affect the potential value of those partnerships. Additionally, subject to its contractual obligations to us, if one or more of our partners is involved in a business combination, the partner might deemphasize or terminate the development or commercialization of any drug, biologic or therapeutic candidate that utilizes our platform. If one of our SPL customers terminates its agreement with us, we may find it more difficult to attract new partners.

Our partners, and therefore our potential financial outcomes under our agreements, are also subject to inherent industry-wide FDA and other regulatory risk. The number of new drug applications and biologics license applications approved by the FDA varies significantly over time and if there were to be an extended reduction in the number of new drug applications and biologics license applications approved by the FDA, the industry could contract and our business could be materially harmed. Furthermore, regulatory agencies may introduce new submission requirements or implement new regulations for cell and gene therapies which could result in extended timelines for our partners, creating uncertainty or delays in achieving milestones. Such delays in these milestones could materially affect our ability to forecast and receive milestone payments outlined in our license agreements.

Our partners' failure to effectively advance, market and sell suitable drug, biologic and therapeutic candidates developed using our platform could have a material adverse effect on our business, financial condition, results of operations and prospects, and cause the market price of our common stock to decline. In addition to the inherent uncertainty in development addressed above, our ability to forecast our future revenues may be limited.

In recent periods, we have depended on a limited number of partners for our revenue, the loss of any of which could have an adverse impact on our business.

For the year ended December 31, 2023, two cell therapy companies with which we have entered into an SPL partnership accounted for 39% of our total revenue, and our five largest customers accounted for an aggregate of approximately 52% of our total revenue for the year through a combination of instrument license fees, milestones realized and processing assembly revenue. These partnerships cover a large number of programs under contract, and therefore represent a large portion of potential downstream value. In addition, our partnership agreements are typically terminable at will. As a result, if we fail to maintain our relationships with our partners or if any of our partners discontinue their programs or transition to alternative cell engineering technologies, our future results of operations could be materially and adversely affected.

An increasing portion of our revenue is derived from milestone payments from our SPL customers. Accordingly, we may be more dependent on the success of a limited number of our customers' programs than we would be if our revenue was derived more broadly from many customer contracts. The loss of any of our large customers, or significant delays or discontinuations in our customers' programs, could have an adverse effect on our ability to generate revenue.

Our customers' products or product candidates may cause undesirable side effects or have other properties that could delay or prevent their regulatory approval, limit their commercial potential or result in significant negative consequences following any potential marketing approval, which could cause our future results of operations to be materially and adversely affected.

Serious adverse events or undesirable side effects caused by our customers' products or product candidates could cause regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA, the European Medicines Agency or other authorities. Results of our customers' clinical trials could reveal a high and unacceptable severity and prevalence of side effects, toxicities or unexpected characteristics, including death.

If unacceptable side effects or deaths arise in the development of our customers' product candidates, the Institutional Review Boards at the institutions in which their studies are conducted, the FDA or any comparable foreign regulatory authority could suspend or terminate our customers' clinical trials or the FDA or other regulatory authorities could order them to cease clinical trials or deny approval of their product candidates for any or all targeted indications. Undesirable side effects or deaths in clinical trials with our customers' product candidates may cause the FDA or comparable foreign regulatory authorities to place a clinical hold on the associated clinical trials, to require additional studies or otherwise, to delay or deny approval of our customers' product candidates for any or all targeted indications. Treatment-related side effects could also affect patient recruitment or the ability of enrolled patients to complete the trial or result in potential product liability claims. In addition, these side effects may not be appropriately recognized or managed by the treating medical staff. Any of these occurrences could negatively impact the availability of capital for the broader cell therapy development market, reduce the demand for our products and harm our business, financial condition and prospects significantly.

We may pursue collaborations or licensing arrangements, joint ventures, strategic alliances, partnerships or other strategic investment or arrangements, which may fail to produce anticipated benefits and adversely affect our operations.

We may pursue opportunities for collaboration, out-license, joint ventures, acquisitions of products, assets or technology, strategic alliances or partnerships that we believe could advance our development. We may consider pursuing growth through the acquisition of technology, assets or other businesses that may enable us to enhance our technologies and capabilities. Proposing, negotiating and implementing these opportunities may be a lengthy and complex process. Other companies, including those with substantially greater financial, marketing, technology or other business resources, may compete with us for these opportunities or arrangements. We may not be able to identify, secure or complete any such transactions or arrangements in a timely manner, on a cost-effective basis on acceptable terms or at all.

We have limited experience with respect to these business development activities. Management and integration of a licensing arrangement, collaboration, joint venture or other strategic arrangement may disrupt our current operations, decrease our profitability, result in significant expenses or divert management resources that otherwise would be available for our existing business. We may not realize the anticipated benefits of any such transaction or arrangement.

Furthermore, partners, collaborators or other parties to such transactions or arrangements may fail to fully perform their obligations or meet our expectations or cooperate with us satisfactorily for various reasons and subject us to potential risks, including the following:

- Partners, collaborators or other parties have significant discretion in determining the efforts and resources that they will apply to a transaction or arrangement;
- Partners, collaborators or other parties could independently develop, or develop with third parties, services and products that compete directly or indirectly with our products or product candidates;
- Partners, collaborators or other parties may stop, delay or discontinue clinical trials as well as conduct new clinical trials by using our intellectual property or proprietary information;
- Partners, collaborators or other parties may not properly maintain or defend our intellectual property rights or
  may use our intellectual property or proprietary information in a way that gives rise to actual or threatened
  litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to
  potential liabilities;
- Disputes may arise between us and partners, collaborators or other parties that cause the delay or termination of the research, development or commercialization of product candidates, or that result in costly litigation or arbitration that diverts management's attention and resources;
- Partners, collaborators or other parties may be terminated and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable services and products; and
- Partners, collaborators or other parties may own or co-own intellectual properties covering our product candidates that results from our collaborating with them, and in such cases, we may not have the exclusive right to commercialize such intellectual properties.

Any such transactions or arrangements may also require actions, consents, approval, waiver, participation or involvement of various degrees from third parties, such as regulators, government authorities, creditors, licensors or licensees, related individuals, suppliers, distributors, shareholders or other stakeholders or interested parties. There is no assurance that such third parties will be cooperative as we desire, or at all, in which case we may be unable to carry out the relevant transactions or arrangements.

We may engage in future acquisitions that could disrupt our business, cause dilution to our stockholders and harm our financial condition and operating results.

In the future, we may acquire companies, assets or technologies in an effort to complement our existing offerings to enhance our market position. We have not made any acquisitions to date and we currently have no arrangements or commitments with respect to any acquisition. Should we choose to pursue an acquisition in the future, we may not be able to find suitable acquisition candidates and we may not be able to complete acquisitions on favorable terms, if at all. Any future acquisitions we make could subject us to a number of risks, including:

• Purchase prices we pay could significantly deplete our cash reserves, impair our future operating flexibility or result in dilution to our existing stockholders;

- We may find that the acquired company, assets or technology does not further improve our financial and strategic position as planned;
- We may find that we overpaid for the company, asset or technology, or that the economic conditions underlying our acquisition have changed;
- We may have difficulty integrating the operations and personnel of the acquired company;
- We may have difficulty retaining the employees with the technical skills needed to enhance and provide services with respect to the acquired assets or technologies;
- Acquisitions may be viewed negatively by customers, financial markets, or investors;
- We may have difficulty incorporating the acquired technologies or products with our existing products;
- We may encounter difficulty entering and competing in new product or geographic markets;
- We may encounter a competitive response, including price competition or intellectual property litigation;
- We may have product liability, customer liability or intellectual property liability associated with the sale of the acquired company's products;
- We may be subject to litigation by terminated employees or third parties;
- We may incur debt and restructuring charges;
- We may acquire goodwill and other intangible assets that are subject to impairment tests, which could result in future impairment charges;
- Our ongoing business and management's attention may be disrupted or diverted by transition or integration issues and the complexity of managing geographically or culturally diverse enterprises; and
- Our due diligence process may fail to identify significant existing issues with the target company's product
  quality, product architecture, financial disclosures, accounting practices, internal controls, legal contingencies,
  intellectual property and other matters.

Acquisitions may not generate sufficient revenue to offset the associated costs of the transactions or may result in other adverse effects, which could have a material adverse effect on our business, operating results, and financial condition. In addition, negotiations for acquisitions, collaborations or investments that are not ultimately consummated could result in significant diversion of management time, as well as substantial out-of-pocket costs, any of which could have a material adverse effect on our business, operating results and financial condition.

#### Risks Related to the Supply and Manufacturing of Our Products

We depend on continued supply of high-quality components and raw materials for our ExPERT instruments and PAs from third-party suppliers, and if shortages of these components or raw materials arise, we may not be able to secure enough components to build new products to meet customer demand or we may be forced to pay higher prices for these components.

We rely on a limited number of suppliers for certain key components utilized in the assembly of our ExPERT instruments and manufacture of our PAs and buffer, and in some cases, such as certain instrument components (*e.g.*, CPU chips or PA electrodes), we rely on a single supplier for a particular component, subassembly or consumable. Approximately 56% of our inventory purchased during the year ended December 31, 2023 was purchased from one

supplier. Although in many cases we use standard components in our products, in some cases, components may only be purchased from a limited number of suppliers or a single supplier. Identifying and qualifying alternate sources may take time and involve additional expense, and there is no guarantee that current suppliers or alternate sources will timely deliver materials that meet our needs. If our customers experience a shortage or delay in delivery of our ExPERT instruments, PAs or buffers our business could be materially and adversely impacted.

We presently do not have long-term supply contracts for these components, and none of our third-party suppliers is obligated to supply products to us for any specific period or in any specific quantities, except as may be provided for in submitted and accepted purchase orders. We are not a major customer of many of our suppliers, and these suppliers may therefore give other customers' needs higher priority than ours. Our industry has experienced component shortages and delivery delays in the past, and we may experience shortages or delays of critical components in the future as a result of strong demand in the industry, high demand in unrelated industries such as shortages of electronic components due to digitization in the automotive industry, or other factors. Many of the other components required to build our ExPERT instruments are also occasionally in short supply. Global supply chain constraints during 2021 and 2022 have resulted in some of our suppliers having to prioritize certain customers. While we seek to maintain priority with our suppliers and have not experienced significant delays to date, there can be no guarantee that we will not experience shortages as a result of supply chain issues. In addition, geopolitical tensions, and sanctions imposed in response thereto, may create new supply chain issues or exacerbate current supply chain challenges. If shortages or delays arise, we may not be able to timely secure enough components at reasonable prices or of acceptable quality to build new products, resulting in an inability to meet customer demand or our own operating goals, which could adversely affect our customer relationships, business, operating results and financial condition.

Many of the components that we use are part of the global supply chain and may be manufactured overseas. Therefore, our access to, or ability to acquire, components may be impacted by trade disputes, geopolitical conflicts, public health emergencies, or importation restrictions resulting from such trade disputes between governments. These events may result in increased tariffs, duties or taxes that will increase the cost of the components and we may have to increase the price of our products, or incur an impact on our margins, both of which can materially affect customer demand and resulting revenues.

Additionally, damage to a manufacturing facility or other property of any of our suppliers or their distribution channels due to fire, flood or other natural disaster or casualty event may have a material adverse effect on our business, financial condition and results of operations.

We have limited experience manufacturing our PAs and may be unable to manufacture our PAs in high-quality commercial quantities successfully and consistently to meet demand, which could limit our growth.

We have limited experience manufacturing our products and only began to manufacture our PAs in-house in 2022. To manufacture our PAs in the quantities that we believe will be required to meet the currently anticipated market demand, we will need to increase manufacturing capacity, which will involve significant challenges and may require additional quality controls. We may not successfully complete any required increase to existing manufacturing capacity in a timely manner, or at all.

If there is a disruption to our manufacturing operations or inventory management, we may have limited or no other means of producing our products until we resolve such issues with our manufacturing facilities, develop alternative manufacturing facilities or contract with third-party manufacturers capable of producing our products. Additionally, any damage to or destruction of our manufacturing facilities and/or inventory or equipment may significantly impair our ability to supply PAs on a timely basis. There may also be unforeseen occurrences that increase our costs, such as increased prices of the components of our PAs, changes to labor costs or less favorable terms with third-party suppliers. There can be no assurance that we will not encounter such problems in the future.

If we are unable to manufacture PAs consistently and in sufficient quantities to meet anticipated customer demand, our business, financial condition, results of operations and prospects could be harmed. If we choose to scale the commercial production of our PA and increase our manufacturing capacity, we may encounter quality issues that could

result in product defects, errors or recalls. Manufacturing delays related to quality control could negatively impact our ability to bring our PAs to market, harm our reputation and decrease our revenue. Any defects, errors or recalls could be expensive and generate negative publicity, which could impair our ability to market or sell our products, and adversely affect our results of operations. Our inability, or that of our suppliers, to find and retain the necessary qualified employees to achieve our manufacturing goals could also negatively impact our ability to meet customer needs.

Historically we have sourced components for our PAs from a limited number of manufacturers and, in some cases, sole source manufacturers. In 2022, we also began manufacturing PAs in our own facilities, however, we expect to continue to outsource a portion of the manufacturing of PAs for the foreseeable future. With respect to our PA manufacturers, we are neither a major customer of such manufacturers, nor do we have long-term supply contracts with them. These manufacturers may therefore give other customers' needs higher priority than ours, and we may not be able to obtain adequate supply in a timely manner or on commercially reasonable terms. Qualifying new suppliers may be required from time to time and qualification can take many months. If we were to lose one or more of our sole or single source manufacturers or suppliers, it could take significant time and effort to qualify alternative suppliers, if available. Moreover, in the event that we transition to a new manufacturer, particularly from any of our single source manufacturers, doing so could be time-consuming and expensive, may result in interruptions in our ability to supply our products to the market, could affect the performance of our PAs, resulting in increased costs and negative customer perception, and could have a material adverse effect on our business, financial condition and results of operations.

## Our results of operations will be harmed if we are unable to accurately forecast customer demand for our products and manage our inventory.

To ensure adequate supply of our instruments, PAs and other products, we must forecast the inventory needs of our current and prospective customers and manufacture our products based on our estimates of future demand. Our ability to accurately forecast demand for our products could be negatively affected by a number of factors, many of which are beyond our control, including our failure to accurately manage our expansion strategy, product introductions or failures by competitors, an increase or decrease in customer demand for our products or for products of our competitors, the availability of capital for our customers, our failure to accurately forecast the success of our customers' therapeutic products, market acceptance of new products, changes in general market conditions, seasonal demands, regulatory matters or strengthening or weakening of general economic conditions.

We seek to maintain sufficient levels of inventory of our instruments and other products to protect ourselves from supply interruptions. We rely in part on our commercial team and distributors to supply forecasts of anticipated product orders in their respective territories. If we fail to accurately estimate customer demand for our products, our inventory forecasts may be inaccurate, resulting in shortages or excesses of inventory. Inventory levels in excess of customer demand may result in inventory write-downs or write-offs, which could negatively impact our business, prospects, financial condition and results of operations. Conversely, if we underestimate customer demand for our products, we may not be able to deliver products in a timely manner or at all, and this could result in reduced revenue and damage to our reputation and customer relationships. In addition, if we experience a significant increase in demand, we may not have adequate manufacturing capacity to meet such demand, and additional supplies may not be available when required on terms that are acceptable to us, or at all, or suppliers may not be able to allocate sufficient capacity in order to meet our increased requirements, all of which could negatively affect our business, financial condition and results of operations. If we are unable to meet customer demand, we could lose our existing customers or lose our ability to acquire new customers, which could also negatively impact our business, financial condition and results of operations.

#### Risks Related to Our Product Sales

Our future success depends on our ability to develop and successfully introduce new and enhanced products that meet the needs of our customers.

Our offerings include products such as instruments, single-use disposables and the provision of support services to our customers with the goal of supporting the advancement of our customers' cell-therapies and/or drug or biologic discovery activities. We aim to provide our customers with a single, integrated platform to discover, develop and

manufacture safer, more targeted and increasingly complex cell-based therapies, designed for integration into customers' current good manufacturing practices environments. We cannot guarantee that the market for our current products will continue to generate significant or consistent demand. Demand for our current products could be significantly diminished by competitive technologies or products that replace them or render them obsolete or less desirable. Accordingly, we must continue to invest in research and development to develop competitive products.

Our future success depends on our ability to anticipate our customers' needs and develop new products and enhance current products to address those needs. Introduction of new products and product enhancements will require that we effectively transfer production processes from research and development to manufacturing and coordinate our efforts with those of our suppliers to achieve the desired level of production. If we fail to transfer production processes effectively, develop product enhancements or introduce new products or enabling services in sufficient quantities to meet the needs of our customers, or effectively coordinate with our suppliers, our sales may be reduced and our business could be harmed.

The commercial success of all of our products will depend upon their acceptance by the life science and biopharmaceutical industries. Some of the products that we are developing are based upon new technologies or approaches. As a result, there can be no assurance that these new products, even if successfully developed and introduced, will be accepted by customers. If customers do not adopt our new products, services and technologies, our results of operations may suffer and, as a result, the market price of our common stock may decline.

Many of our customers have limited resources and to the extent they limit development to a smaller number of product candidates or discontinue development of product candidates using our platform, our product sales would be negatively impacted.

Many of our customers are early-stage biopharmaceutical and biotechnology with limited financial resources. These customers necessarily are selective with respect to which product candidates they select for development and advance through clinical trials. During 2023 we observed customers, particularly early-stage customers, reprioritize their spending and operations to focus on lead product candidates rather than secondary or tertiary programs. To the extent that our customers limit development and clinical advancement to a smaller group of product candidates, our opportunities to support them with our platform are reduced. As a result of limited financial resources, our customers may also discontinue development of product candidates. To the extent that any of these product candidates are supported by our platform, our product sales would be negatively impacted.

If we are unable to successfully develop new products, adapt to rapid and significant technological change, respond to introductions of new products by competitors, make strategic and operational decisions to prioritize certain markets, technology offerings or partnerships, and develop and capitalize on markets, technologies or partnerships, our business could suffer.

We currently sell and license our products primarily in the cell therapy market, which is characterized by significant enhancements and evolving industry and regulatory standards and a high degree of regulatory scrutiny. As a result, our customers' needs are rapidly evolving. If we do not appropriately innovate and offer our customers comprehensive solutions and otherwise invest in new technologies, our offerings may become less desirable in the markets we serve, and our customers could move to new technologies offered by our competitors or make products themselves. Without the timely introduction of new instruments, single-use disposables software, services, enhancements and new product integrations with electroporation, our offerings may become less competitive over time, in which case our competitive position and operating results could suffer. Accordingly, we focus significant efforts and resources on the development and identification of new products and applications to further drive adoption of our platform. To the extent we fail to timely introduce new and innovative products, offer enhancements to our existing products, adequately predict our customers' needs or fail to obtain desired levels of market acceptance, our business may suffer and our operating results could be adversely affected.

We believe our products have potential applications across a wide range of markets and we have targeted certain markets in which we believe our technology has significant advantages, or for which we believe we have a higher

probability of success or significant revenue opportunity. For example, we are committed to developing our platform's applications within the life sciences and biotechnology markets, including research, discovery, development, and manufacturing of next-generation autologous and allogeneic cell-based therapeutics, as well as drug or biologic discovery, including protein production for biological therapeutics, viral vectors, vaccines and for the discovery of small molecule drugs. We seek to maintain a process of prioritization and resource allocation among our programs to maintain a balance between advancing near-term opportunities and exploring additional markets and uses for our technology. However, due to the significant resources required for the development of applications data for our products or services for new markets, we must make decisions on which markets to pursue and the amount of resources to allocate to each. Our decisions concerning the allocation of research, development, collaboration, management and financial resources toward particular markets, products or services may not lead to the development of any viable products or services and may divert resources away from better opportunities. Similarly, our potential decisions to delay, terminate or collaborate with third parties in respect of certain markets may subsequently also prove to be suboptimal and could cause us to miss valuable opportunities. In particular, if we are unable to successfully achieve on-going adoption of our electroporation platform technology, it could slow or stop our business growth and negatively impact our business, financial condition, results of operations and prospects.

New product development involves a lengthy and complex process and we may be unable to develop or commercialize products on a timely basis, or at all.

Products from our research and development programs will take time and considerable resources to develop, and may include improvements or changes to our current products, and we may not be able to complete development and commercialization of new or enhanced products on a timely basis, or at all. There can be no assurance that our research and development efforts will produce commercially viable products and solutions and before we can commercialize any new products, we will need to expend significant funds in order to, for example:

- conduct substantial research and development;
- in some cases, obtain necessary regulatory clearance or approval;
- further develop and scale our laboratory, engineering and manufacturing processes to accommodate different products;
- source and enter into agreements with new suppliers and manufacturers; and
- further develop and scale our infrastructure.

Our product development processes involve a high degree of risk, and these efforts may be delayed or fail for many reasons, including failure of the product to perform as expected and failure to reliably demonstrate the advantages of the product.

Even if we are successful in developing new products, it will require us to make significant additional investments in marketing and selling resources to commercialize any such products. As a result, we may be unsuccessful in commercializing new products that we develop, which could adversely affect our business, financial condition, results of operations and prospects.

Our systems are complex in design and may contain defects that are not detected until deployed by our customers, which could harm our reputation, increase our costs and reduce our sales. If our products do not perform as expected or the reliability of the technology on which our products are based is questioned, our operating results, reputation and business will suffer.

Our success depends on our ability to provide reliable, high-quality products that enable high performance cell engineering through flexible, efficient and cost-effective solutions. Our systems are complex in design and involve a highly complex and precise manufacturing process. As a result of the technological complexity of our systems, changes

in our suppliers' manufacturing processes or the inadvertent use of defective materials by us or our suppliers could result in a product recall, or an adverse effect on our ability to achieve acceptable manufacturing quality and product reliability. To the extent that we do not achieve and maintain our projected quality or product reliability, our reputation, business, operating results, financial condition and customer relationships could be adversely affected.

Our customers may discover defects in our products after the products have been fully installed and operated. In addition, some of our products include components from other vendors, which may contain defects. As a result, should problems occur, it may be difficult to identify the source of the problem. If we are unable to identify and fix defects or other problems, we could experience, among other things:

- product recalls and replacement costs;
- loss of customers or orders;
- damage to our brand reputation;
- failure to attract new customers;
- diversion of development, engineering and manufacturing resources;
- regulatory actions by governmental authorities; and
- legal actions by our customers.

We believe that customers in our target markets are likely to be particularly sensitive to product defects and errors. Our reputation and the image of our products, services and technologies in our target markets may be impaired if our products or services fail to perform as expected. If our products do not perform, or are perceived to not have performed, as expected or favorably in comparison to competitive products, our operating results, reputation and business will suffer, and we may also be subject to legal claims arising from product limitations, errors, or inaccuracies. Any of the foregoing could have an adverse effect on our business, financial condition and results of operations.

Although our products are tested in accordance with industry standards prior to shipment, defects or errors could nonetheless occur. For example, our instruments or PAs could fail or our partners could use our technology improperly and blame a failure on our systems, resulting in customer complaints and significant resources dedicated to finding the cause of the failure and/or developing a solution. Our operating results depend on our ability to execute and, when necessary, improve our quality management strategy and systems and our ability to effectively train and maintain our employees with respect to quality management. A failure of our quality control systems could result in problems with facility operations or preparation or provision of products. In each case, such problems could arise for a variety of reasons, including equipment malfunction, failure to follow specific protocols and procedures, problems with raw materials or environmental factors and damage to, or loss of, manufacturing operations.

We provide a standard one-year warranty on sold instruments. Existing and future warranties place us at the risk of incurring future repair and/or replacement costs. Since a large portion of our revenue is derived from sales of our PAs, which can only be used when our instruments are functioning, if our instruments fail to function and our customers choose to use alternative cell engineering methods our financial condition and results of operations could suffer. In addition, even after any underlying concerns or problems are resolved, any lingering concerns in our target markets regarding our technology or any manufacturing defects or performance errors, either actual or simply perceived, in our products or services could continue to result in lost revenue, delayed market acceptance, damage to our reputation and claims against us.

If we are unable to successfully expand our commercial operations, including hiring additional qualified sales representatives, application scientists, engineers, scientific personnel and customer support staff, our business may be adversely affected.

Our sales will depend, in large part, on our ability to develop and substantially expand our sales and applications scientist infrastructure, particularly as we enter into new markets, rollout new products and platforms and manage inbound interest from new customers. We sell our products through our direct sales force and field application scientists located in North America, the United Kingdom and Europe, and have field application scientists located in the Asia-Pacific region where sales are currently managed by distributors. Our sales and marketing efforts are targeted at pharmaceutical and biotechnology companies and academic institutions focused on cell engineering and drug or biologic discovery. To continue driving adoption of our products and to support our global brand, we will need to further expand our field sales and application scientist infrastructure by hiring additional, highly qualified sales representatives, field application scientists, engineers and scientific personnel and customer support staff, in addition to increasing our marketing efforts.

Identifying and recruiting qualified personnel globally with sufficient industry experience and training them requires significant time, expense and attention. If we provide inadequate training, fail to increase our sales and marketing capabilities or fail to develop broad brand awareness in our target markets in a cost-effective manner, our business may be harmed. In addition, if our efforts to expand do not generate a corresponding increase in revenue or result in a decrease in our operating margin, our financial results will be adversely impacted. If we are unable to hire, develop and retain talented sales personnel or if new sales personnel are unable to achieve desired productivity levels in a reasonable period of time, we may not be able to realize the expected benefits of this investment or increase our revenue.

Additionally, our highly specialized application scientists and scientific personnel work closely with researchers, clinicians and current and prospective customers to optimize and implement cell engineering methods, processes and applications to meet their specific needs. Hiring these highly skilled application scientists and scientific personnel is competitive due to the limited number of people available with the necessary scientific and technical backgrounds and ability to understand our products at a technical level, and training such individuals requires significant time, expense and attention. Furthermore, we face intense competition in the labor market for such highly skilled specialists from competitors in our industry, our customers and companies in other industries, particularly because of the recent rapid growth in the cell therapy field. To effectively support current and potential customers, we will need to hire, maintain, train and grow globally the number of our applications scientists and add to our customer support staff. If we are unable to maintain, attract, train or retain the number of qualified support personnel that our business needs, our business and prospects may suffer.

If we are unable to expand or leverage the number of peer-reviewed articles published using data generated through the use of our products or otherwise increase brand awareness in our target markets, the demand for our products and our business may be adversely affected.

We rely on a significant base of peer-reviewed publications to showcase and validate the application of our technology in academic and clinical research settings. To date, there have been multiple peer-reviewed articles published, including in prominent journals, using data generated through the use of our technology across a wide range of key scientific research areas, including research, discovery, development and manufacturing of next-generation, cell-based therapeutics, as well as drug and biologic discovery including protein production for biological therapeutics, viral vectors, vaccines and small molecule discovery. We believe that expanding the number and breadth of these publications, and otherwise developing and maintaining awareness of our brand in our target markets in a cost-effective, manner is critical to achieving broad acceptance of our products and attracting new customers. Such publications and other brand promotion activities may not generate customer awareness or increase revenue and, even if they do, any increase in revenue may not offset the costs and expenses we incur in building our brand. If we fail to successfully promote, maintain and protect our brand, we may fail to attract or retain the customers necessary to realize a sufficient return on our brand-building efforts, or to achieve the reputation and widespread brand awareness that is critical for broad customer adoption of our products.

#### Risks Related to Our Regulatory Environment and Our Industry

Our FDA Master File, and equivalent Master and Technical Files in foreign jurisdictions, are an important part of our strategic offering which allows our partners to expedite their cellular therapies or other biologics into and

through clinical development. Delays in filing or obtaining (as applicable in each jurisdiction), or our inability to obtain or retain, acceptance of such filings in individual countries could negatively impact the progress of our partners if they intend to run clinical trials in such countries, and as a result, could negatively affect our reputation and revenues or require disclosure of confidential information to our partners. Further, changes that we are required to make from time to time, or changes to regulations or negative data or adverse events for our partners, could impact references to our FDA Master File and Master and Technical Files by our partners.

Providing our customers with an established regulatory path for use of our technology in the development of their therapeutics is an important value we provide to our customers. We have established and maintained FDA Master Files and equivalent Master and Technical Files in certain other countries to provide that regulatory path. We may be unable in a timely manner, or at all, to provide similar filings in all countries where our customers desire to perform clinical trials, and regulators may refuse to accept such filings or may change their approach to such filings in a manner that weakens our ability to support our customers. If regulators at any point find that such filings have not been sufficiently maintained or are insufficient to support clinical trials or product approvals, as a result we may need to disclose confidential information to our partners to allow them to include such information in their filings.

In addition, while we believe our FDA Master Files and equivalent Master and Technical Files have the potential to create certain efficiencies and reduce certain regulatory development risks for our customers, there is no guarantee that referencing our FDA Master File or Master and Technical Files, as applicable, will result in success in customers' submissions seeking authorization for clinical trials or marketing authorization. We cannot be certain that the FDA or foreign regulators will not require audits of and information on our ExPERT systems used in clinical development as our partners advance their cellular therapies from preclinical through clinical development toward marketing approval. Such additional information requests and audits of our facilities could result in delays in the development and potential regulatory approval of our partners' cellular therapy product candidates, affecting timing of milestone payments and our future ability to enter into new SPL agreements. Failure to adequately respond to any such regulatory requests could result in the regulator preventing our electroporation system from being utilized for a partner's cellular therapy. This could result in our partners not utilizing our ExPERT system for their other clinical programs and negatively impact our ability to enter into partnership agreements with other cellular therapy developers.

# Changes in tariffs or other government trade policies may materially adversely affect our business and results of operations, including by reducing demand for our products.

The imposition of tariffs and trade restrictions as a result of international trade disputes or changes in trade policies may adversely affect our sales and profitability. For example, in recent years, the U.S. government imposed and proposed, among other actions, new or higher tariffs on specified imported products originating from China in response to what it characterized as unfair trade practices, and China responded by imposing and proposing new or higher tariffs on specified U.S. products. There can be no assurance that a broader trade agreement will be successfully negotiated between the United States and China to reduce or eliminate these tariffs. These tariffs, and the related geopolitical uncertainty between the United States and China, may cause decreased demand for our products or increase cost of components used in our products, which could have a material adverse effect on our business and results of operations. For example, certain of our foreign customers may respond to the imposition of tariffs or threat of tariffs on products we produce by delaying purchase orders or purchasing products from our competitors. Ongoing international trade disputes and changes in trade policies could also impact economic activity and lead to a general contraction of customer demand. In addition, tariffs on components that we may import from China or other nations will adversely affect our profitability unless we are able to exclude such components from the tariffs or we raise prices for our products, which may result in our products becoming less attractive relative to products offered by our competitors. Future actions or escalations by either the United States or China that affect trade relations may also negatively affect our business, or that of our suppliers or customers, and we cannot provide any assurances as to whether such actions will occur or the form that they may take. To the extent that our sales or profitability are negatively affected by any such tariffs or other trade actions, our business and results of operations may be materially adversely affected.

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

Exports of our products are subject to export controls and sanctions laws and regulations imposed by the U.S. government and administered by the U.S. Departments of State, Commerce and Treasury. U.S. export control laws may require a license or other authorization to export products to certain destinations and end users. In addition, U.S. economic sanctions laws include restrictions or prohibitions on the sale or supply of certain products to U.S. embargoed or sanctioned countries, governments, persons and entities. Obtaining export licenses can be difficult, costly and time-consuming and we may not always be successful in obtaining necessary export licenses, and our failure to obtain required export approval for our products or limitations on our ability to export or sell our products imposed by export control or sanctions laws may harm our revenues and adversely affect our business, financial condition, and results of operations. Noncompliance with these laws could have negative consequences, including government investigations, penalties and reputational harm.

We are subject to stringent and changing U.S. and foreign laws, regulations, rules, contractual obligations, policies and other obligations related to data privacy and security. Our actual or perceived failure to comply with such obligations could lead to adverse business consequences.

In the ordinary course of business, we collect, receive, store, process, generate, use, transfer, disclose, make accessible, protect, secure, dispose of, transmit, and share (collectively, process) personal information and other sensitive information, including proprietary and confidential business data, trade secrets, intellectual property, data previously collected about clinical trial participants, and sensitive third-party data collected under confidentiality agreements with our customers and potential customers, including scientific plans (collectively, sensitive information). Our data processing activities subject us to numerous data privacy and security obligations, such as various laws, regulations, guidance, industry standards, external and internal privacy and security policies, contractual requirements, and other obligations that govern the processing of personal information in the jurisdictions in which we operate.

In the United States, federal, state, and local governments have enacted numerous data privacy and security laws, including data breach notification laws, personal information privacy laws, consumer protection laws (e.g., Section 5 of the Federal Trade Commission Act), and other similar laws (e.g., wiretapping laws). For example, the Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), as amended by the Health Information Technology for Economic and Clinical Health Act ("HITECH"), imposes specific requirements relating to the privacy, security, and transmission of individually identifiable health information. In addition, the California Consumer Privacy Act ("CCPA") applies to personal information of consumers, business representatives, and employees, and requires businesses to provide specific disclosures in privacy notices and honor requests of California residents to exercise certain rights related to their personal information. The CCPA allows for statutory fines for noncompliance (up to \$7,500 per violation) and allows private litigants affected by certain data breaches to recover significant statutory damages. Although the CCPA exempts some data processed in the context of clinical trials, the CCPA increases compliance costs and potential liability with respect to other personal information we maintain about California residents. In addition, the CPRA, expanded the CCPA's requirements, including by adding a new right for individuals to correct their personal information and establishing a new regulatory agency, the California Privacy Protection Agency, to implement and enforce the law, which could increase the risk of enforcement. Other states, such as Virginia, Colorado, Connecticut and Utah, have enacted comprehensive data privacy laws, and similar laws have been proposed in several other states, as well as at the federal, state, and local levels — while some of these also exempt data processed in the context of clinical trials, these data privacy laws could nonetheless further complicate compliance efforts.

Outside the United States, an increasing number of laws, regulations, and industry standards apply to data privacy and security. For example, the EU General Data Protection Regulation (the "EU GDPR"), the UK GDPR (the "UK GDPR"), and China's Personal Information Protection Law ("PIPL") impose strict requirements for processing personal information. Under the EU GDPR and UK GDPR, government regulators may impose temporary or definitive bans on data processing and other corrective actions; fines of up to €20 million (£17.5 million under the UK GDPR) or up to 4% of the total worldwide annual turnover of the preceding financial year, whichever is higher; or private litigation related to the processing of personal information brought by classes of data subjects or consumer protection organizations

authorized at law to represent their incidents. Furthermore, the EU GDPR provides that EEA Member States may introduce specific requirements related to the processing of "special categories of personal data," including personal information related to health and genetic information, which we may process in connection with clinical trials or otherwise. In the United Kingdom, the UK Data Protection Act 2018 complements the UK GDPR in this regard. This fact may lead to greater divergence on the law that applies to the processing of such personal information across the EEA and/or United Kingdom, which may increase our costs and overall compliance risk. We also target customers in Asia and have operations, distributors, contractors or employees located or active in Asian countries including, but not limited to China, Japan, Australia, and South Korea and are subject to new and emerging data privacy regimes in Asia, including China's Personal Information Protection Law, Japan's Act on the Protection of Personal Information, and Singapore's Personal Data Protection Act.

In the ordinary course of business, we may transfer personal information from Europe and other jurisdictions to the United States or other countries. Europe and other jurisdictions have enacted data localization laws and cross-border personal information transfer laws. For example, the EEA and the United Kingdom have significantly restricted the transfers of personal information, to the United States and other countries whose privacy laws they believe are inadequate. Although there are currently various mechanisms that may be used to legally transfer personal information from the EEA and United Kingdom to the United States, such as the EEA and United Kingdom's standard contractual clauses, these mechanisms are subject to potential legal challenges and there exists some uncertainty regarding whether the standard contractual clauses will remain a valid, reliable mechanism for lawfully transferring personal information to the United States. If we are unable to implement a valid solution for cross-border data transfers, or if the requirements for a legally-compliant transfer are too onerous, we may face significant adverse consequences, including limitations on our ability to collaborate with partners as well as other service providers, contractors and other companies in Europe; the need to increase our processing capabilities within Europe at significant expense or otherwise change the geographical location or segregation of our relevant systems and operations, and increased exposure to regulatory actions, substantial fines and penalties, and injunctions against our processing or transferring of personal information necessary to operate our business —any or all of which could adversely affect our operations or financial results. Additionally, companies that transfer personal information out of the EEA and United Kingdom to other jurisdictions, particularly to the United States, are subject to increased scrutiny from regulators, individual litigants, and activist groups. Some European regulators have ordered certain companies to suspend or permanently cease certain transfers out of Europe for allegedly violating the EU and UK GDPR's cross-border data transfer limitations. Furthermore, other countries outside of Europe have enacted or are considering enacting similar cross-border data transfer restrictions and laws requiring local data residency, which could increase the cost and complexity of delivering our services and operating our business.

In addition to data privacy and security laws, we are contractually subject to industry standards adopted by industry groups and may become subject to such obligations in the future. We are also bound by contractual obligations related to data privacy and security, and our efforts to comply with such obligations may not be successful. For example, certain privacy laws, such as the EU and UK GDPR and the CCPA, require us to impose specific contractual restrictions on our service providers. We publish privacy policies, marketing materials and other statements regarding data privacy and security. If these policies, materials or statements are found to be deficient, lacking in transparency, deceptive, unfair, or misrepresentative of our practices, we may be subject to investigation, enforcement actions by regulators or other adverse consequences.

Our obligations related to data privacy and security are quickly changing, becoming increasingly stringent, and creating regulatory uncertainty. Additionally, these obligations may be subject to differing applications and interpretations, which may be inconsistent or conflict among jurisdictions. Preparing for and complying with these obligations requires us to devote significant resources (including, without limitation, financial and time-related resources), which could distract management or divert resources from other initiatives and projects, interrupt or delay our development activities, or necessitate changes to our information technologies, systems, and practices and to those of any third parties that process personal information on our behalf. In addition, these obligations may require us to change our business model. Although we endeavor to comply with all applicable data privacy and security obligations, we may at times fail (or be perceived to have failed) to do so. Moreover, despite our efforts, our personnel or third parties upon whom we rely may fail to comply with such obligations, which could negatively impact our business operations and compliance posture. If we or the third parties on which we rely fail, or are perceived to have failed, to address or comply with applicable data privacy and security obligations, we could face significant consequences, including but not limited

to: government enforcement actions (e.g., investigations, fines, penalties, audits, inspections, and similar); litigation (including class-related claims);additional reporting requirements and/or oversight; temporary or permanent bans on all or some processing of personal information; orders to destroy or not use personal information; and imprisonment of company officials.

Further, individuals or other relevant stakeholders could bring a variety of claims against us for our actual or perceived failure to comply with all applicable data privacy and security obligations. Any of these events could have a material adverse effect on our reputation, business or financial condition, including but not limited to: loss of actual or prospective customers, collaborators or partners; interruptions or stoppages in our business operations; inability to process personal information or to operate in certain jurisdictions; limited ability to develop or commercialize our products; expenditure of time and resources to defend any claim or inquiry; adverse publicity; or revision or restructuring of our business model or operations.

We are subject to U.S. and certain foreign anti-corruption and anti-money laundering laws and regulations. We can face criminal liability and other serious consequences for violations, which can harm our business.

We are subject to anti-corruption and anti-money laundering laws and regulations, including the FCPA, the U.S. domestic bribery statute contained in 18 U.S.C.§ 201, the U.S. Travel Act, the USA PATRIOT Act, and other state and national anti-bribery and anti-money laundering laws in the countries in which we conduct or may in the future conduct activities. Anti-corruption laws are interpreted broadly and prohibit companies and their employees, agents, contractors and other third-party collaborators from authorizing, promising, offering, providing, soliciting or receiving, directly or indirectly, improper payments or anything else of value to or from persons in the public or private sector. The FCPA also requires public companies to make and keep books and records that accurately and fairly reflect the transactions of the corporation and to devise and maintain an adequate system of internal accounting controls.

In addition to selling our products internationally directly through our sales teams, we currently engage third parties outside of the United States and may engage additional third parties outside of the United States, to sell our products internationally and to obtain necessary permits, licenses, patent registrations and other regulatory approvals. We have direct or indirect interactions with officials and employees of government agencies or government-affiliated hospitals, universities and other organizations. We can be held liable for the corrupt or other illegal activities of our employees, agents, contractors and other third-party collaborators, even if we do not explicitly authorize or have actual knowledge of such activities. Any violations of the laws and regulations described above may result in substantial civil and criminal fines and penalties, imprisonment, the loss of export or import privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm, and other consequences.

Our customers who use our platform and may be exposed to broadly applicable U.S. federal and state healthcare laws and regulations, including those relating to kickbacks and false claims, transparency, and health information privacy and security law. Failure to comply with such laws and regulations may result in substantial penalties.

Our customers who use our platform and we, if we develop a product, may be subject to broadly applicable healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we research, market, sell, and distribute our products. Such laws include federal and state anti-kickback laws, false claims laws, transparency laws, and health information privacy and security laws.

Violations of such laws may result in substantial criminal, civil and administrative penalties, including imprisonment, exclusion from participation in federal healthcare programs, such as Medicare and Medicaid, and significant fines, monetary penalties, forfeiture, disgorgement and damages, contractual damages, reputational harm, administrative burdens, diminished profits and future earnings and the curtailment or restructuring of operations.

Additionally, in the United States and some foreign jurisdictions there have been, and continue to be, several legislative and regulatory changes and proposed reforms of the healthcare system in an effort to contain costs, improve quality and expand access to care, including the proposed modification to some of the aforementioned laws. In the United States, there have been and continue to be a number of healthcare-related legislative initiatives that have

significantly affected the healthcare industry. These reform initiatives may, among other things, result in modifications to the aforementioned laws and/or the implementation of new laws affecting the healthcare industry. Similarly, a significant trend in the healthcare industry is cost containment. Third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. Our customers and collaborators' ability to commercialize their products successfully, will depend in part on the extent to which coverage and adequate reimbursement for these products and will be available from third-party payors. As such, cost containment reform efforts may result in an adverse effect on our operations.

Our business is subject to environmental regulation and regulations relating to the protection of health and safety matters that could result in compliance costs. Any violation or liability under environmental laws or health and safety regulations could harm our business.

We are subject to environmental and safety laws and regulations governing the use, storage and disposal of hazardous substances or wastes and imposing liability for the cleanup of contamination from these substances. We handle hazardous substances in our manufacturing processes, and we could be liable for any improper use, storage, or disposal of such substances. We cannot completely eliminate the risk of contamination or injury from hazardous substances or waste, and, in the event of such an incident, we could be held liable for any resulting damages. In addition, we may be required to incur significant additional costs to comply with environmental laws and regulations in the future.

The Occupational Safety and Health Act of 1970 ("OSHA"), establishes certain employer responsibilities, including maintenance of a workplace free of recognized hazards likely to cause death or serious injury, compliance with standards promulgated by the Occupational Safety and Health Administration and various record keeping, disclosure and procedural requirements. Various OSHA standards may apply to our operations. We have incurred, and will continue to incur, capital and operating expenditures and other costs in the ordinary course of our business in complying with OSHA and other state and local laws and regulations.

The failure to comply with these regulations could result in fines by government authorities and payment of damages to private litigants, which could harm our business.

#### Risks Related to Our Financial Position and Capital Requirements

We may need additional funding and may be unable to raise capital when needed, which could force us to delay, reduce, eliminate or abandon our commercialization efforts or product development programs.

We cannot be certain that our anticipated cash flow from operations will be sufficient to meet all of our cash requirements or our growth plan. We intend to continue to make investments to support our business growth and may require additional funds to:

- expand the commercialization of our products and execute on our growth strategy;
- fund our operations and product development;
- finance the expansion into new international markets;
- expand our manufacturing capabilities;
- defend, in litigation or otherwise, any claims that we infringe, misappropriate or otherwise violate third-party patents or other intellectual property rights;
- commercialize our new products; and
- acquire companies and in-license products or intellectual property.

We believe our existing cash balances and cash receipts generated from sales of our products will be sufficient to meet our anticipated cash requirements for the foreseeable future. However, we may need additional funding sooner than expected and our business and future funding requirements can change unpredictably due to a variety of factors, including acquisitions, which could affect our funding needs or cash flows from operations. We may be unable to raise additional funds in a timely manner or on terms that are acceptable to us. If we do not have, or are not able to obtain, sufficient funds, we may have to delay the further development or commercialization of our products. We also may have to reduce marketing, customer support or other resources devoted to our products.

Our results of operations and liquidity needs could be materially and adversely affected by market fluctuations, an economic downturn, inflation, increases in interest rates and other macroeconomic conditions.

Our results of operations and liquidity could be materially and adversely affected by economic conditions generally, both in the United States and elsewhere around the world. Domestic and international equity and debt markets experienced in 2022 and 2023, and may continue to experience, heightened volatility and turmoil, including, among other things, severely diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, supply chain shortages, increases in inflation rates, higher interest rates and uncertainty about economic stability. The Federal Reserve raised interest rates multiple times in response to concerns about inflation and it may raise them again. Higher interest rates, coupled with reduced government spending and volatility in financial markets may increase economic uncertainty and affect consumer or business spending. In the event the markets continue to remain volatile, our results of operations and liquidity could be adversely affected by those factors in many ways, including making it more difficult or costly for us to raise funds if necessary, and our stock price may decline. Increased inflation rates can adversely affect us by increasing our costs, including labor and employee benefit costs. In addition, we maintain significant amounts of cash and cash equivalents at one or more financial institutions, some of which may not be federally insured. If economic instability were to occur, we cannot be certain that we would not experience losses on these cash and cash equivalents.

In addition, our available cash and cash equivalents are held in accounts managed by third party financial institutions and consist of cash in our operating accounts and cash invested in money market funds. At any point in time, the funds in our operating accounts may exceed the Federal Deposit Insurance Corporation insurance limits. While we monitor the cash balances in our operating accounts and adjust the cash balances as appropriate, these cash balances could be impacted if the underlying financial institutions fail. To date, we have experienced no material loss or material lack of access to cash in our operating accounts or our invested cash or cash equivalents; however, we can provide no assurances that access to our operating cash or invested cash and cash equivalents will not be impacted by adverse conditions in the financial markets.

Our operating results may fluctuate significantly, 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 any of our products, which may vary significantly;
- timing and cost of, and level of investment in, research, development, manufacturing, regulatory approval and commercialization activities for partners relating to our products, which may change from time to time;
- size, seasonality and customer mix of the cell engineering market;
- start, milestone attainment and completion of programs in which our platform is utilized;
- sales and marketing efforts and expenses we incur;

- rate at which we grow our sales force and the speed at which newly-hired salespeople become effective; changes in the productivity of our sales force;
- positive or negative coverage in the media or publications of our products or competitive products;
- cost of manufacturing our products, which may vary depending on the quantity of production and the terms of our arrangements with our suppliers;
- degree of competition in our industry and any change in the competitive landscape of our industry, including the introduction of new products or enhancements or technologies by us or others in the cell engineering market and competition-related pricing pressures;
- changes in governmental regulations or in the status of regulatory approvals or applications;
- future accounting pronouncements or changes in our accounting policies;
- disruptions to our business and operations or to the business and operations of our suppliers, distributors, and
  other third parties with whom we conduct business resulting from the COVID-19 public health emergency or
  other widespread public health emergencies;
- future global financial crises and economic downturns, including those caused by widespread public health emergencies or geopolitical conflicts; and
- general 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. If our revenue or 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, the price of our common stock could decline substantially. Such a stock price decline could occur even when we have met any previously publicly stated guidance we may provide.

## Our ability to use our net operating losses, business tax credits and similar tax attributes to offset future taxable income or taxes may be subject to certain limitations.

As of December 31, 2023, we had U.S. federal and state net operating loss carryforwards of \$88.9 million. Under current law, U.S. federal net operating losses incurred in tax years beginning after December 31, 2017, may be carried forward indefinitely, but the deductibility of such federal net operating losses in tax years beginning after December 31, 2020 is limited to 80% of taxable income. It is uncertain if and to what extent various states will conform to federal tax laws. In addition, under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, and corresponding provisions of state law, if a corporation undergoes an "ownership change," which generally is defined as a greater than 50% change, by value, in its equity ownership over a three-year period, the corporation's ability to use its pre-change net operating loss and tax credit carryforwards to offset its post-change income or taxes may be limited. We previously experienced an ownership change and we may experience additional ownership changes in the future as a result of subsequent shifts in our stock ownership, some of which may be outside of our control. If an ownership change occurs and our ability to use our net operating loss carryforwards is materially limited, it could harm our future operating results by effectively increasing our future tax obligations. Similar provisions of state law also may apply to limit the use of our state net operating loss carryforwards. In addition, at the state level, there may be periods during which the use of net operating losses is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed.

#### **Risks Related to Our Operations**

A pandemic, epidemic, outbreak of an infectious disease or other public health emergency in the United States or worldwide could adversely affect our business and the businesses of our partners.

If a pandemic, epidemic, outbreak of an infectious disease, or other public health emergency occurs in the United States or worldwide, our business may be adversely affected, by, among other things, disruptions to the research and development activities of our customers, disruptions to the development of our collaboration partners' product candidates, disruptions to our ability to enter into new collaborations with potential partners in a timely manner, disruptions in the operations of our third-party manufacturing organizations upon whom we rely for the production and supply of our products, and other disruptions to our operations. In response to COVID-19 in 2020, we temporarily closed our headquarters and other offices, and our employees and contractors who were able to perform their duties remotely continue to do so. We also implemented travel restrictions and other significant changes in how we operate our business. The operations of our partners and customers were likewise altered. Potential implications of future public health emergencies may include:

- our customer prospects and our existing customers may experience slowdowns in their businesses, and our
  academic institution customers may experience decreases in government funding of research and development,
  which in turn may result in reduced demand for our products, lengthening of sales cycles, loss of customers,
  difficulties in collections, and inaccurate inventory forecasting;
- limitations on our business operations by local, state, provincial and/or federal governments that could impact
  our ability to sell products to customers, and visit customers for process optimization of their cellular
  therapies;
- delays in negotiations with partners and potential partners;
- interruption of or delays in receiving supplies from the third parties we rely on to manufacture components to our products, which may impair our ability to sell our products;
- interruption of or delays in installation of our products for our customers and partners;
- interruption of or delays in the shipments of purchased products to customers or to our distribution partners;
- decreased employee productivity and morale, with increased employee attrition and risk of a cyberattack resulting from our employees working from home;
- disruptions and significant costs to our growth planning, such as for facilities and international expansion;
- costs in fully returning to work from our facilities around the world, including changes to the workplace, such as space planning, food service and amenities;
- legal liability for safe workplace claims;
- loss of critical vendors or third-party partners, which may go out of business; and
- continued cancellation of in-person marketing events, including industry conferences, and prolonged delays in our ability to reschedule or conduct in-person marketing events and other sales and marketing activities.

The impact of any of the foregoing, individually or collectively, could adversely affect our business, financial condition, and results of operations.

If our information technology systems, or those of third parties upon which we rely, or our data, are or were compromised, we could experience adverse consequences resulting from such compromise, including but not limited to regulatory investigations or actions; litigation; fines and penalties; disruptions of our business operations; reputational harm; loss of revenue or profits; loss of customers or sales; and other adverse consequences.

We rely to a large extent upon sophisticated information technology systems to operate our business. In the ordinary course of business, we process personal information (such as health-related data), and other sensitive information, including proprietary and confidential business data, trade secrets, intellectual property, data previously collected about clinical trial participants, and sensitive third-party data collected under confidentiality agreements with our customers and potential customers, including scientific plans.

Cyber-attacks, malicious internet-based activity, online and offline fraud, and other similar activities threaten the confidentiality, integrity, and availability of our sensitive information and information technology systems, and those of the third parties upon which we rely. Such threats are prevalent and continue to increase, are becoming increasingly difficult to detect, and come from a variety of sources, including traditional computer "hackers," threat actors, "hacktivists," organized criminal threat actors, personnel (such as through theft or misuse), sophisticated nation-states, and nation-state-supported actors. Some actors now engage and are expected to continue to engage in cyber-attacks including without limitation nation-state actors for geopolitical reasons and in conjunction with military conflicts and defense activities. During times of war and other major conflicts, we and the third parties upon which we rely may be vulnerable to a heightened risk of these attacks, including retaliatory cyberattacks that could materially disrupt our systems and operations, supply chain, and ability to produce, sell and distribute our goods. These risks, as well as the number and frequency of cybersecurity events globally, may also be heightened during times of geopolitical tension or instability between countries, including, for example, the ongoing armed conflict between Russia and Ukraine, from which a number of cybersecurity events have been alleged to have originated.

We and the third parties upon which we rely are subject to a variety of evolving threats, including but not limited to, malicious code (such as viruses and worms), personnel misconduct or error, malware (including as a result of advanced persistent threat intrusions), ransomware attacks, denial-of-service attacks (such as credential stuffing), credential harvesting, socialengineering attacks (including through phishing attacks), ransomware attacks, supply-chain attacks, personnel misconduct or error, software bugs, server malfunctions, software or hardware failures, loss of data or other information technology assets, adware, telecommunications failures, earthquakes, fires, floods, and other similar threats. In particular, severe ransomware attacks, including those perpetrated by organized criminal threat actors, nation-states, and nation-state-supported actors, are becoming increasingly prevalent and can lead to significant interruptions in our operations, loss of sensitive information and income, reputational harm, and diversion of funds. Extortion payments may alleviate the negative impact of a ransomware attack, but we may be unwilling or unable to make such payments due to, for example, applicable laws or regulations prohibiting such payments. Remote work has become more common and also poses increased risks to our information technology systems and data, as more of our employees utilize network connections, computers and devices outside our premises or network, including working at home, while in transit and in public locations. Future or past business transactions (such as acquisitions or integrations) could also expose us to additional cybersecurity risks and vulnerabilities, as our systems could be negatively affected by vulnerabilities present in acquired or integrated entities' systems and technologies. Furthermore, we may discover security issues that were not found during due diligence of such acquired or integrated entities, and it may be difficult to integrate companies into our information technology environment and security program.

We have outsourced significant elements of our operations to third parties, including significant elements of our information technology infrastructure and, as a result, we are managing many independent vendor relationships with third parties who may have access to our information. The size and complexity of our information security systems, and those of our third-party vendors with whom we contract (and the large amounts of information that is present on them), make such systems potentially vulnerable to service interruptions or to security breaches from inadvertent or intentional actions by our employees, vendors or from malicious attacks by third parties. Our ability to monitor these third parties' cybersecurity practices is limited, and these third parties may not have adequate information security measures in place. We may share or receive sensitive information with or from third parties. If our third-party service providers experience a security incident or other interruption, we could experience adverse consequences. While we may be entitled to damages if our third-party service providers fail to satisfy their privacy or security-related obligations to us, any award may be insufficient to cover our damages, or we may be unable to recover such award. In addition, supply-chain attacks have increased in frequency and severity, and we cannot guarantee that third parties and

infrastructure in our supply chain or our third-party partners' supply chains have not been compromised or that they do not contain exploitable defects or bugs that could result in a breach of or disruption to our information technology systems (including our products) or the third-party information technology systems that support us and our services.

Any of the previously identified or similar threats could cause a security incident or other interruption in our systems that could result in unauthorized, unlawful, or accidental acquisition, modification, destruction, loss, alteration, encryption, disclosure of, or access to our sensitive information or our information technology systems, or those of the third parties upon whom we rely. A security incident or other interruption could disrupt our ability (and that of third parties upon whom we rely) to provide our products. We may expend significant resources or modify our business activities (including our clinical trial activities) in an effort to protect against security incidents. Certain data privacy and security obligations may require us to implement and maintain specific security measures, or industry-standard or reasonable security measures to protect our information technology systems and sensitive information.

While we have invested significantly in the implementation of security measures designed to protect against security incidents, there can be no assurance that our efforts will prevent service interruptions or security incidents. We take steps to detect and remediate vulnerabilities, but we may not be able to detect and remediate all vulnerabilities in our information technology systems because such threats and techniques used to exploit the vulnerability change frequently, are often sophisticated in nature, and may not be detected until after a security incident has occurred. Despite our efforts to identify and remediate vulnerabilities, if any, in our information technology systems, our efforts may not be successful. These vulnerabilities pose material risks to our business. Further, we may experience delays in developing and deploying remedial measures designed to address any such identified vulnerabilities.

Applicable data privacy and security obligations may require us to notify relevant stakeholders of security incidents. Such disclosures are costly, and the disclosure or the failure to comply with such requirements could lead to adverse consequences. If we (or a third party upon whom we rely) experience a cyberattack or security incident or are perceived to have experienced a security incident, we may experience adverse consequences, such as government enforcement actions (for example, investigations, fines, penalties, audits, and inspections; additional reporting requirements and/or oversight; restrictions on processing sensitive information, including personal information; litigation, including class claims; indemnification obligations; negative publicity; harm to our reputation; monetary fund diversions; interruptions in our operations (including availability of data); financial loss; and other similar harms. Security incidents and attendant consequences may cause customers to stop using our products, deter new customers from using our products, and negatively impact our ability to grow and operate our business. In addition, we could be subject to regulatory actions and/or claims made by individuals and groups in private litigation related to data collection and use practices and other data privacy laws and regulations, including claims for misuse or inappropriate disclosure of data as well as unfair or deceptive practices.

Our contracts may not contain limitations of liability, and even where they do, there can be no assurance that limitations of liability in our contracts are sufficient to protect us from liabilities, damages, or claims related to our data privacy and security obligations. We cannot be sure that our insurance coverage will be adequate or sufficient to protect us from or to mitigate liabilities arising out of our privacy and security practices, that such coverage will continue to be available on commercially reasonable terms or at all, or that such coverage will pay future claims. Although we have cyber-insurance coverage that may cover certain events described above, this insurance is subject to deductibles and coverage limitations and we may not be able to maintain this insurance.

We outsource certain aspects of our cybersecurity risk management program to a third-party Managed Services Provider ("MSP") to monitor the security and privacy of our information assets, and any failure to provide such services could have a material adverse effect on our business.

We utilize our MSP, which provides, as a service, a security operations center ("SOC") that is operated 24/7/365, for certain aspects of our cybersecurity risk management, including monitoring our devices and networks for malicious activity. In addition to antivirus endpoint protection on Company devices, our IT managed services provider also, for example, monitors IT system metadata around suspicious events, evidence of tactics, tools, or procedures used by attackers, and monitors remote privileged activity. While we regularly review the cybersecurity tools and other security protection provided by this MSP and this MSP regularly runs intrusion and other security tests on services provided to us, there can be no guarantee that this MSP will be able to

detect or protect against all cybersecurity threats or incidents. Moreover, our failure to adequately monitor our MSP could result in the failure of all or a portion of our information assets and materially or adversely impact our operations. In addition to the services currently provided, we may utilize the MSP for additional aspects of our cybersecurity risk management in the future.

If our IT systems were to fail, including as a result of the threats of unauthorized intrusions and attackers, we may not be able to sufficiently recover to avoid the loss of data or any adverse impact on our operations that are dependent on such IT systems. Our MSP also could be subject to break-ins, cyber-attacks (including through the use of malware, software bugs, computer viruses, ransomware, social engineering, and denial of service), sabotage, intentional acts of vandalism and other misconduct, from a spectrum of actors ranging in sophistication from threats common to most industries to more advanced and persistent, highly organized adversaries. Any security breach or incident, including personal data breaches, that we experience could result in unauthorized access to, or misuse, modification, destruction or unauthorized acquisition of, our internal sensitive corporate data, such as personal data, financial data, trade secrets, intellectual property, or other competitively sensitive or confidential data. Such unauthorized access, misuse, acquisition, or modification of sensitive data may result in data loss, corruption or alteration, interruptions in our operations or damage to our computer hardware or systems or those of our employees or customers.

In addition, if we were to lose the availability of the MSP's services due to a dispute, termination of or inability to renew the contract, or business continuity issues due to events beyond their control such as fires, floods, earthquakes, hurricanes, epidemics, quarantines, wars, civil unrest, strikes or governmental action, such loss could have a material adverse effect on our operations. Although multiple providers of such services exist, there can be no assurance that we could secure another source to handle these transactions on acceptable terms or otherwise to our specifications in the event of a disruption of services.

## We are highly dependent on our senior management team and key personnel and our business could be harmed if we are unable to attract and retain personnel necessary for our success.

We are highly dependent on our senior management team and key personnel. Our success will depend on our ability to retain senior management and to attract and retain qualified personnel in the future, including sales, marketing, scientific and technical professionals, and to integrate current and additional personnel in all departments. The loss of members of our senior management, sales, marketing, scientific and technical professionals could result in lower than expected sales and delays in product development. If we are not successful in attracting and retaining highly qualified personnel, our business, financial condition and results of operations, may be negatively impacted.

Competition for skilled personnel in our market is intense and may limit our ability to hire and retain highly qualified personnel on acceptable terms, or at all. To induce valuable employees to remain at our company, in addition to salary and cash incentives, we have issued, and will in the future issue, equity awards that vest over time. The value to employees of equity awards that vest over time may be significantly affected by movements in our stock price that are beyond our control and may at any time be insufficient to counteract more lucrative offers from other companies. Our employment arrangements with our employees provide for at-will employment, which means that any of our employees could leave our employment at any time, with or without notice. Despite our efforts to retain valuable employees, they may terminate their employment with us on short notice.

Many of the other cell engineering or therapeutic development companies that we compete against for qualified personnel have greater financial and other resources, different risk profiles and a longer history in the industry than we do. They may also provide more diverse opportunities, better chances for career advancement and higher compensation. Some of these characteristics are more appealing to high-quality candidates than what we can offer. Further, if we hire employees from competitors or other companies, their former employers may attempt to assert that these employees or we have breached legal obligations, resulting in a diversion of our time and resources and, potentially, damages.

In addition, job candidates and existing employees often consider the value of the equity awards they receive in connection with their employment. If the perceived benefits of our stock awards decline, either because we are a public company or for other reasons, it may harm our ability to recruit and retain highly skilled employees. Many of our

employees have become or will soon become vested in a substantial amount of their equity awards. Our employees may be more likely to leave us if the equity they own have significantly appreciated in value relative to the original purchase prices of the shares, or if the exercise prices of the options that they hold are significantly below the market price of our common stock.

Our future success also depends on our ability to continue to attract and retain additional executive officers and other key employees as we expand our business and operations. If we fail to attract new personnel or fail to retain and motivate our current personnel, it will negatively affect our business, financial condition and results of operations.

## Recent changes to our leadership team and the resulting management transition might harm our future operating results.

On December 10, 2023, the Board appointed Maher Masoud as our Chief Executive Officer, replacing Doug Doerfler, who had served in that role since 1999.

Although we believe this leadership transition is in the best interest of the Company and its stockholders, changes in executive management inherently create uncertainty. Such transition involves the loss of personnel with deep institutional and technical knowledge, could divert management's attention from business concerns, or could impact our public or market perception, all of which could have a negative impact on our business. The transition also could potentially disrupt our operations and relationships with employees, suppliers, partners, and customers due to added costs, operational inefficiencies, decreased employee productivity and increased turnover. We must successfully integrate our new leadership team within our organization to achieve our operating objectives; as such, the leadership transition may temporarily affect our business performance and results of operations while the new members of our leadership team engage in their new roles within our business. In addition, our competitors may seek to use this transition and the related potential disruptions to gain a competitive advantage over us. Our future operating results depend substantially upon the continued service of our key personnel and in significant part upon our ability to attract and retain qualified management personnel. If we are unable to mitigate these or other similar risks, our business, results of operations and financial condition may be materially and adversely affected.

We have increased the size of our organization and expect to further increase it in the future, and we may experience difficulties in managing our growth. If we are unable to manage the anticipated growth of our business, our future revenue and operating results may be harmed.

As of December 31, 2023, we had 143 full-time employees, which represents a notable increase from 125 employees at the end of 2022. As our sales and marketing strategies develop, we expect to need additional managerial, operational, sales, marketing, financial and other personnel. Future growth would impose significant added responsibilities on members of management, including:

- identifying, recruiting, integrating, maintaining and motivating additional employees;
- managing our internal development efforts effectively, while complying with our contractual obligations to contractors and other third parties; and
- improving our operational, financial and management controls, reporting systems and procedures.

We have experienced significant growth in recent years and anticipate further growth in our business operations both inside and outside the United States. This future growth could strain our organizational, administrative and operational infrastructure, including quality control, operational, finance, customer service and sales organization management. We expect to continue to increase our headcount and to hire more specialized personnel in the future as we grow our business. We will need to continue to hire, train and manage additional qualified scientists, engineers, technical personnel, sales and marketing staff, and improve and maintain our products to properly manage our growth. Rapid expansion in personnel could mean that less experienced people develop, market and sell our products, which could

result in inefficiencies and unanticipated costs, reduced quality and disruptions to our operations. If our new hires perform poorly, if we are unsuccessful in hiring, training, managing and integrating these new employees or if we are not successful in retaining our employees, our business may be harmed. We may not be able to maintain the quality or expected turnaround times of our products or satisfy customer demand as it grows. Our ability to manage our growth properly will require us to continue to improve our operational, financial and management controls as well as our reporting systems and procedures. The time and resources required to implement these new systems and procedures is uncertain, and failure to complete this in a timely, efficient and effective manner could adversely affect our operations.

Our officers, employees, independent contractors, consultants and commercial partners may engage in misconduct or activities that are improper under other laws and regulations, or make significant errors, which could create liability for us.

We are exposed to the risk that our officers, employees, independent contractors, consultants, commercial partners, suppliers, and third-party distributors may engage in fraudulent conduct or other illegal activity. Misconduct by these parties could include intentional, reckless or negligent conduct or disclosure of unauthorized activities to us. Applicable laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Misconduct by these parties could also involve the improper use of individually identifiable information, which could result in regulatory sanctions and serious harm to our reputation. While we regularly monitor our activities to detect misconduct, it is not always possible to identify and deter misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant civil, criminal, and administrative penalties, including without limitation, damages, fines, imprisonment, exclusion from participation in government healthcare programs, and the curtailment or restructuring of our operations.

If we were to be sued for product liability, we could face substantial liabilities that exceed our resources, limit sales of our existing products and limit commercialization of any products that we may develop.

The marketing, sale and use of our products could lead to the filing of product liability claims where someone may allege that our products identified inaccurate or incomplete information or otherwise failed to perform as designed. We may also be subject to liability for errors, in a misunderstanding of or inappropriate reliance, upon the information we provide in the ordinary course of our business activities. A product liability claim could result in substantial damages and be costly and time-consuming for us to defend. If we cannot successfully defend ourselves against product liability claims, we will incur substantial liabilities and reputational harm. In addition, regardless of merit or eventual outcome, product liability claims may result in:

- substantial litigation costs;
- distraction of management's attention from our primary business;
- the inability to commercialize our products or new products;
- decreased demand for our products;
- damage to our business reputation;
- product recalls or withdrawals from the market;
- loss of sales; or
- termination of existing agreements by our partners and potential partners failing to partner with us.

We maintain product liability insurance, but this insurance is subject to deductibles and may not fully protect us from the financial impact of defending against product liability claims. Any product liability claim brought against us, with or without merit, could increase our insurance rates or prevent us from securing insurance coverage in the future.

While we may attempt to manage our product liability exposure by proactively recalling or withdrawing from the market any defective products, any recall or market withdrawal of our products may delay the supply of those products to our customers and may impact our reputation. We may not be successful in initiating appropriate market recall or market withdrawal efforts that may be required in the future and these efforts may not have the intended effect of preventing product malfunctions and the accompanying product liability that may result. Such recalls and withdrawals may also harm our reputation with customers, which could negatively affect our business, financial condition and results of operations.

If our customers fail to safely and appropriately use our products, or if we are unable to train our customers on the safe and appropriate use of our products, our reputation may be negatively impacted and we may be unable to achieve our expected sales, growth or profitability.

An important part of our sales process includes training our customers on how to safely and appropriately use our products. If our customers are not properly trained, they may misuse or ineffectively use our products. Any improper use of our products may result in unsatisfactory outcomes, negative publicity or lawsuits against us, any of which could harm our reputation and affect future product sales. Even if our products are used improperly by customers, we may face reputational damage if our products are associated with negative outcomes or injuries. Damage to our reputation could make it more difficult for us to sell our products and enter into new partnerships. Accordingly, if our customers fail to safely and appropriately use our products or if we are unable to train our customers on the safe and appropriate use of our products, our reputation may be negatively impacted and we may be unable to achieve our expected sales, growth or profitability.

#### Litigation and other legal proceedings may harm our business.

While we have never been involved in legal proceedings relating to patent and other intellectual property matters, product liability claims, employee claims, tort or contract claims, federal or state regulatory investigations, securities class actions and other legal proceedings or investigations, we may become involved in such legal proceedings which could have a negative impact on our reputation, business and financial condition and divert the attention of our management from the operation of our business. Litigation is inherently unpredictable and can result in excessive or unanticipated verdicts and/or injunctive relief that affect how we operate our business. We could incur judgments or enter into settlements of claims for monetary damages or for agreements to change the way we operate our business, or both. There may be an increase in the scope of these matters or there may be additional lawsuits, claims, proceedings or investigations in the future, which could harm our business, financial condition and results of operations. Adverse publicity about regulatory or legal action against us could damage our reputation and brand image, undermine our customers' confidence and reduce long-term demand for our products, even if the regulatory or legal action is unfounded or not material to our operations.

## We may be subject to damages resulting from claims that we or our employees have wrongfully used or disclosed alleged trade secrets of our employees' former employers.

As we continue to expand our workforce, some employees may have previously been employed at universities or other life sciences companies, including our competitors or potential competitors. Although no claims against us are currently pending, we or our employees may be subject to claims that these employees or we have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers. Litigation may be necessary to defend against these claims. If we fail in defending such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights. A loss of key research personnel's work product could hamper or prevent our ability to commercialize certain potential products, which could severely 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.

## Business disruptions could seriously harm our future revenue and financial condition and increase our costs and expenses.

Our operations, including our manufacturing operations, and the operations of our customers, partners, distributors and collaborators could be subject to earthquakes, power shortages, telecommunications failures, water shortages, floods, hurricanes, typhoons, fires, extreme weather conditions, medical epidemics and pandemics, including COVID-19, other natural or man-made disasters or business interruptions, and geopolitical conflicts, for which we are predominantly self-insured. Our ability to obtain components for our products could be disrupted if the operations of our suppliers were affected by a man-made or natural disaster or other business interruption. The occurrence of any of these business disruptions could seriously harm our operations and financial condition and increase our costs and expenses.

We manufacture our ExPERT instruments at our manufacturing facilities located in Maryland, and we rely on various suppliers in the United States. Should our manufacturing facilities or the facilities of our suppliers be damaged or destroyed by natural or man-made disasters, such as earthquakes, fires or other events, or should events such as political unrest unfold, it could take months to relocate or rebuild, during which time our manufacturing and the operations of our suppliers could cease or be delayed and our products may be unavailable. The inability to perform our manufacturing activities, combined with our limited inventory of materials and components and manufactured products, or the inability of our suppliers to continue their operations, may cause us to be unable to meet customer demand or harm our reputation, and we may be unable to reestablish relationships with such customers in the future. Consequently, a catastrophic event or business interruption at our manufacturing facilities or at our suppliers' facilities could harm our business, financial condition and results of operations.

## Our insurance policies are expensive and protect us only from some business risks, which leaves us exposed to significant uninsured liabilities.

We do not carry insurance for all categories of risk that our business may encounter. Although we have general and product liability insurance that we believe is appropriate, this insurance is subject to deductibles and coverage limitations. Our current product liability insurance may not continue to be available to us on acceptable terms, if at all, and, if available, coverage may not be adequate to protect us against any future product liability claims. If we are unable to obtain insurance at an acceptable cost or on acceptable terms or otherwise protect against potential product liability claims, we could be exposed to significant liabilities. A product liability claim, recall or other claim with respect to uninsured liabilities or for amounts in excess of insured liabilities could negatively affect our business, financial condition and results of operations. We do not carry specific hazardous waste insurance coverage, and our property, casualty and general liability insurance policies specifically exclude coverage for damages and fines arising from hazardous waste exposure or contamination. Accordingly, in the event of contamination or injury, we could be held liable for damages or be penalized with fines in an amount exceeding our resources. Although we carry cyber insurance, the coverage may not be sufficient to cover our losses in the event of a security incident that results in any data loss, deletion or destruction; unauthorized access to, or acquisition, disclosure or exposure of information; or compromise related to the security, confidentiality, integrity or availability of information technology, software, services, communications or data.

Operating as a public company in the United States has also made it more difficult and more expensive for us to obtain director and officer liability insurance, and we may in the future be required to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage that we currently have. As a result, it may be more difficult for us to attract and retain qualified people to serve on our board of directors, on our board committees or as executive officers. We do not know, however, if we will be able to maintain existing insurance with adequate levels of coverage. Any significant uninsured liability may require us to pay substantial amounts, which could negatively affect our business, financial condition and results of operations.

The majority of our operations are currently conducted at a single location and any disruption at our facility could negatively impact our operations and increase our expenses.

Our headquarters in Maryland contains most of our corporate and administrative functions, the majority of our research, and all of our in-house manufacturing, inventory and distribution functions. A natural or other disaster, such as a fire or flood, could cause substantial delays in our operations, damage or destroy our manufacturing equipment or inventory, and cause us to incur additional expenses. The insurance we maintain against fires, floods and other natural disasters may not be adequate to cover our losses in any particular case. With or without insurance, damage to our manufacturing facility or our other property, or to any of our suppliers, due to fire, flood or other natural disaster or casualty event may have a material adverse effect on our business, financial condition and results of operations.

#### We may face exposure to foreign currency exchange rate fluctuations.

Our results of operations and cash flows are subject to fluctuations due to changes in foreign currency exchange rates, particularly changes in the Euro and the British pound. We expect our non-U.S. operations to continue to grow in the near term and we are continually monitoring our foreign currency exposure to determine if we should consider a hedging program. Today, our non-U.S. contracts are generally denominated in U.S. Dollars, while our non-U.S. operating expenses are often denominated in local currencies. Additionally, as we expand our non-U.S. operations, a larger portion of our operating expenses may be denominated in local currencies. Therefore, increases in the value of the U.S. Dollar and decreases in the value of foreign currencies could result in the dollar equivalent of our revenue being lower, which could negatively affect our reported results of operations.

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

Our ability to compete and the success of our business could be jeopardized if we are unable to protect our intellectual property adequately.

Our success depends to a degree upon the protection of our proprietary technology and obtaining, maintaining and enforcing our intellectual property and other proprietary rights. We rely on a combination of trade secrets, patents, copyrights, trademarks and contractual provisions with employees, contract manufacturers, consultants, customers and other third parties to establish and protect our intellectual property rights, all of which offer only limited protection. Other parties may not comply with the terms of their agreements with us, and we may not be able to enforce our rights adequately against these parties.

Although we enter into confidentiality, assignments of proprietary rights and license agreements, as appropriate, with our employees and third parties, including our contract manufacturers, contract engineering firms and generally, control access to and distribution of our technologies, documentation and other proprietary information, we cannot be certain that the steps we take to prevent unauthorized use of our intellectual property rights are sufficient to prevent their misappropriation, particularly in foreign countries where laws or law enforcement practices may not protect our intellectual property rights as fully as in the United States. In addition, we rely on trade secrets and know-how to protect certain of our technologies, especially where we do not believe patent protection is appropriate or obtainable. However, trade secrets and know-how are difficult to protect, as trade secrets do not protect against independent development of a technology by third parties. Although we use reasonable efforts to protect our trade secrets and know-how, our employees and third parties to whom our trade secrets and know-how are disclosed may unintentionally or willfully disclose our information to competitors. Enforcing a claim that a third-party entity illegally obtained and is using any of our trade secrets is expensive and time-consuming, and the outcome is unpredictable. In addition, courts outside the United States are sometimes less willing to protect trade secrets. Moreover, our competitors may independently develop equivalent knowledge, methods and know-how.

If competitors are able to use our technology, our ability to compete effectively could be harmed. For example, if a competitor were to gain use of certain of our proprietary technology, they might be able to develop and manufacture similarly designed solutions at a reduced cost, which could result in a decrease in demand for our products.

Furthermore, we have adopted a strategy of seeking limited patent protection both in the United States and in foreign countries with respect to the technologies used in or relating to our products. Although we generally apply for patents in those countries where we expect to have material sales of our patented products, we may not accurately predict all of the countries where patent protection will ultimately be desirable. If we fail to timely file a patent application in any such country, we may be precluded from doing so at a later date. We do not know whether any of our pending patent applications will result in the issuance of patents or whether the examination process will require us to narrow our claims, and even if patents are issued, they may be contested, circumvented, modified, revoked, found to be unenforceable, or invalidated over the course of our business. Moreover, the rights granted under any issued patents may not provide us with proprietary protection, barriers to entry or competitive advantages, and, as with any technology, competitors may be able to develop and obtain patents for technologies that are similar or superior to our technologies. If that happens, we may need to license these technologies and we may not be able to obtain licenses on reasonable terms, if at all, thereby causing great harm to our business. Additionally, the determination that a patent application or patent claim meets all of the requirements for patentability is a subjective determination based on the application of law in any given jurisdiction. The ultimate determination by the United States Patent and Trademark Office (the "USPTO"), or by a court or other trier of fact in the United States, or corresponding foreign national patent offices or courts, on whether a claim meets all requirements of patentability cannot be assured. Accordingly, we cannot predict the breadth of claims that may be allowed or enforced in our patents or patent applications, in our licensed patents or patent applications or in thirdparty patents. Moreover, given that patents have a limited term, our patent protection will expire over time.

We rely on our trademarks, trade names, and brand names to distinguish our products from the products of our competitors and have registered or applied to register many of these trademarks. We cannot guarantee that our trademark applications will be approved. Third parties may also oppose our trademark applications, or otherwise challenge our use of the trademarks. In the event that our trademarks are successfully challenged, we could be forced to rebrand our products, which could result in loss of brand recognition, and could require us to devote resources to the advertising and marketing of new brands.

#### Legal proceedings to assert our intellectual property rights could be costly and could impair our operations.

Even in those instances where we have determined that another party is breaching our intellectual property and other proprietary rights, enforcing our legal rights with respect to such breach may be expensive and difficult. We may need to engage in litigation to enforce or defend our intellectual property and other proprietary rights, which could result in substantial costs and diversion of management resources. Further, many of our current and potential competitors are substantially larger than we are and have the ability to dedicate substantially greater resources to defending any claims by us that they have breached our intellectual property rights. If we are unsuccessful in enforcing our intellectual property rights, it could have a material adverse effect on our business, results of operations and financial condition.

#### We may be sued by third parties for alleged infringement of their proprietary rights, which could be costly and timeconsuming and which could limit our ability to use certain technologies in the future or to develop future products.

We may be subject to claims that our technologies infringe upon the intellectual property or other proprietary rights of third parties. Any claims, even those without merit, could be time-consuming and expensive, and could divert our management's attention away from the execution of our business plan. Moreover, any settlement or adverse judgment resulting from the claim could require us to pay substantial amounts or obtain a license to continue to use the technology that is the subject of the claim, or otherwise restrict or prohibit our use of the technology. There can be no assurance that we would be able to obtain a license from the third party asserting the claim on commercially reasonable terms, if at all, that we would be able to develop alternative technology on a timely basis, if at all, or that we would be able to obtain a license to use a suitable alternative technology to permit us to continue offering, and our customers to continue using, our affected product.

Changes in U.S. patent law could diminish the value of patents in general, thereby impairing our ability to protect our products.

Depending on future actions by the U.S. Congress, the federal courts and the U.S. Patent and Trademark Office ("USPTO"), the laws and regulations governing patents could change in unpredictable ways that could weaken our ability to obtain new patents or to enforce our existing patents as well as patents that we might obtain in the future. Further, we cannot predict how this and future decisions by these governing bodies may impact the value of our patents. Any similar adverse changes in the patent laws of other jurisdictions could also harm our business, financial condition, results of operations and prospects.

We may be obligated to disclose our proprietary technology to our customers, which may limit our ability to protect our intellectual property.

Certain customer agreements contain provisions permitting the customer to become a party to, or a beneficiary of, a technology escrow agreement under which we place proprietary know-how and source code for our products in escrow with a third party. Under these escrow agreements, the know-how and source code to the applicable product may be released to the customer, typically for its use to further develop, maintain, modify and enhance the product, upon the occurrence of specified events, such as our filing for bankruptcy and breaching our representations, warranties or covenants of our agreements with our customers. Disclosing this know-how and source code may limit the intellectual property protection we can obtain or maintain for that know-how or source code or the products embodying or containing that know-how or source code and may facilitate intellectual property infringement claims against us. Each of these could harm our business, results of operations and financial condition.

#### General Risk Factors Associated with an Investment in Our Common Stock

Our common stock is traded on two separate stock markets and investors seeking to take advantage of price differences between such markets may create unexpected volatility in our share price; in addition, investors may not be able to easily move shares for trading between such markets.

Our shares of common stock are traded on both AIM, a market operated by the London Stock Exchange plc (the "London Stock Exchange"), and the Nasdaq Global Select Market. Price levels for our common stock may fluctuate significantly on either market, independent of our common stock price on the other market. Investors could seek to sell or buy our common stock to take advantage of any price differences between the two markets through a practice referred to as arbitrage. Any arbitrage activity could create unexpected volatility in both our common stock prices on either market and the volumes of shares of our common stock available for trading on either market. In addition, holders of common stock on either market will not be immediately able to transfer such common stock for trading on the other market without effecting necessary procedures with our transfer agent. This could result in time delays and additional costs for our stockholders. Further, if we are unable to continue to meet the regulatory requirements for admission to AIM or listing on the Nasdaq Global Select Market, we may lose our admission to AIM or listing on the Nasdaq Global Select Market, which could impair the liquidity of shares of our common stock. Investors whose source of funds for the purchase of shares of our common stock is denominated in a currency other than U.S. Dollars may also be adversely affected by fluctuations in the exchange rate between such currency and the U.S. Dollar.

Securities traded on AIM may carry a higher risk than securities traded on other markets, which may impact the value of your investment.

Our shares of common stock are currently traded on AIM. Investment in equities traded on AIM is sometimes perceived to carry a higher risk than an investment in equities quoted on markets with more stringent listing requirements, such as the main market of the London Stock Exchange, New York Stock Exchange or Nasdaq. This is because AIM is less heavily regulated and imposes less stringent corporate governance and ongoing reporting requirements than those other markets. In addition, AIM requires only half-yearly, rather than quarterly, financial reporting. You should be aware that the value of our shares of common stock may be influenced by many factors, some of

which may be specific to us and some of which may affect AIM companies generally, including the depth and liquidity of the market, our performance, a large or small volume of trading in our shares of common stock, legislative changes and general economic, political or regulatory conditions, and that the prices may be volatile and subject to extensive fluctuations. Therefore, the current market price of our shares of common stock may not reflect the underlying value of our company.

#### The price of our common stock is likely to be volatile and may fluctuate due to factors beyond our control.

The market price of our common stock may be highly volatile and may fluctuate or decline substantially as a result of a variety of factors, some of which are beyond our control, including:

- actual or anticipated fluctuations in our financial condition or results of operations;
- variance in our financial performance from expectations of securities analysts;
- changes in our projected operating and financial results;
- announcements by us or our competitors of significant business developments, acquisitions, or new offerings;
- announcements by our partners on clinical development delays for products being enabled by our technology;
- announcements or concerns regarding real or perceived safety or efficacy issues with our products or similar products of our competitors;
- adoption of new regulations applicable to our industry or the expectations concerning future regulatory developments;
- our involvement in litigation;
- future sales of our common stock by us or our stockholders;
- changes in senior management, the board of directors or key personnel;
- the trading volume of our common stock;
- changes in the anticipated future size and growth rate of our market; and
- general economic, macroeconomic and market conditions.

Broad market and industry fluctuations, as well as general economic, political, regulatory and market conditions, may also negatively impact the market price of our common stock.

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

The trading market for our common stock will depend in part on the research and reports that securities or industry analysts publish about us or our business. If no or too few securities or industry analysts commence coverage of us, the trading price for our common stock could be negatively affected. In the event securities or industry analysts initiate coverage, if one or more of the analysts who cover us downgrade our common stock or publish inaccurate or unfavorable research about our business, the price of our common stock could decline. If one or more of these analysts cease coverage of us or fail to publish reports on us regularly, demand for our common stock could decrease, which might cause the price of our common stock and trading volume to decline.

The requirements of being a public company in the United States may strain our resources, increase our operating costs, divert management's attention, and affect our ability to attract and retain qualified board members or executive officers.

We became a public company in the United States in July 2021. As a U.S. public company, we incur significant legal, accounting, and other expenses, including costs associated with public company reporting requirements.

We also have incurred and will continue to incur costs associated with the Sarbanes-Oxley Act of 2002, as amended, the Dodd-Frank Wall Street Reform and Consumer Protection Act and related rules implemented or to be implemented by the SEC and the Nasdaq Global Select Market. The expenses incurred by public companies generally for reporting and corporate governance purposes have been increasing. We expect these rules and regulations to increase our legal and financial compliance costs and to make some activities more time-consuming and costly and divert management's time and attention from revenue-generating activities to compliance activities. It could also make it more difficult or costly for us to obtain certain types of insurance, including director and officer liability insurance, and we may be forced to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. These laws and regulations could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, our board committees, or as our executive officers and may divert management's attention. Furthermore, if we are unable to satisfy our obligations as a U.S. public company, we could be subject to delisting of our common stock, fines, sanctions and other regulatory action and potentially civil litigation.

Increasing scrutiny and evolving expectations from customers, regulators, investors, and other stakeholders with respect to our environmental, social and governance practices may impose additional costs on us or expose us to new or additional risks.

Companies are facing increasing scrutiny from customers, regulators, investors and other stakeholders related to their environmental, social and governance ("ESG") practices and disclosure. Investor advocacy groups, investment funds and influential investors are also increasingly focused on these practices, especially as they relate to the environment, health and safety, diversity, labor conditions and human rights. Increased ESG-related compliance costs could result in increases in our overall operational costs. Failure to adapt to or comply with regulatory requirements or investor or stakeholder expectations and standards could negatively impact our reputation, ability to do business with certain partners, and our stock price. New government regulations could also result in new or more stringent forms of ESG oversight and expanding mandatory and voluntary reporting, diligence and disclosure.

#### Future sales of our common stock in the public market could cause our share price to fall.

Our stock price could decline as a result of sales of a large number of shares of our common stock or the perception that these sales could occur, including by our officers, directors and their respective affiliates. These sales, or the possibility that these sales may occur, also might make it more difficult for us to sell equity securities in the future at a time and at a price that we deem appropriate.

We register the offer and sale of all shares of common stock that we may issue under our equity compensation plans. In addition, in the future, we may issue additional shares of common stock or other equity or debt securities convertible

into common stock in connection with a financing, acquisition, litigation settlement, employee arrangements or otherwise. Any such future issuance could result in substantial dilution to our existing stockholders and could cause our stock price to decline.

Because we do not expect to pay dividends on our common stock in the foreseeable future, capital appreciation, if any, would be your sole source of gain.

We have never declared or paid any dividends on our common stock. We currently anticipate that we will retain future earnings for the development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. The decision to pay future dividends to stockholders will be at the discretion of our board of directors after taking into account various factors including our business prospects, cash requirements, financial performance and new product development. Accordingly, investors cannot rely on dividend income from our common stock and any returns on an investment in our common stock will likely depend entirely upon any future appreciation in the price of our common stock.

Provisions in our governing documents will require disclosure of information about stockholders that would not otherwise be required to be disclosed under applicable U.S. state or federal laws.

In accordance with the AIM Rules for Companies published by the London Stock Exchange (the "AIM Rules"), we are required to disclose information regarding the legal and beneficial owners, whether directly or indirectly, of three percent or more of our outstanding common stock. In order to allow us to comply with the AIM Rules, our certificate of incorporation contains a provision requiring any legal or beneficial owner of three percent or more of the voting power attributable to our outstanding common stock to notify us of his, her or its holdings, as well as of any change in his, her or its legal or beneficial ownership above three percent of our outstanding common stock, which increases or decreases his, her or its holding through any single percentage. Comparatively, none of the U.S. state or federal laws, or the rules of the SEC or the Nasdaq Global Select Market require stockholders to report this beneficial ownership information to us or us to disclose this information to the public or a regulatory body. We are required to make this information public in the United Kingdom under the AIM Rules, thereby revealing certain stockholders' holdings in our Company. In addition, we do not control the identity of our stockholders and the market price of our shares of common stock could possibly be impacted by the disclosure of the identity of certain stockholders that legally or beneficially own three percent or more of our outstanding common stock.

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

We are an "emerging growth company," as defined in the Jumpstart Our Business Startups Act of 2012 (the "JOBS Act"), and we may take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not "emerging growth companies," including the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act, or Section 404, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. Pursuant to Section 107 of the JOBS Act, as an emerging growth company, we have elected to use the extended transition period for complying with new or revised accounting standards until those standards would otherwise apply to private companies. As a result, our financial statements may not be comparable to the financial statements of issuers who are required to comply with the effective dates for new or revised accounting standards that are applicable to public companies, which may make our common stock less attractive to investors. In addition, if we cease to be an emerging growth company, we will no longer be able to use the extended transition period for complying with new or revised accounting standards.

We will remain an emerging growth company until the earliest of: (i) December 31, 2026, which is the last day of the fiscal year following the fifth anniversary of our initial public offering in the United States; (ii) the last day of the

first fiscal year in which our annual gross revenue is \$1.235 billion or more; (iii) the date on which we have, during the previous rolling three-year period, issued more than \$1 billion in non-convertible debt securities; and (iv) the last day of the fiscal year in which the market value of our common stock held by non-affiliates exceeded \$700 million as of June 30 of such fiscal year.

We are also a "smaller reporting company" as defined by Rule 12b-2 of the Exchange Act. We may continue to be a smaller reporting company even after we are no longer an emerging growth company. We may take advantage of certain of the scaled disclosures available to smaller reporting companies and will be able to take advantage of these scaled disclosures for so long as the market value of our common stock held by non-affiliates is less than \$250.0 million measured on the last business day of our second fiscal quarter, or our annual revenue is less than \$100.0 million during the most recently completed fiscal year and the market value of our common stock held by non-affiliates is less than \$700.0 million measured on the last business day of our second fiscal quarter.

We cannot predict if investors will find our common stock less attractive if we choose to rely on these exemptions. For example, if we do not adopt a new or revised accounting standard, our future results of operations may not be as comparable to the results of operations of certain other companies in our industry that adopted such standards. 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.

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 or prevent fraud. As a result, stockholders could lose confidence in our financial and other public reporting, which could harm our business and the trading price of our common stock.

Effective internal control over financial reporting is 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 addition, any testing by us conducted in connection with Section 404, or any subsequent testing by our independent registered public accounting firm, may reveal deficiencies in our internal controls over financial reporting that are deemed to be material weaknesses or that may require prospective or retroactive changes to our financial statements or identify other areas for further attention or improvement. Inferior 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 changes made in our internal controls and procedures on a quarterly basis and our management is required to assess the effectiveness of these controls annually. 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. An independent assessment of the effectiveness of our internal controls could detect problems that our management's assessment might not. Undetected material weaknesses in our internal controls could lead to financial statement restatements and require us to incur the expense of remediation.

Anti-takeover provisions in our charter documents and under Delaware law could make an acquisition of our company more difficult, limit attempts by our stockholders to replace or remove our current management and limit the market price of our common stock.

Provisions in our current certificate of incorporation and bylaws, and provisions of Delaware law applicable to us, may have the effect of delaying or preventing a change of control or changes in our management. Our current certificate of incorporation and bylaws include provisions that:

authorize our board of directors to issue, without further action by the stockholders, shares of undesignated
preferred stock with terms, rights, and preferences determined by our board of directors that may be senior to
our common stock;

- require that any action to be taken by our stockholders be effected at a duly called annual or special meeting and not by written consent;
- specify that special meetings of our stockholders can be called only by our board of directors, the chairperson of our board of directors, or our chief executive officer;
- establish an advance notice procedure for stockholder proposals to be brought before an annual meeting, including proposed nominations of persons for election to our board of directors;
- establish that our board of directors is divided into three classes, with each class serving three- year staggered terms;
- prohibit cumulative voting in the election of directors;
- provide that our directors may be removed (i) with or without cause, upon the vote of at least 50% of the outstanding shares of voting stock or (ii) with cause, by the affirmative vote or consent of at least two-thirds of the other members of our board of directors; and
- provide that vacancies on our board of directors may be filled only by a majority of directors then in office, even though less than a quorum.

These provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors, which is responsible for appointing the members of our management. In addition, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which generally, subject to certain exceptions, prohibits a Delaware corporation from engaging in any of a broad range of business combinations with any "interested" stockholder for a period of three years following the date on which the stockholder became an "interested" stockholder.

Our certificate of incorporation designates the Court of Chancery of the State of Delaware and, to the extent enforceable, the federal district courts of the United States of America as the exclusive forums for substantially all disputes between us and our stockholders, which will restrict our stockholders' ability to choose the judicial forum for disputes with us or our directors, officers or employees.

Our current certificate of incorporation provides that the Court of Chancery of the State of Delaware (or, if and only if the Court of Chancery of the State of Delaware lacks subject matter jurisdiction, any state court located within the State of Delaware or, if and only if all such state courts lack subject matter jurisdiction, the federal district court for the District of Delaware) is the exclusive forum for the following types of actions or proceedings under Delaware statutory or common law:

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

The provisions would not apply to suits brought to enforce a duty or liability created by the Securities Act or the Securities Exchange Act of 1934, as amended. Furthermore, Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all such Securities Act actions.

Accordingly, both state and federal courts have jurisdiction to entertain such claims. To prevent having to litigate claims in multiple jurisdictions and the threat of inconsistent or contrary rulings by different courts, among other considerations, our certificate of incorporation provides that the federal district courts of the United States of America will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act of 1933, as amended, and any rules and regulations promulgated thereunder. While the Delaware courts have determined that such choice of forum provisions are facially valid, a stockholder may nevertheless seek to bring a claim in a venue other than those designated in the exclusive forum provisions. In such instance, we would expect to vigorously assert the validity and enforceability of the exclusive forum provisions of our certificate of incorporation. This may require significant additional costs associated with resolving such action in other jurisdictions and there can be no assurance that the provisions will be enforced by a court in those other jurisdictions.

These choice of forum provisions may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees. If a court were to find either choice of forum provision contained in our certificate of incorporation to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could seriously harm our business.

#### Item 1B. Unresolved Staff Comments.

None.

# Item 1C. Cybersecurity

As a company that provides enabling platform technologies to advance the discovery, development and commercialization of next-generation cell therapeutics for customers, we are committed to protecting the confidentiality, integrity and availability of our and our customers' information assets. We recognize the importance of assessing, identifying, and managing material risks associated with cybersecurity threats and cybersecurity incidents, as such terms are defined in Item 106(a) of Regulation S-K. Our exposure to applicable cybersecurity risks is described more fully under the Risk Factors in Item 1A in this annual report on Form 10-K.

As described further below, we maintain a formal and comprehensive information security management framework informed by the National Institute of Standards and Technology ("NIST") cybersecurity framework and have implemented several dozen policies governing our information security program, which we revise and update annually. Our Board, including the Audit Committee of our Board, and our management team are actively involved in the oversight of our enterprise risk management program, of which cybersecurity represents an important component.

#### Risk Management and Strategy

Monitoring and assessing cybersecurity risk is a critical part of our overall enterprise risk management ("ERM"). Our Board regularly discusses significant areas of risk, including those that may be related to cybersecurity, as necessary. We have designed and implemented an information security program tailored to our operations, the nature of our products and services, and the sensitivity of the data that we process. We have implemented cybersecurity risk management processes that include, for example, developing organizational understandings to manage cybersecurity risk, identifying asset vulnerabilities, threats to internal and external organizational resources, and risk response activities, and developing a vendor risk management policy for assessing supply chain and vendor-related risks. As part of these processes, we have implemented an Incident Response Plan, which provides protocols for incident evaluation, including processes for notification and internal escalation of information to our senior management and the appropriate Board committees. Our Incident Response Plan is updated annually and tested in tabletop exercises.

We utilize the cybersecurity services of our IT MSP, which is a SOC that is operated 24/7/365 and monitors our devices and networks for malicious activity. In addition to antivirus endpoint protection on Company devices, our IT MSP

also, for example, monitors IT system metadata around suspicious events, evidence of tactics, tools, or procedures used by attackers, and monitors remote privileged activity.

We engaged a third party to perform a cybersecurity audit in the fourth quarter of 2021 and intend to undertake another cybersecurity audit in the third quarter of 2024. To date, we have not identified any risks from cybersecurity threats, including as a result of previous cybersecurity incidents, that have materially affected us, our business strategy, results of operation, or financial condition. To date, we have not experienced a material cybersecurity attack, such as a cybersecurity threat, a ransomware attack, computer viruses or other malicious codes, security breaches, unauthorized access, phishing attacks, or system failures. The Company carries cybersecurity insurance and considers our coverage to be adequate.

#### Governance

Our Board, including the Audit Committee of the Board, and our management team are actively involved in the oversight of risks from cybersecurity threats.

Our Audit Committee discusses risks related to cybersecurity quarterly, and reports to the Board quarterly on such risks and events. Our Senior Director of Information Systems presents information to the Audit Committee regarding cybersecurity risks and events quarterly. The full Board also discusses cybersecurity risks and events annually. If there are direct risks rising to the level of potential materiality, the management team reports such risks and events to the Board.

Our Senior Director of Information Systems and our Director of Information Systems are responsible for day-to-day oversight of cybersecurity risk. The individual currently holding the position of Senior Director of Information Systems has held the role for two years, has sixteen years of experience in IT and software development (with eight of those years in management roles), and holds certification from MIT Sloan School of Management in cybersecurity risk management. The individual currently holding the position of Director of Information Systems—who reports directly to the Senior Director of Information Systems—was formerly an IT Audit Senior Associate at PricewaterhouseCoopers, performed security assessments as a consultant at PricewaterhouseCoopers, and passed his CISA exam (though certification is currently pending). These individuals are responsible for coordinating resources internally and externally regarding cybersecurity risk management and incident response, and they report directly to our Chief Administrative Officer.

Our management team has also established a Cybersecurity Incident Response Team (the "CSIRT"), which is comprised of our Chief Executive Officer, the Chair of the Audit Committee of our Board, our General Counsel, our Chief Administrative Officer, and our Senior Vice President of Human Resources. The CSIRT is also responsible for responding to cybersecurity incidents.

# Item 2. Properties.

During 2022, we relocated our corporate headquarters, research and development facilities and manufacturing and distribution centers to Rockville, Maryland, where we currently lease approximately 67,000 square feet of space under an operating lease.

The lease term for our facilities continues through August 31, 2035, subject to three five-year options that we may exercise to extend the term of the lease.

We believe that our current facilities are adequate and suitable to meet our current requirements. We may need to obtain additional facility space to meet future needs as our operations grow over time. We believe we will be able to obtain additional space on acceptable and commercially reasonable terms if and as required.

# Item 3. Legal Proceedings.

From time to time, we may become involved in legal proceedings arising in the ordinary course of our business. We are not currently a party to any material legal proceedings, and we are not aware of any pending or threatened legal

proceedings against us that we believe will have, individually or in the aggregate, a material adverse effect on our business, financial condition or results of operations.

# 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.

# Certain Information Regarding the Trading of Our Common Stock

Our common stock trades under the symbol "MXCT" on the Nasdaq Global Select Market. Trading of our common stock commenced on July 30, 2021 in connection with our initial public offering ("IPO"), in the United States. Prior to that time, there was no established public market for our common stock in the United States. Since 2016, our common stock has traded on AIM, and currently trades on AIM under the symbol "MXCT."

#### **Holders of Our Common Stock**

As of March 5, 2024, there were approximately 35 holders of record of our common stock. The actual number of holders of our common stock is greater than this number of record holders and includes stockholders who are beneficial owners, but whose shares are held in "street name" by brokers or held by other nominees. The number of holders of record also does not include stockholders whose shares may be held in trust by other entities.

# **Dividend Policy**

We have never declared or paid any dividends on our common stock. We currently intend to retain all available funds and future earnings, if any, to fund the development and expansion of our business, and we do not anticipate declaring or paying any cash dividends in the foreseeable future.

# **Recent Sales of Unregistered Equity Securities**

None.

# **Use of Proceeds from Registered Securities**

#### Initial Public Offering

On August 3, 2021, we closed our IPO, in which we issued and sold 15,525,000 shares of common stock at a price to the public of \$13.00 per share, inclusive of 2,025,000 shares sold pursuant to the full exercise of the underwriters' option to purchase additional shares. The IPO generated gross proceeds to us of \$201.8 million. We received net proceeds of \$184.3 million after deducting aggregate underwriting commissions and offering expenses of \$17.6 million. All of the shares of common stock issued and sold in the offering were registered under the Securities Act pursuant to a registration statement on Form S-1 (File No. 333 257810), which was declared effective by the SEC on July 29, 2021. The joint book-running managers of the offering were Cowen and Company, LLC, Stifel, Nicolaus & Company, Incorporated and William Blair & Company, L.L.C.

In connection with our IPO, no payments were made by us to directors, officers or persons owning ten percent or more of our common stock or to their associates or to our affiliates.

Cash used since the IPO is described elsewhere in the "Management's Discussion and Analysis of Financial Condition and Results of Operations" section of our periodic reports filed with the SEC. As of the date of this filing, there has been no material change in the planned use of proceeds from the IPO as described in the final prospectus for our IPO.

# **Issuer Purchases of Equity Securities**

None.

#### Item 6. [Reserved]

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

You should read the following discussion and analysis of our financial condition and results of operations in conjunction with our consolidated financial statements and related notes thereto included elsewhere in this Annual Report on Form 10-K, as well as the other information provided from time to time in our other filings with the SEC. Some of the information contained in this discussion and analysis or set forth elsewhere in this annual report, including information with respect to our plans and strategy for our business, includes forward-looking statements that involve risks and uncertainties. As a result of many factors, our actual results could differ materially from those discussed in or implied by these forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, those discussed in the section of this Annual Report on Form 10-K titled "Risk Factors." Please also see the section titled "Special Note Regarding Forward-Looking Statements."

#### Overview

We are a leading commercial cell engineering company focused on providing enabling platform technologies to advance the discovery, development and commercialization of next-generation cell therapeutics and to support innovative cell-based research and development. Over more than two decades, we have developed and commercialized our proprietary Flow Electroporation technology, which facilitates complex engineering of a wide variety of cells. Electroporation is a method of transfection, or the process of deliberately introducing molecules into cells, that involves applying an electric field in order to temporarily increase the permeability of the cell membrane. This precisely controlled increase in permeability allows the intracellular delivery of molecules, such as genetic material and proteins, that would not normally be able to cross the cell membrane as easily.

Our ExPERT platform, which is based on our Flow Electroporation technology, has been designed to address this rapidly expanding cell therapy market and can be utilized across the continuum of the high-growth cell therapy sector, from discovery and development through commercialization of next-generation, cell-based therapies. The ExPERT family of products includes four instruments, which we call the ATx, STx, GTx and VLx, and related software protocols, as well as a portfolio of proprietary related disposables and consumables. We launched the VLx instrument in September 2022.

Our disposables and consumables include PAs designed for use with our instruments, as well as accessories supporting PAs such as electroporation buffer solution and software protocols. We have garnered meaningful expertise in cell engineering via our internal research and development efforts as well as our customer-focused commercial approach, which includes a growing application scientist team. The platform is also supported by a robust intellectual property portfolio with more than 150 granted U.S. and foreign patents and more than 95 pending patent applications worldwide.

From leading commercial cell therapy drug and biologic developers and top biopharmaceutical companies to top academic and government research institutions, including the NIH, our customers have extensively validated our technology. We believe the features and performance of our platform have led to sustained customer engagement. Our existing customer base ranges from large biopharmaceutical companies, including a majority of the top 25 pharmaceutical companies based on 2022 global revenue, to hundreds of biotechnology companies and academic centers focused on translational research. As of December 31, 2023, we have placed more than 680 of our electroporation instruments with customers worldwide.

Historically, we have financed our operations primarily from the issuance and sale of equity securities, previous debt borrowings and cash flows from operations. On August 3, 2021, we issued and sold 15,525,000 shares of common stock in our U.S. IPO at a price to the public of \$13.00 per share, inclusive of 2,025,000 shares issued pursuant to the full exercise of the underwriters' option to purchase additional shares. The IPO generated gross proceeds to us of \$201.8 million. We received aggregate net proceeds of \$184.3 million after deducting aggregate underwriting commissions and offering costs of \$17.6 million.

We believe that our current cash, cash equivalents and short-term investments will enable us to fund our operating expenses and capital expenditure requirements for at least the next 12 months from the date of the filing of this Annual Report. We have based this estimate on assumptions that may prove to be wrong, however, and we could exhaust our available capital resources sooner than we expect. See "Liquidity and Capital Resources" below for more information about our current capital resources.

Since our inception, we have incurred significant operating losses. Our ability to generate revenue sufficient to achieve profitability will depend on the successful further development and commercialization of our products. We generated revenue of \$41.3 million and \$44.3 million for the years ended December 31, 2023 and 2022, respectively, and incurred net losses of \$37.9 million and \$23.6 million for those same years. As of December 31, 2023, we had an accumulated deficit of \$175.8 million. We expect to continue to incur net losses as we focus on growing commercial sales of our products in both the United States and international markets, including growing our sales teams, scaling our manufacturing operations, continuing research and development efforts to develop new products and further enhance our existing products.

We believe we have a diversified revenue model with revenue generated from multiple sources including instrument leases with recurring license fees, sales of instruments and related disposables and participation in the clinical and commercial success of some of our customers through milestone and sales-based payments under SPL agreements.

# **Key Factors Affecting Our Performance**

We believe that our financial performance has been, and in the foreseeable future will continue to be, primarily driven by the following factors. While each of these factors presents significant opportunities for our business, they also pose challenges that we must successfully address in order to sustain our growth and improve our results of operations. Our ability to successfully address the factors below is subject to various risks and uncertainties, including those described in this Annual Report under the heading "Risk Factors."

# Sales and Leases of Instruments

Our financial performance has largely been driven by, and in the future will continue to be impacted by, the rate of sales and leases of our ExPERT family of proprietary Flow Electroporation instruments to existing and new customers. We currently market four versions of our instruments, the ATx, the STx, the GTx and the VLx. The ATx is primarily sold across geographic markets in which we currently sell our technology. The STx is primarily sold to end users for research and drug discovery purposes, and the GTx is leased to customers for research, clinical or commercial use or sold for research use in certain circumstances or sold to academic centers for research or clinical use. We launched the VLx in September 2022 to provide our customers with an easier to use system that incorporates the benefits of the ExPERT platform. We view the demand for our instruments, whether in the form of sales or leases, as an indicator of the health of our current business and as a predictor of future instrument sale and lease revenue. As described below, we separately sell proprietary single-use disposables, which we call PAs, that are necessary for our customers to use our electroporation instruments. Therefore, depending on the number of instruments that have been sold or are under active lease, we have insight into the demand for PAs that will also translate to future revenue for us.

Our sales model varies based on the activity of the end customer, such as whether they are a translational research center, an academic center, a company focused on drug or biologic discovery, or a company engaged in cell therapy development, and the customer's intended use of our platform. If our customer intends to use our platform for research or discovery only, we typically sell the instrument outright. Each of the ATx, STx, GTx and VLx instruments have different prices based on the instrument's features, with the VLx being the most expensive. When we sell an instrument, we also provide a non-exclusive license to our intellectual property for the customer to use the instrument broadly for research or discovery, as applicable. In the case of a sale, title to the instrument conveys to the buyer, but we retain ownership of intellectual property rights and software and protocols loaded onto the instruments.

The sales cycle for our cell engineering instruments varies widely and typically ranges from approximately six to approximately 12 months, with the actual period depending on project stage, budget process, equipment prioritization

and the general financial status of the customer or the market in general. As a result of this lengthy and unpredictable sales cycle, we expect that we may be prone to quarterly fluctuations in our instrument sales revenue.

For cell therapy customers who use our technology to develop engineered cells for human therapeutic use in clinical trials or, if approved by regulatory authorities, for commercial sale, we license our platform on a non-exclusive basis in exchange for an annual fee per instrument licensed. This license fee varies based on whether the instrument is being used for preclinical or clinical purposes. Once we have leased an instrument to a customer, we generally have high visibility into future lease revenue from this customer. It is possible, however, that our future lease revenue could be impacted by failure of the customer therapeutic candidates to progress through clinical development for reasons unrelated to the successful use of our instruments, such as toxicity, lack of efficacy, funding constraints, changes in development priorities, patient access limitations or regulatory challenges. For any of these reasons, a customer could determine not to renew or to enter into additional instrument leases with us, which could result in our actual future lease revenues differing from our estimates and projections.

Our installed base of electroporation instruments has grown to over 680 instruments as of December 31, 2023. This installed base includes both instruments sold to customers and instruments licensed for research and clinical use. Because of the size of the drug and biologic discovery market and our long history in that market, the installed base of instruments is currently weighted more heavily towards instruments sold for discovery and research applications. However, since each licensed instrument provides us with ongoing license revenues, the share of revenues from licensed instruments may grow as a share of our total revenue mix.

We plan to further grow our installed base of ExPERT instruments through additional sales and leases to our current customers and through the sale or lease of instruments to new cell therapy, product discovery, academic and other customers. To achieve this goal, we intend to further expand our commercial infrastructure, including through the expansion of our sales force and field application scientists. We have expanded our sales force and field application scientist count over the past several years and now have over 36 dedicated field sales and application scientist professionals globally. Our candidate identification and hiring process is stringent, and there can be no assurance that we will be able to continue to recruit the high level of candidates that make up our current team.

In addition, we have numerous collaborations in place with academic and commercial institutions to further expand our capabilities and supporting data in new cell engineering applications. Recent sales efforts have also focused on expanding our presence in translational academic centers, which we view as a potentially meaningful source of installed base expansion given the increased industry focus on, and government funding allocated to, cell therapy. Academic translational centers have been a strong source of cell therapy innovation and commercial spinouts in the cell therapy sector.

We expect revenue from instruments leased to cell therapy customers to continue to grow as those customers move their existing drug or biologic development programs into later-stage clinical trials and advance their preclinical pipeline programs into clinical development. In addition, we expect new customers to emerge and contribute to these revenues, particularly given the underlying growth in the cell therapy pipeline among companies in this industry, availability of capital to support such companies, and in particular the switch by some of these cell therapy companies away from viral approaches to non-viral approaches.

# Sales of Processing Assemblies

In addition to instrument sales, our current and future revenue is dependent on sales of our proprietary PAs, as well as the sale of our proprietary electroporation buffer solution, for use with our instruments. We sell PAs that are intended either to support research use or use in cGMP clinical research applications. The PAs differ in terms of their volume capacities and the associated numbers of cells that can be processed in each electroporation sequence with a particular PA, as well as the number of transfection experiments that can be performed in a single electroporation process. Our PA pricing varies based on the volume of cells processed and the number of transfections per PA.

We expect that as our installed instrument base grows, our sales of PAs and electroporation buffer solutions will grow accordingly, especially as cell therapy programs continue to progress through clinical development and potentially

become commercial-stage, thereby increasing the number of PAs needed by customers. We are also developing and intend to launch new PAs that target previously unserved subsegments across the bioprocessing and cell therapy markets, which could further increase our PA sales. However, both the number of PAs used per instrument, as well as the specific PA used, is highly variable across our customer base and depends on several factors, including:

- the purpose for which the customer is using the platform;
- the relative pricing of our PAs;
- the progression of cell therapy products through preclinical and clinical development;
- whether the cell therapy customer uses a centralized or decentralized manufacturing process;
- the customer's target indication, which can result in variations in patient numbers needed for clinical trials; and
- whether the cells to be processed using our platform are patient-derived, donor-derived or cell line-derived.

With considerable variability of processes, even within the same indication, such as is the case for allogeneic genetically-modified cell therapies, such as CAR-Ts, and the nascency of the cell therapy industry, we expect that it may take several years for us to gain visibility into how these factors will impact our PA revenue over time.

We continuously re-evaluate our PA portfolio based on customer needs and have introduced, and intend to continue to introduce, new PAs, improvements to existing PAs, and complementary products. Some new PAs may fail to be used in line with our expectations when they are launched. While we also price PAs based on the value provided to the customer, introduction of new PAs could cannibalize our existing PA portfolio more than we anticipated if customers find the new products to be a better solution for their applications or workflows.

# Strategic Platform Licenses (SPLs)

Typically, our cell therapy customers will either purchase our ATx instrument for research purposes or purchase or obtain a research use license under lease of our GTx instrument technology in order to validate the use of our technology in their programs and to progress their preclinical work towards clinic trials. However, once a cell therapy customer using one of our ExPERT instruments advances their preclinical research to a stage where they are planning to enter clinical development, they need to enter into a licensing arrangement with us for the rights to clinical and/or commercial use of our instrument. Our customers typically negotiate the terms of those licenses during research and preclinical development.

We refer to these arrangements as SPL partnerships, the terms of which contain not only higher annual, non-exclusive fees for the clinical use of the instrument, but also allow us to share in the economics of the customer's programs. From 2017 through February 2024, we have entered into 26 SPL partnerships with commercial cell therapy developers, and those licenses currently allow for over 160 clinical development programs in the aggregate. On average, our current SPL partnerships allow for approximately six product candidates per license, although this average may change over time. SPL partnerships typically include potential payments to us upon the customer's achievement of specified clinical development or regulatory milestones, as well as potential sales-based payments to us, which could be payments based upon the achievement of specified sales levels and/or royalty payments that are a percentage of the customer's net sales. The amount of each milestone payment is typically correlated in size with value-creating, precommercial clinical progress events or commercial sales levels.

Of the over 160 programs associated with our current SPLs, one is in commercial stage, and 16 of those programs are currently active in clinical development, meaning they have at least an FDA-cleared IND application or foreign equivalent. Our 26 SPLs have the potential to generate over \$1.95 billion in precommercial milestone payments, if all product candidates allowed under those agreements were to fully progress through clinical development and obtain regulatory approval. However, our actual milestone revenue from these agreements will likely be considerably lower than this amount, as not all programs covered by each agreement will become and remain active programs in a

customer's development pipeline or successfully complete the clinical development process. Further, each agreement typically includes programs that have not been specifically identified, or for which a candidate may never be identified or developed by the customer.

Our strategy is to capitalize on the growth in the number of cell therapy developers by entering into new SPL partnerships. We entered into seven agreements in 2023 and have entered into three agreements thus far in 2024 as of March 1, 2024.

For the year ended December 31, 2023, two cell therapy companies with which we have entered into an SPL accounted for 39% of our total revenue, and our five largest SPL partners accounted for an aggregate of approximately 52% of our total revenue for the year through a combination of instrument license fees, milestones realized and processing assembly revenue.

Our future milestone revenue under our SPL partnerships will depend in large part on the clinical and regulatory achievements of our customers. Generally, precommercial milestone payments become larger as programs move through clinical development. We rely in part on our customers' public disclosures around regulatory timelines to forecast our receipt of precommercial milestone payments. While we expect our forecasting ability to improve over time as more of our customers' programs advance through clinical development and the number of clinical programs covered by our licenses expands, given the early nature of the cell therapy clinical market, we expect our realization of precommercial milestones to be somewhat unpredictable.

In addition, the potential for sales-based payments once a customer's product is approved and in commercial use is unknown and variable based on a number of factors, including inherent clinical risk, potential changes in the customer's strategy, the designated indication and its impact on the potential number of patients to be served and the competitive products available to patients, product pricing and reimbursement structures, our customer's commercial manufacturing plans and the inherent unknowns in adoption of next-generation cell therapies relative to other modalities.

# **Gross Margins**

We have generated overall gross margins of nearly 90% for the last six years, although our margins vary depending on our revenue mix from instruments, PAs and milestones under SPL partnerships and other factors. We price our instruments at a premium given what we believe to be the broad benefits of our platform, and the limited availability of alternative, clinically validated non-viral delivery approaches. However, the market for non-viral delivery is highly competitive, and introduction of a cGMP-grade platform by a competitor that delivers similar performance across a similar diversity of cell types could negatively impact our business and lead to increased price pressure that could negatively impact our gross margins. In addition, part of our growth strategy is to expand into new regional markets, which could require the use of distributors and/or our participation in more competitive environments, which could impact our ability to price our instruments at a premium and could negatively impact our ability to enter into SPL partnerships on terms similar to those currently in effect.

We expect our gross margins to benefit from realization of the economics from our SPL partnership agreements described above, to the extent that such milestones and/or sales-based payments grow to be a significant proportion of overall revenues, as there is no cost of goods sold associated with such revenue. However, realization of these potential revenues is uncertain. Margins may also experience downward pressure during the investment phase of our internal PA production ramp up, increases in labor and materials costs, expansion of our PA portfolio, future design changes or the mix of PAs sold, or other factors, but may benefit in the mid-to-long term as PA production becomes more automated.

# **Key Business Metrics**

In addition to revenue, we regularly review several key business metrics to evaluate our business, measure our performance, identify trends affecting our business, formulate financial projections and make strategic decisions. These key metrics include:

- the number of cumulative instruments that we have placed with our customers, either by sale or lease, which we refer to as our installed base and consider to be an indication of our traction within the non-viral delivery market and other markets and indicative of the potential future recurring revenue generated from those instruments, including disposables and annual fees;
- the number of active (customers with rights to develop one or more clinical programs) SPL partnerships that we have entered into with cell therapy developers, as well as the total number of our customers' clinical programs, whether active or contemplated, that are covered by such active SPL partnerships and the percentage of those clinical programs that are under an active IND application (or foreign equivalent), meaning that the customer is cleared to commence clinical trials;
- the aggregate potential precommercial milestone payments under active SPL partnerships, representing the
  maximum potential milestone payments to us if all programs covered by each SPL partnership were to achieve
  regulatory approval;
- the aggregate number of potential programs licensed for clinical use, whether active or contemplated, that are covered by our SPL partnerships; and
- the aggregate number of programs licensed for clinical use and covered by our SPL partnerships that are currently in clinical development.

With respect to the numbers of programs under license, in many cases we make estimates of such programs based on our contract terms with our customers and our knowledge about our customers' clinical progression of their programs. We rely, in part, on our customers' public disclosures around regulatory timelines to forecast our receipt of precommercial milestone payments. However, it is possible that some programs may have become dormant or inactive without our knowledge, some new programs may be identified and some programs may progress further in clinical development without our knowledge if the customer has not made a public announcement. While we expect our forecasting ability to continue to improve over time as more of our customers' programs move through clinical development and the number of clinical programs covered by our licenses expands, given the early nature of the cell therapy clinical market, we expect our realization of precommercial milestones to be somewhat unpredictable. This number may fluctuate due to the success of our commercial partners. Additionally, the addition of a large SPL partnership in which one SPL partner uses multiple instruments as part of their research, clinical or commercial program, may dilute the percentage of commercial programs currently in the clinic.

As of the dates presented, our key metrics described above were as follows:

		As of December 31,	,
	2023	2022	2021
Installed base of instruments (sold or leased)	683	616	502
Core revenue generated by SPL clients as a percentage of core revenue	48%	42%	40%
Number of active SPLs	23	18	15
Total number of licensed clinical programs (SPL clients only)	>160	>125	>95
Total number of licensed clinical programs under SPLs currently in the			
clinic	16	16	15
Total number of licensed clinical programs under SPLs currently			
commercial	1	-	-
Total potential pre-commercial milestones under SPLs	>\$1.95 billion	>\$1.55 billion	>\$1.25 billion

\* Number of licensed clinical programs under SPL partnerships are by number of product candidates and not by indication.

# **Components of Our Results of Operations**

#### Revenue

We generate revenue principally from the sale of instruments, single-use PAs and buffers as well as from the lease of instruments to our customers. Our SPL partnerships also include associated clinical progress milestones and salesbased payments to us, in addition to annual lease payments. Sales of instruments and disposables under contracts with customers are classified as product sales in our consolidated financial statements. Revenue from instrument leases, including payments that we may receive from our customers based on their achievement of specified clinical development or commercialization milestones, are classified as leased elements in our consolidated financial statements.

Our business and revenue growth strategy currently consists of the sale or lease of instruments and the sale of disposables. We record revenue from the sale of instruments or PAs upon shipment to a customer. Instrument leases are typically invoiced annually at the start of each instrument license period and are accounted for as monthly revenue over the lease term with the expectation of continuing customer renewals of their instrument leases. As our customers achieve clinical progress milestones and/or sales-based payment milestones, we recognize the full value of the milestone as revenue. In addition, as customers use instruments they have either purchased or leased, they typically replenish their supplies of disposables through recurring purchases. Although customers are not contractually obligated to renew their instrument leases or to purchase additional disposables and may decide not to do so solely in their own discretion, leased instruments and disposables revenue streams have historically formed an important component of our revenues, and we believe they provide insight into our future performance. We consider these sales and lease revenue streams to be recurring revenues.

In order to evaluate how our sales are trending across key markets, as well as the contribution of program economics from our SPL partnerships, we separately analyze revenue derived from our cell therapy customers and drug discovery customers, as well as the performance-based milestone revenues we recognize under our SPL partnerships. Cell therapy includes revenue from instruments sold, annual license fees for instruments under lease, and sales of our proprietary disposables. Drug discovery includes revenue from instruments sold, sales of our proprietary disposables and, occasionally, instruments leased, in each case under contracts with drug discovery customers. Core revenue includes sales and leases of instruments and disposables to cell therapy and drug discovery customers, excluding SPL program-related revenue.

Program-related revenue includes precommercial milestones earned and recognized as revenue during the period. Once SPL customers achieve regulatory approval for and commercialize their products, in nearly all cases we will also be entitled to receive sales-based payments which may be milestone payments upon achievement of specified levels of net sales and/or royalties expressed as a percentage of net sales. We have not received any commercial payments from our SPL customers to date. As our customers progress their programs and achieve additional milestones, our SPL program revenue is expected to constitute a growing portion of our total revenues in future periods.

We also offer our customers extended warranty and service plans. Our extended warranty and service plans are offered for periods beyond the standard no-fee, one-year warranty that customers who purchase instruments receive. Leases of instruments include warranty during the lease term without additional charge. Extended warranty and service plans generally have fixed fees and terms ranging from one additional year to four additional years and include an annual calibration. We recognize revenue from the sale of extended warranty and service plans over the respective coverage period, which approximates the service effort provided by us. Warranties are typically not a material revenue stream for us.

# **Product Sales**

Revenue from contracts with customers includes revenue from the sale of instruments, PAs and buffers. Customers purchase an ATx, STx, GTx or VLx depending upon their intended use and all customers purchase PAs for use with our instruments. Commercial customers may not use a purchased instrument for clinical or commercial processes.

We expect product sales revenue to increase in future periods as our market and customer base grow.

#### Leased Elements

Revenue from leased elements consists of revenue from the leasing of instruments to customers (typically the GTx). Our leases of instruments to customers consist of fixed license/lease payments and variable milestone payments that are dependent on our customer's achievement of clinical milestones. Typically, instrument leases that provide for clinical or commercial use also include sales-based milestone payments (and/or sales-based royalties in some cases) upon the commercialization of the customer's product. Under our instrument lease arrangements, we lease our instruments to customers and provide associated software licenses to allow customers non-exclusive use of our technology for research and/or specific clinical programs, typically along with rights for commercial use upon regulatory approval of the customer's products. We also provide scientific and regulatory support to our clinical use licensees to help them improve process optimization and facilitate their regulatory submission process.

We expect leased elements revenue to increase in future periods as our market and customer base grow.

# Cost of Goods Sold

Cost of goods sold primarily consists of costs for raw material parts, contract manufacturer costs, salaries, overhead, other direct costs related to sales recognized as revenue in the period, and leased equipment depreciation.

We expect that our cost of goods sold will increase or decrease primarily to the extent that our instrument and disposables revenue increases and decreases.

# Gross Profit and Gross Margin

Gross profit is calculated as revenue less cost of goods sold. Gross margin is gross profit expressed as a percentage of revenue. Our gross profit in future periods will depend on a variety of factors, including sales mix among instruments, disposables and milestones, the specific mix among types of instruments or disposables, the proportion of revenues associated with instrument leases as opposed to sales, the share of revenues composed of milestones, changes in the costs to produce our various products, the launch of new products or changes in existing products, our cost structure for manufacturing including changes in production volumes, the proportion of sales made through third-party distributors, and the pricing of our products which may be impacted by market conditions.

# **Operating Expenses**

#### Research and Development

Research and development expenses consist primarily of costs incurred for our research activities related to advancing our technology and development of applications for our technology, including research into specific applications and associated data development, process development, product development (e.g., development of instruments and disposables, including hardware and software engineering) and design and other costs not directly charged to inventory or cost of goods sold, such as supply chain development and design and management of quality systems.

These expenses include employee-related costs, such as salaries, benefits, incentive compensation, stock-based compensation, and travel, as well as consultant services, facilities, and other expenses, laboratory supplies and materials expenses for employees and contractors engaged in research and development. These expenses are exclusive of depreciation and amortization. We expense research and development costs as incurred in the period in which the underlying activity is undertaken.

We believe that our continued investment in research and development is essential to our long-term competitive position. We expect to continue to incur substantial research and development expenses as we invest in research and development to support our customers, develop new uses for our existing technology and develop improved and/or new offerings to our customers and partners. As a result, we expect that our research and development expenses will continue to increase in absolute dollars in future periods and vary from period to period as a percentage of revenue.

#### Sales and Marketing

Our sales and marketing expenses consist primarily of salaries, commissions and other variable compensation, benefits, stock-based compensation and travel costs for employees within our commercial sales and marketing functions, as well as third-party costs associated with our marketing activities. These expenses are exclusive of depreciation and amortization.

We expect our sales and marketing expenses to increase in future periods as we expand our commercial sales, marketing and business development teams, increase our presence globally, and increase marketing activities to drive awareness and adoption of our products.

#### General and Administrative

General and administrative expenses primarily consist of salaries, benefits, stock-based compensation and travel costs for employees in our executive, accounting and finance, legal, corporate development, human resources, and office administration functions as well as professional services fees, such as consulting, audit, tax and legal fees, general corporate costs, facilities and allocated overhead expenses and costs associated with being a Nasdaq and AIM listed public company such as director fees, U.K. Nominated Advisor and broker fees, investor relations consultants and insurance costs. These expenses are exclusive of depreciation and amortization.

We expect that our general and administrative expenses will continue to increase in absolute dollars in future periods, primarily due to increased headcount to support anticipated growth in the business and due to incremental costs associated with operating as a public company listed on a U.S. exchange, including insurance (particularly directors and officers insurance), costs to comply with the rules and regulations applicable to companies listed on a U.S. securities exchange and costs related to compliance and reporting obligations pursuant to the rules and regulations of the SEC and stock exchange listing standards, investor relations and professional services. We expect these expenses to vary from period to period as a percentage of revenue.

#### Depreciation and Amortization

Depreciation expense consists of the depreciation of property and equipment used actively in the business, primarily by research and development activities. Amortization expense includes the amortization of leasehold improvements over their respective lease terms.

# Other Income (Expense)

Interest income includes interest earned on cash balances in our cash accounts and interest earned on money market funds, commercial paper and corporate bonds as well as miscellaneous income unrelated to our core operations. Other expense for the year ended December 31, 2022 related to a write-off of leasehold improvements due to early termination of a prior facility lease.

# **Provision for Income Taxes**

We did not recognize a benefit for the net operating losses we incurred for the years ended December 31, 2023 and 2022. As of December 31, 2023, we had U.S. net operating loss carryforwards of \$88.9 million, which may be available to offset future taxable income and begin to expire in 2025, as well as net operating losses in the various states in which we file. We have recorded a full valuation allowance against our net deferred tax assets at each balance sheet date since, due to our history of net losses, we have determined that it is not currently more likely than not that our net deferred tax assets are recoverable.

# **Results of Operations**

# Comparison of the Years Ended December 31, 2023 and 2022

The results of operations presented below should be reviewed in conjunction with the consolidated financial statements and notes included elsewhere in this Annual Report. The following tables set forth our results of operations for the periods presented:

		Ended ber 31,
	2023	2022
		usands)
Total revenue	\$ 41,288	\$ 44,261
Cost of goods sold	4,742	5,098
Gross profit	36,546	39,163
Operating expense		
Research and development	23,817	19,514
Sales and marketing	26,975	18,653
General and administrative	30,068	25,829
Depreciation and amortization	3,985	2,528
Total operating expense	84,845	66,524
Operating loss	(48,299)	(27,361)
Other income (expense)		
Other expense	_	(127)
Interest and other income	10,376	3,917
Total other income (expense)	10,376	3,790
Net loss	\$ (37,923)	\$ (23,571)

# Revenue

The following table provides details regarding the sources of revenue for the periods presented:

	Year Ended December 31,			Change		
	 2023		2022	Amount	%	
(in thousands, except percentages)						
Core Revenue:						
Cell therapy	\$ 22,829	\$	30,546	\$ (7,717)	(25%)	
Drug discovery	 6,994		9,100	(2,106)	(23%)	
Total core revenue	29,823		39,646	(9,823)	(25%)	
Program-related	11,465		4,615	6,850	148%	
Total revenue	\$ 41,288	\$	44,261	\$ (2,973)	(7%)	

The following table provides details regarding our core business revenue for the periods presented:

	Year Ended December 31.				Change		
	2023 2022			Amount	%		
(in thousands, except percentages)							
Core revenue:							
Instrument revenue	\$	8,317	\$	11,704	\$	(3,387)	(29%)
Disposables revenue		10,283		16,027		(5,744)	(36%)
Lease revenue		10,326		10,897		(571)	(5%)
Other revenue		897		1,018		(121)	(12%)
Total core revenue	\$	29,823	\$	39,646	\$	(9,823)	(25%)

Total revenue for the year ended December 31, 2023 was \$41.3 million, a decrease of \$3.0 million, or 7%, compared to revenue of \$44.3 million during the year ended December 31, 2022. The decrease was primarily driven by the decreases in total core revenue described below.

Total core revenue for the year ended December 31, 2023 was \$29.8 million, a decrease of \$9.8 million, or 25%, compared to core revenue of \$39.6 million for the year ended December 31, 2022. Our overall decrease in core revenue was primarily driven by revenue decreases in instrument sales and disposable sales in the cell therapy market and drug discovery markets. Revenue from instrument sales and disposable sales decreased by \$3.4 million and \$5.7 million, respectively, in part due to the timing of purchases by customers and partially attributable to challenges in the macro environment affecting the cell therapy and drug discovery markets. Revenue from lease elements and other core revenue decreased \$0.6 million and \$0.1 million, respectively, for the year ended December 31, 2023 compared to the year ended December 31, 2022.

The \$6.9 million increase in program-related revenues resulted from achievement of contractually specified clinical and regulatory milestones and reflects the expected variability from period to period in the level of program-related revenue given the small number of individual triggering events which currently generate this portion of revenue. We expect program-related revenue to continue to experience variability for some time, although we anticipate that variability may moderate as the volume of SPL partnerships and associated milestones grows.

# Cost of Goods Sold and Gross Profit

	Year Ended	Change		
	2023	2022	Amount	%
(in thousands, except percentages)				
Cost of goods sold	\$ 4,742	\$ 5,098	\$ (356)	(7%)
Gross profit	\$ 36,546	\$ 39,163	\$ (2,617)	(7%)
Gross margin	89%	88%		

Cost of goods sold decreased by \$0.4 million, or 7%, for the year ended December 31, 2023, compared to the year ended December 31, 2022. The decrease was primarily driven by decreased revenue from instrument sales and disposable sales.

Gross profit decreased by \$2.6 million, or 7%, for the year ended December 31, 2023, compared to the year ended December 31, 2022. The decrease was primarily driven by decreased revenue from instrument and disposable sales, offset by an increase in inventory reserves of \$0.7 million.

During the year ended December 31, 2023, gross margin was 89%, compared to 88% in the same period of 2022. The increase was primarily driven by an increase in program related revenue, offset by an increase in cost of goods sold due to initial scale-up of our in-house manufacturing and inventory reserves.

# **Operating Expenses**

Research and Development

	Year Ended	Year Ended December 31,		
	2023	2022	Amount	%
(in thousands, except percentages)				
Research and development	\$ 23,817	\$ 19,514	\$ 4,303	22%

Research and development expenses increased by \$4.3 million, or 22%, for the year ended December 31, 2023 compared to the year ended December 31, 2022. The increase was primarily driven by a \$1.2 million increase in compensation expenses as a result of increases in headcount, a \$1.1 million increase in lab expense and new product development, a \$1.0 million increase in stock-based compensation, a \$0.5 million increase in travel expenses, \$0.4 million increase in professional service fees relating to new product and regulatory consultants and a \$0.1 million increase in other expenses.

Sales and Marketing

	Year Ended	December 31,	Change	
	2023	2022	Amount	%
(in thousands, except percentages)	<u> </u>			
Sales and marketing	\$ 26,975	\$ 18,653	\$ 8,322	45%

Sales and marketing expenses increased by \$8.3 million, or 45%, for the year ended December 31, 2023, compared to the year ended December 31, 2022. The increase was primarily driven by a \$4.3 million increase in compensation expenses as a result of increases in headcount, a \$1.2 million increase in occupancy expenses, a \$0.8 million increase in travel expenses, a \$0.7 million increase in stock-based compensation, a \$0.6 million increase in marketing expenses, a \$0.4 million increase in professional fees, and a \$0.3 million increase in general office expenses.

General and Administrative

	Year Ended	December 31,	Change		
	2023	2022	Amount	%	
(in thousands, except percentages)					
General and administrative	\$ 30,068	\$ 25,829	\$ 4,239	16%	

General and administrative expense increased by \$4.2 million, or 16%, for the year ended December 31, 2023, compared to the year ended December 31, 2022. The increase was primarily driven by a \$1.9 million increase in compensation expenses, a \$1.6 million increase in professional fees, a \$0.7 million increase in general office expenses, a \$0.5 million increase in stock-based compensation, a \$0.5 million increase in legal fees, a \$0.2 million increase in memberships, and a \$0.2 million increase in travel and other expenses, partially offset by a \$0.9 million reduction in public company fees, and a \$0.5 million decrease in occupancy expenses.

Depreciation and Amortization

	Ye	Year Ended December 31,			Change	
		2023		2022	Amount	%
(in thousands, except percentages)						
Depreciation and amortization	\$	3,985	\$	2,528	\$ 1,457	58%

Depreciation and amortization expense increased by \$1.5 million, or 58%, for the year ended December 31, 2023, compared to the year ended December 31, 2022. The increase was primarily driven by increases in leasehold improvements and investments in laboratory equipment and consignment instruments.

# Interest and Other Income (Expense)

	Year Ended	Year Ended December 31,		
	2023	2022	Amount	%
(in thousands, except percentages)				
Other expense	\$ —	\$ (127)	\$ 127	100%
Interest and other income	\$ 10,376	\$ 3,917	\$ 6,459	165%

Other expense for the year ended December 31, 2022 was primarily related to a write-off of leasehold improvements due to early termination of a prior facility lease. We did not incur other expense for the year ended December 31, 2023. The increase in interest and other income was driven by increases in interest rates and a higher weighted average balance of interest-bearing securities held during the year ended December 31, 2023.

# **Liquidity and Capital Resources**

Since our inception, we have experienced losses and negative cash flows from operations. For the years ended December 31, 2023 and 2022, we incurred net losses of \$37.9 million and \$23.6 million, respectively. As of December 31, 2023, we had an accumulated deficit of \$175.8 million. To date, we have funded our operations primarily with proceeds from sales of common stock, borrowings under loan agreements and cash flows associated with sales and licenses of our products to customers. On August 3, 2021, we completed our U.S. IPO, generating gross proceeds of \$201.8 million. We received net proceeds of \$184.3 million after deducting aggregate underwriting commissions and offering expenses of \$17.6 million. As of December 31, 2023, we had cash and cash equivalents and short-term investments of \$168.3 million.

We expect to incur near-term operating losses as we continue to invest in expanding our business through growing our sales and marketing efforts, continued research and development, product development and expanding our product offerings. Based on our current business plan, we believe that our existing cash, cash equivalents, short-term investments and internally generated cash flows will enable us to fund our operating expenses and capital expenditure requirements for at least the next 12 months.

We have based this estimate on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we expect. Our future funding requirements will depend on many factors, including:

- transaction and capital expenditures necessitated by strategic activities;
- market acceptance of our products;
- the cost and timing of establishing additional sales, marketing and distribution capabilities;
- the cost of our research and development activities and successful development of data supporting use of our products for new applications, and timely launch of new features and products;
- sales to existing and new customers and the progress of our SPL partners in developing their pipelines of product candidates;
- our ability to enter into additional SPL partnerships and licenses for clinical use of our platform in the future;
- changes in the amount of capital available to existing and emerging customers in our target markets;

- the effect of competing technological and market developments; and
- the level of our selling, general and administrative expenses.

If we are unable to execute on our business plan and adequately fund operations, or if the business plan requires a level of spending in excess of cash resources, we may have to seek additional equity or debt financing. If additional financings are required from outside sources, we may not be able to raise such capital on terms acceptable to us or at all. To the extent that we raise additional capital through the sale of equity or debt securities, the ownership interest of our stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our common stockholders. Debt financing, if available, may involve agreements that include covenants restricting our ability to take specific actions, such as incurring additional debt, selling or licensing our assets, making product acquisitions, making capital expenditures or declaring dividends. If we raise additional funds through collaboration and licensing arrangements with third parties, it may be necessary to relinquish some rights to our technologies or our products, or grant licenses on terms that are not favorable to us. If we are unable to raise additional capital when desired, we may have to delay development or commercialization of future products. We also may have to reduce marketing, customer support or other resources devoted to our existing products.

# Cash Flows

The following table summarizes our uses and sources of cash for the periods presented:

	Year Ended December 31,		
(in thousands)	2023	2022	
Net cash provided by (used in):			
Operating activities	\$ (21,686)	\$ (14,783)	
Investing activities	54,984	(24,823)	
Financing activities	2,143	2,888	
Net increase (decrease) in cash and cash equivalents	\$ 35,441	\$ (36,718)	

# Operating Activities

Net cash used in operating activities for the year ended December 31, 2023 was \$21.7 million, and consisted primarily of our net loss of \$37.9 million, offset in part by net non-cash expenses of \$12.4 million, including stock-based compensation of \$14.0 million, depreciation and amortization expenses of \$4.2 million, an increase in our inventory reserve of \$0.7 million, and other non-cash expenses totaling \$0.6 million, offset by the amortization of \$7.1 million of discounts on investments. We also had net cash inflows of \$3.8 million due to net changes in our operating assets and liabilities. Net changes in our operating assets and liabilities consisted primarily of a \$5.2 million decrease in accounts receivable, a \$1.9 million decrease in tenant improvement allowances receivable, a \$3.3 million increase in accounts payable, accrued expenses and other, and a \$0.4 million decrease in other assets, offset by a \$4.5 million increase in inventory, a \$1.6 million decrease in deferred revenue, a \$0.6 million decrease in prepaid expenses and other current assets, and a \$0.2 million decrease in operating lease and other liabilities.

Net cash used in operating activities for the year ended December 31, 2022 was \$14.8 million, and consisted primarily of our net loss of \$23.6 million, offset in part by net non-cash expenses of \$12.8 million, including stock-based compensation of \$11.8 million, depreciation and amortization expenses of \$2.7 million, non-cash lease expense and other non-cash charges of \$1.0 million, offset by the amortization of \$2.7 million of discounts on investments. We also had net cash outflows of \$3.2 million due to net changes in our operating assets and liabilities. Net changes in our operating assets and liabilities consisted primarily of an increase in lease liabilities of \$5.5 million, an increase in other liabilities of \$0.9 million and a decrease in prepaid expenses and other current assets of \$0.3 million, partially offset by a \$4.6 million increase in accounts receivable, a \$3.5 million increase in inventory, a \$1.9 million increase in tenant improvement allowances receivable and a \$0.5 million increase in other assets.

#### Investing Activities

Cash provided by investing activities during the year ended December 31, 2023 was \$55.0 million, which was primarily attributable to maturities of investments of \$313.8 million, partially offset by purchases investments of \$255.1 million, and purchases of property and equipment of \$3.7 million. Purchases of investments are made as part of ordinary course investing activities in compliance with our investment policy which has as its primary objective preservation of principal.

Cash used in investing activities during the year ended December 31, 2022 was \$24.8 million, which was primarily attributable to maturities of investments of \$284.6 million, partially offset by purchases of investments of \$290.9 million, capitalized lease-related construction expenses of \$14.2 million, purchases of equipment and furniture of \$3.9 million and capitalized internal-use software of \$1.0 million.

# Financing Activities

Net cash provided by financing activities during the year ended December 31, 2023 was \$2.1 million, which consisted of proceeds from the exercise of stock options and employee purchases from our employee stock purchase plan.

Net cash provided by financing activities during the year ended December 31, 2022 was \$2.9 million, which consisted exclusively of proceeds from the exercise of stock options.

# **Contractual Obligations and Commitments**

Our contractual obligations and commitments as of December 31, 2023 consisted exclusively of operating lease obligations. In May 2021, we entered into an operating lease for new office, lab and warehouse/manufacturing space. The lease for the new facility consists of three phases, with Phase 1 having commenced in December 2021, Phase 2 having commenced in the first quarter of 2022 and Phase 3 commenced in November 2023. The lease term for all phases expires on August 31, 2035. We designed and constructed the leasehold improvements with the approval of the landlord. The lease provides that the landlord will reimburse us for costs of property improvements up to amounts specified in the lease. The total incremental non-cancellable lease payments under the lease agreement are \$29.6 million through the lease term. We expect to be able to fund our obligations under the new lease, both in the short term and in the long term, from cash on hand, short-term investments and operating cash flows. See Part I, Item 2, "Facilities" in this Annual Report for additional information regarding the new office lease.

On June 8, 2021, we exercised our option to early terminate one of our office and lab space lease arrangements associated with our former headquarters facility. That amended office lease expired on June 7, 2022. In June 2022, we exercised our option to early terminate our remaining subleased office, laboratory, manufacturing and other spaces associated with our former headquarters facility, which became effective in July and August 2022. These subleases previously had expiration dates in October 2023.

We had no debt obligations as of December 31, 2023 or 2022.

Purchase orders or contracts for the purchase of supplies and other goods and services are based on our current procurement or development needs and are generally fulfilled by our vendors within short time horizons.

# **Critical Accounting Estimates**

We have prepared our consolidated financial statements in accordance with generally accepted accounting principles in the United States. Our preparation of these consolidated financial statements requires us to make estimates, assumptions and judgments that affect the reported amounts of assets, liabilities, revenue, expenses and related disclosures. We evaluate our estimates and judgments on an ongoing basis. We base our estimates on historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form

the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources.

Actual results could therefore differ materially 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 the following accounting policies to be critical to the judgments and estimates used in the preparation of our consolidated financial statements.

# Revenue Recognition

We derive revenue from two primary sources, product sales, which are comprised primarily of instrument and disposables revenue, and leased elements, which are comprised of revenue associated with instrument leases.

For revenue generated pursuant to contracts with customers, we recognize revenue when our customer obtains control of promised goods or services, in an amount that reflects the consideration that we expect to receive in exchange for those goods or services. In determining the appropriate amount of revenue to be recognized as we fulfill our obligations under our arrangements, we perform the following 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. At contract inception, we assess the goods or services promised within each contract, determine which goods or services are performance obligations and assess whether each promised good or service is distinct.

We enter into instrument lease and licensing arrangements that are accounted for using lease accounting rather than accounted for as pursuant to contracts with customers. Under these arrangements, we license to third parties the rights to use our products and embedded software. The terms of these arrangements typically include payment to us of one or more of the following: instrument lease fees, and clinical progress milestones and may, under the terms of existing agreements, include regulatory and/or sales milestone payments and/or royalties. Revenue from instrument leases is recognized ratably over the determined contractual term of the lease agreement and revenue from associated milestones is recognized when each specific milestone event is achieved by the customer.

In some product sale arrangements, products and services have been sold together representing distinct performance obligations. In such arrangements we allocate the sale price to the various performance obligations in the arrangement on a relative standalone selling price basis. Under this basis, the Company determines the estimated selling price of each performance obligation in a manner that is consistent with that used to determine the price to sell the deliverable on a standalone basis.

Taxes, such as sales, value-add and other taxes, collected from customers concurrent with revenue generating activities and remitted to governmental authorities are not included in revenue. Shipping and handling costs associated with outbound freight are primarily directly paid by customers as pass-through costs.

Amounts received under lease arrangements prior to revenue recognition are recorded as deferred revenue in our consolidated balance sheets. Amounts expected to be recognized as revenue within the 12 months following the balance sheet date are classified as current portion of deferred revenue in our consolidated balance sheets. Amounts not expected to be recognized as revenue within the 12 months following the balance sheet date are classified as other liabilities in our consolidated balance sheets.

#### Stock-based Compensation

We maintain an incentive compensation plan under which stock options and restricted stock units are granted primarily to employees, consultants and non-employee directors. We measure stock-based compensation expense on the

date of grant and recognize the corresponding compensation expense of those awards over the requisite service period, which is generally the vesting period of the respective award. We record forfeitures as they occur.

We estimate the fair value of stock options granted to our employees and directors based on the closing price of our common stock on the grant date and the resulting stock-based compensation expense using the Black-Scholes option-pricing model. The fair value is based on the value of our common stock on the Nasdaq Global Select Market on the grant date. The Black-Scholes option-pricing model requires the use of assumptions regarding a number of variables that are complex, subjective and generally require significant judgment to determine. The assumptions include expected volatility using either publicly traded peer group companies' common stock (for grants before July 1, 2022) or the Company's own common stock (for grants beginning on July 1, 2022), expected dividend yield, risk-free rate of interest and the expected term using the simplified method.

# **Recent Accounting Pronouncements**

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

# **Emerging Growth Company Status**

We are an "emerging growth company," or EGC, under the JOBS Act. Section 107 of the JOBS Act provides that 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 avail ourselves of the delayed adoption of new and revised accounting standards and, therefore, we will be subject to the same requirements to adopt new or revised accounting standards as private entities. We also intend to rely on other exemptions provided by the JOBS Act, including not being required to comply with the auditor attestation requirements of Section 404(b) of the Sarbanes-Oxley Act.

We will remain an EGC until the earliest of: (i) December 31, 2026, which is the last day of the fiscal year following the fifth anniversary of our initial public offering in the United States; (ii) the last day of the first fiscal year in which our annual gross revenue is \$1.235 billion or more; (iii) the date on which we have, during the previous rolling three-year period, issued more than \$1 billion in non-convertible debt securities; and (iv) the last day of the fiscal year in which the market value of our common stock held by non-affiliates exceeded \$700 million as of June 30 of such fiscal year.

We are also a "smaller reporting company," as defined by Rule 12b-2 of the Exchange Act. We may continue to be a smaller reporting company if either (i) the market value of our stock held by non-affiliates is less than \$250 million as of the last business day of our second fiscal quarter or (ii) our annual revenue is less than \$100 million during the most recently completed fiscal year and the market value of our stock held by non-affiliates is less than \$700 million as of the last business day of our second fiscal quarter. If we are a smaller reporting company at the time we cease to be an emerging growth company, we may continue to rely on exemptions from certain disclosure requirements that are available to smaller reporting companies. Specifically, as a smaller reporting company we have elected to present only the two most recent fiscal years of audited financial statements in this Annual Report. In addition, similar to emerging growth companies, smaller reporting companies have reduced disclosure obligations regarding executive compensation.

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

#### **Interest Rate Risk**

We are exposed to market risk for changes in interest rates related primarily to balances of our financial instruments including cash and cash equivalents and short-term investments. The primary objective of our investment approach is to preserve principal and provide liquidity. As a result, a 10% change in the level of market interest rates would not be expected to have a material effect on our business, financial condition or results of operations.

# Foreign Currency Risk

We are exposed to financial risks as a result of exchange rate fluctuations between the U.S. Dollar and certain foreign currencies and the volatility of these rates. In the normal course of business, we earn revenue primarily denominated in U.S. Dollars as well as in Euros and British Pounds. We incur expenses primarily in U.S. Dollars as well as in Euros, British Pounds and other currencies. Our reporting currency is the U.S. Dollar. We hold our cash primarily in U.S. Dollars as well as in Euros and British Pounds. We do not expect that foreign currency gains or losses will have a material effect on our financial position or results of operations in the foreseeable future. We have not entered into any hedging arrangements with respect to foreign currency risk. As our international operations grow, we will continue to reassess our approach to managing risks relating to fluctuations in currency exchange rates.

#### **Inflation Risk**

During the last two years, inflation and changing prices have not had a material effect on our business. We are unable to predict whether inflation or changing prices will materially affect our business in the foreseeable future.

# Item 8. Financial Statements and Supplementary Data.

# MaxCyte, Inc.

# **Index to Consolidated Financial Statements**

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# Report of Independent Registered Public Accounting Firm

To the Board of Directors and Stockholders of MaxCyte, Inc.

# **Opinion on the Consolidated Financial Statements**

We have audited the accompanying consolidated balance sheets of MaxCyte, Inc. (the "Company") as of December 31, 2023 and 2022, and the related consolidated statements of operations, changes in stockholders' equity, and cash flows for the years then ended, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of the Company as of December 31, 2023 and 2022, and the results of their operations and their cash flows for the years then ended, in conformity with accounting principles generally accepted in the United States of America.

# **Basis for Opinion**

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's consolidated financial statements based on our 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 audit, we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our 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/ CohnReznick LLP

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

Tysons, Virginia March 12, 2024

# MaxCyte, Inc. Consolidated Balance Sheets (in thousands, except share and per share amounts)

	De	ecember 31, 2023	Do	ecember 31, 2022
Assets				
Current assets:				
Cash and cash equivalents	\$	46,506	\$	11,065
Short-term investments, at amortized cost		121,782		216,275
Accounts receivable, net		5,778		11,175
Accounts receivable - TIA (Note 8)		_		1,912
Inventory		12,229		8,581
Prepaid expenses and other current assets		3,899		3,258
Total current assets		190,194		252,266
Investments, non-current, at amortized cost		42,938		_
Property and equipment, net		23,513		23,725
Right-of-use asset - operating leases		11,241		9,853
Other assets		388		809
Total assets	\$	268,274	\$	286,653
Liabilities and stockholders' equity				
Current liabilities:				
Accounts payable	\$	743	\$	292
Accrued expenses and other		11,269		8,265
Operating lease liability, current		774		157
Deferred revenue, current portion		5,069		6,713
Total current liabilities		17,855		15,427
Operating lease liability, net of current portion		17,969		15,938
Other liabilities		283		1,320
Total liabilities		36,107		32,685
1 Otta Intollities		00,107		02,000
Commitments and contingencies (Note 8)				
Stockholders' equity				
Preferred stock, \$0.01 par value; 5,000,000 shares authorized and no shares issued and				
outstanding at December 31, 2023 and December 31, 2022		_		_
Common stock, \$0.01 par value; 400,000,000 shares authorized, 103,961,670 and				
102,397,913 shares issued and outstanding at December 31, 2023 and				
December 31, 2022, respectively		1,040		1,024
Additional paid-in capital		406,925		390,819
Accumulated deficit		(175,798)		(137,875)
Total stockholders' equity		232,167		253,968
Total liabilities and stockholders' equity	\$	268,274	\$	286,653

# MaxCyte, Inc. Consolidated Statements of Operations (in thousands, except share and per share amounts)

		Year Ended December 31,			
		2023		2022	
Revenue	\$	41,288	\$	44,261	
Cost of goods sold		4,742		5,098	
Gross profit		36,546		39,163	
Operating expenses:					
Research and development		23,817		19,514	
Sales and marketing		26,975		18,653	
General and administrative		30,068		25,829	
Depreciation and amortization		3,985		2,528	
Total operating expenses		84,845		66,524	
Operating loss		(48,299)		(27,361)	
Other income and expense:					
Other expense				(127)	
Interest income		10,376		3,917	
Total other income		10,376		3,790	
Provision for income taxes				_	
Net loss	\$	(37,923)	\$	(23,571)	
Basic and diluted net loss per share	\$	(0.37)	\$	(0.23)	
Weighted average shares outstanding, basic and diluted	_	103,268,502	1	101,702,664	

MaxCyte, Inc.

# Consolidated Statements of Changes in Stockholders' Equity (in thousands, except share amounts)

	Common S	Stock Amount	Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity
Balance at December 31, 2021	101,202,705	\$ 1,012	\$ 376,191	\$ (114,304)	\$ 262,899
Stock-based compensation expense		´ —	11,752		11,752
Exercise of stock options	1,195,208	12	2,876	_	2,888
Net loss	_		_	(23,571)	(23,571)
Balance at December 31, 2022	102,397,913	1,024	390,819	(137,875)	253,968
Stock-based compensation expense			13,979		13,979
Vesting of restricted stock units	288,550	3	(3)	_	
Issuance of common stock under employee stock purchase plan	82,423	1	268	_	269
Exercise of stock options	1,192,784	12	1,862	_	1,874
Net loss				(37,923)	(37,923)
Balance at December 31, 2023	103,961,670	\$ 1,040	\$ 406,925	\$ (175,798)	\$ 232,167

# MaxCyte, Inc. Consolidated Statements of Cash Flows (in thousands)

		Year Ended December 31,		
		2023		2022
Cash flows from operating activities:				
Net loss	\$	(37,923)	\$	(23,571)
Adjustments to reconcile net loss to net cash used in operating activities:		4 171		2 (00
Depreciation and amortization		4,171		2,698
Non-cash lease expense		395		767
Net book value of consigned equipment sold		94		76
Loss on disposal of fixed assets		30		139
Stock-based compensation		13,979		11,752
Bad debt expense		171		
Change in excess/obsolete inventory reserve		697		_
Amortization of discounts on investments		(7,120)		(2,667)
Changes in operating assets and liabilities:				
Accounts receivable		5,226		(4,569)
Accounts receivable - TIA		1,912		(1,912)
Inventory		(4,534)		(3,493)
Prepaid expense and other current assets		(641)		320
Other assets		421		(492)
Accounts payable, accrued expenses and other		3,252		(150)
Operating lease liability		(133)		5,482
Deferred revenue		(1,644)		(34)
Other liabilities		(39)		871
Net cash used in operating activities		(21,686)	_	(14,783)
a contract which is opening with the		(21,000)		(1.,,,,,,)
Cash flows from investing activities:				
Purchases of investments		(255,095)		(290,942)
Maturities of investments		313,770		284,596
Purchases of property and equipment		(3,700)		(18,477)
Proceeds from sale of equipment		9		
Net cash provided by (used in) investing activities		54,984		(24,823)
Cash flows from financing activities:				
Proceeds from exercise of stock options		1,874		2,888
Proceeds from issuance of common stock under employee stock purchase plan		269		2,000
Net cash provided by financing activities		2,143		2,888
Net increase (decrease) in cash and cash equivalents		35,441		(36,718)
Cash and cash equivalents, beginning of year				
	Ф	11,065	Ф	47,783
Cash and cash equivalents, end of year	\$	46,506	\$	11,065
Supplemental disclosure of non-cash investing and financing activities:				
	\$	566	\$	363
	\$		\$	540
	\$	1,782	\$	5,476

# MaxCyte, Inc. Notes to Consolidated Financial Statements (in thousands, except par value, share and per share amounts)

# 1. Organization and Description of Business

MaxCyte, Inc. (the "Company" or "MaxCyte") was incorporated as a majority owned subsidiary of EntreMed, Inc. ("EntreMed") on July 31, 1998, under the laws and provisions of the state of Delaware and commenced operations on July 1, 1999. In November 2002, MaxCyte was recapitalized and EntreMed was no longer deemed to control the Company.

MaxCyte is a global life sciences company focused on advancing the discovery, development and commercialization of next-generation cell therapies. MaxCyte leverages its proprietary cell engineering technology platform to enable the programs of its biotechnology and pharmaceutical company customers who are engaged in cell therapy, including gene editing and immuno-oncology, as well as in drug and biologic discovery and development and biomanufacturing. The Company licenses and sells its instruments and technology and sells its consumables to developers of cell therapies and to pharmaceutical and biotechnology companies for use in drug and biologic discovery and development and biomanufacturing.

The Company's registration statement on Form S-1 related to its initial public offering of common stock in the United States (the "IPO") was declared effective on July 29, 2021, and the Company's common stock began trading on the Nasdaq Global Select Market on July 30, 2021. On August 3, 2021, the Company issued and sold 15,525,000 shares of common stock in the IPO at a price to the public of \$13.00 per share, inclusive of 2,025,000 shares issued pursuant to the full exercise of the underwriters' option to purchase additional shares. The IPO generated gross proceeds to the Company of \$201,825. The Company received aggregate net proceeds of \$184,268 from the IPO after deducting aggregate underwriting commissions and offering costs of \$17,557.

# 2. Summary of Significant Accounting Policies

#### **Basis of Presentation**

The accompanying consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America ("US GAAP").

#### **Use of Estimates**

The preparation of consolidated financial statements in conformity with US GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the consolidated financial statements and the reported amount of revenues and expenses during the reporting period. In the accompanying consolidated financial statements, estimates are used for, but not limited to, revenue recognition, stock-based compensation, allowance for credit losses, allowance for inventory obsolescence, accruals for contingent liabilities, deferred taxes and valuation allowance, and the depreciable lives of fixed assets. Actual results could differ from those estimates.

# **Principles of Consolidation**

The consolidated financial statements include the accounts of the Company and its wholly-owned subsidiary. All significant intercompany balances have been eliminated in consolidation.

# Reclassifications

Certain reclassifications have been made to prior years' financial statements to conform to current year presentation. These reclassifications had no effect on previously reported results of operations or accumulated deficit.

#### **Concentrations of Risk**

Financial instruments that potentially subject the Company to concentrations of credit risk consist primarily of cash and cash equivalents, investments and trade receivables. The Company's cash and cash equivalents balances may exceed federally insured limits and cash may also be deposited in foreign bank accounts that are not covered by federal deposit insurance. The Company does not believe that this results in any significant credit risk. The Company invests its excess cash in money market funds, commercial paper and corporate debt. The Company has established guidelines relative to credit ratings, diversification and maturities that seek to maintain safety and liquidity.

Significant customers are those that accounted for 10% or more of the Company's total revenue for the period or accounts receivable as the end of a reporting period. During the years ended December 31, 2023 and 2022, one customer represented 30% and 23% of revenue, respectively. As of December 31, 2023, three customers accounted for 38% of accounts receivable. As of December 31, 2022, one customer accounted for 14% of accounts receivable.

Certain components included in the Company's products are obtained from a single source or a limited group of suppliers. Of the inventory on hand at December 31, 2023 and 2022, the Company purchased approximately 56% and 34%, respectively, from a single supplier. At December 31, 2023, no supplier accounted for 10% or more of the Company's total accounts payable. At December 31, 2022, amounts payable to two suppliers totaled 34% of total accounts payable.

# **Foreign Currency**

The Company's functional currency is the US Dollar. Transactions denominated in foreign currencies are transacted at the exchange rate in effect at the date of each transaction. Differences in exchange rates during the period between the date a transaction denominated in foreign currency is consummated and the date on which it is either settled or at the reporting date are recognized in the consolidated statements of operations as general and administrative expense. For the years ended December 31, 2023 and 2022, the Company recognized \$84 and \$79 in foreign currency transaction loss, respectively.

#### Fair Value

Fair value is the price that would be received from the sale of an asset or paid to transfer a liability assuming an orderly transaction in the most advantageous market at the measurement date. US GAAP establishes a hierarchical disclosure framework which prioritizes and ranks the level of observability of inputs used in measuring fair value. These tiers include:

- Level 1—Quoted prices (unadjusted) in active markets that are accessible at the measurement date for identical assets or liabilities. The fair value hierarchy gives the highest priority to Level 1 inputs.
- Level 2—Observable market-based inputs other than quoted prices in active markets for identical assets or liabilities.
- Level 3—Unobservable inputs are used when little or no market data is available. The fair value hierarchy gives the lowest priority to Level 3 inputs.

See Note 6 for additional information regarding fair value.

#### Cash and Cash Equivalents and Investments

Cash and cash equivalents consist of financial instruments including money market funds and commercial paper with original maturities of less than 90 days. Short-term investments consist of commercial paper, corporate bonds and U.S. Treasury securities and government agency bonds with original maturities greater than 90 days and less than one year. Long-term investments consist of U.S. Treasury securities and government agency bonds with maturities greater than one year. All money market funds and investments are recorded at amortized cost unless they are deemed to be impaired on an other-than-temporary basis, at which time they are recorded at fair value using Level 2 inputs and there were no changes from Level 2 for the years ended December 31, 2023 and 2022, respectively.

# **Inventory**

The Company sells or licenses products to customers. The Company uses the average cost method of accounting for its inventory and adjustments resulting from periodic physical inventory counts are reflected in costs of goods sold in the period of the adjustment. Inventory is carried at the lower of cost or net realizable value. Inventory that is obsolete or in excess of forecasted usage is written down to its estimated net realizable value based on assumptions about future demand and market conditions. Inventory write-downs are charged to cost of goods sold and establish a new cost basis for the inventory.

# **Accounts Receivable**

Accounts receivable are reduced by an allowance for expected credit losses if needed. The allowance for expected credit losses reflects the best estimate of probable losses determined principally on the basis of historical experience and specific allowances for known troubled accounts. All accounts or portions thereof that are deemed to be uncollectible or to require an excessive collection cost are written off to the allowance for expected credit losses. The Company recorded an allowance for expected credit losses of \$130 at December 31, 2023. The Company determined no allowance was necessary at December 31, 2022.

# **Property and Equipment**

Property and equipment are stated at cost. Depreciation is computed using the straight-line method. Office equipment (principally computers) is depreciated over an estimated useful life of three years. Laboratory equipment is depreciated over an estimated useful life of five years. Furniture is depreciated over a useful life of five to seven years. Leasehold improvements are amortized over the shorter of the estimated lease term or useful life. Instruments represent equipment held at a customer's site that is typically leased to customers on a short-term basis and is depreciated over an estimated useful life of five years.

Property and equipment include capitalized costs to develop internal-use software. Applicable costs are capitalized during the development stage of the project and include direct internal costs, third-party costs and allocated interest expenses as appropriate.

Management reviews property and equipment for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Recoverability of the long-lived asset is measured by a comparison of the carrying amount of the asset to future undiscounted net cash flows expected to be generated by the asset. If such assets are considered to be impaired, the impairment to be recognized is measured by the amount by which the carrying amount of the assets exceeds the estimated fair value of the assets. The Company recognized no impairment for the years ended December 31, 2023 or 2022.

# **Revenue Recognition**

The Company analyzes contracts to determine the appropriate revenue recognition using the following steps:
(i) identification of contracts with customers; (ii) identification of distinct performance obligations in the contract; (iii) determination of contract transaction price; (iv) allocation of contract transaction price to the performance obligations; and (v) determination of revenue recognition based on timing of satisfaction of the performance obligations.

In some arrangements, product and services have been sold together representing distinct performance obligations. In such arrangements the Company allocates the sale price to the various performance obligations in the arrangement on a relative selling price basis. Under this basis, the Company determines the estimated selling price of each performance obligation in a manner that is consistent with that used to determine the price to sell the deliverable on a standalone basis.

The Company recognizes revenue upon the satisfaction of its performance obligation (generally upon transfer of control of promised goods or services to its customers) in an amount that reflects the consideration to which it expects to be entitled in exchange for those goods or services.

The Company defers incremental costs of obtaining a customer contract and amortizes the deferred costs over the period that the goods and services are transferred to the customer. The Company had no material incremental costs to obtain customer contracts in any period presented.

Deferred revenue results from amounts billed in advance to customers or cash received from customers in advance of services being provided.

#### **Cost of Goods Sold**

Cost of goods sold primarily consists of costs for raw material parts, contract manufacturer costs, salaries, overhead, leased equipment depreciation and other direct costs related to sales recognized as revenue in the period.

# **Research and Development Costs**

Research and development costs consist of independent proprietary research and development costs and the costs associated with work performed for fees from third parties. Research and development costs are expensed as incurred. Research costs performed for fees paid by customers are included in cost of goods sold.

# **Stock-Based Compensation Expense**

Stock-based compensation expense is measured based on grant-date fair value. The Company grants stock-based awards in exchange for employee, consultant and non-employee director services. The value of the award is recognized as expense on a straight-line basis over the requisite service period.

The Company uses the market closing price of its common stock as reported on the Nasdaq Global Select Market for the fair value of equity awards. The grant-date fair value of stock options is estimated using the Black-Scholes option pricing model for estimating fair value of its stock options granted. Option valuation models, including the Black-Scholes option pricing model, require the input of highly subjective assumptions, and changes in the assumptions used can materially affect the grant-date fair value of an award. These assumptions include the expected volatility, expected dividend yield, risk-free rate of interest and the expected life of the award. Historically, the Company exclusively used identified comparable companies' stock price volatility to calculate expected volatility for the periods presented due to lack of history with its own common stock available to determine its volatility. Beginning with the third quarter of 2022, the Company has observed sufficient historical information regarding its common stock to use the Company's common stock for the estimate of volatility in the Black-Scholes option pricing model. Management's methodology for developing other assumptions has not changed from prior periods. A discussion of management's methodology for developing each of the assumptions used in the Black-Scholes option pricing model is as follows:

# **Expected Volatility**

Volatility is a measure of the amount by which a financial variable such as a share price has fluctuated (historical volatility) or is expected to fluctuate (expected volatility) during a period. For the first two quarters of 2022, the Company identified several public entities of similar size, complexity and stage of development to calculate historical volatility using the volatility of these companies. Beginning with the third quarter of 2022, the Company estimates its expected stock volatility based on historical volatility of its own common stock.

#### **Expected Dividend Yield**

The Company has never declared or paid common stock dividends and has no plans to do so in the foreseeable future. Therefore, the Company used an expected dividend yield of zero.

#### **Risk-Free Interest Rate**

This approximates the US Treasury rate for the day of each option grant during the year, having a term that closely resembles the expected term of the option. For the Employee Stock Purchase Plan ("ESPP"), the US Treasury rate on each Offering Date is used for a term that approximates the Purchase Period.

#### **Expected Term**

This is the period that the options granted are expected to remain unexercised. Options granted have a maximum term of ten years. The Company estimates the expected term of the options to be approximately six years for options, with a majority vesting over a four-year period, using the simplified method. Over time, management intends to track estimates of the expected term of the option term so that estimates will approximate actual behavior for similar options. For the ESPP, the term of each Offering Period is used.

#### **Expected Forfeiture Rate**

The Company records forfeitures as they occur.

The fair value of stock options was estimated using the Black-Scholes option-pricing model based on the following assumptions during the years ended:

	December	er 31,
	2023	2022
Expected volatility	44-56%	44-58%
Risk-free interest rate	3.3-4.6%	1.9-4.0%
Expected term (in years)	4-6	6

The fair value of the shares under the ESPP was estimated using the Black-Scholes option-pricing model based on the following assumptions during the year ended:

	December 31
	2023
Expected volatility	57-60%
Risk-free interest rate	5.36-5.43%
Expected term (in years)	0.5

See Note 4 for additional information regarding stock-based compensation.

# **Income Taxes**

The Company uses the asset and liability method of accounting for income taxes. Deferred tax assets and liabilities are determined based on differences between the financial reporting and tax basis of assets and liabilities and are measured using the enacted tax rates and laws that are expected to be in effect when the differences are expected to reverse. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in the period that such tax rate changes are enacted. The measurement of a deferred tax asset is reduced, if necessary, by a valuation allowance if it is more-likely-than-not that all or a portion of the deferred tax asset will not be realized.

Management uses a recognition threshold and a measurement attribute for the financial statement recognition and measurement of tax positions taken or expected to be taken in a tax return, as well as guidance on derecognition, classification, interest and penalties and financial statement reporting disclosures. For those benefits to be recognized, a tax position must be more-likely-than-not to be sustained upon examination by taxing authorities. The Company recognizes interest and penalties accrued on any unrecognized tax exposures as a component of income tax expense. The Company has not identified any uncertain income tax positions that could have a material impact on the consolidated financial statements.

The Company is subject to taxation in various jurisdictions in the United States and abroad and remains subject to examination by taxing jurisdictions for 2020 and all subsequent periods. The Company has a federal Net Operating Loss ("NOL") carryforward of approximately \$88.9 million as of December 31, 2023, of which approximately \$32.7 million begins to expire in 2025. Certain of the Company's NOLs were initially limited on an annual basis pursuant to Section 382 of the Internal Revenue Code of 1986 ("Section 382"), as amended, as a result of a cumulative change in ownership that occurred in 2016; however, as of December 31, 2023, the Company has determined that the cumulative limitation amount exceeds the NOLs subject to the limitation and, as a result, no annual limitation remains.

#### Leases

Right-of-use ("ROU") assets represent the Company's right to use an underlying asset for the lease term and lease liabilities represent its obligation to make lease payments arising from the lease. In transactions where the Company is the lessee, at the inception of a contract, the Company determines if the arrangement is, or contains, a lease. Operating lease ROU assets and liabilities are recognized at commencement date based on the present value of lease payments over the lease term. Lease expense is recognized on a straight-line basis over the lease term.

The Company has made certain accounting policy elections for leases where it is the lessee whereby the Company (i) does not recognize ROU assets or lease liabilities for short-term leases (those with original terms of 12-months or less) and (ii) combines lease and non-lease elements of its operating leases. See Note 8 for additional details about leases where the Company is the lessee.

All transactions in which the Company is the lessor are short-term (one year or less) and have been classified as operating leases. All leases require upfront payments covering the full period of the lease and thus, there are no future payments expected to be received from existing leases. See Note 3 for details about revenue recognition related to lease agreements.

# **Comprehensive Loss**

For the years ended December 31, 2023 and 2022, comprehensive loss equaled net loss; therefore, a separate statement of comprehensive loss is not included in the accompanying financial statements.

# **Loss Per Share**

Basic loss per share is computed by dividing net loss available to common stockholders by the weighted average number of shares of Common Stock outstanding during the period.

For periods of net income, and when the effects are not anti-dilutive, diluted earnings per share is computed by dividing net income available to common stockholders by the weighted-average number of shares outstanding plus the impact of all potential dilutive common shares, consisting primarily of common stock options and stock purchase warrants using the treasury stock method.

For periods of net loss, diluted loss per share is calculated similarly to basic loss per share because the impact of all dilutive potential common shares is anti-dilutive. The number of anti-dilutive shares, consisting of stock options and restricted stock units excluded from the computation of diluted loss per share, was 16.7 million and 15.0 million for the years ended December 31, 2023 and 2022, respectively.

# **Recent Accounting Pronouncements**

# New Accounting Pronouncements Recently Adopted

In June 2016, the Financial Accounting Standards Board ("FASB") issued guidance with respect to measuring credit losses on financial instruments, including trade receivables. The guidance eliminates the probable initial recognition threshold that was previously required prior to recognizing a credit loss on financial instruments. The credit loss estimate can now reflect an entity's current estimate of all future expected credit losses. Under the previous guidance, an entity only considered past events and current conditions. The guidance is effective for fiscal years beginning after December 15, 2022, including interim periods within those fiscal years. The adoption of certain amendments of this guidance must be applied on a modified retrospective basis and the adoption of the remaining amendments must be applied on a prospective basis. The Company adopted this new accounting pronouncement effective January 1, 2023 and the adoption did not have a material impact on its consolidated financial statements.

The Company has evaluated all other issued and unadopted Accounting Standards Updates and believes the adoption of these standards will not have a material impact on its results of operations, financial position or cash flows.

#### 3. Revenue

Revenue is principally from the sale of instruments and processing assemblies, and extended warranties and the lease of instruments, which lease agreements also include customer-specific milestone payments. In some arrangements, product and services have been sold together representing distinct performance obligations. In these arrangements the Company allocates the sale price to the various performance obligations in the arrangement on a relative selling price basis. Under this basis, the Company determines the estimated selling price of each performance obligation in a manner that is consistent with that used to determine the price to sell the deliverable on a standalone basis.

Revenue is recognized at the time control is transferred to the customer and the performance obligation is satisfied. Revenue from the sale of instruments and processing assemblies is generally recognized at the time of shipment to the customer, provided no significant vendor obligations remain and collectability is reasonably assured. Revenue from equipment leases is recognized ratably over the contractual term of the lease agreement and when specific milestones are achieved by a customer. Licensing fee revenue is recognized ratably over the license period. Revenue from fees for research services is recognized when services have been provided.

Disaggregated revenue for the year ended December 31, 2023 was as follows:

		Year ended December 31, 2023					
	Cor	Revenue from Contracts with Customers		Revenue from Lease Elements		Total Revenue	
Product sales	\$	18,600	\$		\$	18,600	
Lease elements				21,791		21,791	
Other		897		_		897	
Total	\$	19,497	\$	21,791	\$	41,288	

Disaggregated revenue for the year ended December 31, 2022 was as follows:

	 Year ended December 31, 2022				
	Revenue from Contracts with Customers		Revenue from Lease Elements		Total Revenue
Product sales	\$ 27,730	\$		\$	27,730
Lease elements	_		15,513		15,513
Other	1,018		_		1,018
Total	\$ 28,748	\$	15,513	\$	44,261

# Additional disclosures relating to Revenue from Contracts with Customers

Changes in deferred revenue for the years ended December 31, 2023 and 2022 were as follows:

	Year Ended December 31,			nber 31,
		2023		2022
Balance at January 1	\$	7,036	\$	7,197
Revenue recognized in the current period from amounts included in the beginning				
balance		(6,507)		(6,738)
Current period deferrals, net of amounts recognized in the current period		4,823		6,577
Balance at December 31	\$	5,352	\$	7,036

Remaining contract consideration for which revenue has not been recognized due to unsatisfied performance obligations with a duration greater than one year was \$368 at December 31, 2023, of which the Company expects to recognize \$85 in 2024, \$81 in 2025, \$39 in 2026, \$21 in 2027, and \$142 thereafter.

In the years ended December 31, 2023 and 2022, the Company did not incur, and therefore did not defer, any material incremental costs to obtain contracts or costs to fulfil contracts.

# 4. Stockholders' Equity

#### Common Stock

During the year ended December 31, 2023, the Company issued 1,192,784 shares of common stock resulting from stock option exercises, receiving gross proceeds of \$1,874 and issued 288,550 shares from the vesting of restricted stock units, and issued 82,423 shares to employees pursuant to the Employee Stock Purchase Plan ("ESPP"), receiving gross proceeds of \$269.

During the year ended December 31, 2022, the Company issued 1,195,208 shares of common stock as a result of stock option exercises, receiving gross proceeds of \$2,888.

# **Preferred Stock**

The Company's certificate of incorporation authorizes 5,000,000 shares of preferred stock, par value \$0.01 per share. As of December 31, 2023 and 2022, no shares of preferred stock were issued or outstanding.

#### **Stock Incentive Plans**

The Company adopted the MaxCyte, Inc. Long-Term Incentive Plan (the "2016 Plan") in January 2016 to provide for the awarding of (i) stock options, (ii) restricted stock, (iii) incentive shares, and (iv) performance awards to employees, officers, and directors of the Company and to other individuals as determined by the board of directors.

In December 2021, the Company adopted the MaxCyte, Inc. 2021 Inducement Plan (the "Inducement Plan") to provide for the awarding of (i) non-qualified stock options; (ii) stock appreciation rights; (iii) restricted stock awards; (iv) restricted stock unit awards; (v) performance awards; and (vi) other awards only to persons eligible to receive grants of awards who satisfy the standards for inducement grants under Nasdaq Marketplace Rule 5635(c)(4) or 5635(c)(3), if applicable, and the related guidance under Nasdaq IM 5635-1. The board of directors reserved 2,500,000 shares for issuance under the Inducement Plan. As of December 31, 2023, options to purchase 818,400 shares remain outstanding under the Inducement Plan.

In May 2022, the Company's board of directors adopted, and in June 2022 the Company's stockholders approved, the MaxCyte, Inc. 2022 Equity Incentive Plan (the "2022 Plan") to provide for the awarding of (i) incentive stock options, (ii) non-qualified stock options, (iii) stock appreciation rights, (iv) restricted stock awards, (v) restricted stock unit awards, (vi) performance awards, and (vii) other awards. Following the approval of the 2022 Plan, no additional awards can be granted under the 2016 Plan or the Inducement Plan, but all outstanding awards will continue to remain subject to the terms of the applicable plan.

Upon the effectiveness of the 2022 Plan, a total of 3,692,397 shares were initially reserved for issuance pursuant to future awards under the 2022 Plan, consisting of 1,928,000 new shares and 1,764,397 shares previously available under the 2016 Plan. If and to the extent that outstanding options under the 2016 Plan or the Inducement Plan are forfeited, the shares underlying such forfeited options will become available for issuance under the 2022 Plan. At the Company's Annual Meeting of Stockholders held on June 22, 2023, the Company's stockholders voted to reserve an additional 6,069,000 shares of issuance pursuant to future awards under the 2022 Plan.

## Stock Option Activity

A summary of stock option activity for the years ended December 31, 2023 and 2022 is as follows:

	Number of Options	Weighted Average ercise Price	Weighted- Average Remaining Contractual Life (in years)		ggregate insic Value
Outstanding at January 1, 2022	12,433,739	\$ 6.03	7.5	\$	66,547
Granted	4,408,400	\$ 6.45	,	-	00,01,
Exercised	(1,195,208)	\$ 2.38		\$	4,163
Forfeited	(1,285,839)	\$ 7.31			
Outstanding at December 31, 2022	14,361,092	\$ 5.94	7.2	\$	23,825
Granted	2,713,395	\$ 4.36			
Exercised	(1,192,784)	\$ 1.58		\$	4,106
Forfeited	(460,390)	\$ 9.18			
Expired	(3,327)	\$ 6.46			
Outstanding at December 31, 2023	15,417,986	\$ 5.90	6.9	\$	15,854
Exercisable at December 31, 2023	9,638,499	\$ 5.42	5.9	\$	14,511

The weighted-average fair value of the options granted during the years ended December 31, 2023 and 2022 was estimated to be \$2.05 and \$3.48, respectively.

The value of a stock option is recognized as expense on a straight-line basis over the requisite service period. As of December 31, 2023, total unrecognized compensation expense for outstanding stock options was \$18,931, which will be recognized over the next 2.0 years.

## Restricted Stock Unit Activity

During the years ended December 31, 2023 and 2022, the Company issued restricted stock unit awards ("RSUs") under the 2022 Plan. Each RSU represents the contingent right to receive one share of common stock.

A summary of RSU activity for the years ended December 31, 2023 and 2022 is as follows:

	Number of		Weighted Average	Weighted- Average Remaining Contractual Life
	RSUs	Grant	Date Fair Value	(in years)
Outstanding at January 1, 2022	_	\$	_	
Granted	662,900	\$	5.56	
Forfeited	(19,300)	\$	5.39	
Outstanding at December 31, 2022	643,600	\$	5.57	3.2
Granted	1,043,150	\$	4.21	
Vested and released	(288,550)	\$	5.48	
Forfeited	(102,020)	\$	4.70	
Outstanding at December 31, 2023	1,296,180	\$	4.57	2.8

The value of an RSU is recognized as expense on a straight-line basis over the requisite service period. As of December 31, 2023, total unrecognized compensation expense for outstanding RSUs was \$4,589, which will be recognized over the next 2.8 years.

## Employee Stock Purchase Plan

The Company commenced the initial offering (the "Initial Offering") under the MaxCyte, Inc. 2021 Employee Stock Purchase Plan (the "ESPP"). The ESPP provides an offering period of 24 months, with four purchase periods that are generally six months long (the "Purchase Period").

The ESPP allows eligible employees to purchase a number of shares of the Company's Common Stock up to a maximum of 15% of the employee's earnings during the Purchase Period subject to certain limitations. The purchase price will be the lesser of 85% of the fair market value of shares on the beginning of each Purchase Period or on the Purchase Date (i.e., the last day of the Purchase Period). Participants may decrease their contribution level or withdraw from the ESPP at any time during the Purchase Period subject to certain conditions.

The first purchase period began on May 19, 2023 and ended on November 17, 2023. The second purchase period began on November 20, 2023. For the year ended December 31, 2023, the Company recognized \$127 in compensation cost related to the ESPP. As of December 31, 2023, total unrecognized compensation expense related to the ESPP was \$81, which will be recognized over the next 0.4 years.

## Stock-based Compensation Expense

Stock-based compensation expense recognized in connection with stock options, RSUs and the ESPP for the years ended December 31, 2023 and 2022 was classified as follows on the consolidated statements of operations:

	 Year ended December 31,		
	2023		2022
General and administrative	\$ 6,114	\$	5,621
Sales and marketing	3,252		2,517
Research and development	4,613		3,614
Total	\$ 13,979	\$	11,752

## 5. Consolidated Balance Sheet Components

## **Inventory**

The following tables show the components of inventory:

	Dec	cember 31, 2023	Dec	2022
Raw materials inventory	\$	5,694	\$	5,651
Finished goods inventory		5,977		2,930
Work in progress		558		—
Total inventory	\$	12,229	\$	8,581

The Company reserved \$697 in an allowance at December 31, 2023. The Company determined no allowance was necessary as of December 31, 2022.

## Property and Equipment, Net

Property and equipment, net comprised the following:

	De	December 31, 2023		cember 31, 2022
Leasehold improvements	\$	14,654	\$	14,196
Furniture and equipment		12,288		9,516
Internal-use software		4,106		3,221
Instruments		2,441		2,440
Construction in process		310		627
Accumulated depreciation and amortization		(10,286)		(6,275)
Property and equipment, net	\$	23,513	\$	23,725

For the years ended December 31, 2023 and 2022, the Company transferred \$189 and \$265, respectively, of instruments previously classified as inventory to property and equipment leased to customers.

For the years ended December 31, 2023 and 2022, the Company incurred depreciation and amortization expense of \$4,171 and \$2,698, respectively.

Maintenance and repairs are charged to expense as incurred.

## 6. Fair Value

The Company's consolidated balance sheets include various financial instruments (primarily cash and cash equivalents, short-term investments, accounts receivable and accounts payable) that are carried at cost, which approximates fair value due to the short-term nature of the instruments.

Financial Assets and Liabilities Measured at Fair Value on a Recurring Basis

The Company had no financial assets or liabilities measured at fair value on a recurring basis as of December 31, 2023 or 2022.

Financial Assets and Liabilities Measured at Fair Value on a Non-Recurring Basis

Money market funds, commercial paper and corporate debt instruments classified as held-to-maturity are measured at fair value on a non-recurring basis when they are deemed to be impaired on an other-than-temporary basis. No such fair value impairment was recognized during the years ended December 31, 2023 or 2022.

The following table summarizes the Company's financial instruments that were measured at fair value on a non-recurring basis at December 31, 2023:

<b>5</b>		Amortized	Gross unrecognized	Gross unrecognized	Aggregate
Description	Classification	cost	holding gains	holding losses	fair value
Money market funds and cash equivalents	Cash equivalents	\$ 22,693	\$ —	\$ —	\$ 22,693
US Treasury securities and government					
agency bonds	Cash equivalents	20,986	3	_	20,989
Commercial paper	Short-term investments	107,131	100	(1)	107,230
US Treasury securities and government					
agency bonds	Short-term investments	14,651	28	(6)	14,673
US Treasury securities and government					
agency bonds	Long-term investments	42,938	282	(2)	43,218
Total cash equivalents and short-term	-				
investments		\$ 208,399	\$ 413	\$ (9)	\$ 208,803

The following table summarizes the Company's financial instruments that were measured at fair value on a non-recurring basis at December 31, 2022:

		Amortized	Gross unrecognized	Gross unrecognized	Aggregate
Description	Classification	cost	holding gains	holding losses	fair value
Money market funds and cash equivalents	Cash equivalents	\$ 5,742	\$ —	\$ —	\$ 5,742
Commercial paper	Short-term investments	172,741	156	(236)	172,661
Corporate debt	Short-term investments	5,792	_	(43)	5,749
US Treasury securities and government					
agency bonds	Short-term investments	37,742	5	(196)	37,551
Total cash equivalents and short-term					
investments		\$ 222,017	\$ 161	\$ (475)	\$ 221,703
mvestments		Φ 222,017	ψ 101	$\Psi$ ( $\pm 73$ )	Ψ 221,703

Non-Financial Assets and Liabilities Measured at Fair Value on a Recurring Basis

The Company has no non-financial assets and liabilities that are measured at fair value on a recurring basis.

Non-Financial Assets and Liabilities Measured at Fair Value on a Non-Recurring Basis

The Company measures its long-lived assets, including property and equipment, at fair value on a non-recurring basis. These assets are recognized at fair value when they are deemed to be impaired. No such fair value impairment was recognized during the years ended December 31, 2023 or 2022.

## 7. Income Taxes

The Company's provision (benefit) for income taxes in 2023 and 2022 consisted of the following:

	December 31,			Ι,
		2023		2022
Current provision (benefit):				
Federal	\$	_	\$	
State				_
Total current provision				
Deferred tax provision (benefit):				
Federal		(8,752)		(2,581)
State		(3,542)		(659)
Change in valuation allowance		12,294		3,240
Total deferred provision		_		_
Total provision (benefit) for income taxes	\$		\$	

The Company is required to establish a valuation allowance for deferred tax assets if, based on the weight of available evidence, it is more likely than not that some or all the deferred tax assets will not be realized. The ultimate realization of deferred tax assets is dependent upon the generation of future taxable income during the periods in which those temporary differences become deductible. The Company considers projected future taxable income and tax planning strategies in making this assessment. As of December 31, 2023 and 2022, the Company established a full valuation allowance against its net deferred tax assets.

Net deferred tax assets as of December 31, 2023 and 2022 are presented in the table below:

	 December 31,		
	2023		2022
Deferred tax assets:			
Net operating loss carryforwards	\$ 22,472	\$	22,298
Research and development credits	8,144		3,733
Stock-based compensation	9,158		5,649
Deferred revenue	1,517		1,808
Lease liability	5,313		4,135
Tenant incentive	1,528		1,330
Accruals and other	2,092		1,250
Deferred tax liabilities:			
ROU asset	(3,187)		(2,532)
Depreciation	(1,396)		(4,605)
	 45,641		33,066
Valuation allowance	(45,641)		(33,066)
Net deferred tax assets	\$ 	\$	

The difference between the expected income tax provision (benefit) from applying the U.S. Federal statutory rate to pre-tax income (loss) and the actual income tax provision (benefit) for the years ended December 31, 2023 and 2022 relates primarily to the effect of the following:

	Year Ended December 31,			per 31,
		2023		2022
Federal income taxes (benefit) at statutory rates	\$	(7,964)	\$	(4,950)
State income taxes (benefit), net of Federal benefit		(2,901)		(968)
Excess tax benefits		(610)		(562)
Permanent differences, rate changes and other		(819)		3,240
Change in valuation allowance		12,294		3,240
Total Income Tax Expense	\$	_	\$	_

On August 16, 2022, the U.S. Inflation Reduction Act of 2022 (the "Inflation Reduction Act") was signed into law. The Inflation Reduction Act includes, among other provisions, (i) a new corporate alternative minimum tax of 15 percent on the adjusted financial statement income (AFSI) of corporations with average AFSI exceeding \$1.0 billion over a three-year period, and (ii) a new excise tax of 1 percent on the fair market value of net corporate stock repurchases. The provisions of the Inflation Reduction Act are effective for tax years beginning after December 31, 2022. The Company does not expect the Inflation Reduction Act to have a material impact on its provision for income taxes.

The Tax Cuts and Jobs Act of 2017 (TCJA) amended IRC Section 174 to require capitalization of all research and developmental ("R&D") costs incurred in tax years beginning after December 31, 2021. These costs are required to be amortized over five years if the R&D activities are performed in the United States or over 15 years if the activities were performed outside the United States. The Company capitalized approximately \$19,204 and \$15,433 of R&D expenses incurred during the years ended December 31, 2023 and 2022, respectively.

## 8. Commitments and Contingencies

#### Leases

## Operating Leases

The Company was a party to various leases for office and laboratory and other space that were terminated in 2022. One portion of leased space was an operating lease (the "Original Headquarters Lease"), which was originally scheduled to expire in October 2023. The Original Headquarters Lease was early terminated as allowed for under the lease on June 9, 2022. The Company was also a sublessee of certain additional office, laboratory, and other space under several subleases (the "Original Headquarters Subleases") that were originally scheduled to expire in October 2023, all of which were terminated as allowed for under the subleases on various dates between June and August 2022.

A member of the Company's board of directors is the Chief Executive Officer and a member of the board of directors of the sublandlord under the Original Headquarters Subleases, and the Company's Chairman is also a member of the sublandlord's board of directors. The Company's rent payments to the sublandlord totaled \$296 for the year ended December 31, 2022.

In May 2021, the Company entered into a lease for its new headquarters (the "New Headquarters Lease"), consisting of an operating lease agreement, as amended, for new office, laboratory, manufacturing and other space. The New Headquarters Lease consists of three phases, with Phase 1 having commenced in December 2021 and Phase 2 having commenced in the first quarter of 2022, and Phase 3 having commenced in November 2023. The current lease term for all phases will expire on August 31, 2035. The New Headquarters Lease agreement includes a landlord-provided tenant improvement allowance ("TIA") of \$6.3 million to offset the cost of construction of leasehold improvements. As of December 31, 2023, the Company had received all reimbursements from the TIA. Under the New

Headquarters Lease, the Company has three five-year options to extend the term of the lease. However, the Company is not reasonably certain to exercise any of these options.

The initial monthly base rents for Phases 1, 2 and 3 are \$66, \$72 and \$32 respectively, with such base rent increasing during the initial term by 3% annually on the anniversary of each Phase commencement date. The Company is obligated to pay its portion of real estate taxes and costs related to the lease premises, including costs of operations, maintenance, repair, replacement and management of the new leased premises. The total incremental non-cancellable lease payments under the New Headquarters Lease are approximately \$29.6 million over the lease term. During the years ended December 31, 2023 and 2022, the Company paid \$1,293 and \$622 included in the measurement of lease liabilities, respectively.

The components of lease cost and balance sheet information for the Company's lease portfolio were as follows:

		Year ended December 31,		
		2023		2022
Operating lease cost	\$	1,620	\$	1,624
Short-term lease cost		39		47
Variable lease cost		983		530
Total lease cost	\$	2,642	\$	2,201
	As of l	December 31,	As of	December 31,
		2023		2022
Operating leases				
Assets:				
Operating lease right-of-use assets	\$	11,241	\$	9,853
Liabilities				
Current portion of operating lease liabilities	\$	774	\$	157
Operating lease liabilities, net of current portion		17,969		15,938
Total operating lease liabilities	\$	18,743	\$	16,095
Other information				
Weighted-average remaining lease term (in years)		11.7		12.7
Weighted-average incremental borrowing rate		7.0%		6.5%

As of December 31, 2023, maturities of lease liabilities were as follows:

	Oper	ating Leases
2024	\$	1,927
2025		2,171
2026		2,225
2027		2,281
2028		2,338
2029 and thereafter		17,156
Total undiscounted lease payments		28,098
Discount factor		(9,355)
Present value of lease liabilities	\$	18,743

# 401(k) Retirement Plan

The Company sponsors a defined-contribution 401(k) retirement plan covering eligible employees. Participating employees may voluntarily contribute up to limits provided by the Internal Revenue Code of 1986, as amended. The Company matches employee contributions equal to 50% of the salary deferral contributions, with a maximum Company

contribution of 5% of the employees' eligible compensation. In the years ended December 31, 2023 and 2022, Company matching contributions amounted to \$867 and \$723 respectively.

## **Board Member Consulting Agreement**

Effective January 1, 2024 the Company entered into a consulting agreement with a member of the Board of Directors to provide consulting services to the Company for a 12-month period for an amount not to exceed \$150.

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

None.

#### Item 9A. Controls and Procedures.

#### **Evaluation of Disclosure Controls and Procedures**

We carried out an evaluation, under the supervision and with the participation of management, including our Chief Executive Officer and Chief Financial Officer, of the effectiveness of our "disclosure controls and procedures" as defined in Rules 13a-15(e) and 15d-15(e) of the Exchange Act as of December 31, 2023, the end of the period covered by this Annual Report. The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company's management, including its principal executive and principal financial officers, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure.

Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives, and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on our evaluation, our Chief Executive Officer and Chief Financial Officer concluded that the design and operation of these disclosure controls and procedures were effective as of December 31, 2023, at a reasonable assurance level.

## 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 Rule 13a-15(f) under the Exchange Act). Under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, we conducted an assessment of the effectiveness of our internal control over financial reporting as of December 31, 2023 based on the criteria set forth in Internal Control – Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013). Based on this assessment, management has concluded that our internal control over financial reporting was effective as of December 31, 2023 to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements in accordance with U.S. GAAP.

This Annual Report on Form 10-K does not include an attestation report of our independent registered public accounting firm on internal control over financial reporting due to the deferral allowed under the JOBS Act for emerging growth companies.

#### **Changes in Internal Control over Financial Reporting**

There were no changes in our internal control over financial reporting (as defined in Rule 13a-15(f) under the Exchange Act) during the fourth quarter of 2023 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

## Item 9B. Other Information.

None.

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections.

None.

#### **PART III**

We will file a definitive Proxy Statement for our 2024 Annual Meeting of Stockholders (the "2024 Proxy Statement") with the SEC, pursuant to Regulation 14A, not later than 120 days after the end of our fiscal year. Accordingly, certain information required by Part III has been omitted under General Instruction G(3) to Form 10-K. Only those sections of the 2024 Proxy Statement that specifically address the items set forth herein are incorporated by reference.

### Item 10. Directors, Executive Officers and Corporate Governance.

The information required by this item is hereby incorporated by reference to the sections of the 2024 Proxy Statement under the captions "Information Regarding the Board of Directors and Corporate Governance," "Election of Directors," and "Executive Officers."

## **Item 11. Executive Compensation.**

The information required by this item is hereby incorporated by reference to the sections of the 2024 Proxy Statement under the captions "Executive Compensation" and "Director Compensation."

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

The information required by this item is hereby incorporated by reference to the sections of the 2024 Proxy Statement under the captions "Security Ownership of Certain Beneficial Owners and Management" and "Securities Authorized for Issuance under Equity Compensation Plans."

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

The information required by this item is hereby incorporated by reference to the sections of the 2024 Proxy Statement under the captions "Transactions with Related Persons" and "Independence of the Board of Directors."

## Item 14. Principal Accountant Fees and Services.

The information required by this item is hereby incorporated by reference to the sections of the 2024 Proxy Statement under the caption "Ratification of Selection of Independent Auditors."

## **PART IV**

## Item 15. Exhibits and Financial Statement Schedules.

(a) The following documents are filed as part of this Annual Report on Form 10-K:

# (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) List of Exhibits required by Item 601 of Regulation S-K

See the Exhibit Index in Item 15(b) below.

## (b) Exhibit Index.

		Incorporated by Reference			
Exhibit					
Number	Description	Form	File No.	Exhibit	Filing Date
3.1	Amended and Restated Bylaws of the Registrant.	8-K	001-4067 4	3.1	August 4, 2021
3.2	Fifteenth Amended and Restated Certificate of Incorporation.	S-1	333-2578 10	3.1	July 26, 2021
4.1	Description of Certain of Registrant's Securities.	10-K	001-4067 4	4.1	March 22, 2022
10.1#	MaxCyte, Inc. Long-Term Incentive Plan.	S-1/A	333-2578 10	10.1	July 26, 2021
10.2#	Form of New Hire Stock Option Agreements under the MaxCyte, Inc. Long-Term Incentive Plan.	S-1/A	333-2578 10	10.2	July 26, 2021
10.3#	Form of Performance Stock Option Agreements under the MaxCyte, Inc. Long- Term Incentive Plan.	S-1/A	333-2578 10	10.3	July 26, 2021
10.4#	Form of Director Stock Option Agreements under the MaxCyte, Inc. Long-Term Incentive Plan.	S-1/A	333-2578 10	10.4	July 26, 2021
10.5#	MaxCyte, Inc. Inducement Plan.	10-K	001-4067 4	10.5	March 22, 2022
10.6#	MaxCyte, Inc. Form of Stock Option Grant Notice (2021 Inducement Plan), dated as of January 1, 2022.	10-Q	001-4067 4	10.4	August 10, 2022
10.7#	Form of 2022 Employee Stock Purchase Plan.	S-8	333-2661 33	99.2	July 14, 2022
10.8#	Form of Indemnification Agreement by and between the Registrant and each director and executive officer.	S-1/A	333-2578 10	10.8	July 26, 2021
10.9#	MaxCyte, Inc. 2022 Equity Incentive Plan.	8-K	001-4067 4	10.1	June 30, 2022
10.10#	MaxCyte, Inc. Form of RSU Award Grant Notice (2022 Equity Incentive Plan), dated as of July 19, 2022.	10-Q	001-4067 4	10.5	August 10, 2022

10.11#	MaxCyte, Inc. Form of Stock Option Grant Notice (2022 Equity Incentive Plan), dated as of July 19, 2022.	10-Q	001-4067 4	10.6	August 10, 2022
10.12#	Severance Agreement, dated July 20, 2021, between the Registrant and Doug Doerfler.	S-1/A	333-2578 10	10.13	July 26, 2021
10.13#	Separation Agreement, by and between the Company and Amanda Murphy, dated as of May 6, 2022.	10-Q	001-4067 4	10.2	August 10, 2022
10.14#	Consulting Agreement, by and between the Company and Amanda Murphy, effective as of April 15, 2022.	10-Q	001-4067 4	10.3	August 10, 2022
10.15#	Severance Agreement, dated March 8, 2017, between the Registrant and Ron Holtz.	10-K	001-4067 4	10.5	March 15, 2023
10.16	Deed of Lease, dated as of May 27, 2021, between Key West MD Owner LLC and Registrant.	10-K	001-4067 4	10.6	March 15, 2023
10.17	Amendment to Deed of Lease, dated as of November 16, 2021, between Key West MD Owner LLC and Registrant.	10-K	001-4067 4	10.7	March 15, 2023
10.18#	Severance Agreement, dated as of March 27, 2023, by and between the Registrant and Douglas J. Swirsky	8-K	001-4067 4	10.1	March 28. 2023
10.19#	Amendment and Restatement of the MaxCyte 2022 Equity Incentive Plan	8-K	001-4067 4	10.1	June 23, 2023
10.20#*	Separation and Consulting Agreement, dated as of December 11, 2023 by and between the Registrant and Douglas Doerfler.				
10.21#*	Promotion Letter, dated as of December 11, 2023, by and between the Registrant and Maher Masoud				
21.1*	Subsidiaries of the Registrant.				
23.1*	Consent of Independent Registered Public Accounting Firm				
24.1*	Power of Attorney (contained on the signature page to this Form 10-K).				
31.1*	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				
31.2*	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				
32.1@	Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.				
32.2@	Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.				

97*	Amended and Restated Incentive Compensation Recoupment Policy of the Registrant
101.INS*	Inline XBRL Instance Document.
101.SCH*	XBRL Taxonomy Extension Schema Document
101.CAL*	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF*	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB*	XBRL Taxonomy Extension Label Linkbase Document
101.PRE*	XBRL Taxonomy Extension Presentation Linkbase Document
104*	Cover Page Interactive Data File (formatted as inline XBRL with applicable taxonomy extension information contained in Exhibits 101.SCH, 101.CAL, 101.DEF, 101.LAB and 101.PRE).

<sup>\*</sup> Filed herewith.

@ This exhibit shall not be deemed "filed" for purposes of Section 18 of the Exchange Act or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933 or the Exchange Act of 1934, whether made before or after the date hereof and irrespective of any general incorporation language in such filings.

# Item 16. Form 10-K Summary

None.

<sup>#</sup> Indicates management contract or compensatory plan.

## **SIGNATURES**

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

MaxCyte Inc.

Date: March 12, 2024 By: /s/ Douglas Swirsky

Name: Douglas Swirsky
Title: Chief Financial Officer
(On Behalf of the Registrant)

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Maher Masoud and Douglas Swirsky, jointly and severally, as his or her true and lawful attorneys-in-fact and agents, with full power of substitution and resubstitution, for him or her and in his or her name, place and stead, in any and all capacities, to sign this Annual Report on Form 10-K of MaxCyte, Inc., and any or all amendments thereto, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents full power and authority to do and perform each and every act and thing requisite or necessary to be done in and about the premises hereby ratifying and confirming all that said attorneys-in-fact and agents, or his, her or their substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

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

Signature	Title	Date
/s/ Maher Masoud	President, Chief Executive Officer and Director	March 12, 2024
Maher Masoud	(Principal Executive Officer)	
/s/ Douglas Swirsky	Chief Financial Officer	March 12, 2024
Douglas Swirsky	(Principal Financial Officer and Principal Accounting Officer)	
/s/ Richard Douglas	Chairman of the Board of Directors	March 12, 2024
Richard Douglas, PhD		
/s/ Yasir Al-Wakeel	Director	March 12, 2024
Yasir Al-Wakeel, BM BCh		
/s/ Patrick J. Balthrop, Sr.	Director	March 12, 2024
Patrick J. Balthrop, Sr.	_	
/s/ Will Brooke	Director	March 12, 2024
Will Brooke		
/s/ Stanley C. Erck	Director	March 12, 2024
Stanley C. Erck		
/s/ Rekha Hemrajani	Director	March 12, 2024
Rekha Hemrajani		
/s/ John Johnston	Director	March 12, 2024
John Johnston		
/s/ Art Mandell	Director	March 12, 2024
Art Mandell		

## **BOARD OF DIRECTORS**

**Maher Masoud**, Director President and Chief Executive Officer

**Richard Douglas**, Chairman of the Board of Directors

Yasir Al-Wakeel, Director

Patrick J. Balthrop, Director

Will Brooke, Director

Stan Erck, Director

Rekha Hemrajani, Director

John Johnston, Director

Art Mandell, Director

## **EXECUTIVE OFFICERS**

## **Maher Masoud**

President and Chief Executive Officer

## **Douglas Swirsky**

Chief Financial Officer

## Thomas M. Ross

Executive Vice President, Global Sales and Marketing

#### **David Sandoval**

Senior Vice President, General Counsel and Secretary

## CORPORATE HEADQUARTERS

MaxCyte, Inc. 9713 Key West Avenue, Suite 400 Rockville, Maryland 20850

T: (301) 944-1700 www.maxcyte.com

#### **COMMON STOCK LISTING**

Nasdaq Global Select Market Ticker Symbol: MXCT

#### ANNUAL MEETING OF STOCKHOLDERS

Tuesday, June 11, 2024, at 11:00 a.m. Eastern Time at: www.proxyvote.com

#### REGISTRAR AND TRANSFER AGENT

Computershare Trust Company, N.A. 150 Royall Street Canton, MA 02021

#### LEGAL COUNSEL

Sidley Austin LLP, Baltimore, MD

## INDEPENDENT AUDITORS

CohnReznick LLP, 800 Towers Crescent Drive, Suite 1000, Tysons, Virginia, U.S.A.

## **INVESTOR RELATIONS**

MaxCyte, Inc.
Investor Relations
9713 Key West Avenue, Suite 400,
Rockville, Maryland 20850
E: ir@maxcyte.com
T: (301) 944-1700

