Table of Contents

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 10-K

(Mark One)

☒ **Annual report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934**
For the fiscal year ended December 31, 2022
or

☐ **Transition report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934**
For transition period from to

Commission File Number: 001-39577

Aziyo Biologics, Inc.
(Exact name of registrant as specified in its charter)

Delaware	**47-4790334**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

12510 Prosperity Drive, Suite 370
Silver Spring, MD 20904
(Address of principal executive offices and Zip Code)

(240) 247-1170
(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Securities Exchange Act of 1934:

Title of each class	**Trading Symbol(s)**	**Name of each exchange on which registered**
Class A Common Stock, par value $0.001 per share	AZYO	The Nasdaq Capital Market

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

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

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

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

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

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

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

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

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

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act) Yes ☐ No ☒

The aggregate market value of the voting and non-voting stock held by non-affiliates of the registrant, as of June 30, 2022, the last business day of the registrant's most recently completed second fiscal quarter, was approximately $31,067,793 based on the closing price of $7.07 of the registrant's Class A common stock as reported on the Nasdaq Capital Market on such date. Solely for the purposes of this disclosure, shares of common stock held by the registrant's executive officers, directors and certain of its stockholders as of such date have been excluded because such holders may be deemed to be affiliates.

As of March 17, 2023, there were 11,876,792 shares of the registrant's Class A common stock and 4,313,406 shares of the registrant's Class B common stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive proxy statement for its 2023 annual meeting of stockholders, which the registrant intends to file pursuant to Regulation 14A with the Securities and Exchange Commission not later than 120 days after the registrant's fiscal year ended December 31, 2022, are incorporated by reference into Part III of this Annual Report on Form 10-K.

TABLE OF CONTENTS

FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K (the "Annual Report") contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. We intend such forward-looking statements to be covered by the safe harbor provisions for forward-looking statements contained in Section 27A of the Securities Act of 1933, as amended (the "Securities Act") and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). All statements other than statements of historical facts contained in this Annual Report, including, without limitation, statements regarding our results of operations, financial position, projected growth in total net sales, increases in expenses, seasonality, business strategy, policies and approach, including, without limitation, expectations regarding our products and their targeted effects, plans for our sales and marketing growth and anticipated expansion of our product development and clinical and research activities, expectations regarding competition, our competitive advantages, regulations that impact our business, and overall clinical and commercial success, expectations regarding the pending lawsuits and claims related to our recall of a single lot of Fiber Viable Bone Matrix ("FiberCel"), amounts recoverable under insurance, indemnity and contribution agreements and the impact of such lawsuits and claims on our future financial position; results of operations or business; our expectations and plans regarding pursuit of any strategic transactions; our expectations relating to the FDA regulatory process for the CanGaroo RM Antibacterial Envelope; our plans and expectations relating to our workforce reduction; and the potential impact of COVID-19 pandemic on our business are forward-looking statements. These statements involve known and unknown risks, uncertainties and other important factors 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.

Without limiting the foregoing, as the words "aim," "believe," "may," "will," "should," "expect," "exploring," "plan," "anticipate," "could," "intend," "target," "project," "contemplate," "believe," "estimate," "predict," "potential," "seeks," or "continue" or the negative of these terms or other similar expressions, are intended to identify forward-looking statements, although not all forward-looking statements contain these words. These forward-looking statements are not a guarantee of future results, performance, or achievements, and one should avoid placing undue reliance on such statements.

These forward-looking statements are based on our management's beliefs and assumptions and on information currently available to us. Such beliefs and assumptions may or may not prove to be correct. Additionally, such forward-looking statements are subject to a number of known and unknown risks, uncertainties, and other important factors that may cause our actual results, performance or achievements to be materially different from and actual results, performance or achievements to be materially different from any future results, performance or achievements due to various factors, including, but not limited to those identified in Part I, Item 1A. "Risk Factors" and Part II, Item 7. "Management's Discussion and Analysis of Financial Condition and Results of Operations" in this Annual Report and in our other filings with the Securities and Exchange Commission (the "SEC"), each of which filings are accessible on the SEC's website at www.sec.gov and the Investor Relations page of our website at https://investors.aziyo.com/financials/sec-filings.

Moreover, we operate in an evolving environment. New risk factors and uncertainties may emerge from time to time, and it is not possible for management to predict all risk factors and uncertainties.

You should read this Annual Report and the documents that we reference in this Annual Report completely and with the understanding that our actual future results may be materially different from what we expect. We qualify all of our forward-looking statements by these cautionary statements. Except as required by applicable law, we do not plan to publicly update or revise any forward-looking statements contained herein, whether as a result of any new information, future events, changed circumstances or otherwise.

As used in this Annual Report, unless otherwise specified or the context otherwise requires, references to "we," "us," "our," the "Company" and "Aziyo" refer to the operations of Aziyo Biologics, Inc. and its consolidated subsidiaries.

TRADEMARKS, TRADE NAMES AND SERVICE MARKS

This Annual Report includes our trademarks, trade names and service marks, including, without limitation, "Aziyo®," "CanGaroo®," "ProxiCor®," "Tyke®," "VasCure®," "ViBone®," "OsteGro®," "SimpliDerm®" and our logo, which are our property and are protected under applicable intellectual property laws. This Annual Report also

contains trademarks, trade names and service marks of other companies, which are the property of their respective owners. Solely for convenience, trademarks, trade names and service marks may appear in this Annual Report without the ®, TM and SM symbols, but such references are not intended to indicate, in any way, that we or the applicable owner forgo or will not assert, to the fullest extent permitted under applicable law, our rights or the rights of any applicable licensors to these trademarks, trade names and service marks. We do not intend our use or display of other parties' trademarks, trade names or service marks to imply, and such use or display should not be construed to imply, a relationship with, or endorsement or sponsorship of us by, these other parties.

INDUSTRY AND OTHER DATA

Unless otherwise indicated, information contained in this Annual Report concerning our industry and the markets in which we operate, including our general expectations, market position and market opportunity, is based on our management's estimates and research, as well as industry and general publications and research, surveys and studies conducted by third parties. We believe the information from these third-party publications, research, surveys and studies included in this Annual Report is reliable. Management's estimates are derived from publicly available information, their knowledge of our industry and their assumptions based on such information and knowledge, which we believe to be reasonable. This data involves a number of assumptions and limitations which are necessarily subject to a high degree of uncertainty and risk due to a variety of factors, including those described in this Annual Report under "Forward Looking Statements" and Part I, Item 1A "Risk Factors." These and other factors could cause our future performance to differ materially from our assumptions and estimates.

RISK FACTORS SUMMARY

Our business is subject to numerous risks and uncertainties, including those described in Part I, Item 1A. "Risk Factors" in this Annual Report. You should carefully consider these risks and uncertainties when investing in our common stock. The principal risks and uncertainties affecting our business include the following:

- we have incurred operating losses and may continue to do so for the near-term future, and we cannot assure you that we will be able to generate sufficient revenue to achieve or sustain profitability;
- adverse changes in general domestic and global economic conditions and instability and disruption of credit markets could adversely affect our business, financial condition, results of operations and liquidity;
- we have identified conditions and events that raise substantial doubt regarding our ability to continue as going concern;
- our long-term growth depends on our ability to enhance our products, expand our product indications and develop, acquire and commercialize additional product offerings;
- the regulatory approval, certification and clearance processes of the FDA and comparable foreign authorities and notified bodies are lengthy, time consuming and inherently unpredictable, and if we are ultimately unable to obtain regulatory approval or other marketing authorizations for our products and product candidates, our business will be substantially harmed;
- a substantial portion of our net sales is generated through our commercial partners and independent sales agents, which subjects us to various risks;
- our revenue and profitability could be materially and adversely affected if we fail to maintain our relationships with our existing contract manufacturing customers or enter into agreements with new contract manufacturing customers, or if existing contract manufacturing customers reduce purchases of our products. Our relationships with these customers also subject us to certain risks;
- we face significant litigation related to FiberCel;

- we face the risk of product liability claims and may not be able to obtain or maintain adequate product liability insurance;
- our future growth depends on physician awareness of the distinctive characteristics, benefits, safety, clinical efficacy and cost-effectiveness of our products;
- our success depends on the continued and future acceptance of our products by the medical community;
- we face significant and continuing competition from other companies, some of which have longer operating histories, more established products and/or greater resources than we do, which could adversely affect our business, financial condition and results of operations;
- pricing pressure as a result of cost-containment efforts of our customers, purchasing groups, third-party payors and governmental organizations could adversely affect our sales and profitability;
- the processing of human and porcine tissue for our products is technically complex, requiring high levels of quality control and precision, which subjects us to increased production risks;
- because we depend upon a limited number of third-party suppliers and manufacturers and, in certain cases, exclusive suppliers for products essential to our business, we may incur significant product development costs and experience material delivery delays if we lose any significant supplier, which could materially and adversely affect our business, financial condition and results of operations; and
- if we are unable to obtain, maintain and adequately protect our intellectual property rights, our competitive position could be harmed or we could be required to incur significant expenses to enforce or defend our rights.

PART I

Item 1. Business.

Overview

We are a commercial-stage regenerative medicine company focused on creating the next generation of differentiated products and improving outcomes in patients undergoing surgery. We seek to leverage our unique understanding of biologics to improve the interaction between medical devices and patients, with the goal of reducing complications and improving healing. From our proprietary tissue processing platforms, we have developed a portfolio of advanced regenerative medical products that are designed to mimic the healing response of natural biological material. Our proprietary products are designed to address the device protection, women's health, orthobiologics and cardiovascular markets, which we believe represent a combined $3 billion market opportunity in the United States. To expand our commercial reach, we have commercial relationships with major medical device companies, such as Boston Scientific, Biotronik and beginning in March 2023, Sientra, to promote and sell some of our products. We believe our focus on our unique regenerative medicine platforms will ultimately maximize our probability of continued clinical and commercial success and will create a long-term competitive advantage for us.

We estimate that, over the past two years, approximately two million patients per year in the United States were implanted with either medical devices, such as pacemakers, defibrillators, neuro-stimulators, spinal fusion and trauma fracture hardware or tissue expanders for breast reconstruction. This number has been driven by advances in medical device technologies, reimbursement models focused on patient outcomes, and an aging population with a growing incidence of comorbidities, including diabetes, obesity and cardiovascular and peripheral vascular diseases. These comorbidities can exacerbate various immune responses and contribute to other complications upon device implant.

Our products are targeted to address unmet clinical needs with the goal of promoting healthy tissue formation and avoiding complications associated with medical device implants, such as infection, scar-tissue formation, capsular contraction, erosion, migration, non-union of implants and implant rejection. We have products in each of our four priority markets: device protection, cardiovascular, orthobiologics and women's health. In device protection, we sell the only biological envelope, protected by a global patent portfolio, that forms a natural, systemically vascularized pocket for holding implanted electronic devices. In cardiovascular, we sell our specialized porcine small intestine submucosa ("SIS ECM") for use as an intracardiac and vascular patch. In orthobiologics, we have a proprietary processing technology for manufacturing a comprehensive portfolio of bone regenerative products designed to promote the body's ability to regenerate healthy bone, osteogenesis, while decreasing cell apoptosis, or programmed cell death. In women's health, we have a patented cell removal technology that produces undamaged extracellular dermal matrices with superior handling, designed to promote faster healing and reduce inflammation. In pre-clinical and clinical studies, our products have supported and, in some cases, accelerated tissue healing, which has contributed to improved patient outcomes.

We operate in four segments that align with our major product groupings – Device Protection, Women's Health, Orthobiologics and Cardiovascular. Our product portfolio and contract manufacturing capabilities within each of these segments are highlighted in the table below.

Market	Product Brands	Description	Go-To-Market Strategy
Device Protection	CanGaroo	Biological envelope that remodels into systemically connected, vascularized tissue for the long-term pocket protection of certain cardiac and neurostimulator implantable electronic devices	Direct and supported by commercial partners
Women's Health	SimpliDerm	Pre-hydrated, human acellular dermal matrix, or HADM, that is designed to enable rapid integration, cellular repopulation and rapid revascularization at the surgical site	Independent sales agents
Orthobiologics	ViBone OsteGro V Fiber VBM	Variety of viable matrices, produced with a proprietary process that is designed to protect and preserve native bone cells and reduce programmable cell death, for use in bone repair and fusion procedures	Commercial partners
	Various Products	Contract manufacturing of particulate bone, precision milled bone, cellular bone matrix, acellular dermis, amnion and other soft tissue products to utilize fully our starting human biological materials, leverage our existing overhead and improve our cash flow	Corporate customers
Cardiovascular	Proxicor Tyke VasCure	Portfolio of extracellular matrices that retain the natural composition of collagen, growth factors and proteins for use in vascular and cardiac repair and pericardial closure	Direct and independent sales agents

Our growth strategy is focused on increasing penetration in each of the device protection, women’s health, orthobiologics and cardiovascular markets. We believe we can grow our business by increasing our commercial footprint, developing clinically exceptional products and, when possible and appropriate, through inorganic opportunities.

Our go-to-market strategy includes a hybrid of a direct sales force, commercial partners and independent sales agents. As of December 31, 2022, we had 24 direct sales representatives who focus on gaining additional market access and driving market penetration, not only by selling our products, but also, where appropriate, by managing our commercial partners and providing technical assistance for selling our products. Through our direct sales force and leveraging our existing commercial partners, we believe we can expand our customer base and further strengthen our existing customer relationships and increase penetration in our priority markets.

We have a well-established and scalable manufacturing platform, consisting of two facilities that are supported by our corporate headquarters and other administrative location. Our Silver Spring, Maryland location is our headquarters and functions as a research and development and corporate support center. Our Roswell, Georgia location is our processing, production and distribution facility for all of our implantable electronic device protection and cardiovascular products. Our Richmond, California location is our human tissue processing and distribution facility for our orthobiologics and soft tissue reconstruction products. Our San Diego, California location provides additional administrative oversight and support. We believe we have sufficient operating capacity at both our Roswell and Richmond facilities to support future growth.

Our Competitive Strengths

Our mission is to provide advanced regenerative care products that improve the outcomes in patients primarily undergoing implantable device-related surgery. To accomplish this mission, we intend to establish our products as the standard of care for treating patients undergoing such procedures. We believe our key competitive strengths position us well to execute on our growth strategy. Our key competitive strengths are:

Our Integrated Company. Our end-to-end capabilities spanning research and development (R&D), manufacturing and commercialization enables us to continually advance our product portfolio and drive commercial growth. For example, our integrated structure allows us to receive market feedback from our sales team on unmet physician and patient needs, providing us with invaluable direction on our innovation priorities. It is this feedback that allowed us to refine our SimpliDerm product to what we believe to have industry-leading handling properties. Our integrated structure also allows us to leverage our R&D capabilities to continually improve our manufacturing processes to lower our production costs.

Well-positioned in Large, Attractive and Growing Markets. We believe that the device protection, women's health, orthobiologics and cardiovascular markets, which we believe represent a combined $3 billion market opportunity in the United States, will continue to experience accelerated growth, given advancements in implantable medical device technologies and surgical techniques; shifting global demographics that include an aging population with a greater incidence of comorbidities, and increasing procedure volumes. We believe there is growing adoption of regenerative medicine products by the medical community as physicians become aware of the benefits of natural products, including improved healing and reduced inflammation, scar-tissue formation and foreign body response.

Regenerative Medicine Technology Focus. Our scientific expertise, commercial-scale manufacturing and know-how in regenerative medicine technology has allowed us to develop and process our proprietary platforms to create differentiated biomaterials, including our CanGaroo, ProxiCor, Tyke, VasCure, Fiber VBM, ViBone, OsteGro V and SimpliDerm product lines. These types of products, which are designed to more closely resemble natural products than highly processed or synthetic substitutes, have enabled us to advance the science of regenerative medicine as well as to process tissue and produce products at commercial scale.

Broad Portfolio of Regenerative Medicine Products to Address the Needs of Physicians, Patients and Providers. Physicians use our broad portfolio of regenerative medicine products to meet the needs of individual patients. The breadth of our current portfolio, which includes products used in device protection, women's health, orthobiologics and cardiovascular markets, gives us the flexibility to target a broad set of procedures, each with a full suite of products to accommodate both the clinical and economic factors that may affect purchasing decisions. Our experienced contracting and direct sales force teams are highly trained to assist clinicians in effectively selecting and using the full complement of our products.

Large and Growing Body of Clinical Data. We have and continue to develop a body of pre-clinical, clinical and patient outcomes data, including third-party publications and patient registries that provide evidence supporting the technical and clinical attributes of our products. We believe that our extensive in vivo and clinical data give us a competitive advantage.

Commercial Relationships with Major Medical Device Companies. We have commercial agreements with major medical device companies, including our strategic relationships with Boston Scientific, Biotronik and beginning in March 2023, Sientra, which, along with others, we collectively refer to as our commercial partners, to promote or commercialize some of our products. These commercial partners use their own network of more than 1,400 sales representatives, clinical specialists and independent sales agents, including approximately 1,200 of which are focused on our CanGaroo product. We leverage this additional presence in targeted markets to significantly increase our opportunity to cost-effectively penetrate these large markets.

Established and Scalable Manufacturing and Commercial Infrastructure. We have well-established relationships to obtain the human and animal tissues, which we need to manufacture our products, in the quantity needed and in a manner that preserves their integrity. We have sufficient capacity to increase the scale of our manufacturing, and the required quality control and regulatory capabilities to ensure that our products meet established specifications. We have developed rigorous medical, clinical, manufacturing, distribution and logistics capabilities designed to comply with FDA requirements. We pair our operational capabilities with a strong commercial team of sales, marketing and contracting professionals. Our established regulatory, operational and commercial infrastructure provides a firm foundation for growth as we continue to scale our business.

Executive Management Team with Extensive Experience in Regenerative Medicine. Our executive management team has extensive experience in the regenerative medicine and medical device industries, spanning R&D, operations, manufacturing and commercial. This experience allows us to operate with a deep understanding of the underlying trends in regenerative medicine and the intertwined scientific, clinical, regulatory, commercial and manufacturing functions that drive success in this industry. We believe our team has the necessary experience to lead us through our continued commercial expansion and the development and launch of our pipeline products.

Our Growth Strategy

The key elements of our growth strategy are:

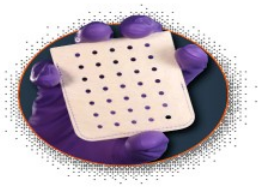
Increase Penetration in Our Target Markets. We believe that the potential for growth in regenerative medicine in our target market segments presents a long-term opportunity to increase the use of our products. We plan to continue our growth and accelerate our penetration into our target markets through our direct sales force and by leveraging our relationships with our commercial partners that have well-established and significant cardiac rhythm and orthopedic/spinal sales infrastructure and experience in our target markets. We believe the breadth and flexibility of our current portfolio of products provides us with the capability to address a wider variety of implantable device procedures and soft tissue reconstructions, all of which should offer significant new growth opportunities.

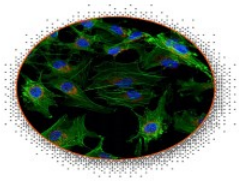
Robust Pipeline of Innovative Core Products from Our Proven Research and Development Capabilities. We have brought to market two commercial products in the past three years. We intend to continue to pursue FDA clearance for the next generation of our flagship CanGaroo product, the CanGaroo RM. CanGaroo RM is a device-protection pouch designed to combine the regenerative properties of biological materials with the antibacterial effects of two antibiotics. If cleared by the FDA, we plan to launch CanGaroo RM in collaboration with our commercial partners and maximize market penetration. In addition to our current commercial products and our intended path involving CanGaroo RM, we intend to develop additional product candidates for the device protection, women’s health and orthobiologics markets. We will continue to conduct pre-clinical and clinical studies, gather patient data and perform other research to support the further adoption of our products in the marketplace.

Additional Growth through Selective Acquisitions. We have demonstrated our ability to identify acquisition opportunities and integrate assets that complement our strategy and generate revenue and incremental gross profits. We were created in 2015 through the spin-out of the musculoskeletal division of Tissue Banks International ("TBI") now KeraLink International ("KeraLink"), which provided us with tissue processing capabilities. We created additional value from this transaction by hiring scientific expertise to enhance these assets and develop a next generation of products. We then formed strategic partnerships to sell these products and improve our financial performance. Similarly, in 2017, we acquired biomaterial medical device assets, centered around the product we now sell as CanGaroo, from CorMatrix Cardiovascular. We followed the model that we had developed with the TBI asset acquisition. We brought in experienced leadership and expanded our clinical and commercial teams, which provided us with the opportunity to form new partnerships and commercialize CanGaroo. As a result, we again accelerated the growth of our revenue stream. We will continue to evaluate possible acquisitions that complement our existing portfolio and leverage our established commercial and manufacturing infrastructure.

Our Proprietary Products/Solutions

Our portfolio of regenerative medicine products has been developed to address the following specific markets:





ORTHOBIOLOGICS

WOMEN'S HEALTH RECONSTRUCTION

Device Protection and Cardiovascular Markets

Market Opportunity

In 2019, we estimate, based on industry sources and other third-party estimates, that there were more than 600,000 procedures in the United States to install or replace implantable electronic devices ("IED"), such as pacemakers, pulse generators and defibrillators, as well as spinal cord neuromodulators and vagus nerve, deep brain and sacral nerve stimulators, which represents an estimated $600 million opportunity.

Limitations of Existing Solutions

IEDs are now the standard of care for patients suffering from cardiac arrhythmias and heart failure. Such devices, cardiac implantable electronic devices ("CIED"), are implanted in soft tissue, which is not heavily vascularized, and its implantation may trigger a biologic response that results in inflammation and fibrosis, leading to the device and its wire leads being encased in dense or calcified fibrous material.

In 2015, a group of third-party researchers published a systematic review and meta-analysis of 60 published reports, consisting of 21 prospective, nine case-control and 30 retrospective cohort studies published between 1981 and 2013, each of which examined the rate of infection associated with the implantation of electronic devices. The average rate of infection was between 1.0 and 1.3% and the reported rates of infection ranged from 0.3% to 16.4%. In 2019, a different group of third-party researchers published the results of a global, prospective randomized clinical study focused on infection complications of implantable electronic cardiovascular devices which identified a 1.2% infection rate during 12-month follow-up in the control arm (3,488 patients), and this was later reported by other third-party researchers in 2020 to rise to 1.9% at the 36 months follow-up. However, infection is not the only significant complication associated with implantation. Data from third-party studies published in 2011 and 2016 indicated that migration occurred in 0.5% to 10.9%

of such procedures, and data from third-party studies published in 2001 and 2007 indicated that erosion of the device through the skin occurred in 0.2% to 5.0% of such procedures. Thus, migration and erosion have been shown to be similarly frequent and can both result in infection or require replacement of the device. Other complications include those associated with Twiddler's syndrome, which is a malfunction of a pacemaker due to manipulation of the device by the patient, and discomfort at the implant site. In addition, capsular contracture can occur when scar tissue, or a capsule, around the device tightens and squeezes the implant. Capsular contraction may be more common following infection, collection of blood, or hematoma, and collection of the watery portion of blood, or seroma.

As patients with implants live longer, device reoperations are ever more common, including those to replace or upgrade the device, or to replace or revise the wire leads. The dense, under-vascularized capsule surrounding a device and its wire leads makes replacement or revision more difficult, increases the time needed for the extraction and replacement procedure and progressively increases the risk of infection. An increasing proportion of these cardiovascular electronic devices, that is, cardioverter/defibrillators, are now larger, heavier and more complex and have a greater frequency of complications associated with them than the smaller, less heavy and less complex devices. For neurostimulator devices, the common location of these devices, which is in the soft tissue of the abdomen or back, increases the risk of migration and erosion and that of patient discomfort when sleeping or sitting.

In 1972, Dr. Victor Parsonnet reported that enclosing pulse generators in a polyester pouch prevented migration and extrusion of the implanted device through the skin. BARD Vascular Systems manufactured the Parsonnet pouch, which was used in patients with little subcutaneous tissue. In 2008, TyRx Pharma ("TyRx") introduced AIGSRX, a synthetic, permanent mesh envelope, which was intended to securely hold either a pacemaker pulse generator or defibrillator and provide a safe space for these implants to be acclimated by the body. To prevent infections associated with the implantation procedure, the non-resorbable mesh was coated with a bioabsorbable material, which dissolved over a period of seven to ten days, during which time the antibiotics rifampicin and minocycline were released. In 2013, TyRx replaced the original product with AIGISRXR, a comparable product with the same two intended uses, but totally bioresorbable. In 2014, Medtronic acquired TyRx and now sells this totally bioresorbable synthetic product under the name TYRX.

TYRX is a relatively stiff synthetic mesh with rough edges available in only two sizes, which may require the surgeon to make a larger incision than is needed only to implant the electronic device. The larger incision can lead to longer surgery times and complications at the time of replacement or upgrade of the implantable device. Third-party studies have shown that the synthetic TYRX mesh is broken down and reabsorbed within approximately nine weeks. According to published literature, synthetic mesh, unlike biological mesh, does not promote biological signaling needed to mitigate the anticipated and well-documented foreign body response that results in the production of scar tissue to form a capsule surrounding an implantable device. TYRX's primary benefit is to dispense antibiotics to reduce the rate of infection associated with device implantation.

Our Solution

CanGaroo was designed to mitigate complications deriving from implantable electronic devices and the shortcomings of synthetic envelopes. We believe that CanGaroo is the only biological product that forms a natural, systemically vascularized pocket that conforms to and securely holds implantable electronic devices. CanGaroo is cleared for use with pacemaker pulse generators, defibrillators and other cardiac implantable electronic devices as well as vagus nerve stimulators, spinal cord neuromodulators, deep brain stimulators and sacral nerve stimulators.

The CanGaroo Envelope is constructed from perforated, multi-laminate sheets of decellularized, non-crosslinked, lyophilized SIS ECM, derived from porcine small intestinal submucosa, a natural biomaterial, which is rich in natural growth factors, structural proteins and collagens. The ECM is sewn into the shape of a pouch, into which the device is placed. We sell the biological envelope in a variety of sizes, which allows it to accommodate various sized electronic devices, and it has a shelf life of 30 months.

CanGaroo is soft and pliable and is designed to conform to the implantable device for easy handling and implantation. The SIS ECM is designed to mitigate the biologic foreign body response that normally occurs around the electronic device. CanGaroo is remodeled into a surrounding layer of vital, vascularized tissue, potentially reducing the

risk of capsular formation, migration and erosion of the implantable device through the skin, and complications associated with Twiddler's syndrome. CanGaroo may also facilitate the process of implantation and of device removal during its replacement, as well as enhance patient comfort.

Product	Description	Regulatory Pathway
CanGaroo Envelope 	Naturally occurring ECM scaffold intended to hold securely implantable electronic devices, creating an environment designed to enhance patient comfort and reduce device migration	Medical Device 510(k)

Development Pipeline

We are currently developing a version of the CanGaroo Envelope, the CanGaroo RM, that combines the envelope with antibiotics and is designed to reduce the risk of infection following surgical implantation of an electronic device. Based on feedback from the FDA, CanGaroo RM will require clearance of a 510(k) submission to be marketed in the United States. We submitted the required 510(k) in April 2022 and, in March 2023, received a Not Substantially Equivalent ("NSE") letter from FDA requiring us to address questions relating to drug testing, primarily a request by FDA to modify an *in vitro* drug release assay employed as a manufacturing control. We intend to address the questions raised in the NSE letter and continue to work with FDA for potential clearance via the 510(k) pathway.

Commercial Approach

We sell CanGaroo in the United States and globally using our direct sales force and our commercial partners, Boston Scientific and Biotronik, which act as sales agents and give us access to approximately 1,200 sales representatives and clinical specialists to further expand our footprint and accelerate our sales. Our primary customers are electrophysiologists, cardiac surgeons and neurosurgeons. Our direct sales force is focused on gaining additional market access and driving market penetration, not only by selling our products, but also, where appropriate, by managing our commercial partners and providing technical assistance for selling our products. Our sales team provides the critical knowledge of the advantages that CanGaroo provides for patients over those of our competitors. We ship the product directly to hospitals.

Cardiovascular Products

Through our direct sales force and independent sales agents, we also sell additional cardiovascular products derived from our specialized SIS ECM, all of which received 510(k) regulatory clearance as medical devices:

- ProxiCor is cleared for use as an intracardiac patch or pledget for tissue repair, i.e., atrial septal defect, ventricular septal defect and suture-line buttressing, as well as for the repair and reconstruction of the pericardium. ProxiCor enables cardiac and congenital heart surgeons to reestablish the essential native anatomical structures of the heart and pericardium by providing a natural bio-scaffold that allows the patient's own cells to form a new pericardial layer. Typically, the absence of a pericardial barrier often leads to scarring and the formation of adhesions between the heart and sternum, impairing normal heart function. We believe that the use of ProxiCor for pericardial repair potentially avoids adverse events associated with the use of synthetic materials or highly processed biological materials, which can trigger an immune response, resulting in fibrotic or calcified scarring at the implant site.

- Tyke was developed based on a request by pediatric cardiovascular surgeons to deliver an ECM material that maintained the biomechanical properties found in our existing products, but was thinner, more pliable and better suited for intracardiac and branch pulmonary artery use in neonates and infants. Tyke is cleared for use in neonates and infants for the repair of pericardial structures; as an epicardial covering for damaged or

repaired cardiac structures; and as a patch material for intracardiac defects, septal defect and annulus repair, suture-line buttressing and cardiac repair. We believe that Tyke is the only extracellular material that has been specifically cleared for use in neonates and infants to repair pericardial structures.

- VasCure is cleared for use, and is used by, cardiovascular, vascular and general surgeons as, a patch material to repair or reconstruct the peripheral vasculature, including the carotid, renal, iliac, femoral and tibial blood vessels, by modeling into site-specific tissue and conforming to repair defects easily. VasCure is also cleared and is used for the closure of vessels, as a pledget, or for suture line buttressing when repairing vessels. It is designed to prevent and stop bleeding, resulting in minimal bleeding at suture lines. Unlike synthetic or cross-linked materials, VasCure approximates normal tissue and, we believe, is, therefore, less likely to provoke an immune response.

Women's Health Market

Market Opportunity

According to certain third-party estimates, there were more than 100,000 procedures in the United States in 2019 using biologic matrices for plastic and reconstructive surgery, which constituted an approximately $500 million market. Such surgery is performed to treat structures of the human body that are affected aesthetically or functionally due to defects, abnormalities, trauma, infection, burns, tumors or disease. Plastic and reconstructive surgery is generally performed to improve function and ability, but it may also be performed to achieve a more natural appearance of the affected anatomical structure. Clinical practice of plastic and reconstructive surgery includes excision of tumors of the skin, vasculature, chest, oral and oropharyngeal cavities and extremities and reconstructions of the same; debridement, skin grafting and skin flaps for burn reconstructions; trauma surgery for the hands, upper and lower limbs and facial region; congenital or acquired malformations related to the hands, face, skull and jaw; surgical removal of vascular abnormalities; a range of aesthetic surgeries; and reconstructions of the breast.

One of the most common applications of biologic matrices in plastic and reconstructive surgery is breast reconstruction surgery during or after mastectomy. Mastectomy is a method of tumor removal for breast cancer in which all breast tissue, including the cancerous cells, is surgically removed. In the United States in 2020, there were more than 100,000 post-mastectomy breast reconstructions, of which approximately 66% were bilateral operations, that is, both breasts were reconstructed. Breast reconstruction surgery is a surgical procedure generally used to restore a breast to near normal shape and appearance and can be performed using either a prosthetic breast implant, referred to as implant-based reconstruction, or the patient's own tissue, referred to as autologous reconstruction. Additional reconstructive surgeries may be required following the initial breast reconstruction, including breast lift, also known as mastopexy, or breast revision surgery, in which the surgeon adjusts the position and shape of the breast.

In 2020, plastic surgeons used human acellular dermal matrices ("HADMs") in approximately 59,000 women (approximately 98,000 breasts). The use of these materials is well-characterized in the clinical literature and recommended by recent U.S. and European consensus guidelines for certain surgical techniques. However, as of March 6, 2023, no biologic matrix or any other soft tissue reinforcement material, including our product, had been approved or cleared by the FDA specifically for use in breast reconstruction surgery.

Limitations of Existing Solutions

Autologous tissue repair procedures are options for stabilizing soft tissue defects in various applications. However, these methods have limitations. The procedure may not be surgically feasible or the patient may decline its use. In addition, autologous tissue reconstruction may cause complications, such as infection, extended recovery and healing time, loss of sensation or weakness at the donor site and prolonged time under anesthesia during surgery.

Synthetic products provide a substitute when autologous reconstruction is not feasible or desired. Yet, they too have their limitations. Implantation of products not recognized by the body as "self" may trigger a foreign body reaction. The result of this signaling cascade is encapsulation of the foreign body in fibrotic tissue, which may impede tissue healing

and cause pain or other complications. Other major issues are damage to the surrounding soft tissue, altering of the mechanical properties or appearance of the original tissue and increased risk of infection.

HADM products offer an “off the shelf” biologic choice for reconstructive procedures, but they have their own limitations. The use of harsh chemicals to remove the cells can damage the extracellular matrix. The products can lack uniformity as determined by pliability in each direction, elasticity and non-uniform thickness. Such issues can affect how rapidly, and the extent to which the implant is integrated, as well as the resulting tissue strength. In addition, there is a limited availability in larger sizes for some of these products.

Our Solution

SimpliDerm was designed to offer improved biocompatibility and better functioning in the patient. It is marketed for use for the repair or replacement of damaged or insufficient integumental tissue or for the repair, reinforcement or supplemental support of soft tissue defects or any other homologous use of human integument. SimpliDerm is a pre-hydrated, HADM manufactured with our patented cell removal technology, a process that maintains the biological and structural integrity of the tissue’s extracellular matrix components and is designed to allow for rapid integration, cellular repopulation and revascularization at the surgical site. Its structurally intact extracellular matrix is designed to closely resemble natural, healthy tissue.

Product	Description	Regulatory Pathway
SimpliDerm 	Hydrated human acellular dermis designed to be used for repair or replacement of damaged or inadequate integumental tissue	HCT/Ps

Development Pipeline

Breast implants are generally placed below the pectoral muscle, known as subpectoral positioning. This approach has limitations, such as decreased arm strength, muscle spasms, animation deformities, implant movement and pain. Changes in mastectomy techniques, including the preservation of more sub-dermal tissue on skin flaps, as well as advances in fat grafting and the availability of acellular dermal matrix (“ADM”), for augmenting the tissue pocket have all created the opportunity to place the implant above the pectoral muscle, known as prepectoral positioning, and, in doing so, address complications arising from subpectoral placement. While the use of ADM to support and reinforce the skin has a strong scientific rationale for these prepectoral procedures, the sizes of ADMs required may be three to four times the magnitude used for subpectoral reconstructions, exposing the patient to greater quantities of ADM and adding proportional additional expense to the procedure. The use of ADM for these prepectoral procedures requires optimization of larger size pieces with uniform thickness, pliability and elasticity. Given the market potential and current FDA guidance, we would evaluate the anticipated regulatory and investment requirements for a specific indication for prepectoral procedures.

Commercial Approach

SimpliDerm is sold through independent sales agents to plastic and reconstructive surgeons, and we ship this product directly to hospitals.

Orthobiologics Market

Market Opportunity

According to industry sources, in the United States in 2019, there were an estimated 1.5 million surgical procedures for orthopedic and spinal repair, which, excluding the cost for spinal and orthopedic hardware, used bone repair products valued at more than $2 billion. The number of such surgeries has increased over the last several years, driven, in

part, by an increase in minimally invasive surgical procedures, an aging population, increasing sports injuries and a higher incidence of comorbidities and chronic inflammatory and degenerative conditions, including osteoarthritis.

Spinal fusion, the leading application for bone fusion surgeries in the United States, involves the use of biological grafting material to cause two vertebrae to grow together into one unit. In the United States in 2019, medical facilities performed 695,000 spinal fusion surgeries, of which approximately 400,000 were lumbar operations. Lower extremity applications, including ankle arthrodesis, or surgical immobilization of a joint by fusion of the adjacent bones, now represent a bone fusion market of approximately 165,000 fusions. With improving fixation methods, success rates have improved across these applications.

Limitations of Existing Solutions

Although success rates for orthopedic and spinal fusion have improved, inadequate bone healing remains one of the leading causes of failure for any fusion procedure. Fusion is especially challenging in patients who have underlying healing deficiencies because of comorbidities, such as diabetes and obesity.

The addition of a biological bone material to sites of defects or for creating fusion acts synergistically with hardware devices to enhance and accelerate the achievement of boney union. Autologous bone, which is harvested from the patient, is considered the gold standard for bone fusions. However, obtaining sufficient autologous material may not always be possible, may not yield good quality material, may cause donor site damage and pain and has an additional cost associated with its harvest.

Bone morphogenetic protein-2 (“BMP-2”) is currently the only FDA-approved osteoinductive growth factor for use as a bone graft substitute. However, with increasing clinical use of BMP-2, a growing and well-documented side effect profile has emerged. This profile includes postoperative inflammation and associated adverse effects, bone formation in unusual locations, bone resorption and inappropriate formation of fat cells.

Human graft products, sourced from a different individual than the patient receiving the tissue, are called allografts. These allograft products are typically processed using techniques that damage the extracellular matrix and induce cellular apoptosis, which results in premature cellular death. This cellular death impairs osteogenic differentiation and impedes the activity of osteoblasts, cells which form new bone. Synthetic materials and damaged allogenic bone lack or have diminished osteogenic properties.

Our Solution

Our bone regenerative products are processed by a proprietary method designed to protect and preserve the native bone cells (osteogenic) needed for bone formation and to decelerate cell apoptosis. Our products, besides being osteogenic, are also osteoinductive (ability to recruit cells and to signal the need for bone formation) and osteoconductive (provide a three-dimensional scaffold to promote bone formation). These products, which have beneficial handling properties, support integration with the patient’s bone, and are used to enhance the bone repair process. The inflammatory response and unintended bone formation observed with BMP-2 has not been observed with our products. We offer three viable cellular bone matrixes, including Fiber VBM, ViBone and OsteGro V.

Our viable cellular bone matrixes are bone repair products made from human tissue and engineered to be like natural tissue. Each formulation is marketed for use in orthopedic or reconstructive bone grafting procedures in combination with autologous bone or other forms of allograft bone or alone as a bone graft. Each product is designed to provide superior handling properties that are critical for use as a bone void filler in various orthopedic and spinal

procedures. We have also developed a proprietary processing methodology, optimized to protect and preserve the critical bone elements required for regenerative bone formation.

Product	Description	Regulatory Pathway
Fiber VBM, ViBone and OsteGro V 	Allografts that perform and handle similarly to an autograft as a result of proprietary processing designed to protect the tissue environment and the cells	HCT/Ps

Development Pipeline

We are currently developing new bone fusion and repair product candidates that offer features that we believe could improve upon currently available technologies or offer new features. These product candidates are currently in development, and we believe these product candidates will be regulated by the FDA as HCT/Ps.

Commercial Approach

Our commercial approach to the orthopedic/spinal repair market has been to leverage commercial partners with existing sales and marketing infrastructure in these areas, while we focus on research and development and the manufacturing of products. We currently have agreements in place with many spine and orthopedic companies for the distribution of our viable bone matrix products. Under the terms of those agreements, these customers purchase products from us at specified prices and resell such products in the United States to the primary customers, which are hospitals and other healthcare facilities. We fulfill most orders from our commercial partners by shipping these products directly to these hospitals and other healthcare facilities.

Additional Orthobiologics Products/Contract Manufacturing

In addition to our proprietary products, we fulfill tissue processing contracts based on product specifications established by our customers through contract manufacturing services at our Richmond, California facility. We provide these services in order to utilize as much as possible of the starting human biological material from which we produce our proprietary orthobiologic products, leverage our existing overhead and improve our cash flow. The resulting processed materials, including particulate bone, precision milled bone, cellular bone matrix, acellular dermis and other soft tissue products, are sold to medical/surgical companies as finished products and as a subcomponent of their products. Additionally, we process amniotic membrane as finished product for select customers.

Clinical Data

We have accumulated a substantial body of clinical and pre-clinical data for our proprietary products. We believe that the reported outcomes from our studies help to differentiate our products in the marketplace.

Device Protection

Pre-clinical Studies

Recently published pre-clinical data from a rabbit model showed that the CanGaroo Envelope was more successful in providing a barrier surrounding a CIED compared to a pacemaker canister alone. When implanted with a pacemaker, CanGaroo Envelopes were observed to promote significantly greater stabilization of the device and more vascularized tissue ingrowth within the pocket compared to implantation with only standard fixation methods, such as

sutures through the CIED header or no fixation at all. These data were initially presented as a live podium presentation at the ASAIO 2022 annual conference and published in abstract form in ASAIO Journal.

Clinical Studies

To evaluate our CanGaroo Envelope, we have conducted multiple post-market studies and are currently conducting retrospective studies including over 2,000 patients in total. We believe the results from the completed studies provide evidence supporting the safety of the CanGaroo Envelope when used for the implantation of CIEDs in humans.

CARE Study and SECURE Study

The CARE Study was a retrospective, post market study. Data from 96 consecutive patients who underwent simultaneous CIED and CanGaroo Envelope implantation at a single institution were retrospectively reviewed for the occurrence of CIED-related complications and infection. The SECURE Study was a prospective, single arm, observational, post-market study assessing 1,026 patients enrolled at 39 centers who underwent the implantation of a CIED in a CanGaroo Envelope.

The endpoints of the studies were to evaluate: (a) the proportion of patients with CanGaroo-related adverse events and (b) the incidence of major infections observed in the pocket. Data from these two studies were combined to determine overall clinical outcomes and adverse events, and resulted in a large dataset from 40 centers throughout the United States of 1,102 total patients with an average number of 2.3 infection risk factors and mean follow up time of 223 days. The most common risk factors among enrolled patients included oral systemic anticoagulants, obesity, diabetes, congestive heart failure, device replacement/revision, and renal insufficiency.

This real-world dataset revealed physician practice patterns for usage of the CanGaroo Envelope, and the type of hydration solutions that were chosen by the treating physician. Physicians demonstrated a preference for usage of an antibiotic hydration solution in higher infection risk patients ($p<.05$), particularly gentamicin, and those patients had an equivalent major infection rate to lower risk patients receiving a saline soaked CanGaroo (p=NS). Of the total sample population, 14 patients (1.3%) developed hematoma requiring intervention, and 12 patients (1.1%) developed a pocket infection - 10 of which (0.9%) came from the antibiotic without gentamicin hydration group. The use of gentamicin was associated with a threefold reduction in infection risk (OR 3.0, 95% CI, 1.0 – 10.0). A major contributing factor to pocket infection rate was whether the site also employed guideline recommended preoperative intravenous antibiotics (IV ABX) alongside use of an antibacterial envelope; sites utilizing IV ABX on ≥80% of their patients had significantly lower infection rates than sites that used it on <80% of their patients (0.8% vs. 5.6%, p=.008). There were no reports of device migration in the total dataset. These results were presented and published as separate sub-analyses of the dataset at multiple national conferences between 2017 – 2022, and collectively in a recent publication, and highlight the importance of evaluating real world evidence for CIED envelopes, and conjunctive use alongside other guideline recommendations for high infection risk patients. We believe the low rates of CanGaroo Envelope complications observed in the CARE and SECURE Studies support the safety of the product when used clinically in human CIED implantation.

CARE Plus Study

The CARE Plus Study was a single-center, post-market, retrospective cohort study to evaluate outcomes in patients who received a biologic CanGaroo Envelope, Medtronic's non-biologic TYRX envelope, or no envelope during CIED implantation. Adverse patient outcomes and any adverse events that occurred following implantation out to 12 months were analyzed.

The results of 455 patients (165 CanGaroo, 219 TYRX and 71 no envelope) were published in *Cureus* in May 2022. The results indicated that most patients with at least two infection risk factors received an antibacterial envelope (77.9% any envelope vs. 52.1% no envelope, $p<.001$). The overall rate of adverse events was 9.2% (n = 42). Rates of pocket infection (0.4%) and hematoma (2.6%) were low, with no significant differences between groups in overall or individual adverse event rates. We believe these data support the use of antibiotic eluting CIED envelopes to limit infection risk in high-risk patients. A decision tree was proposed by the author based on their patient selection criteria for real world envelope usage and other supporting data that may aid clinical decision-making when considering CIED envelope usage.

HEAL Study

The HEAL Study is an ongoing retrospective cohort study of CIED patients who are presenting for their latest reoperation after a previous implantation that is designed to identify and compare the characteristics of soft tissue healing surrounding cardiovascular implantable electronic device implants. As of December 31, 2022 there were 45 patients enrolled. Patients evaluated in the study will be from one of three cohorts based on whether a biologic CanGaroo Envelope, Medtronic's non-biologic TYRX Envelope, or no envelope was used during the prior implantation. At reoperation, the current implant pockets of the patients will be examined and compared by a blinded histological biopsy and visually using photographs.

An interim analysis was performed in May 2022 on 21 patients that were enrolled at the time (9 CanGaroo and 12 no envelope) as of a cutoff date of April 25, 2022, and the results were presented as a poster at the American Heart Association (AHA) Conference in November 2022 and published in *Circulation*. The CanGaroo cohort required 63% fewer capsulectomies, and treating physicians scored capsular lead adhesion classification as significantly less severe than the no envelope cohort (*p=.02*). On a 10-point scale, physicians scored CanGaroo reoperations as significantly less difficult in generator mobilization (39% easier, *p=.04*), lead mobilization (43% easier, *p=.01*), and overall procedural difficulty (45% easier, *p=.01*). On average, CanGaroo capsules were found via blinded histologic assessment to have a 39% thinner fibrotic capsule compared to the no envelope capsules (*p=.05*). Although the study is ongoing, we believe these interim results suggest that use of a biologic CanGaroo Envelope at initial CIED implantation has the potential to prevent operative complications, facilitate reoperative procedures, and enhance clinical outcomes.

CanGaroo S-ICD Pilot Study

A retrospective, single-center, post-market pilot study was designed to evaluate whether low voltage lead impedance (LVZ), as routinely measured by subcutaneous implantable cardioverter defibrillators (S-ICDs), could be a clinically relevant assessment. These devices sense changes in impedance, which could be influenced by fibrotic tissue surrounding the S-ICD. Such encapsulation could complicate future procedures for patients.

LVZ changes from 0 to 4 years post implantation of a S-ICD were analyzed in 24 patients, half of whom received CanGaroo Envelope and half received no envelope. LVZ measurements reliably detected changes in impedance over time and between groups. After an initial decrease in both groups in the first month, impedance changes appeared to increase more slowly in the CanGaroo cohort compared to patients in the no envelope cohort out to 30 months. The data, presented at the European Society of Cardiology 2022 Congress and published in *European Heart Journal*, suggest that LVZ may provide a non-invasive assessment of surrounding tissue quality. Further study is needed to determine whether use of a CanGaroo Envelope may stabilize impedance changes long-term.

CanGaroo Registry Study

The CanGaroo Registry Study is a prospective, multi-center registry with 500 patients enrolled (329 CanGaroo and 171 no envelope) as of December 31, 2022. The objective is to explore clinical profiles, procedural details, and post-implant outcomes of patients who received the CanGaroo Envelope or no envelope at time of initial (*de novo*) CIED implantation. All patients will be followed for three months postoperatively, and a subgroup of patients aged 65 years or younger at time of enrollment will undergo extended follow-up for up to five years.

Soft Tissue Reconstruction

Pre-clinical Studies

In vitro studies were conducted to evaluate and compare SimpliDerm to native human dermis and two other commercially available HADMs, in terms of morphological structure, composition, physical characteristics and chemical and thermal stability. Histology slides of SimpliDerm and native dermal matrix were examined microscopically, using three different stains. Stained samples of SimpliDerm retained the collagen structure (density and orientation), elastin, blood vessels and basement membrane complex that was observed in the native dermal matrix. Transmission electron microscopy demonstrated intact collagen fibril structures in native dermis and SimpliDerm, supporting the conclusion that

the decellularization process used to produce SimpliDerm did not damage the ultrastructural architecture of the collagen matrix.

Additional testing was performed that compared the properties of SimpliDerm, AlloDerm RTU and DermACELL to native Dermis. These tests included glycosaminoglycan content, matrix protein stability and differential scanning calorimetry. The glycosaminoglycan content of SimpliDerm and Alloderm RTU was similar, with a substantial reduction in the amount of glycosaminoglycans observed in DermACELL. Matrix protein stability was evaluated by determining acid-soluble collagen content and by performing collagenase degradation on the product samples. SimpliDerm was closest to native dermal matrix in both acid-soluble collagen content and collagenase degradation. Differential scanning calorimetry was performed on the samples, and SimpliDerm and AlloDerm RTU were equivalently close to native dermis, while DermACELL showed the largest difference. The combined testing indicates that SimpliDerm had a structurally intact matrix that was closest overall to native human dermis among the HADMs evaluated.

In addition, a non-human primate study was conducted evaluating the ability of SimpliDerm and AlloDerm RTU to regenerate host tissue two weeks, four weeks and three months after implantation. Explanted samples were subjected to analysis that included histology, growth factor analysis and gene expression characterization. H&E and VVG stains and staining for macrosialin (“CD68”) were used to prepare tissue samples for microscopic observation. AlloDerm RTU samples demonstrated faster implant degradation and cell infiltration, and more inflammatory cells than SimpliDerm. Growth factor analysis of samples for tumor necrosis factor, an indicator for an inflammatory environment, was higher for AlloDerm RTU than SimpliDerm at three months. Gene expression analysis was performed for samples at all time points. Markers for evidence of an inflammatory response to the implants, including collagen synthesis, vascularization, fibrosis, myofibroblast presence and collagen crosslinking, were analyzed and compared. AlloDerm RTU was found to exhibit higher amounts of these inflammatory response markers. The histology, growth factor testing and gene expression data support the conclusion that compared to AlloDerm RTU, SimpliDerm showed less acute and chronic inflammation and less fibrosis, leading to a pro-remodeling microenvironment that promoted tissue repair and regeneration by three months post-implantation.

Clinical Studies

A retrospective, multi-center study evaluating patients who have undergone breast reconstruction post-mastectomy with SimpliDerm and patients receiving other HADMs was published. A total of 107 patients (181 breasts) who underwent immediate, 2-stage breast reconstruction with tissue expanders and either SimpliDerm (n=38) or AlloDerm RTU (n=69) after mastectomy, were followed to exchange to permanent implant(s) or tissue expander(s) explant. Reconstructions were predominantly prepectoral (82.3%). Patients were followed for a median of 134 days. A total of 35 adverse events (AEs) occurred in 27 (25.2%) patients, with no difference in AE type or rates between ADM groups, and no AEs deemed related. The observed AE profiles and rates were similar to those published for other ADMs in breast reconstruction. These results demonstrate comparable clinical outcomes of SimpliDerm and AlloDerm RTU following 2-stage breast reconstruction.

Orthobiologics

Pre-clinical Studies

In vitro and in vivo characterization studies were conducted to compare whether the manufacturing processes for our viable bone matrices improve certain product characteristics versus traditional viable bone matrix manufacturing processes. The characteristics evaluated addressed the three key elements for bone formation: osteogenesis, osteoconduction and osteoinduction. The assays included those for apoptosis, cell proliferation, osteogenic potential and osteoinduction, as well as for specific bone morphogenic proteins, bone formation factors, alkaline phosphatase and chemotaxis. Compared to viable bone matrices prepared with traditional processing methods, our viable bone matrices were superior in all of the characteristics examined, including less cell death. For example, our viable bone matrix formulations exhibited 58% less apoptosis and had a two-fold greater cell proliferation capability as compared to allografts processed by traditional methods, suggesting greater osteogenic potential. One particular viable bone matrix formulation was tested for osteoinductive properties and was observed to have at least four-fold higher levels of bone morphogenic protein-2 and bone morphogenic protein-7 than traditionally processed allografts. An alkaline phosphatase (“ALP”) assay

was used as an indicator to determine cellular activity after exposure to C2C12 cells, which are model cells used for evaluating differentiation to bone forming cells. The ALP activity of cells exposed to this viable bone matrix formulation was 6-fold greater than traditionally processed allografts.

Clinical Studies

A prospective, multi-center, post-market clinical study was conducted to evaluate outcomes in 95 patients undergoing 1 – 3 level cervical (n=48) or lumbar (n=47) interbody fusion surgery using ViBone. Patients were evaluated clinically and radiographically at baseline, 6- and 12-months. Clinical assessment included Visual Analog Scale for pain (VAS-pain), the Neck Disability Index (NDI) for patients with cervical pathologies, and the Oswestry Disability Index (ODI) for patients with lumbar pathologies. Fusion success defined by an independent radiologist was determined radiographically by plain films. All patients reached the minimum clinically significant mean reduction in subjective pain and disability scores at 12 months. Spinal fusion rates as measured by independent radiologic evaluation were found to be comparable to the published rates of iliac crest bone autograft and other viable bone matrix grafts: at 12 months, the fusion rate per patient averaged 88.1% in cervical and 97.6% in lumbar patients, while per-level fusion was 98.5% for cervical and 100% for lumbar segments.

Competition

We operate in highly competitive markets that are subject to rapid technological change. Success in these markets depends on product efficacy, ease of product use, product price, availability of payor coverage and adequate third-party reimbursement, customer support services for technical, clinical and reimbursement support and customer preference for, and loyalty to, the products.

We believe that the demonstrated clinical efficacy of our products, the breadth of our product portfolio, our in-house customer support services, our customer relationships and our reputation offer us advantages over our competitors.

Our products compete primarily with implantable electronic device envelopes and other cardiovascular repair products, other orthobiologics and human-derived acellular dermis products. The CanGaroo Envelope competes with the synthetic envelope TYRX from Medtronic. ProxiCor, Tyke and VasCure compete with bovine pericardium produced by numerous companies, including Gore's Goretex and Terumo's Vascutek. Fiber VBM, ViBone and OsteGro V compete with other viable bone matrices, such as Smith & Nephew's Bio4, MTF's Trinity ELITE, NuVasive's OsteoCel, Vivex Biologics' VIA Graft and LifeNet Health's ViviGen. SimpliDerm competes primarily against human-derived acellular dermis matrix meshes, including AbbVie's AlloDerm, Stryker's DermACELL and MTF's FlexHD. SimpliDerm also competes against animal-derived biological mesh products, such as AbbVie's Strattice and Integra's SurgiMend, as well as various synthetic mesh products.

We also compete in the marketplace to recruit and retain qualified scientific, management and sales personnel, as well as to acquire technologies and technology licenses complementary to our products or advantageous to our business.

Our competitors' products in the soft tissue repair market have been approved or certified and available for use for multiple years. During this time, private payors have developed policies for coverage based on available data and literature. Third-party payors generally do not currently cover SimpliDerm or procedures using SimpliDerm.

We are aware of several companies that compete, or are developing technologies, in our current and future product areas. As a result, we expect competition to remain intense. Our ability to compete successfully will depend primarily on our ability to develop proprietary products that reach the market in a timely manner, are used in procedures that receive adequate payor coverage and reimbursement, are cost-effective, and are safe and effective, as well as our reputation in the market and success of our sales strategy. See Part I, Item 1A. "Risk Factors - Risks Related to Our Business - *We face significant and continuing competition from other companies, some of which have longer operating histories, more established products and/or greater resources than we do, which could adversely affect our business, financial condition and results of operations."*

Sales and Marketing

We have dedicated substantial resources to establishing a multi-faceted sales and marketing organization in the United States. We sell CanGaroo in the United States using our direct sales force and our commercial partners, Boston Scientific and Biotronik, which act as sales agents, marketing CanGaroo and obtaining orders, and give us access to approximately 1,200 sales representatives and clinical specialists to further expand our footprint and accelerate our sales. Under the terms of these agreements, Boston Scientific and Biotronik receive a commission equal to a specified dollar amount per unit sold. Our additional cardiovascular products, ProxiCor, Tyke and VasCure, are sold using our direct sales force and other independent sales agents. Our commercial approach to the orthobiologics market has been to leverage commercial partners with existing sales and marketing infrastructure in these areas, while we focus on research and development and the manufacturing of products. We currently have an agreement with many commercial partners for the sale of our viable bone matrix products. Under the terms of those agreements, these commercial partners purchase products from us at specified prices and resell such products in the United States to the primary customers, which are hospitals and other healthcare facilities. We fulfill most orders from our commercial partners by shipping these products directly to these hospitals and other healthcare facilities. SimpliDerm, our women's health product, is sold using independent sales agents which beginning in March 2023, includes Sientra. We may also explore additional distribution partnerships across our other product categories.

As of December 31, 2022, we had 24 direct sales representatives who focus on gaining additional market access and driving market penetration, not only by selling our products, but also, where appropriate, by managing our commercial partners and providing technical assistance for selling our products. These sales representatives are supported by teams of professionals focused on sales management, sales operations, ongoing training, analytics and marketing.

We have historically focused our market development and commercial activities primarily in the United States. However, we have obtained marketing registrations, developed commercial and distribution capabilities and are currently selling CanGaroo and cardiovascular products in several countries outside of the United States. Independent sales agents in Argentina, Australia, the European Economic Area, the European Union, Latin America and Mexico sell our products. Sales generated in the United States represented greater than 98% of our net sales in 2022.

Research and Development

Our research and development team has extensive experience in developing regenerative medicine products and works to design products that are intended to improve patient outcomes, simplify techniques, shorten procedures, reduce hospitalization and rehabilitation times, and, as a result, reduce costs. We have recruited and retained staff with significant experience and skills, gained through both industry experience and training at leading colleges and universities. In addition to our internal staff, our external network of development laboratories, testing laboratories and physicians aids us in our research and development process.

Manufacturing and Suppliers

We manufacture our orthobiologics and soft tissue reconstruction products in our Richmond, California facility. We manufacture CanGaroo and our cardiovascular products in our Roswell, Georgia facility and use Cook Biotech as our sole porcine tissue supplier for these products. We have significant expansion capabilities in our in-house manufacturing facilities. Cook Biotech has previously successfully expanded and, we believe, is well-positioned to support future expansion. However, they are our sole source, and we cannot guarantee that an interruption in supply will not occur. If necessary, we could engage an alternate supplier or set-up, validate and gain regulatory authorization to manufacture these products in our own facilities, although it would require significant time, expense and regulatory clearance.

We have robust internal compliance processes to maintain the high quality and reliability of our products. We use annual internal audits, combined with external audits by regulatory agencies and commercial partners to monitor our quality control practices. Our Roswell, Georgia and Richmond, California facilities are registered with the FDA as medical device and human cell and tissue manufacturing establishments, respectively. We are also accredited by the American Association of Tissue Banks ("AATB") and are licensed with several states per their tissue bank regulations.

We use third-party suppliers to support our internal manufacturing processes. We select our suppliers through a rigorous process to ensure high quality and reliability with the capacity to support our expanding production levels. Only raw material from approved suppliers is used in the manufacture of our products. To confirm quality and identify any risks, our approved suppliers are audited annually. To date, we have not experienced any significant difficulty locating and obtaining the suppliers or materials necessary to fulfill our production requirements.

Manufacture of all of our products is dependent on the availability of sufficient quantities of source tissue, which is the primary component of our products. Source tissue includes porcine tissue and donated human tissue. We acquire donated human tissue directly through tissue procurement firms engaged by us. Cook Biotech, our sole porcine tissue supplier, is registered with the FDA and ISO 13485 certified. Our processing of these tissues is, and our supplier sources are required to be, compliant with applicable FDA current Good Tissue Practice ("cGTP") regulations, AATB standards, international standards and U.S. Department of Agriculture ("USDA") requirements.

Intellectual Property

We rely on a combination of patents, trademarks, confidentiality agreements and security procedures to protect our proprietary products, preservation technology, trade secrets and know-how. We believe that our patents, trade secrets, trademarks and technology licensing rights provide us with important competitive advantages. We have also obtained additional rights through license agreements for additional products and technologies. As of December 31, 2022, we owned approximately 15 U.S. patents, seven U.S. patent applications, six foreign patents (in Australia, Germany, Spain, France, Great Britain and Italy), and four foreign patent applications (in Australia, Canada, and Europe, as well as applications with the World Intellectual Property Organization); and we in-licensed three U.S. patents, 12 foreign patents (in Australia, Canada, Japan, Denmark, Germany, Great Britain, Ireland, Italy and the Netherlands), and two U.S. and five foreign patent applications (in Brazil China, Japan as well as an application with the European Patent Office). Our owned patent portfolio includes 14 U.S. patents and six U.S. patent applications that relate to our technology for CanGaroo, including issued claims covering biological envelopes and pending claims covering their use. In addition, we own one patent that relates to our technology for SimpliDerm that claims a method of preparing an acellular dermal matrix. Excluding any patent term extension, our issued patents relating to our technology for CanGaroo are anticipated to expire starting in 2027, and our issued patent that relates to our technology for SimpliDerm is anticipated to expire in 2033. There can be no assurance that any pending patent applications will ultimately be issued as patents. We do not own or in-license any patents or patent applications covering our other products.

As with other medical device and regenerative medicine companies, our ability to maintain and solidify our proprietary and intellectual property position for our product candidates will depend on our success in obtaining effective patent claims and maintaining and enforcing claims that are granted. However, our owned and licensed patents could be invalidated or narrowed or otherwise fail to adequately protect our proprietary and intellectual property position and our pending owned and licensed patent applications, and any patent applications that we may in the future file or license from third parties may not result in the issuance of patents.

In addition, the term of individual issued patents depends upon the legal term for patents in the countries in which they are obtained. In most countries in which we have filed, including the United States, the patent term is 20 years from the earliest filing date of a non-provisional patent application. The life of a patent, and the protection it affords, is therefore limited and once the patent lives of our issued patents have expired, we may face competition, including from other competing technologies. The term of a patent that covers a drug or biological product may also be eligible for patent term extension when FDA approval is granted for a portion of the term effectively lost as a result of the FDA regulatory review period, subject to certain limitations and provided statutory and regulatory requirements are met. Any such patent term extension can be for no more than five years, only one patent per approved product can be extended, the extension cannot extend the total patent term beyond 14 years from approval, and only those claims covering the approved drug or biological product, a method for using it or a method for manufacturing it may be extended. We may not receive an extension if we fail to exercise due diligence during the testing phase or regulatory review process, fail to apply within applicable deadlines, fail to apply prior to expiration of relevant patents or otherwise fail to satisfy applicable requirements. Moreover, the length of the extension could be less than we request. In the future, we expect to apply for patent term extensions on certain issued patents covering our products, depending upon the length of the clinical studies for each product and other factors. There can be no assurance that we will benefit from any patent term extension or favorable adjustment to the term

of any of our patents. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours. For more information, see Part I, Item 1A. “Risk Factors - Risks Related to Intellectual Property.”

As of December 31, 2022, we had 17 registered trademarks and one pending trademark application worldwide, including trademark registrations for “Aziyo,” “CanGaroo,” “ProxiCor,” “Tyke,” “VasCure,” “ViBone,” “OsteGro” and “SimpliDerm” in the United States, and trademark registrations for CanGaroo in the European Union, United Kingdom and Japan.

We have confidentiality agreements with our employees, consultants, independent sales agents and third-party vendors to maintain the confidentiality of our trade secrets and proprietary information. There can be no assurance that the obligations of our employees, consultants, independent sales agents and third parties, with whom we have entered into confidentiality agreements, will effectively prevent disclosure of our confidential information or provide meaningful protection for our confidential information if there is unauthorized use or disclosure, or that our trade secrets or proprietary information will not be independently developed by our competitors. See Part I, Item 1A. “Risk Factors - Risks Related to Intellectual Property” for additional information regarding these and other risks related to our intellectual property portfolio and their potential effect on us.

License Agreement with Cook Biotech

On May 31, 2017, we entered into a license agreement, which we refer to as the Cook License Agreement, with Cook Biotech Incorporated (“Cook Biotech”) under which Cook Biotech granted to us an exclusive worldwide sublicensable license under certain licensed patents to make, have made, use, offer for sale, sell and import CorMatrix ECM for Pericardial Closure, CorMatrix ECM for Cardiac Tissue Repair, CorMatrix ECM for Carotid Repair, CorMatrix ECM for Vascular Repair, TYKE Patch, Pledget and Intracardiac, and CanGaroo ECM Envelope (into which implantable cardiac pacemaker or defibrillator devices are to be inserted). Cook Biotech retained certain co-exclusive rights to the CorMatrix ECM for Vascular Repair. The Cook License Agreement was amended on December 21, 2017 to expand our field of use for SIS pouch devices to include other implantable electronic cardiac stimulation devices, electronic neurostimulation devices for deep brain stimulation, spinal nerve and sacral nerve stimulation to relieve chronic pain and nerve stimulation to control bladder, digestive, abdomen and bowel movements, and also add additional payment requirements.

Under the Cook License Agreement, we agree to use commercially reasonable efforts to promote, solicit and expand the licensed products in certain fields of use. We are subject to a minimum purchase requirement for the SIS ECM for the fields of use added in connection with the December 21, 2017 amendment, or the Subfields, and certain diligence obligations for commercial sales in the Subfields. The license requires that we order and pay for a minimum of at least $500,000 of SIS ECM per calendar year for use in the Subfields. Cook Biotech has the right to terminate the license granted to us in the Subfields or convert such license to a non-exclusive license, if we fail to comply with such minimum purchase requirement or diligence obligations. We have the first right, but not the obligation to initiate legal proceedings against any patent infringement in our fields of use by a third-party product that is the same as one of the licensed products.

Under the Cook License Agreement and SIS Material Supply Agreement, Cook Biotech is the exclusive supplier of the SIS ECM used in the licensed products. Under certain circumstances we will have the right to manufacture the SIS ECM used in the licensed products, provided that in such cases we are required to pay Cook Biotech a low single digit royalty on net sales of the licensed products that include the SIS ECM material manufactured by us and that are covered by a valid enforceable claim of a licensed patent.

As consideration for the license, we paid Cook Biotech a $200,000 license fee in 2018 and a $100,000 license fee in years 2019 through 2022, and are responsible for a yearly license fee of $100,000 until 2026. Upon a change in control transaction, which includes an acquisition of 50% or more of our then outstanding capital stock, we will be obligated to pay Cook Biotech the total amount of all license fees that have not yet been paid within a specified period after the consummation of such change in control transaction.

The Cook License Agreement continues in effect until the date of expiration of the last to expire of the licensed patents, including any renewals or extensions. The expiration date for the last to expire of the licensed patents is currently expected to be 2031 (excluding any patent term adjustments or extensions). Either party may terminate the Cook License Agreement for any material breach by the other party uncured within a specified period. In addition, the Cook License Agreement terminates automatically if we no longer possess the rights to the licensed products sold by CorMatrix related to our acquisition of all of the commercial assets and related intellectual property of CorMatrix Cardiovascular, Inc. in 2017 (the "CorMatrix Acquisition"). Cook Biotech has the right to terminate the Cook License Agreement in its entirety, or convert the exclusive license of any field of use to a non-exclusive license if we fail to make any license fee when due.

Regulatory Matters

Government Regulation

Our products and our operations are subject to extensive regulation by the FDA and other federal and state authorities in the United States, as well as comparable authorities in any foreign jurisdictions in which we market our products. In the United States, our products are subject to regulation as medical devices under the Federal Food, Drug, and Cosmetic Act (the "FDCA") or as biological products or HCT/Ps under the Public Health Service Act (the "PHSA"), each as implemented and enforced by the FDA. The FDA and other United States and foreign governmental agencies regulate, among other things, the development, design, nonclinical and clinical research, manufacturing, safety, efficacy, labeling, packaging, storage, installation, servicing, recordkeeping, premarket clearance or approval, import, export, adverse event reporting, advertising, promotion, marketing and distribution, and import and export of medical devices and biological products to ensure that such products distributed domestically are safe and effective for their intended uses and otherwise meet the requirements of the FDCA or PHSA.

FDA Premarket Clearance and Approval Requirements

Unless an exemption applies, each medical device commercially distributed in the United States requires either FDA clearance of a 510(k) premarket notification, or approval of a premarket approval ("PMA") application. Under the FDCA, medical devices are classified into one of three classes - Class I, Class II or Class III - depending on the degree of risk associated with each medical device and the extent of manufacturer and regulatory control needed to ensure its safety and effectiveness. Class I includes devices with the lowest risk to the patient and are those for which safety and effectiveness can be assured by adherence to the FDA's General Controls for medical devices, which include compliance with the applicable portions of the Quality System Regulation (the "QSR") facility registration and product listing, reporting of adverse medical events, and truthful and non-misleading labeling, advertising, and promotional materials. Class II devices are subject to the FDA's General Controls, and special controls as deemed necessary by the FDA to ensure the safety and effectiveness of the device. These special controls can include performance standards, post-market surveillance, patient registries and FDA guidance documents.

While most Class I devices are exempt from the 510(k) premarket notification requirement, manufacturers of most Class II devices are required to submit to the FDA a premarket notification under Section 510(k) of the FDCA requesting permission to commercially distribute the device. The FDA's permission to commercially distribute a device subject to a 510(k) premarket notification is generally known as 510(k) clearance. Devices deemed by the FDA to pose the greatest risks, such as life sustaining, life supporting or some implantable devices, or devices that have a new intended use, or use advanced technology that is not substantially equivalent to that of a legally marketed device, are placed in Class III, requiring approval of a PMA. Some pre-amendment devices are unclassified, but are subject to FDA's premarket notification and clearance process in order to be commercially distributed.

510(k) Clearance Marketing Pathway

Certain of our ECM products are subject to premarket notification and clearance under section 510(k) of the FDCA. To obtain 510(k) clearance, a product sponsor must submit to the FDA a premarket notification submission demonstrating that the proposed device is "substantially equivalent" to a predicate device already on the market. A predicate device is a legally marketed device that is not subject to premarket approval, i.e., a device that was legally marketed prior to May 28, 1976 and for which a PMA is not required, a device that has been reclassified from Class III to

Class II or I, or a device that was found substantially equivalent through the 510(k) process. The FDA's 510(k) clearance process usually takes from three to twelve months, but often takes longer. The FDA may require additional information, including clinical data, to make a determination regarding substantial equivalence. In addition, FDA collects user fees for certain medical device submissions and annual fees and for medical device establishments. If the FDA agrees that the device is substantially equivalent to a predicate device currently on the market, it will grant 510(k) clearance to commercially market the device. If the FDA determines that the device is "not substantially equivalent" to a previously cleared device, the device is automatically designated as a Class III device. The device sponsor must then fulfill more rigorous PMA requirements, or can request a risk-based classification determination for the device in accordance with the "*de novo*" process, which is a route to market for novel medical devices that are low to moderate risk and are not substantially equivalent to a predicate device.

After a device receives 510(k) marketing clearance, any modification that could significantly affect its safety or effectiveness, or that would constitute a major change or modification in its intended use, will require a new 510(k) clearance or, depending on the modification, PMA approval or *de novo* reclassification. The FDA requires each manufacturer to determine whether the proposed change requires submission of a 510(k), *de novo* request or a PMA in the first instance, but the FDA can review any such decision and disagree with a manufacturer's determination. If the FDA disagrees with a manufacturer's determination, the FDA can require the manufacturer to cease marketing and/or request the recall of the modified device until 510(k) marketing clearance or until PMA approval is obtained or a *de novo* request is granted. Also, in these circumstances, the manufacturer may be subject to significant regulatory fines or penalties.

PMA Approval Pathway

Class III devices require PMA approval before they can be marketed, although some pre-amendment Class III devices for which FDA has not yet required a PMA are cleared through the 510(k) process. The PMA process is more demanding than the 510(k) premarket notification process. In a PMA, the manufacturer must demonstrate that the device is safe and effective, and the PMA must be supported by extensive data, including data from pre-clinical studies and human clinical studies. The PMA must also contain a full description of the device and its components, a full description of the methods, facilities, and controls used for manufacturing, and proposed labeling. Following receipt of a PMA, the FDA determines whether the application is sufficiently complete to permit a substantive review. If FDA accepts the application for review, it has 180 days under the FDCA to complete its review of a PMA, although in practice, the FDA's review often takes significantly longer, and can take up to several years. An advisory panel of experts from outside the FDA may be convened to review and evaluate the application and provide recommendations to the FDA as to the approvability of the device. The FDA may or may not accept the panel's recommendation. In addition, the FDA will generally conduct a pre-approval inspection of the applicant or its third-party manufacturers' or suppliers' manufacturing facility or facilities to ensure compliance with the QSR.

The FDA will approve the new device for commercial distribution if it determines that the data and information in the PMA constitute valid scientific evidence and that there is reasonable assurance that the device is safe and effective for its intended use(s). The FDA may approve a PMA with post-approval conditions intended to ensure the safety and effectiveness of the device, including, among other things, restrictions on labeling, promotion, sale and distribution, and collection of long-term follow-up data from patients in the clinical study that supported PMA approval or requirements to conduct additional clinical studies post-approval. The FDA may condition PMA approval on some form of post-market surveillance when deemed necessary to protect the public health or to provide additional safety and efficacy data for the device in a larger population or for a longer period of use. In such cases, the manufacturer might be required to follow certain patient groups for a number of years and to make periodic reports to the FDA on the clinical status of those patients. Failure to comply with the conditions of approval can result in material adverse enforcement action, including withdrawal of the approval.

Certain changes to an approved device, such as changes in manufacturing facilities, methods, or quality control procedures, or changes in the design performance specifications, which affect the safety or effectiveness of the device, require submission of a PMA supplement. PMA supplements often require submission of the same type of information as a PMA, except that the supplement is limited to information needed to support any changes from the device covered by the original PMA and may not require as extensive clinical data or the convening of an advisory panel. Certain other changes to an approved device require the submission of a new PMA, such as when the design change causes a different

intended use, mode of operation, and technical basis of operation, or when the design change is so significant that a new generation of the device will be developed, and the data that were submitted with the original PMA are not applicable for the change in demonstrating a reasonable assurance of safety and effectiveness.

None of our products are currently marketed pursuant to a PMA.

Clinical Studies

Clinical studies are almost always required to support a PMA and are sometimes required to support a 510(k) submission. All clinical investigations in the United States of devices to determine safety and effectiveness must be conducted in accordance with the FDA's investigational device exemption (IDE) regulations which govern investigational device labeling, prohibit promotion of the investigational device, and specify an array of recordkeeping, reporting and monitoring responsibilities of study sponsors and study investigators. If the device presents a "significant risk," to human health, as defined by the FDA, the FDA requires the device sponsor to submit an IDE application to the FDA, which must become effective prior to commencing human clinical studies. If the device under evaluation does not present a significant risk to human health, then the device sponsor is not required to submit an IDE application to the FDA before initiating human clinical studies, but must still comply with abbreviated IDE requirements when conducting such studies. A significant risk device is one that presents a potential for serious risk to the health, safety or welfare of a patient and either is implanted, used in supporting or sustaining human life, substantially important in diagnosing, curing, mitigating or treating disease or otherwise preventing impairment of human health, or otherwise presents a potential for serious risk to a subject. An IDE application must be supported by appropriate data, such as animal and laboratory test results, showing that it is safe to test the device in humans and that the testing protocol is scientifically sound. The IDE will automatically become effective 30 days after receipt by the FDA unless the FDA notifies the company that the investigation may not begin. If the FDA determines that there are deficiencies or other concerns with an IDE for which it requires modification, the FDA may permit a clinical study to proceed under a conditional approval.

Regardless of the degree of risk presented by the medical device, clinical studies must be approved by, and conducted under the oversight of, an IRB for each clinical site. The IRB is responsible for the initial and continuing review of the IDE, and may pose additional requirements for the conduct of the study. If an IDE application is approved by the FDA and one or more IRBs, human clinical studies may begin at a specific number of investigational sites with a specific number of patients, as approved by the FDA. If the device presents a non-significant risk to the patient, a sponsor may begin the clinical study after obtaining approval for the study by one or more IRBs without separate approval from the FDA, but must still follow abbreviated IDE requirements, such as monitoring the investigation, ensuring that the investigators obtain informed consent, and labeling and record-keeping requirements. Acceptance of an IDE application for review does not guarantee that the FDA will allow the IDE to become effective and, if it does become effective, the FDA may or may not determine that the data derived from the studies support the safety and effectiveness of the device or warrant the continuation of clinical studies. An IDE supplement must be submitted to, and approved by, the FDA before a sponsor or investigator may make a change to the investigational plan that may affect its scientific soundness, study plan or the rights, safety or welfare of human subjects.

During a study, the sponsor is required to comply with the applicable FDA requirements, including, for example, study monitoring, selecting clinical investigators and providing them with the investigational plan, ensuring IRB review, adverse event reporting, record keeping and prohibitions on the promotion of investigational devices or on making safety or effectiveness claims for them. The clinical investigators in the clinical study are also subject to FDA's regulations and must obtain patient informed consent, rigorously follow the investigational plan and study protocol, control the disposition of the investigational device, and comply with all reporting and recordkeeping requirements. Additionally, after a study begins, we, the FDA or the IRB could suspend or terminate a clinical study at any time for various reasons, including a belief that the risks to study subjects outweigh the anticipated benefits.

Post-market Regulation

After a device is cleared or approved for marketing, numerous and pervasive regulatory requirements continue to apply. These include:

- establishment registration and device listing with the FDA;
- QSR requirements, which require manufacturers, including third-party manufacturers, to follow stringent design, testing, control, documentation and other quality assurance procedures during all aspects of the design and manufacturing process;
- labeling regulations and FDA prohibitions against the promotion of investigational products, or the promotion of "off-label" uses of cleared or approved products;
- requirements related to promotional activities;
- clearance or approval of product modifications to 510(k)-cleared devices that could significantly affect safety or effectiveness or that would constitute a major change in intended use of one of our cleared devices, or approval of certain modifications to PMA-approved devices;
- medical device reporting regulations, which require that a manufacturer report to the FDA if a device it markets may have caused or contributed to a death or serious injury, or has malfunctioned and the device or a similar device that it markets would be likely to cause or contribute to a death or serious injury, if the malfunction were to recur;
- correction, removal and recall reporting regulations, which require that manufacturers report to the FDA field corrections and product recalls or removals if undertaken to reduce a risk to health posed by the device or to remedy a violation of the FDCA that may present a risk to health;
- the FDA's recall authority, whereby the agency can order device manufacturers to recall from the market a product that is in violation of governing laws and regulations; and
- post-market surveillance activities and regulations, which apply when deemed by the FDA to be necessary to protect the public health or to provide additional safety and effectiveness data for the device.

The FDA has broad regulatory compliance and enforcement powers. If the FDA determines that we failed to comply with applicable regulatory requirements, it can take a variety of compliance or enforcement actions, which may result in any of the following sanctions:

- warning letters, untitled letters, fines, injunctions, consent decrees and civil penalties;
- recalls, withdrawals, or administrative detention or seizure of our products;
- operating restrictions or partial suspension or total shutdown of production;
- refusing or delaying requests for 510(k) marketing clearance or PMA approvals of new products or modified products;
- withdrawing 510(k) clearances or PMA approvals that have already been granted;
- refusal to grant export approvals for our products; or
- criminal prosecution.

FDA Regulation of Combination Products

Certain products may be comprised of components, such as drug components and device components that would normally be regulated under different types of regulatory authorities, and frequently by different centers at the FDA. These products are known as combination products. Under the FDCA and its implementing regulations, the FDA is charged with assigning a center with primary jurisdiction, or a lead center, for review of a combination product. The designation of a lead center generally eliminates the need to receive approvals from more than one FDA component for combination products, although it does not preclude consultations by the lead center with other components of FDA. The determination of which center will be the lead center is based on the "primary mode of action" of the combination product. Thus, if the primary mode of action of a drug-device combination product is attributable to the drug product, the FDA center responsible for premarket review of the drug product would have primary jurisdiction for the combination product. The FDA has also established an Office of Combination Products to address issues surrounding combination products and provide more certainty to the regulatory review process. That office serves as a focal point for combination product issues for agency reviewers and industry. It is also responsible for developing guidance and regulations to clarify the regulation of combination products, and for assignment of the FDA center that has primary jurisdiction for review of combination products where the jurisdiction is unclear or in dispute. For example, a combination product with a drug primary mode of action generally would be reviewed and approved pursuant to the drug approval processes, and a combination product with a device primary mode of action would be reviewed and cleared, approved or classified pursuant to the medical device review processes, in each case under the FDCA. In reviewing the application for a combination product, however, FDA reviewers in the lead center will generally consult with their counterparts in other centers to ensure that each component meets applicable requirements regarding safety, effectiveness, durability and performance.

FDA Regulation of HCT/Ps

Certain of our products, including certain of our spinal and orthopedic products are regulated by the FDA as HCT/Ps, which may be regulated under Section 361 of the PHSA, which among other things, authorizes the FDA to issue regulations to prevent the introduction, transmission or spread of communicable disease. HCT/Ps regulated as "361" HCT/Ps are subject to requirements relating to registering facilities and listing products with the FDA, screening and testing for tissue donor eligibility, and Good Tissue Practice when processing, storing, labeling and distributing HCT/Ps, including required labeling information, stringent record keeping and adverse event reporting, among other applicable requirements and laws. Section 361 HCT/Ps do not require 510(k) clearance, PMA approval, Biologics License Application ("BLA") submissions, or other premarket authorization from the FDA to be legally marketed in the United States. However, to be regulated as a Section 361 HCT/P, the product must, among other things, be "minimally manipulated," which for structural tissue products, means that the manufacturing processes do not alter the original relevant characteristics of the tissue relating to the tissue's utility for reconstruction, repair, or replacement. For cells or nonstructural tissue products, "minimal manipulation" means that the manufacturing processes do not alter the relevant biological characteristics of cells or tissues. A Section 361 HCT/P must also be intended for "homologous use," which refers to use in the repair, reconstruction, replacement, or supplementation of a recipient's cells or tissues with an HCT/P that performs the same basic function or functions in the recipient as in the donor. The HCT/P must also either have no systemic effect and not be dependent upon the metabolic activity of living cells for its primary function or, if it has a systemic effect, be intended for autologous use, for allogeneic use in a first-degree or second-degree blood relative, or for reproductive use. HCT/Ps that do not meet the criteria of Section 361 are regulated under Section 351 of the PHSA. Unlike 361 HCT/Ps, HCT/Ps regulated as "351" HCT/Ps are subject to premarket review and approval by the FDA.

International Requirements

Sales of medical devices and shipments of human tissues outside the United States are subject to international regulatory requirements that vary widely from country to country. Approval or certification of a product by comparable regulatory authorities of other countries or notified bodies must be obtained and compliance with applicable regulations for tissues must be met prior to commercial distribution of the products or human tissues in those countries. The time required to obtain these approvals or certifications may be longer or shorter than that required for FDA approval. Countries, in which we distribute products and tissue, may perform inspections or audits of our facilities to ensure compliance with local country regulations.

Regulation of Medical Devices in the European Union

The European Union ("EU") has adopted specific directives and regulations regulating the design, manufacture, clinical investigation, conformity assessment, labeling and adverse event reporting for medical devices.

Until May 25, 2021, medical devices were regulated by Council Directive 93/42/EEC (the "EU Medical Devices Directive"), which has been repealed and replaced by Regulation (EU) No 2017/745 (the "EU Medical Devices Regulation"). We have CE mark for four of our cardiovascular products and in January 2021, we obtained certification for updated labeling of our CanGaroo Envelope to allow for the addition of the antibiotic gentamicin. Our current CE certificates have been granted under the Medical Devices Directive whose regime is described below. However, as of May 26, 2021, some of the EU Medical Devices Regulation requirements apply in place of the corresponding requirements of the EU Medical Devices Directive with regard to registration of economic operators and of devices, post-market surveillance and vigilance requirements. Pursuing marketing of medical devices in the EU will notably require that our devices be certified under the new regime set forth in the EU Medical Devices Regulation when our current certificates expire.

Medical Devices Directive

Under the Medical Devices Directive, all medical devices placed on the market in the EU must meet the relevant essential requirements laid down in Annex I to the EU Medical Devices Directive, including the requirement that a medical device must be designed and manufactured in such a way that it will not compromise the clinical condition or safety of patients, or the safety and health of users and others. In addition, the device must achieve the performance intended by the manufacturer and be designed, manufactured, and packaged in a suitable manner. The European Commission has adopted various standards applicable to medical devices. These include standards governing common requirements, such as sterilization and safety of medical electrical equipment and product standards for certain types of medical devices. There are also harmonized standards relating to design and manufacture. While not mandatory, compliance with these standards is viewed as the easiest way to satisfy the essential requirements as a practical matter as it creates a rebuttable presumption that the device satisfies that essential requirement.

To demonstrate compliance with the essential requirements laid down in Annex I to the EU Medical Devices Directive, medical device manufacturers must undergo a conformity assessment procedure, which varies according to the type of medical device and its (risk) classification. As a general rule, demonstration of conformity of medical devices and their manufacturers with the essential requirements must be based, among other things, on the evaluation of clinical data supporting the safety and performance of the products during normal conditions of use. Specifically, a manufacturer must demonstrate that the device achieves its intended performance during normal conditions of use, that the known and foreseeable risks, and any adverse events, are minimized and acceptable when weighed against the benefits of its intended performance, and that any claims made about the performance and safety of the device are supported by suitable evidence. Except for low-risk medical devices (Class I non-sterile, non-measuring devices), where the manufacturer can self-assess the conformity of its products with the essential requirements (except for any parts which relate to sterility or metrology), a conformity assessment procedure requires the intervention of a notified body. Notified bodies are independent organizations designated by EU member states to assess the conformity of devices before being placed on the market. A notified body would typically audit and examine a product's technical dossiers and the manufacturer's quality system (the notified body must presume that quality systems which implement the relevant harmonized standards – which is ISO 13485:2016 for Medical Devices Quality Management Systems – conform to these requirements). If satisfied that the relevant product conforms to the relevant essential requirements, the notified body issues a certificate of conformity, which the manufacturer uses as a basis for its own declaration of conformity. The manufacturer may then apply the CE mark to the device, which allows the device to be placed on the market throughout the EU.

Throughout the term of the certificate of conformity, the manufacturer will be subject to periodic surveillance audits to verify continued compliance with the applicable requirements. In particular, there will be a new audit by the notified body before it will renew the relevant certificate(s).

Medical Devices Regulation

The regulatory landscape related to medical devices in the EU recently evolved. On April 5, 2017, the EU Medical Devices Regulation was adopted with the aim of ensuring better protection of public health and patient safety. The EU Medical Devices Regulation establishes a uniform, transparent, predictable and sustainable regulatory framework across the EU for medical devices and ensures a high level of safety and health while supporting innovation. Unlike the EU Medical Devices Directive, the EU Medical Devices Regulation is directly applicable in EU member states without the need for member states to implement into national law.

The EU Medical Devices Regulation became effective on May 26, 2021. Devices lawfully placed on the market pursuant to the Medical Devices Directive prior to May 26, 2021 may generally continue to be made available on the market or put into service until May 26, 2025, provided that the requirements of the transitional provisions are fulfilled. In particular, the certificate in question must still be valid and no substantial modification must be made to the device. However, even in this case, manufacturers must comply with a number of new or reinforced requirements set forth in the EU Medical Devices Regulation, in particular the obligations described below. Recently, the European Parliament voted to extend the Medical Devices Regulation (MDR) transition period. The conformity assessment process for MDR needs to be completed by the end of 2027 for high-risk devices and the end of 2028 for lower-risk devices. Our products for implantation would be in the category of high-risk devices.

The EU Medical Devices Regulation requires that before placing a device, other than a custom-made device, on the market, manufacturers (as well as other economic operators such as authorized representatives and importers) must register by submitting identification information to the electronic system (Eudamed), unless they have already registered. The information to be submitted by manufacturers (and authorized representatives) also includes the name, address and contact details of the person or persons responsible for regulatory compliance. The EU Medical Devices Regulation also requires that before placing a device, other than a custom-made device, on the market, manufacturers must assign a unique identifier to the device and provide it along with other core data to the unique device identifier (“UDI”) database. These new requirements aim at ensuring better identification and traceability of the devices. Each device – and as applicable, each package – will have a UDI composed of two parts: a device identifier (“UDI-DI”) specific to a device, and a production identifier (“UDI-PI”) to identify the unit producing the device. Manufacturers are also notably responsible for entering the necessary data on Eudamed, which includes the UDI database, and for keeping it up to date. The obligations for registration in Eudamed will become applicable at a later date (as Eudamed is not yet fully functional). Until Eudamed is fully functional, the corresponding provisions of the EU Medical Devices Directive continue to apply for the purpose of meeting the obligations laid down in the provisions regarding exchange of information, including, and in particular, information regarding registration of devices and economic operators.

All manufacturers placing medical devices on the market in the EU must comply with the EU medical device vigilance system which has been reinforced by the EU Medical Devices Regulation. Under this system, serious incidents and Field Safety Corrective Actions (“FSCAs”) must be reported to the relevant authorities of the EU member states. These reports will have to be submitted through Eudamed – once functional – and aim to ensure that, in addition to reporting to the relevant authorities of the EU member states, other actors such as the economic operators in the supply chain will also be informed. Until Eudamed is fully functional, the corresponding provisions of the EU Medical Devices Directive continue to apply. Manufacturers are required to take FSCAs, which are defined as any corrective action for technical or medical reasons to prevent or reduce a risk of a serious incident associated with the use of a medical device that is made available on the market. A serious incident is any malfunction or deterioration in the characteristics or performance of a device on the market (e.g., inadequacy in the information supplied by the manufacturer, undesirable side-effect), which, directly or indirectly, might lead to either the death or serious deterioration of the health of a patient, user, or other persons, or to a serious public health threat. An FSCA may include the recall, modification, exchange, destruction or retrofitting of the device. FSCAs must be communicated by the manufacturer or its legal representative to its customers and/or to the end users of the device through Field Safety Notices. For similar serious incidents that occur with the same device or device type and for which the root cause has been identified or a FSCA implemented or where the incidents are common and well documented, manufacturers may provide periodic summary reports instead of individual serious incident reports.

The advertising and promotion of medical devices is subject to some general principles set forth in EU legislation. According to the EU Medical Devices Regulation, only devices that are CE marked may be marketed and advertised in the EU in accordance with their intended purpose. Directive 2006/114/EC concerning misleading and comparative

advertising and Directive 2005/29/EC on unfair commercial practices, while not specific to the advertising of medical devices, also apply to the advertising thereof and contain general rules, for example, requiring that advertisements are evidenced, balanced and not misleading. Specific requirements are defined at a national level. EU member states' laws related to the advertising and promotion of medical devices, which vary between jurisdictions, may limit or restrict the advertising and promotion of products to the general public and may impose limitations on promotional activities with healthcare professionals.

Many EU member states have adopted specific anti-gift statutes that further limit commercial practices for medical devices, in particular vis-à-vis healthcare professionals and organizations. Additionally, there has been a recent trend of increased regulation of payments and transfers of value provided to healthcare professionals or entities and many EU member states have adopted national "Sunshine Acts" which impose reporting and transparency requirements (often on an annual basis), similar to the requirements in the United States, on medical device manufacturers. Certain countries also mandate implementation of commercial compliance programs.

In the EU, regulatory authorities have the power to carry out announced and, if necessary, unannounced inspections of companies, as well as suppliers and/or sub-contractors and, where necessary, the facilities of professional users. Failure to comply with regulatory requirements (as applicable) could require time and resources to respond to the regulatory authorities' observations and to implement corrective and preventive actions, as appropriate. Regulatory authorities have broad compliance and enforcement powers and if such issues cannot be resolved to their satisfaction can take a variety of actions, including untitled or warning letters, fines, consent decrees, injunctions, or civil or criminal penalties

The aforementioned EU rules are generally applicable in the European Economic Area ("EEA") which consists of the 27 EU member states plus Norway, Liechtenstein and Iceland.

Regulation of Medical Devices in the United Kingdom

The Medicines and Healthcare products Regulatory Agency ("MHRA"), is now the standalone regulator in the United Kingdom ("UK"). Although the UK and EU have now reached an agreement on its future trading relationship (implemented in the EU-UK Trade and Cooperation Agreement from January 1, 2021, ("TCA")), the agreement does not cover all regulatory areas regarding medical devices, which may be subject to future bilateral discussions going forward and could further change the relationship between the UK and the EU in this regard.

EU laws which were directly applicable before the end of the transitional period or have been transposed into UK law through secondary legislation continue to be applicable as "retained EU law." However, under the Retained EU Law (Revocation and Reform) Bill 2022, which is currently before the UK parliament, any retained EU law not expressly preserved and "assimilated" into domestic law or extended by ministerial regulations (to no later than June 23, 2026) will automatically expire and be revoked by December 31, 2023. In addition, new legislation such as the EU Medical Devices Regulation is not applicable. The UK government has introduced a new Medicines and Medical Devices Act which seeks to address regulatory gaps through implementing regulations and delegated powers covering the fields of human medicines, clinical studies of human medicines, and medical devices.

Significantly, under the TCA there is no mutual recognition of regulatory regimes and certifications between the EU and the UK. Since January 1, 2021, all medical devices placed on the market in the UK must be registered with the MHRA. Manufacturers based outside the UK will also need to appoint a UK Responsible Person (which may be an individual or a corporate entity). Only a manufacturer established in the UK or a UK Responsible Person will be able to place a device on the market in Great Britain. Under the terms of the Ireland/Northern Ireland Protocol, products placed on the market in Northern Ireland will continue to be subject to the EU regulatory regime.

On June 26, 2022, the MHRA published its response to a 10-week consultation on the post-Brexit regulatory framework for medical devices and diagnostics. The MHRA proposes amendments to the UK Medical Devices Regulations 2002 (which are based on EU legislation, primarily the EU Medical Devices Directive), in particular to create new access pathways to support innovation, create an innovative framework for regulating software and artificial intelligence as medical devices, reform in vitro diagnostic regulation, and foster sustainability through the reuse and

remanufacture of medical devices. Regulations implementing the new regime were originally scheduled to come into force in July 2023, but the UK Government has recently confirmed that this date has been postponed until July 2024. Devices which have valid certification issued by EU notified bodies under the EU Medical Devices Regulation or EU Medical Devices Directive are subject to transitional arrangements. In its consultation response, the MHRA indicated that the future UK regulations will allow devices certified under the EU Medical Devices Regulation to be placed on the market in Great Britain under the CE mark until either the certificate expires or for five years after the new regulations take effect, whichever is sooner. Devices certified under the EU Medical Devices Directive could continue to be placed on the market until either the certificate expires or for three years after the new regulations take effect, whichever is sooner. Following these transitional periods, it is expected that all medical devices will require a UK Conformity Assessment ("UKCA") mark. Manufacturers may choose to use the UKCA mark on a voluntary basis prior to the regulations coming into force. However, from July 2024, products which do not have existing and valid certification under the EU Medical Devices Directive or EU Medical Devices Regulation and are therefore not subject to the transitional arrangements will be required to carry the UKCA mark if they are to be sold into the market in Great Britain. UKCA marking will not be recognized in the EU. The rules for placing medical devices on the market in Northern Ireland, which is part of the UK, differ from those in Great Britain (England, Scotland and Wales) and continues to be based on EU law.

Our CE mark cardiovascular products are registered with the MHRA and are legally marketed in the UK.

Other International Regulations

The Australian Therapeutic Goods Administration, Korean Ministry of Food and Drug Safety (“KFDA”), and DEKRA Certification B.V. (our EU notified body) perform periodic on-site inspections to review independently our compliance with systems and regulatory requirements. A number of countries outside of the EEA accept the CE mark in lieu of marketing submissions, as an addendum to that country’s application process.

Government Advocacy

We engage in public policy advocacy with policymakers and continue to work to demonstrate that our therapeutic products provide value to patients and to those who pay for healthcare. We advocate with government policymakers to encourage a long-term approach to sustainable healthcare financing that ensures access to innovative medicines and does not disproportionately target FDA-regulated medical devices and biologics as a source of budget savings. In markets with historically low rates of healthcare spending, we encourage those governments to increase their investments and adopt market reforms in order to improve their citizens’ access to appropriate healthcare.

Regulations Governing Fraud and Abuse

Within the United States, our products and our customers are subject to extensive regulation by a wide range of federal and state agencies that govern business practices in the medical device and healthcare industry. These laws include federal and state anti-kickback, false claims, physician payment transparency, anti-corruption, and other fraud and abuse statutes and regulations. Internationally, other governments also impose regulations in connection with their healthcare reimbursement programs and the delivery of healthcare items and services.

In the United States, federal healthcare fraud and abuse laws generally apply to our activities because procedures using our products are covered under federal healthcare programs including Medicare and Medicaid. The Anti-Kickback Statute is particularly relevant because of its broad applicability. Specifically, the Anti-Kickback Statute prohibits persons from knowingly and willfully soliciting, offering, receiving, or providing remuneration, directly or indirectly, in exchange for, or to induce, either the referral of an individual, or the furnishing, arranging for or recommending a good or service for which payment may be made in whole or part under federal healthcare programs, such as the Medicare and Medicaid programs. Statutory exceptions and regulatory safe harbors protect certain interactions if specific requirements are met. Failure to meet all of the requirements of a particular applicable statutory exception or regulatory safe harbor, however, does not make the conduct per se illegal under the U.S. federal Anti-Kickback Statute. Instead, the legality of the arrangement will be evaluated on a case by case basis based on a cumulative review of all its facts and circumstances. Further, a person or entity does not need to have actual knowledge of the Anti-Kickback Statute or specific intent in order to violate it to have committed a violation.

Another development affecting the healthcare industry is the increased use of the federal Civil False Claims Act and, in particular, actions brought pursuant to the False Claims Act's "whistleblower" or "qui tam" provisions. The False Claims Act imposes liability on any person or entity that, among other things, knowingly presents, or causes to be presented, a false or fraudulent claim for payment by a federal healthcare program. In addition, the government may assert that a claim, including items or services resulting from a violation of the federal Anti-Kickback Statute, constitutes a false or fraudulent claim for purposes of the federal False Claims Act or federal civil money penalties statute. The qui tam provisions of the False Claims Act allow a private individual to bring actions on behalf of the federal government, alleging that the defendant has submitted a false claim to the federal government, and to share in any monetary recovery. In recent years, the number of suits brought against healthcare providers by private individuals has increased dramatically. In addition, insurance companies may also bring a private cause of action for treble damages against a manufacturer for a pattern of causing false claims to be filed under the federal Racketeer Influenced and Corrupt Organizations Act (the "RICO").

The federal Health Insurance Portability and Accountability Act of 1996, as amended by the Health Information Technology for Economic and Clinical Health Act (the "HIPAA"), among other things, created two new federal crimes: healthcare fraud and false statements relating to healthcare matters. The HIPAA healthcare fraud statute prohibits, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, including private payors. A violation of this statute is a felony and may result in fines, imprisonment, and/or exclusion from government sponsored programs. The HIPAA false statements statute prohibits, among other things, knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement or representation in connection with the delivery of, or payment for, healthcare benefits, items or services. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the Anti-Kickback Statute or specific intent in order to violate it to have committed a violation.

The federal Physician Payment Sunshine Act requires, among other things, manufacturers of drugs, devices, biologicals and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report annually to the government information related to payments or other transfers of value made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), certain non-physician practitioners (physician assistants, nurse practitioners, clinical nurse specialists, certified nurse anesthetists, anesthesiologist assistants and certified nurse midwives) and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members.

Similar state, local and foreign laws and regulations may also restrict business practices in the medical device and pharmaceutical industries, such as state anti-kickback and false claims laws, which may apply to business practices, including but not limited to, research, distribution, sales and marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers, or by patients themselves; state laws that require pharmaceutical companies to comply with the industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state laws and regulations that require drug manufacturers to file reports relating to pricing and marketing information; and state and local laws which require tracking gifts and other remuneration and transfer of value provided to physicians, other healthcare providers and entities.

Violations of fraud and abuse laws, including federal and state anti-kickback and false claims laws, may be punishable by criminal and civil sanctions, including fines and civil monetary penalties, the possibility of exclusion from federal healthcare programs (including Medicare and Medicaid), disgorgement and corporate integrity agreements, which impose, among other things, rigorous operational and monitoring requirements on companies. Similar sanctions and penalties, as well as imprisonment, also can be imposed upon executive officers and employees of such companies.

Anti-Bribery Laws

Our international operations are subject to compliance with a variety of complex foreign and United States laws that increase our costs of doing business in internal jurisdictions and could expose us or our employees to fines and penalties in the United States and abroad. Among others, we are subject to the United States Foreign Corrupt Practices Act of 1977 (the "FCPA"), which prohibits us, our officers, directors, employees, shareholders and agents acting on our behalf

from offering, promising, authorizing or making corrupt payments to foreign officials for the purpose of influencing official decisions or securing an improper advantage to obtain or retain business.

Data Privacy and Security Laws

Numerous state, federal and foreign laws, including consumer protection laws and regulations, govern the collection, dissemination, use, access to, confidentiality and security of personal information, including health-related information. In the United States, numerous federal and state laws and regulations, including data breach notification laws, health information privacy laws, and consumer protection laws and regulations govern the collection, use, disclosure and protection of health-related and other personal information could apply to our operations or the operations of our partners. In addition, certain foreign laws govern the privacy and security of personal data, including health-related data. Privacy and security laws, regulations, and other obligations are constantly evolving, may conflict with each other to complicate compliance efforts, and can result in investigations, proceedings, or actions that lead to significant civil and/or criminal penalties and restrictions on data processing.

Coverage and Reimbursement

Market acceptance and sales of our products to our customers, who primarily consist of hospitals, government facilities, and ambulatory surgery centers, will depend on the availability of payor coverage and the adequacy of reimbursement, for the procedures using our products, by government insurance programs and other third-party payors. Payor coverage and reimbursement for procedures using medical devices in the United States and international markets vary significantly by country.

In the United States, our currently approved products are commonly treated as general supplies utilized in surgical procedures and if covered by third-party payors, are paid for as part of the procedure. Outside of the United States, there are many reimbursement programs through private payors as well as government programs. In some countries, government reimbursement is the predominant program available to patients and hospitals. Our commercial success depends in part on the extent to which governmental authorities, private health insurers and other third-party payors provide coverage for and establish adequate reimbursement levels for the procedures during which our products are used. Failure by physicians, hospitals, ambulatory surgery centers and other users of our products to obtain sufficient coverage and reimbursement from third-party payors for procedures in which our products are used, or adverse changes in government and private third-party payors' coverage and reimbursement policies.

Based on our experience to date, third-party payors generally reimburse for the surgical procedures in which our products are used only if the patient meets the established medical necessity criteria for surgery. Some payors are moving toward a managed care system and control their healthcare costs by limiting authorizations for surgical procedures, including elective procedures using our devices. Although no uniform policy of coverage and reimbursement among payors in the United States exists and coverage and reimbursement for procedures can differ significantly from payor to payor, reimbursement decisions by particular third-party payors may depend upon a number of factors, including the payor's determination that use of a product is:

- a covered benefit under its health plan;
- appropriate and medically necessary for the specific indication;
- cost effective; and
- neither experimental nor investigational.

Third-party payors are increasingly auditing and challenging the prices charged for medical products and services with concern for upcoding, miscoding, using inappropriate modifiers, or billing for inappropriate care settings. Some third-party payors must approve coverage for new or innovative devices or procedures before they will reimburse healthcare providers who use the products or therapies. Even though a new product may have been cleared for commercial distribution

by the FDA, we may find limited demand for the product unless and until reimbursement approval has been obtained from governmental and private third-party payors.

The Centers for Medicare & Medicaid Services ("CMS") is responsible for administering the Medicare program and sets coverage and reimbursement policies for the Medicare program in the United States. CMS, in partnership with state governments, also administers the Medicaid program and Children's Health Insurance Program ("CHIP"). CMS policies may alter coverage and payment related to our product portfolio in the future. These changes may occur as the result of national coverage determinations issued by CMS or as the result of local coverage determinations by contractors under contract with CMS to review and make coverage and payment decisions. Medicaid programs are funded by both federal and state governments, and may vary from state to state and from year to year and will likely play an even larger role in healthcare funding pursuant to the Affordable Care Act.

A key component in ensuring whether the appropriate payment amount is received for physician and other services, including those procedures using our products, is the existence of a Current Procedural Terminology ("CPT") code, to describe the procedure in which the product is used. To receive payment, healthcare practitioners must submit claims to insurers using these codes for payment for medical services. CPT codes are assigned, maintained and annually updated by the American Medical Association and its CPT Editorial Board. If the CPT codes that apply to the procedures performed using our products are changed or deleted, reimbursement for performances of these procedures may be adversely affected.

In the United States, some insured individuals enroll in managed care programs, which monitor and often require pre-approval of the services that a member will receive. Some managed care programs pay their providers on a per capita (patient) basis, which puts the providers at financial risk for the services provided to their patients by paying these providers a predetermined payment per member per month and, consequently, may limit the willingness of these providers to use our products.

We believe the overall escalating cost of medical products and services being paid for by the government and private health insurance has led to, and will continue to lead to, increased pressures on the healthcare and medical device industry to reduce the costs of products and services. All third-party reimbursement programs are developing increasingly sophisticated methods of controlling healthcare costs through prospective reimbursement and capitation programs, group purchasing, redesign of benefits, requiring second opinions prior to major surgery, careful review of bills, encouragement of healthier lifestyles and other preventative services and exploration of more cost-effective methods of delivering healthcare.

In addition to uncertainties surrounding coverage policies, there are periodic changes to reimbursement levels. Third-party payors regularly update reimbursement amounts and also from time to time revise the methodologies used to determine reimbursement amounts. This includes routine updates to payments to physicians, hospitals and ambulatory surgery centers for procedures during which our products are used. These updates could directly impact the demand for our products.

In international markets, reimbursement and healthcare payment systems vary significantly by country, and many countries have instituted price ceilings on specific product lines and procedures. There can be no assurance that procedures using our products will be covered for a specific indication, that our products will be considered cost-effective by third party payors, that an adequate level of reimbursement will be available or that the third-party payors' reimbursement policies will not adversely affect our ability to sell our products profitably. Local, product specific reimbursement law is increasingly being applied as an overlay to medical device regulation, which has provided an additional layer of clearance requirement. Specifically, Australia now requires clinical data for clearance and reimbursement be in the form of prospective, multi-center studies, a high bar not previously applied. In addition, in France, certain innovative devices have been identified as needing to provide clinical evidence to support a "mark-specific" reimbursement. It is our intent to complete the requisite clinical studies and obtain coverage and reimbursement approval in countries where it makes economic sense to do so.

Healthcare Reform

Since its enactment, there have been judicial, executive and Congressional challenges to certain aspects of the ACA. On June 17, 2021, the U.S. Supreme Court dismissed a challenge on procedural grounds that argued the ACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress. Thus, the ACA will remain in effect in its current form. Further, prior to the U.S. Supreme Court ruling, President Biden issued an executive order that initiated a special enrollment period for purposes of obtaining health insurance coverage through the ACA marketplace from February 15, 2021 through August 15, 2021. The executive order instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the ACA. It is unclear how other healthcare reform measures of the Biden administration will impact our business.

Other legislative changes have been proposed and adopted in the United States since the ACA was enacted, including aggregate reductions of Medicare payments to providers, which went into effect on April 1, 2013 and will remain in effect through 2032, with the exception of a temporary suspension from May 1, 2020, through March 31, 2022, unless additional Congressional action is taken. Moreover, there has recently been heightened governmental scrutiny, including increasing legislative and enforcement interest, over the manner in which manufacturers set prices for their marketed products, which has resulted in several Congressional inquiries and proposed and enacted legislation designed, among other things, to bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for products. Individual states in the United States have also become increasingly active in implementing regulations designed to control product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access, and marketing cost disclosure and transparency measures and, in some cases, mechanisms to encourage importation from other countries. Furthermore, there has been increased interest by third party payors and governmental authorities in reference pricing systems and publication of discounts and list prices.

Human Capital

As of December 31, 2022, we had 164 employees, with nearly 100% of whom were full-time employees. We believe our employee relations are good.

Diversity, Equity and Inclusion

We believe that fostering diversity, equity, and inclusion is a key element to discovering, developing, and bringing transformative products to patients in need. As of December 31, 2022, 43% of our workforce and 37% of our leadership (at the director level and above) were female. In addition, as of December 31, 2022, 59% of our workforce were racially or ethnically diverse. We strive to build a workforce representative of the people we serve and to nurture an inclusive culture where all voices are welcomed, heard, and respected.

Recruiting and Retention

We believe that we have been successful in attracting and retaining qualified personnel with the appropriate background and skills to support our business and its growth. We monitor recruiting efforts using a variety of metrics such as internal placement rates, employee referrals, information on the retention of business critical hires, and the percentage of budgeted openings filled on time and on budget. We also track voluntary and involuntary turnover rates. Although we believe our recruiting efforts have been successful to date, headcount reductions taken as part of cost saving initiatives and as our business strategy evolves may negatively impact our ability to attract qualified personnel in the future. See Part I. Item 1A. Risk Factors - Risks Related to Our Business - *Our success depends on our ability to retain and motivate key management personnel and other employees and consultants, to attract, retain and motivate additional qualified personnel and to effectively navigate changes in our senior management team.*"

Compensation and Benefits

We strive to offer competitive pay and benefits designed to attract and retain exceptional talent and drive company performance. In setting appropriate compensation levels, we look at the average base pay rate for each position based on market data. We also offer an annual cash incentive program and long-term equity incentive plans designed to assist in attracting, retaining and motivating employees, to align their interests with our stockholders and to promote the creation of long-term value for our investors.

Our standard employee benefits include paid and unpaid leaves, medical, dental and vision insurance coverage, a 401(k) plan, short- and long-term disability, life insurance, flexible spending accounts and an employee stock purchase plan. We benchmark our benefits program against others in our industry to help us make decisions on the size and elements of our compensation program.

FiberCel Recall

On June 2, 2021, we issued a voluntary recall pertaining to a single donor lot of our FiberCel Fiber Viable Bone Matrix, a bone repair product formerly distributed by Medtronic, after learning of post-surgical infections reported in several patients treated with the product, including some patients that tested positive for tuberculosis.

After the recall, we worked with the U.S. Food and Drug Administration ("FDA") and the U.S. Centers for Disease Control and Prevention ("CDC") to identify and secure all unused product, ascertain the medical status of patients treated with the recalled product, understand whether there is any relationship between the post-surgical infections and the recalled product lot and determine the medical cause of these infections.

We identified the 154 units comprising the single product lot in question. Based on information from the CDC, 136 units within this product lot were implanted into 113 patients and the remaining 18 units were returned to either us or the CDC. The CDC advised us that the CDC, working with state health agencies, contacted all patients treated with the recalled lot of FiberCel to help ensure they were directed to appropriate medical treatment and informed us that all patients were started on standard four-drug treatment for tuberculosis.

Samples of the recalled product underwent PCR analysis by a lab contracted by the CDC and tested positive for the presence of Mycobacterium tuberculosis. Cell culture testing of the recalled product was also conducted by the same lab that showed the presence of Mycobacterium tuberculosis, and this testing corroborated the PCR testing results. Twelve lots of FiberCel produced both before and after the single donor lot at issue underwent PCR analysis and cell culture testing and all tested negative for Mycobacterium tuberculosis. Based on these findings, we have no reason to believe that other units of FiberCel were affected.

As part of our cooperation with the FDA and CDC and our efforts to conduct a prompt and fulsome investigation into this matter, we reviewed the processes for screening donors and producing FiberCel and did not identify any deviations from our established protocols, which are designed to comply with industry standards established by the American Association of Tissue Banks ("AATB") as well as applicable FDA requirements and guidelines.

Our investigation into the available medical records for the donor at issue indicated: (1) the donor's emergency department documentation 10 days before his decease reported "Never had TB"; (2) the donor had a negative tuberculosis skin test approximately four months before decease; (3) a Tuberculosis Risk Assessment Questionnaire administered approximately four months before the donor deceased was reported as showing negative for clinical or physical evidence of a tuberculosis infection; (4) multiple chest x-rays taken during a period of approximately 33 months before the donor deceased were all interpreted as negative for tuberculosis; and (5) a CT abdominal scan taken prior to the donor deceasing was interpreted as showing no evidence of swelling of lymph nodes.

To help ensure the safety of future production lots, we implemented a number of potential safeguards against Mycobacterium tuberculosis that we believe exceed applicable industry standards and currently available FDA-approved testing. We have implemented additional donor screening procedures to include screening for any donor utilizing hemodialysis for an extended period of time and to request additional background and information on any time spent by

the donor outside the United States. In addition, we developed and utilize a methodology for testing processed viable cell bone matrix tissue products for Mycobacterium tuberculosis as a further enhancement to our donor screening. As far as we are aware, there are no commercially available testing methods authorized by the FDA for detecting the presence of Mycobacterium tuberculosis in these products. For an update on the legal proceedings related to the FiberCel Recall, see Part I, Item 3, "Legal Proceedings" and Note 17 to the consolidated financial statements included elsewhere in this Annual Report.

Available Information

We file annual, quarterly and current reports, proxy statements and other information with the U.S. Securities and Exchange Commission (the "SEC"). Our SEC filings are available to the public over the Internet at the SEC's website at www.sec.gov. Our SEC filings are also available free of charge under the Investor Relations section of our website at www.aziyo.com as soon as reasonably practicable after they are filed with or furnished to the SEC. Our website and the information contained on or available through our website is not incorporated into this Annual Report.

We may use our website as a distribution channel of material information about the Company. Financial and other important information regarding the Company is routinely posted on and accessible through the Investor Relations sections of its website at *www.aziyo.com*. In addition, you may automatically receive email alerts and other information about the Company when you enroll your email address by visiting the "Email Alerts" option under the IR Resources menu of the Investor Relations of our website at *www.aziyo.com*. The reference to our website address does not constitute incorporation by reference of the information contained on or available through our website, and you should not consider such information to be a part of this Annual Report.

Item 1A. Risk Factors.

Investing in our common stock involves a high degree of risk. You should carefully consider the risks and uncertainties described below and the other information contained in this Annual Report, including our consolidated financial statements and the related notes, as well as our other public filings with the SEC, before making an investment in our common stock. Our business, financial condition, results of operations and prospects could be materially and adversely affected if any of these risks occur, and as a result, the market price of our common stock could decline and you could lose all or part of your investment. This Annual Report also contains forward-looking statements that involve risks and uncertainties, and our actual results could differ materially and adversely from those anticipated in these forward-looking statements as a result of certain factors, including those set forth below. See "Forward-Looking Statements."

Risks Related to Our Business

We have incurred operating losses and may continue to do so for the near-term future, and we cannot assure you that we will be able to generate sufficient revenue to achieve or sustain profitability.

For the years ended December 31, 2022 and 2021, we had net loss of $32.9 million and $24.8 million, respectively. We expect our losses to continue for the foreseeable future, and these losses will continue to have an adverse effect on our financial position. Because of the numerous risks and uncertainties associated with our commercialization and development efforts, including our ability to obtain FDA clearance for the next generation of our flagship CanGaroo product, CanGaroo RM and successfully commercialize this product, we are unable to predict when we will become profitable. We cannot make assurances that we will ever generate sufficient revenue from our operations to achieve profitability and, even if we achieve profitability, we cannot be sure that we will remain profitable for any substantial period of time. Our inability to achieve and then maintain profitability would negatively affect our business, financial condition, results of operations and cash flows, negatively affect the value of our securities and our ability to raise capital and continue operations**.**

Adverse changes in general domestic and global economic conditions and instability and disruption of credit markets could adversely affect our business, financial condition, results of operations and liquidity.

We are subject to risks arising from adverse changes in general domestic and global economic conditions, including any recession, economic slowdown or disruption of credit markets. During the year ended December 31, 2022, global markets continued to experience significant volatility, driven by concerns over persistent inflation, rising interest rates, slowing economic growth and geopolitical uncertainty. These events, and any financial crisis that may occur in the future, could make it more difficult and more expensive for hospitals and health systems to obtain credit, which may contribute to pressures on their operating margins. As a result, hospitals and healthcare systems may curtail and reduce capital and overall spending, which may have a significant adverse effect on our business. In addition, the current economic downturn related to the COVID-19 pandemic has resulted and may continue to result in, and any economic downturn that may occur in the future may also result in, higher unemployment and a reduction in the number of individuals covered by private insurance, which may result in an increase in the cost of uncompensated care for hospitals. Higher unemployment may also result in a shift in reimbursement patterns as unemployed individuals switch from private plans to public plans such as U.S. Medicaid or Medicare. As economic conditions deteriorate, any significant shift in coverage for the unemployed may have an unfavorable impact on our business.

In addition, we maintain our cash and cash equivalents in accounts with financial institutions that exceed insured limits. Market conditions can impact the viability of these institutions. In the event of failure of any of the financial institutions where we maintain our cash and cash equivalents, we could lose our deposits in excess of the federally insured or protected amounts and there can be no assurance that we will be able to access uninsured funds in a timely manner or at all.

In addition, the current volatility in the capital and credit markets could impede our access to capital. Should we have limited access to additional financing sources, we may need to defer capital expenditures or seek other sources of liquidity, which may not be available to us on acceptable terms or at all. All of these factors related to global economic conditions, which are beyond our control, could adversely impact our business, financial condition, results of operations and liquidity.

We have identified conditions and events that raise substantial doubt regarding our ability to continue as a going concern.

We have incurred net losses since our inception in 2015. For the year ended December 31, 2022, we had net losses of $32.9 million and as of December 31, 2022, we had an accumulated deficit of $138.0 million. To date, we have financed our operations primarily through private placements of our convertible preferred stock, amounts borrowed under our credit facilities and sales of our products and, more recently, with proceeds from offerings and sales of our Class A common stock. We have devoted the majority of our resources to acquisition and integration, manufacturing costs, research

and development, clinical activity and investing in our commercial infrastructure through our direct sales force and commercial partners in order to expand our presence and to promote awareness and adoption of our products.

We expect that our operating expenses will continue to increase as we expand our product development and clinical and research activities, and incur additional costs associated with being a public company. Our ability to achieve profitability will depend on our ability to generate sales from existing or new products sufficient to exceed our ongoing operating expenses and capital requirements. Because of the numerous risks and uncertainties affecting product sales and our ongoing commercialization and product development efforts, we are unable to predict with any certainty whether we will be able to increase sales of our products or the timing or amount of ongoing expenditures we will be required to incur. Sales of our products, as well as meaningful reductions, suspensions or discontinuations of such sales (such as that involving FiberCel), may not offset our operating expenses. As a result, we expect to continue to incur operating losses in the future and may never achieve profitability. Furthermore, even if we do achieve profitability, we may not be able to sustain or increase profitability on an ongoing basis. As a result, we anticipate that we will need additional funding to support our continuing operations and pursue our growth strategy. In order to mitigate the current and potential future liquidity issues, we may seek to raise capital through the issuance of common stock, restructure our Revenue Interest Obligation (as defined below) or pursue asset sale or licensing transactions. However, such transactions may not be successful and we may not be able to raise additional equity, refinance our Revenue Interest Obligation, or sell or license assets on acceptable terms, or at all. As such, there can be no assurance that we will be able to continue as a going concern.

Our long-term growth depends on our ability to enhance our products, expand our product indications and develop, acquire and commercialize additional product offerings.

Our industry is highly competitive and subject to rapid change and technological advancements. Competition intensifies as technical advances in each field are made and become more widely known. We can give no assurance that others will not develop products, services and processes with significant advantages over the products, services and processes that we offer or are seeking to develop. It is, therefore, important to our business that we continue to enhance our existing product offerings, expand our product indications and develop or otherwise introduce and successfully commercialize new products. Developing, acquiring and commercializing products is expensive and time-consuming and could divert management's attention away from our core business. Even if we are successful in developing additional products, the success of any new product offering or enhancements to any of our existing products will depend on several factors, including our ability to:

- properly identify and anticipate physician and patient needs;
- develop and introduce new products and product enhancements in a timely manner;
- distinguish our products from those of our competitors;
- develop an effective and dedicated sales and marketing team;
- enter into successful agreements with commercial partners, independent sales agents and other third parties where it is beneficial for us to do so;
- adequately protect our intellectual property, avoid infringing, misappropriating or otherwise violating the intellectual property rights of third parties and obtain and maintain necessary intellectual property licenses from third parties;
- demonstrate, if required, the safety and efficacy of new products with data from pre-clinical and clinical studies;
- obtain the necessary regulatory clearances, certifications or approvals for new products, product enhancements and expanded indications;

- maintain full compliance with FDA, European Union ("EU") medical devices regulations and other regulatory requirements applicable to new devices or products or modifications of existing devices or products;

- provide adequate training to potential users of our products;

- receive adequate coverage and reimbursement for our products; and

- otherwise compete effectively against products and enhancements developed by our competitors.

If we are not successful in expanding our indications and developing, acquiring and commercializing new products and product enhancements, our ability to increase our net sales may be impaired, which could have a material adverse effect on our business, financial condition and results of operations. In addition, our research and development efforts may require a substantial investment of time and resources before we are adequately able to determine the commercial viability of a new product, technology or other innovation. On March 16, 2023, we received a NSE determination from the FDA for CanGaroo RM, requiring us to address additional items relating to drug testing in furtherance of potential market clearance. If we are not able to obtain FDA regulatory clearance for this product candidate within our planned timeline, if at all, our ability to commercialize this product and generate sales therefrom will be adversely impacted. Even if we are successful in obtaining the required regulatory clearance, there can be no assurances that we will be able to achieve market acceptance or that we will able to realize the intended benefits from commercializing this product candidate. In addition, we will be required to invest additional time and resources to address the outstanding items and provide the additional data requested to FDA, which could divert management's attention from core business and result in additional research and development expenses.

Even if we are able to successfully develop and commercialize new product offerings or enhancements, they may be quickly rendered obsolete by changing customer preferences or the introduction by our competitors of products embodying new technologies or features and/or otherwise not produce sales in excess of the costs of development, any of which could also materially and adversely affect our business, financial condition and results of operations. Furthermore, to the extent we seek to enhance our products and broaden our product portfolio through acquisitions or other commercial transactions, we will be subject to additional risks. See "— *We regularly evaluate opportunities to make acquisitions of, investments in, and licenses or other commercial arrangements involving, other companies or technologies, and to enter into other strategic transactions. These transactions entail significant risks*."

A substantial portion of our net sales is generated through our commercial partners and independent sales agents, which subjects us to various risks.

We currently rely on the efforts of our commercial partners and independent sales agents to generate a substantial portion of our net sales, and we expect to continue to rely on these third parties to generate a substantial portion of our net sales in the future while we work to grow our direct sales force. For example, we have commercial agreements with major medical device companies, including Boston Scientific, Biotronik and beginning in March 2023, Sientra. As a result, the impairment or termination of these relationships for any reason, or the failure of these parties to diligently sell our products and comply with applicable laws and regulations, has and could in the future materially and adversely affect our ability to generate revenue and profits. Because our commercial partners and independent sales agents control the relationships with our end customers, if our relationship with any commercial partner or independent sales agent ends, we will likely also lose our relationship with their customers. Furthermore, our success is partially dependent on the willingness and ability of the sales representatives and other employees of our commercial partners and independent sales agents to diligently sell our products. However, we cannot guarantee that they will be successful in marketing our products. In addition, because our commercial partners and independent sales agents do not sell our products exclusively, they may focus their sales efforts and resources on other products that produce better margins or greater commissions for them or are incorporated into a broader strategic relationship with a partner. Because we do not control the sales representatives and other employees of our commercial partners, we cannot guarantee that our sales processes, regulatory compliance and other priorities will be consistently communicated and executed. In addition, we do not have staff in many of the areas covered by our commercial partners and independent sales agents, which makes it particularly difficult for us to monitor their performance. While we may take steps to mitigate the risks associated with noncompliance by our commercial partners

and independent sales agents, there remains a risk that they will not comply with regulatory requirements or our requirements and policies. Actions by the sales representatives and other employees of our commercial partners and independent sales agents that are beyond our control could adversely impact sales in that territory or result in harm to the reputation of the Company or our products or legal liability, any of which could have a material adverse effect on our business, financial condition and results of operations. In addition to the risk of losing customers, the operation of local laws and our agreements with our commercial partners and independent sales agents would make it difficult for us to replace a commercial partner or independent sales agent we believe is underperforming.

In order to increase our sales, we intend to develop relationships and arrangements with additional commercial partners and/or independent sales agents, which we may not be able to do on commercially reasonable terms or at all. If we are unable to establish new commercial partner and independent sales agent relationships and maintain our relationships with our existing commercial partners and independent sales agents, in each case, on commercially reasonable terms, we will be unable to increase sales of our products, which, in turn, could materially and adversely affect our business, financial condition and results of operations.

In addition, certain of our commercial partners may, from time to time, account for a significant portion of our net sales and/or accounts receivable. Sales to one of our commercial partners accounted for 11% of our net sales during the year ended December 31, 2022 and represented 12% of our accounts receivable as of December 31, 2022. As previously disclosed, in December 2021, we terminated our distribution agreement with Medtronic, which accounted for 11% of our net sales during the year ended December 31, 2021, as a result of our voluntary recall of our FiberCel product.

The loss of one or more significant commercial partners, a material reduction in their purchases of our products, such as what we have experienced with Medtronic, or their inability to perform their contractual obligations, including, for example, committed purchase requirements, has affected and could continue to adversely affect our business, financial condition and results of operations. We are also subject to the risk that any such commercial partner will experience financial difficulties that prevent them from making payments to us on a timely basis or at all.

Our revenue and profitability could be materially and adversely affected if we fail to maintain our relationships with our existing contract manufacturing customers or enter into agreements with new contract manufacturing customers, or if existing contract manufacturing customers reduce purchases of our products. Our relationships with these customers also subject us to certain risks.

Our contract manufacturing operations are an important component of our business, enabling us to utilize as much as possible of the human biological material from which we produce our core orthopedic/spinal repair and soft tissue reconstruction products, leverage our existing overhead and improve our cash flow. In addition, we have historically generated a significant portion of our total net sales from these sales, with such sales representing approximately 26.1% and 20.7% of our total net sales for the years ended December 31, 2022 and 2021, respectively. If we are unable to maintain our relationships and contracts with our existing contract manufacturing customers and establish relationships with new contract manufacturing customers on terms that are favorable to us, or if our existing contract manufacturing customers materially reduce their purchases of our products, our sales and profitability may be adversely affected.

In addition, although we have invested, and expect to continue to invest, significant time and resources cultivating our relationships with these customers, these relationships subject us to certain risks. For example, our contract manufacturing customers may use their experience with our products to develop their own solutions, which they may be able to produce at a lower cost than the price they pay for our products. This is particularly true given that many of our customers are large, established companies that may be able to achieve greater economies of scale in manufacturing and production and/or experience synergies from vertical integration. In addition, our contract manufacturing customers routinely audit and inspect our facilities, processes and practices to ensure that our manufacturing process and products meet their internal standards and applicable regulatory standards. To date, we have passed all such audits and inspections. However, we may not do so in the future, and any failure to perform to our customers' satisfaction in these audits could significantly harm our relationships with them and our reputation, which could materially and adversely affect our business, financial condition and results of operations. Furthermore, the need to comply with our customers' internal requirements could result in increased development, manufacturing, warranty and administrative costs. A significant increase in these costs could adversely affect our business, financial condition and results of operations. There is also a

risk that we may be unable to supply products in the quantities and of the quality required by these customers within their required timeframes, which would also jeopardize our relationships with them. Disagreements or disputes may also arise from time to time. Any of these events, to the extent they cause our customers to reduce purchases of our products or terminate their relationships with us, could have a material adverse effect on our business, financial condition and results of operations.

In addition, our sales to these customers may be impacted by changes in their buying habits over which we have no control. Such changes may be driven by, among other things, changes in market share, cyclicality, inventory reductions, spending patterns, cost-cutting measures, product development activity and timelines and changes in supply chain management, as well as the impact of general economic conditions. These customers may also experience financial difficulties or other problems that may prevent them from making payments to us on a timely basis or at all. Any of these events could cause our operating results to fluctuate from period to period, make it more difficult for us to manage our inventory and production schedules and otherwise adversely affect our business, financial condition and results of operations.

Our business has been, and may continue to be, adversely affected by the COVID-19 pandemic, and we may be adversely affected by any future pandemic, epidemic or outbreak of an infectious disease in the United States or worldwide.

The COVID-19 pandemic continues to evolve, with pockets of resurgence and the emergence of variant strains contributing to continued uncertainty about its scope, duration, severity, trajectory, and lasting impact. The COVID-19 pandemic negatively impacted our business, financial condition and results of operations by intermittently decreasing and delaying the number of procedures performed using our products, as healthcare organizations in the United States prioritized the treatment of patients with COVID-19 or otherwise altered their operations to prepare for and respond to the pandemic. The COVID-19 pandemic has also adversely impacted the initiation, continuation and completion of our clinical studies by, for example, intermittently delaying procedures using our products or reducing the number of patients, healthcare providers or clinical facilities available or willing to participate in the clinical studies. These delays have resulted in increased costs, delays in advancing our product development, delays in testing the effectiveness of our technology or termination of the clinical studies altogether. We have experienced and may in the future experience these or other disruptions from the COVID-19 pandemic or other pandemic, epidemic or outbreak of an infectious disease that could reduce our net sales in the future and negatively impact our business, financial condition and results of operations.

The extent to which the COVID-19 pandemic or any future pandemic, epidemic or outbreak of an infectious disease impacts our business, will depend on future events and developments, which are highly uncertain and cannot be predicted, including the severity and spread of the disease and the effectiveness of actions to contain the disease or treat its impact and the emergence of new variants, among other developments.

Our future growth depends on physician awareness of the distinctive characteristics, benefits, safety, clinical efficacy and cost-effectiveness of our products.

We focus our sales, marketing and training efforts on physicians, surgeons and other healthcare professionals. The acceptance of our products depends in part on our ability to educate these individuals as to the distinctive characteristics, benefits, safety, clinical efficacy and cost-effectiveness of our products compared to alternative products, procedures and therapies. We support our direct sales force, commercial partners and independent sales agents through in-person and online educational programs, among other things. We also produce and distribute marketing and educational materials, including materials outlining our products, for our sales teams using printed, video and multimedia formats. However, our efforts to educate physicians, surgeons and other healthcare professionals regarding our products may not be successful, particularly with respect to our orthobiologics products in light of the recent events involving the FiberCel Recall, and in markets where we rely exclusively on the efforts of our commercial partners and independent sales agents. If we do not adequately educate physicians, surgeons and other healthcare professionals about our products, as well as any adverse events involving these products, our products may not gain or maintain market acceptance, which may adversely affect our business, financial condition and results of operations.

Our success depends on the continued and future acceptance of our products by the medical community.

Even if we are able to increase awareness of our products among healthcare professionals, there can be no assurance that this will translate into greater acceptance of our products by the medical community. We believe physicians, surgeons and other healthcare professionals will only adopt our products if they determine, based on experience, clinical data and published peer reviewed journal articles, that the use of our products in a particular procedure is a favorable alternative to other available methods. In light of the events surrounding the FiberCel Recall, described in Part I, Item 3, "Legal Proceedings" and Note 17 to the consolidated financial statements included elsewhere in this Annual Report, such positive evaluation of our Bone Repair products may become more challenging. Physicians also are more interested in using cost-effective products as they face increasing cost-containment pressure. In general, physicians may be slow to change their medical treatment practices and adopt our products for a variety of reasons, including, among others:

- their lack of experience using our products and the time that must be dedicated to learning how to use our products;
- lack of evidence supporting additional patient benefits from use of our products over conventional methods;
- pressure to contain costs;
- preference for other treatment modalities or our competitors' products;
- perceived liability risks generally associated with the use of new products and procedures; and
- limited availability of coverage and/or reimbursement from third-party payors.

The degree of market acceptance of our products will continue to depend on a number of factors, some of which are outside of our control, including, among other things:

- the actual and perceived safety and efficacy of our products;
- the potential and perceived advantages of our products over alternative treatments;
- clinical data and the clinical indications for which our products are approved or certified;
- product labeling or product insert requirements of the FDA, the EU or other regulatory authorities, including any limitations or warnings contained in approved labeling;
- the cost of using our products relative to the use of our competitors' products or alternative treatment modalities;
- relative convenience and ease of administration;
- the strength of marketing and distribution support;
- the timing of market introduction of competitive products;
- publicity concerning our products or competing products and treatments;
- our reputation and the reputation of our products;
- the prevalence and severity of any adverse events patients experience involving our products;

- the shelf life of our products and our ability to manage the logistics of the end-user supply chain; and
- sufficient and readily accessible third-party insurance coverage and reimbursement for procedures incorporating our products.

In addition, we believe recommendations for, and support of our products by, influential physicians are essential for market acceptance and adoption. If we do not receive this support (e.g., because we are unable to demonstrate favorable long-term clinical data or otherwise), physicians and hospitals may not use our products, which would significantly impair our ability to increase our sales and prevent us from achieving and sustaining profitability.

Unfavorable results from any of our pre-clinical or clinical studies, comparative effectiveness, economic or other studies, or from similar studies conducted by others, may negatively affect the use or adoption of our products by physicians, hospitals and payors, which could have a negative impact on the market acceptance of our products and their profitability.

We regularly conduct a variety of pre-clinical and clinical studies, comparative effectiveness studies and economic and other studies of our products in an effort to generate clinical and real-world outcomes and cost effectiveness data in order to obtain product approval and drive further penetration in the markets we serve. If a clinical study conducted by us or a third party fails to demonstrate statistically significant results supporting performance, use benefits or compelling health or economic outcomes from using our products, physicians may elect not to use our products. Furthermore, in the event of an adverse clinical study outcome, our products may not achieve "standard-of-care" status, where they exist, for the conditions in question, which could deter the adoption of our products. Also, if serious adverse events are reported during the conduct of a study, it could affect continuation of the study, product approval, certification or clearance and product adoption. In addition, U.S. and foreign regulatory authorities routinely conduct audits of clinical studies and such audits may result in adverse regulatory actions. If we are unable to develop a body of statistically significant evidence from our clinical study program, whether due to adverse results or the inability to complete properly designed studies, domestic and international public and private payors could refuse to cover procedures using our products, limit the manner in which they cover our products or reduce the price they are willing to pay or reimburse for procedures using our products. Any of these events could have a negative impact on market acceptance of procedures using our products and their profitability, which could have a material adverse effect on our business, financial condition and results of operations.

We may need to continue to expand our organization and managing growth may be more difficult than we expect.

Managing our growth may be more difficult than we expect. We anticipate that a period of significant expansion will be required to penetrate and service the markets for our existing and anticipated future products and to continue to develop new products. This expansion will place a significant strain on our management, operational and financial resources. To manage the expected growth of our operations and personnel, we must both modify our existing operational and financial systems, procedures and controls and implement new systems, procedures and controls. We must also expand our finance, administrative and operations staff. Management may be unable to hire, train, retain, motivate and manage necessary personnel or to identify, manage and exploit existing and potential strategic relationships and market opportunities. If we fail to meet these challenges effectively, there may be an adverse effect on our business, financial condition and results of operations.

We regularly evaluate opportunities to make acquisitions of, investments in, and licenses or other commercial arrangements involving, other companies or technologies, and to enter into other strategic transactions. These transactions entail significant risks.

Our success depends, in part, on our ability to continually enhance and broaden our product offerings in response to changing customer demands, competitive pressures and advances in technologies. Accordingly, although we have no current commitments with respect to any acquisition or investment, we regularly review potential acquisitions of, investments in, and licenses or other commercial arrangements involving, complementary businesses, products or technologies instead of developing them ourselves. In addition, in regularly evaluating our financial and operating performance, we may decide to sell one or more of our product lines or another portion of our business. Opportunities to engage in these transactions may not be readily available to us at commercially reasonable prices, on other terms acceptable

to us or at all. Even if such opportunities are available, these transactions involve significant risks. In connection with one or more of these transactions, we may:

- issue additional equity securities that would dilute the value of your investment in us;
- use cash that we may need in the future to operate our business;
- incur debt that could have terms unfavorable to us or that we might be unable to repay;
- structure the transaction in a manner that has unfavorable tax consequences, such as a stock purchase that does not permit a step-up in the tax basis for the assets acquired;
- incur asset impairment or other acquisition-related charges, or unforeseen costs, expenditures and risks;
- be unable to realize the anticipated benefits, such as increased revenues, cost savings or synergies from additional sales of existing or newly acquired products;
- experience dissynergies in shared functions following a divestment of any portion of our business;
- be unable to successfully integrate, operate, maintain and manage any newly acquired operations;
- divert management's attention from the existing business to integrate, operate, maintain and manage any newly acquired operations and personnel, or to manage the complexities involved in separating divested operations, services, products and personnel;
- be unable to secure the services of key employees related to an acquisition or, in the case of a divestiture, lose one or more of our key employees;
- face increased scrutiny and review of our company and operations from government and other regulatory authorities; and
- otherwise be unable to succeed in the marketplace with the acquisition.

The occurrence of any of the above could materially and adversely affect our business, financial condition and results of operations. Furthermore, business acquisitions also involve the risk of unknown liabilities associated with the acquired business, which could be material. Such liabilities could include lack of compliance with government regulations that could subject us to investigation, civil and criminal sanctions, litigation and/or other actions that make it impossible to realize the anticipated benefits of the transaction. For example, we may acquire a company that was not compliant with FDA quality requirements or was making payments or other forms of remuneration to physicians to induce them to use their products. Incurring unknown liabilities or the failure to complete or realize the anticipated benefits of an acquisition, sale, investment or other commercial arrangement, whether resulting from one or more of the factors described above or otherwise, could have a material and adverse effect on our business, financial condition and results of operations.

New lines of business and new products and services may subject us to additional risks.

From time to time, we may implement or acquire new lines of business or introduce new products and services within our existing business lines. There are risks and uncertainties associated with these efforts, particularly in instances where the markets are not fully developed or are evolving. In developing and commercializing new lines of business and new products and services, we may invest significant time and resources. External factors, such as regulatory compliance obligations, competitive alternatives, lack of market acceptance and shifting market preferences, may also affect the successful implementation of a new line of business or a new product or service. Failure to successfully plan for and manage these risks in the development and implementation of new lines of business or new products or services could have a material adverse effect on our business, financial condition and results of operations.

We face significant and continuing competition from other companies, some of which have longer operating histories, more established products and/or greater resources than we do, which could adversely affect our business, financial condition and results of operations.

We operate in highly competitive markets that are characterized by intense competition, subject to rapid change and significantly affected by new product introductions, technological advancements and other market activities of industry participants. Our competitors have historically dedicated, and will continue to dedicate, significant resources to promote their products and to develop new products that compete with ours. Customers in our target markets consider many factors when selecting a product, including product efficacy, ease of use, price, availability of payor coverage and adequate third-party reimbursement for procedures using the product, customer support services for technical-, clinical- and reimbursement-related matters and customer preference for, and loyalty to, particular products or a particular manufacturer. We expect competition to remain intense as competitors introduce additional competing products and enhancements to their existing products, and continue expanding into geographic markets where we currently operate or plan to expand. Product introductions or enhancements by competitors, which may have advanced technology, better features or lower pricing, may make our products obsolete or less competitive. As a result, we will be required to devote continued efforts and financial resources to develop and commercialize new products and enhancements to our existing products, deliver cost-effective clinical outcomes, manage our costs and expand our geographic reach.

Many of our current and potential competitors have longer operating histories and substantially greater financial, technical, marketing, sales, distribution and other resources than we do, which may prevent us from achieving significant market penetration or improved operating results. Certain competitors' products, such as competitors of SimpliDerm, are subject to a simpler reimbursement process than are our products. Competitors may also be able to leverage their market share and other resources to set prices at a level below that which is profitable for us. These companies may also enjoy other competitive advantages, including, without limitation:

- greater company, product and brand recognition;
- better quality and greater volume of clinical data;
- more effective marketing to and education of physicians and other healthcare professionals;
- greater control of key intellectual property and more expansive portfolios of intellectual property rights;
- more experience in obtaining and maintaining regulatory clearances, certifications or approvals for products and product enhancements;
- more established relationships with hospitals and other healthcare providers, physicians, suppliers, customers and third-party payors;
- additional lines of products, and the ability to bundle products to offer greater incentives to gain a competitive advantage;
- more established sales, marketing and worldwide distribution networks;
- better product support and service;
- superior product safety, reliability and durability, particularly in light of the events involving the FiberCel Recall; and
- more effective pricing and revenue strategies.

Our ability to achieve and maintain profitability will depend, in part, on our ability to develop or acquire proprietary products that reach the market in a timely manner, receive adequate coverage and reimbursement for

procedures using our products, and are safer and more effective than their alternatives, as well as our ability to otherwise compete effectively on the factors listed above. If we are unable to do so, our sales and/or margins will decrease, which could have a material adverse effect on our business, financial condition and results of operations.

Pricing pressure as a result of cost-containment efforts of our customers, purchasing groups, third-party payors and governmental organizations could adversely affect our sales and profitability.

Medical technology companies, healthcare systems and group purchasing organizations ("GPOs") have intensified competitive pricing pressure as a result of industry trends and new technologies. Rising healthcare costs have resulted in numerous cost reform initiatives by legislators, regulators and third-party payors. This cost reform has triggered a consolidation trend in the healthcare industry to aggregate purchasing power and, as a result, purchasing decisions are increasingly shifting to hospitals, integrated delivery networks ("IDNs") and other hospital groups, and away from individual surgeons and physicians. Many existing and potential facility customers for our products within the United States are members of GPOs and IDNs, including accountable care organizations or public-based purchasing organizations, and our business is partly dependent on contracts with these organizations. Purchases of our products can be contracted under national tenders or with larger hospital GPOs. GPOs and IDNs negotiate pricing arrangements with healthcare product manufacturers and distributors and offer the negotiated prices to affiliated hospitals and other members. GPOs and IDNs typically award contracts on a category-by-category basis through a competitive bidding process and, at any given time, we are typically in various stages of responding to bids and negotiating and renewing GPO and IDN agreements. Bids are generally solicited from multiple manufacturers or service providers with the intention of obtaining lower pricing. Due to the highly competitive nature of the bidding process and the GPO and IDN contracting processes in the United States, we may not be able to obtain or maintain contract positions with major GPOs and IDNs across our product portfolio. Furthermore, GPO and IDN contracts are typically terminable without cause upon 60 to 90 days' notice. In addition, while having a contract with a major purchaser for a given product category can facilitate sales, there can be no guarantee that sales volumes for those products will be maintained. For example, GPOs and IDNs are increasingly awarding contracts to multiple suppliers for the same product category and, even when we are the sole contracted supplier of a GPO or IDN for a certain product category, members of the GPO or IDN are generally free to purchase from other suppliers. If we are unable to maintain and renew our contracts with our current GPO and IDN customers and negotiate contracts with new customers on favorable terms, or if sales volumes under these agreements decline, our business, financial condition and results of operations could be materially and adversely affected.

In addition, most of our customers purchase our products directly and then bill third-party payors for procedures using those products. Because there is typically no separate reimbursement for supplies used in surgical procedures, the additional cost associated with the use of our products can affect the profit margin of the hospital or surgery center where the procedure is performed. Some of our target customers may be unwilling to adopt our products in light of the additional associated cost or may negotiate for lower pricing. Further, any decline in the amount payors are willing to reimburse our customers for procedures using our products, including those as a result of healthcare reform initiatives, could make it difficult for existing customers to continue using or to adopt our products and could create additional pricing pressure for us. In addition to these competitive forces, we continue to see pricing pressure as hospitals introduce new pricing structures into their contracts and agreements, including fixed price formulas, capitated pricing and episodic or bundled payments intended to contain healthcare costs. If we are forced to lower the price we charge for our products, our margins will decrease, which could impair our ability to grow our business and have a material adverse effect on our business, financial condition and results of operations and impair our ability to grow our business.

Outside of the United States, centralized governmental healthcare authorities may exert pricing pressures in an effort to lower healthcare costs. Implementation of healthcare reforms and competitive bidding contract tenders may limit the price or the level at which reimbursement is provided for our products and adversely affect both our pricing flexibility and the demand for our products. Healthcare providers may respond to such cost-containment pressures by substituting lower-cost products or other therapies for our products. Our failure to offer acceptable prices to these customers could adversely affect our sales and profitability in these markets.

We expect that market demand, government regulation, third-party coverage and reimbursement policies and societal pressures will continue to change the healthcare industry worldwide, resulting in further business consolidations and alliances among our customers, which may exert further downward pressure on the prices for our products.

The processing of human and porcine tissue for our products is technically complex, requiring high levels of quality control and precision, which subjects us to increased production risks.

We manufacture our human and porcine tissue products using technically complex processes requiring specialized facilities, highly specific raw materials, skill and diligence by our personnel and other production constraints. The complexity of these processes, as well as strict company and government standards for the manufacture and storage of our products, subjects us to production risks. In addition to ongoing production risks, process deviations or unanticipated effects of approved process changes may result in non-compliance with regulatory requirements, including stability requirements or specifications. For example, our bone allograft products, such as ViBone and OsteGro V, must be shipped and maintained within a specified temperature range. If environmental conditions deviate from that range, our products' remaining shelf-lives could be impaired or their safety and efficacy could be adversely affected, making them unsuitable for use. The occurrence of this or any other actual or suspected production or distribution problem can lead to lost inventory, customer returns and, in some cases, recalls, with consequential damage to our reputation and customer relationships and the risk of product liability.

For example, in June 2021, we issued a voluntary recall pertaining to a single donor lot of our FiberCel Fiber Viable Bone Matrix, a bone repair product made from human tissue that is used in various orthopedic and spinal procedures. Notice of the voluntary recall was issued to hospitals that received product from this specific lot following our learning of post-surgical infections in patients treated with FiberCel, including some patients that tested positive for tuberculosis. The lot consisted of 154 units of FiberCel, all derived from a single donor, that were shipped to facilities in 20 states. We have investigated the source of the infections in coordination with our distributor, the FDA and the U.S. Centers for Disease Control and Prevention ("CDC"). The FDA inspected our Richmond, California production facility, and this inspection did not result in any Form-483 observations. Additionally, multiple product liability lawsuits have been filed against us. See *"We face the risk of product liability claims and may not be able to obtain or maintain adequate product liability insurance"* for additional information about these product liability lawsuits.

This investigation, as well as others that may occur in the future, and the remediation of any potential or identified problems can cause production delays and result in substantial additional expenses and lost revenue. In addition, we may experience difficulties in scaling up processing and production of our human and porcine tissue products, including problems related to yields, quality control and assurance, tissue availability, adequacy of control policies and procedures and availability of skilled personnel. Furthermore, developing and maintaining our production capabilities has required, and will continue to require, the investment of significant resources, and we cannot guarantee that we will be able to achieve economies of scale. If we are unable to process and produce our human tissue products on a timely basis, at acceptable quality and costs and in sufficient quantities, or if we experience technological problems, delays in production, failure in the storage of our products or other loss of supply, our business would be materially and adversely affected.

Performance issues, service interruptions or price increases by our shipping carriers could adversely affect our business, harm our reputation and impair our ability to provide our products on a timely basis or at all.

Expedited, reliable shipping is essential to our operations. We rely heavily on providers of transport services for reliable, timely and secure point-to-point transport of our products to our customers and for tracking of these shipments. Should a carrier encounter delivery performance issues such as loss, delays, damage or destruction of any of our products, it would be costly to replace these products in a timely manner and such occurrences may damage our reputation and lead to decreased demand for our products and increased cost and expense to our business. This risk is particularly high with respect to ViBone, Fiber VBM, and OsteGro V, all of which must be shipped and maintained within a specified temperature range. In addition, any significant increase in shipping rates could adversely affect our operating margins and results of operations. Similarly, strikes, severe weather, natural disasters, equipment malfunctions or other service interruptions affecting the delivery services we use, would impair our ability to process orders for our products on a timely basis or at all, which could have a material adverse effect on our business, financial condition and results of operations.

If our facilities are damaged or become inoperable, we will be unable to continue to research, develop and supply our products and, as a result, there will be an adverse effect on our business until we are able to secure new facilities and rebuild our inventory.

We do not have redundant facilities. We manufacture our human tissue-based products at our facility in Richmond, California. The SIS ECM biomaterial used in our medical device products are manufactured by Cook Biotech at their facility in West Lafayette, Indiana and converted to a finished product at our facility in Roswell, Georgia. Regulatory approvals or certifications of our products are limited to one or more specifically approved manufacturing facilities. As a result, if we fail to produce enough of a product at a facility, or if any of our production facilities were to be shut down or otherwise become unavailable for any reason, finding alternative manufacturing capabilities and obtaining the necessary regulatory approvals or certifications would require a considerable amount of time and expense and would cause a significant disruption in service to our customers.

Disruption to our facilities could arise for a variety of reasons, including technical, labor or other difficulties, equipment malfunction, contamination due to a COVID-19 infection or otherwise, the failure of our employees to follow specific protocols and procedures, the destruction of, or damage to, any facility (as a result of a natural or man-made disaster, including, but not limited to, a tornado, flood, fire, power outage or other event), quality control issues or other reasons. Any disruption in the operation of our facilities as a result of any of the above could impair our product development and commercialization efforts and result in lost sales, lost customers and harm to our reputation, any of which would negatively impact our growth prospects and profitability and have a material adverse effect on our business, financial condition and results of operations. In addition, certain of these events, such as natural or man-made disasters, would cause us to incur additional losses, including the time and expense required to repair and/or replace our equipment and to rebuild our inventory. Our insurance for damage to our property and the disruption of our business may not be sufficient to cover all of our potential losses and may not continue to be available to us on acceptable terms or at all.

Because we depend upon a limited number of third-party suppliers and manufacturers and, in certain cases, exclusive suppliers for products essential to our business, we may incur significant product development costs and experience material delivery delays if we lose any significant supplier, which could materially and adversely affect our business, financial condition and results of operations.

We obtain some of our raw materials from a limited group of suppliers and rely on a single supplier to source the SIS ECM biomaterial used to manufacture CanGaroo and our cardiovascular products for reasons of quality assurance, cost-effectiveness, availability or constraints resulting from regulatory requirements. For us to be successful, our suppliers must be able to provide us with products and components in substantial quantities, in compliance with regulatory requirements, in accordance with agreed upon specifications, at acceptable costs and on a timely basis. Our efforts to maintain a continuity of supply and high quality and reliability may not be successful on a timely basis or at all. Manufacturing disruptions experienced by our suppliers may jeopardize our supply of finished products. Due to the stringent regulations and requirements of the FDA and other similar non-U.S. regulatory agencies regarding the manufacture of our products, we may not be able to quickly establish additional or replacement sources for certain raw materials. A change in suppliers could require significant effort or investment in circumstances where the items supplied are integral to product performance or incorporate unique technology. Transitioning to a new supplier could be time-consuming and expensive, may result in interruptions in our operations and product delivery, could affect the performance specifications of our products or could require that we modify the design of those systems.

A reduction or interruption in manufacturing, or an inability to secure alternative sources of raw materials or supplies, could have a material and adverse effect on our business, financial condition, results of operations and cash flows. One or more of our suppliers may refuse to extend us credit with respect to our purchasing or leasing of equipment, supplies, products or components, or may only agree to extend us credit on significantly less favorable terms or subject to more onerous conditions. This could significantly disrupt our ability to purchase or lease required equipment, supplies, products and components in a cost-effective and timely manner, and could have a material adverse effect on our business, financial condition and results of operations. Any casualty, natural disaster or other disruption of any of our sole-source suppliers' operations, for example due to a COVID-19 infection of employees of the supplier, or any unexpected loss of any existing exclusive supply contract, could have a material adverse effect on our business, financial condition and results of operations. In addition, if a change in manufacturer results in a significant change to any product, a new 510(k) clearance

from the FDA or similar international regulatory authorization, or certification may be necessary before we implement the change, which could cause substantial delays.

Certain of our products are dependent on the availability of tissue from human donors, and any disruption in supply could adversely affect our business, financial condition and results of operations.

The products we manufacture for the orthobiologics and soft tissue reconstruction markets require that we obtain human tissue. The success of our business depends, in part, on the availability of tissue from human donors. Any inability to obtain tissue from our sources will interfere with our ability to effectively meet demand for these products. The recovery of human tissue for our products is very labor-intensive, and it is, therefore, difficult to maintain a steady supply stream. In addition, the availability of acceptable donors is relatively limited and may be impacted by regulatory changes, general public opinion of the donation process and the reputation of our company and the third-party procurement firms with which we partner to manage the donation process. Media reports or other negative publicity concerning both improper methods of tissue recovery from donors and disease transmission from donated tissue, including bones and dermis, may limit widespread acceptance of our products. Unfavorable reports of improper or illegal tissue recovery practices, both in the United States and internationally, as well as incidents of improperly processed tissue leading to transmission of disease, may broadly affect the rate of future tissue donation and market acceptance of allograft technologies and donated tissue use. Potential patients may not be able to distinguish our products, technologies and tissue recovery and processing procedures from others engaged in tissue recovery. In addition, unfavorable reports about us or any of our third-party procurement firms may make families of potential donors or donors themselves, from whom we are required to obtain consent before processing tissue, reluctant to agree to donate tissue to for-profit tissue processors. For the year end December 31, 2022, we received donated tissue from seven third-party procurement firms, including one third-party procurement firm that supplied 52% of the donors received during the year. Any disruption in the supply of any human tissue component could materially harm our ability to manufacture our products until a new source of supply, if any, could be found. We may be unable to find a sufficient alternative supply channel within a reasonable period of time, on commercially reasonable terms or at all, which would have a material adverse effect on our business, financial condition and results of operations.

Increased prices for raw materials or supplies used in our products could adversely affect our business, financial condition and results of operations.

Our profitability is affected by the prices of the raw materials and supplies used in the manufacture of our products. These prices may fluctuate based on a number of factors beyond our control, including changes in supply and demand, general economic conditions, labor costs, delivery costs, competition, import duties, excises and other indirect taxes, currency exchange rates and government regulation. Due to the highly competitive nature of the healthcare industry and the cost containment efforts of our customers and third-party payors, we may be unable to pass along cost increases for key supplies or raw materials through higher prices to our customers. If the cost of key supplies or raw materials increases, and we are unable to fully recover these increased costs through price increases or offset these increases through other cost reductions, we could experience lower margins and profitability. Significant increases in the prices of raw materials and supplies that cannot be recovered through productivity gains, price increases or other methods could adversely affect our business, financial condition and results of operations.

If we are not able to accurately forecast demand for our products and manage our inventory, our margins could decrease and we could lose sales, either of which could have a material adverse effect on our business, financial condition and results of operations.

While we must maintain sufficient inventory levels to operate our business successfully and meet customer demand for our products, we must be careful to avoid amassing excess inventory. To ensure adequate inventory supply, we must forecast inventory needs and place orders with our suppliers based on our estimates of future demand for our products. Demand for our products can change, and has changed, rapidly and unexpectedly, including during the time between when raw materials are ordered from our suppliers and the finished product is offered for sale. 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 by competitors, an increase or decrease in customer demand for our products or for products of our competitors, our failure

to accurately forecast customer acceptance of new products, unanticipated changes in general market conditions, reimbursement or regulatory matters and weakening of economic conditions. Inventory levels that exceed the demand for our products may result in inventory write-downs or write-offs, which would adversely affect our gross margins. For example, since our launch of SimpliDerm 2019, evolving demand for different dimensions of the product have periodically resulted in excess inventory write-downs. Conversely, if we underestimate demand for our products, additional supplies of raw materials or additional manufacturing capacity may not be available when required on terms that are acceptable to us or at all, and suppliers or our third-party manufacturer may not be able to allocate sufficient capacity in order to meet our increased requirements. As a result, we may not be able to meet customer demand for our products, resulting in lost sales and potential damage to our reputation and customer relationships, any of which would adversely affect our business, financial condition and results of operations.

In addition, while we seek to maintain sufficient levels of inventory in order to protect ourselves from supply interruptions, our products generally have a shelf life of two to three years. We are, therefore, subject to the risk that a portion of our inventory will become obsolete or expire, which could have a material adverse effect on our profitability and cash flows due to the resulting inventory impairment charges and costs required to replace such inventory.

If hospitals and other healthcare providers are unable to obtain coverage or adequate reimbursement for procedures performed with our products, it is unlikely our products will be widely used.

In the United States, the commercial success of our existing products and any products we may develop or acquire in the future will depend, in part, on the extent to which governmental payors at the federal and state levels, including Medicare and Medicaid, private health insurers and other third-party payors, provide coverage and establish adequate reimbursement levels for procedures utilizing our products. Hospitals and other healthcare providers that purchase our products for treatment of their patients generally rely on third-party payors to pay for all or part of the costs and fees associated with our products as part of a “bundled” rate for the associated procedures. The existence of coverage and adequate reimbursement for procedures using our products by government and private payors is critical to market acceptance of our existing and future products. Neither hospitals nor surgeons are likely to use our products if they do not receive adequate reimbursement for the procedures utilizing our products.

Many private payors currently base their reimbursement policies on the coverage decisions and payment amounts determined by the CMS which administers the Medicare program. Others may adopt different coverage or reimbursement policies for procedures performed with our products, while some governmental programs, such as Medicaid, have reimbursement policies that vary from state to state, some of which may not pay for the procedures performed with our products in an adequate amount, if at all. Because the Medicare and Medicaid programs are increasingly used as models for how private payors and other governmental payors develop their coverage and reimbursement policies, a Medicare national or local non-coverage decision, denying coverage for procedures using one or more of our products, could result in private and other third-party payors also denying coverage. Third-party payors also may deny reimbursement for procedures using our products if they determine that a product used in a procedure was not medically necessary, was not used in accordance with cost-effective treatment methods, as determined by the third-party payor, or was used for an unapproved use. Unfavorable coverage or reimbursement decisions by government programs or private payors underscore the uncertainty that our products face in the market and could have a material adverse effect on our business.

Many hospitals and clinics in the United States belong to GPOs, which typically incentivize their hospital members to make a relatively large proportion of purchases of similar products from a limited number of vendors that have contracted to offer discounted prices. Such contracts often include exceptions for purchasing certain innovative new technologies, however. Accordingly, the commercial success of our products may also depend to some extent on our ability to either negotiate favorable purchase contracts with key GPOs and/or persuade hospitals and clinics to purchase our product “off contract.”

The healthcare industry in the United States has experienced a trend toward cost containment as government and private payors seek to control healthcare costs by paying service providers lower rates. While it is expected that hospitals will be able to obtain coverage for procedures using our products, the level of payment available to them for such procedures may change over time. State and federal healthcare programs, such as Medicare and Medicaid, closely regulate provider payment levels and have sought to contain, and sometimes reduce, payment levels. Private payors frequently

follow government payment policies and are likewise interested in controlling increases in the cost of medical care. In addition, some payors are adopting pay-for-performance programs that differentiate payments to healthcare providers based on the achievement of documented quality-of-care metrics, cost efficiencies or patient outcomes. These programs are intended to provide incentives to providers to deliver the same or better results while consuming fewer resources. As a result of these programs, and related payor efforts to reduce payment levels, hospitals and other providers are seeking ways to reduce their costs, including the amounts they pay to medical device manufacturers. We may not be able to sell our products profitably if third-party payors deny or discontinue coverage or reduce their levels of payment below that which we project, or if our production costs increase at a greater rate than payment levels. Adverse changes in payment rates by payors to hospitals could adversely impact our ability to market and sell our products and negatively affect our financial performance.

In international markets, medical device regulatory requirements and healthcare payment systems vary significantly from country to country, and many countries have instituted price ceilings on specific product lines. We cannot assure you that our products will be considered cost-effective by international third-party payors, that reimbursement will be available or, if available, that the third-party payors' reimbursement policies will not adversely affect our ability to sell our products profitably. Any failure to receive regulatory or reimbursement approvals would negatively impact market acceptance of our products in any international markets in which those approvals are sought.

We face the risk of product liability claims and may not be able to obtain or maintain adequate product liability insurance.

Our business exposes us to the risk of product liability claims that are inherent in the manufacturing, processing, investigating and marketing of medical devices and human and animal tissue products. For example, since the voluntary recall pertaining to a single donor lot of our FiberCel Fiber Viable Bone Matrix was issued, and as of February 17, 2022, we have received notice of 107 separate lawsuits or claims alleging that the plaintiffs contracted tuberculosis and/or suffered substantial symptoms and complications following the implantation of FiberCel during spinal fusion operations. We have settled 26 of these lawsuits for a total of approximately $7.3 million as of December 31, 2022 and continue to negotiate and attempt to resolve many of these cases. Of these settled matters, 11 cases were both settled and paid as of December 31, 2022 for a total cash outlay of $3.6 million. For the remaining 81 cases for which settlements have not been reached, we estimated a probable loss related to each case and have recorded a liability at an estimated amount of $13.7 million for a total estimated liability at December 31, 2022 of $17.4 million, which is recorded as Contingent Liability for FiberCel Litigation in the accompanying consolidated balance sheets included in this Annual Report. See Part I, Item 3, "Legal Proceedings" and Note 17 to the consolidated financial statements included elsewhere in this Annual Report.

We are, and may in the future be, subject to product liability claims and lawsuits, including potential class actions or mass tort claims, alleging that our products have resulted or could result in an unsafe condition or injury. Product liability claims may be made by patients and their families, healthcare providers or others selling our products. Product liability claims may include, among other things, allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability or a breach of warranties.

Additionally, we may be subject to product liability claims, proceedings and lawsuits, even if the apparent injury is due to the actions of others or the pre-existing health of the patient. For example, we rely on physicians and other healthcare providers to properly and correctly use our products. If these physicians or other healthcare providers are not properly trained or are negligent in using our products, the capabilities of our products may be diminished or the patient may suffer critical injury. In addition, we may be subject to product liability claims, as well as a number of other risks, as a result of physicians and other healthcare providers using our products "off-label." See the risk factor entitled "*The misuse or off-label use of our products may harm our reputation in the marketplace, result in injuries that lead to product liability suits or result in costly investigations, fines or sanctions by regulatory bodies if we are deemed to have engaged in the promotion of these uses, any of which could be costly to our business*" included in this Annual Report.

Defending any current or future claims, proceedings or lawsuits, regardless of merit, could be costly, divert management attention and result in adverse publicity, which could result in the withdrawal of, or reduced acceptance of, our products in the market. If we cannot successfully defend against product liability claims, we could incur substantial liability and costs. In addition, regardless of merit or eventual outcome, product liability claims may result in:

- harm to our business reputation;
- investigations by regulators;
- significant legal costs;
- distraction of management's attention from our primary business;
- substantial monetary awards to patients or other claimants;
- loss of revenue;
- exhaustion of any available insurance and our capital resources; and
- decreased demand for our products.

Our product liability insurance is subject to deductibles and coverage limitations, and we may not be able to maintain this insurance. As of December 31, 2022, we have recorded insurance receivables of $13.8 million on our balance sheet in respect of our insurance coverage for the FiberCel Litigation product liability losses. However, it is possible that future claims related to the FiberCel Litigation or other product liability claims could exceed the limits of, or be excluded from, coverage under our policy, and claims against us could also increase the cost of maintaining our coverage. If these or other claims are excluded from our coverages, or if we are unable to maintain product liability insurance at an acceptable cost or on acceptable terms with adequate coverage or otherwise protect ourselves against potential product liability claims, or if we underestimate the amount of insurance we need, we could be exposed to significant liabilities, which may harm our business. One or more product liability claims could have a significant adverse effect on our business, financial condition and results of operations.

We bear the risk of warranty claims on our products.

We bear the risk of warranty claims on our products. We may not be successful in claiming recovery under any warranty or indemnity provided to us by our suppliers or vendors in the event of a successful warranty claim against us by a customer, and any recovery from such supplier or vendor may not be adequate. Furthermore, we may not have any, or have an adequate, warranty provided by our supplier. In addition, warranty claims brought by our customers related to third-party components may arise after our ability to bring corresponding warranty claims against such suppliers expires, which could result in costs to us. In addition, we have been, and in the future could be, subject to costs related to product recalls, and we could incur significant costs to correct any defects, warranty claims or other problems. Any such events could adversely affect our business, financial condition and results of operations.

Defects, failures or quality issues associated with our products could lead to product recalls or safety alerts, adverse regulatory actions, litigation, including product liability claims, and negative publicity, any of which may erode our competitive advantage and market share and have a material adverse effect on our reputation, business, financial condition and results of operations.

Quality is extremely important to us and our customers due to the serious and costly consequences of product failure. Quality and safety issues may occur with respect to any of our products, and our future operating results will depend on our ability to maintain an effective quality control system and effectively train and manage our workforce with respect to our quality system. The development, manufacture and control of our products are subject to extensive and rigorous regulation by numerous government agencies, including the FDA, the competent authorities of the EU member states and similar foreign agencies. Compliance with these regulatory requirements, including but not limited to the FDA's Quality System Regulation ("QSR"), current Good Manufacturing Practices ("GMPs") and adverse events/recall reporting requirements in the United States and other applicable regulations worldwide, is subject to continual review and is monitored rigorously through periodic inspections by the FDA and foreign regulatory authorities. If we fail to comply with our reporting obligations, the FDA, the competent authorities of the EU member states or other regulatory authority could

take action, including issuance of warning letters and/or untitled letters, administrative actions, criminal prosecution, imposition of civil monetary penalties, revocation of our device clearance, seizure of our products or delay in the clearance of future products.

The FDA and foreign regulatory authorities may also require post-market testing and surveillance to monitor the performance of approved or certified products. Our facilities and those of our suppliers, commercial partners and independent sales agents are also subject to periodic regulatory inspections. If the FDA or a foreign authority were to conclude that we have failed to comply with any of these requirements, it could institute a wide variety of enforcement actions, ranging from a public warning letter to more severe sanctions, such as product recalls or seizures, withdrawals, monetary penalties, consent decrees, injunctive actions to halt the manufacture or distribution of products, import detentions of products made outside the United States, export restrictions, restrictions on operations or other civil or criminal sanctions. Civil or criminal sanctions could be assessed against our officers, employees, or us. Any adverse regulatory action, depending on its magnitude, may restrict us from effectively manufacturing, marketing and selling our products.

If our products do not function as designed, or are designed improperly, we or the third-party manufacturer of such products may withdraw such products from the market, whether by choice or as a result of regulatory requirements. In January 2018, we recalled five of our allograft tissue implants because a pre-sterilized donor culture should have been disqualified, each of which had a negative effect on our business, financial condition and results of operations. In August 2019, we recalled and discarded certain production lots of CanGaroo from the market due to suture breakage. Furthermore, in June 2021, we issued a voluntary recall pertaining to a single donor lot of our FiberCel Fiber Viable Bone Matrix, a bone repair product made from human tissue that is used in various orthopedic and spinal procedures, following our learning of post-surgical infections in patients treated with FiberCel, including some patients that tested positive for tuberculosis. This recall had a negative effect on our business, financial condition and results of operations and resulted in a number of lawsuits filed against us as discussed below under "— *We face significant litigation related to FiberCel.*" Any product recall we or a third-party manufacturer may conduct in the future, whether voluntary or required, may also negatively affect our business, financial condition and results of operations, and this effect may be material.

In addition, we cannot predict the results of future legislative activity or future court decisions, any of which could increase regulatory requirements, subject us to government investigations or expose us to unexpected litigation. Any regulatory action or litigation, regardless of the merits, may result in substantial costs, divert management's attention from other business concerns and place additional restrictions on our sales or the use of our products. In addition, negative publicity, including regarding a quality or safety issue, could damage our reputation, reduce market acceptance of our products, cause us to lose customers and decrease demand for our products. Any actual or perceived quality issues may also result in issuances of physician's advisories against our products or cause us to conduct voluntary recalls. Any product defects or problems, regulatory action, litigation, negative publicity or recalls could disrupt our business and have a material adverse effect on our business, financial condition and results of operations.

We face significant litigation related to FiberCel.

We have been named in multiple lawsuits alleging that the plaintiffs contracted tuberculosis and are suffering substantial adverse symptoms following the implantation of FiberCel during spinal fusion operations. See Part I, Item 3, "Legal Proceedings" and Note 17 to the consolidated financial statements included elsewhere in this Annual Report. We have incurred and will continue to incur costs to defend these lawsuits. Furthermore, these proceedings are still expected to continue for the reasonably foreseeable future, and we cannot predict the course the proceedings will take or their ultimate outcome.

As discussed above under "-- *We face the risk of product liability claims and may not be able to obtain or maintain adequate product liability insurance*", we have recorded a total estimated contingent liability of $17.4 million related to the resolution of all FiberCel lawsuits and claims and have recorded insurance receivables of $13.8 million in respect of our insurance coverage for the FiberCel Litigation product liability losses, as well as related legal defense costs incurred as of December 31, 2022. While we believe our estimated liability to be reasonable, the actual loss amounts are highly variable and turn on a case-by-case analysis of the relevant facts. As such, actual settlement amounts may differ from our estimates and such differences may be material. In addition, this contingent liability excludes the future costs to defend

against the lawsuits and claims. To the extent these costs are not recovered through insurance proceeds, such costs could also have a material adverse effect on our business, cash flow, results of operations, financial position and prospects.

Our operating results may fluctuate significantly from quarter to quarter and year to year due to the seasonality of our business, as well as a variety of other factors, many of which are outside of our control.

Our quarterly and annual results of operations may vary significantly in the future, and period-to-period comparisons of our operating results may not be meaningful. Accordingly, the results of any one quarter or other period should not be relied upon as an indication of our future performance. Our quarterly and annual financial results may fluctuate as a result of a variety of factors, many of which are outside our control and, as a result, may not fully reflect the underlying performance of our business. One such factor includes seasonal variations in our sales. We have experienced and may in the future experience higher sales in the fourth quarter as hospitals in the United States increase their purchases of our products to coincide with the end of their budget cycles. Satisfaction of patient deductibles through the course of the year also results in increased sales later in the year. In general, our first quarter usually has lower sales than the preceding fourth quarter as patient deductibles are re-established with the new year, thereby increasing their out-of-pocket costs.

Other factors that may cause fluctuations in our quarterly and annual results include, among other things:

- the timing of medical procedures using our products;
- the announcement or introduction of new products by our competitors;
- failure of government health benefit programs and private health plans to cover our products or to timely and adequately reimburse the users of our products;
- the impact of the COVID-19 pandemic, or any other pandemic, epidemic or outbreak of an infectious disease in the United States or worldwide that impacts the number of procedures being performed;
- the rate of reimbursement for procedures using our products by government and private insurers;
- whether our products are granted pass-through reimbursement status or included in the “bundled” reimbursement structure;
- changes in purchasing patterns by our commercial partners or customers, or the loss of any significant customer or group of customers;
- our ability to upgrade and develop our systems and infrastructure to accommodate growth;
- the amount and timing of operating costs and capital expenditures relating to the expansion of our business, operations and infrastructure;
- changes in, or enactment of, new laws or regulations promulgated by federal, state or local governments;
- changes in our supply or manufacturing costs;
- cost containment initiatives or policies developed by government and commercial payors that create financial incentives not to use our products;
- our inability to demonstrate that our products are cost-effective or superior to competing products;
- our ability to develop new products;

- the degree of competition in our industry and any changes in the competitive landscape;
- discovery of product defects during the manufacturing process;
- initiation of a government investigation into potential non-compliance with laws or regulations, or the initiation of a voluntary or involuntary recall with respect to one or more of our products;
- sanctions imposed by federal or state governments due to non-compliance with laws or regulations;
- general global economic conditions and political instability, such as the conflict between Russia and Ukraine; and
- economic conditions specific to the healthcare industry.

We have based our current and future expense levels largely on our investment plans and estimates of future events, although certain of our expense levels are, to a large extent, fixed. We may be unable to adjust spending in a timely manner to compensate for any unexpected revenue shortfall. Accordingly, any significant shortfall in sales relative to our planned expenditures would have an immediate adverse effect on our business, results of operations and financial condition. Further, as a strategic response to changes in the competitive environment or to changes in laws and regulations, we may from time to time make certain pricing, service or marketing decisions (e.g., reduce prices) that could have a material and adverse effect on our business, financial condition and results of operations. Due to the foregoing factors, our revenue and operating results are and will remain difficult to forecast.

Our indebtedness and our Revenue Interest Obligation to Ligand Pharmaceuticals Incorporated may limit our flexibility in operating our business and adversely affect our financial health and competitive position.

As of December 31, 2022, we had $24.3 million of indebtedness outstanding, consisting of $25.3 million outstanding under our SWK Loan Facility (as defined under Part II, Item 7. “Management’s Discussion and Analysis of Financial Condition and Results of Operations — Liquidity and Capital Resources — Credit Facilities”), net of $1.0 million of unamortized discount and deferred financing costs, . In addition, we are party to a royalty agreement with Ligand Pharmaceuticals Incorporated (“Ligand”) pursuant to which we assumed a restructured, long-term obligation to Ligand (the “Revenue Interest Obligation”), that requires us to pay Ligand 5.0% of future sales of the products we acquired from CorMatrix (as well as products substantially similar to those products), subject to annual minimum payments of $2.75 million and certain milestone payments if sales of the acquired products exceed certain thresholds. See Part II, Item 7. “Management’s Discussion and Analysis of Financial Condition and Results of Operations — Critical Accounting Policies and Significant Judgment and Estimates — Revenue Interest Obligation.”

In order to service this indebtedness and our Revenue Interest Obligation, and any additional indebtedness or other long-term obligations we may incur in the future, we need to generate sufficient levels of cash from our operating activities. Our ability to generate cash is subject, in part, to our ability to successfully execute our business strategy, as well as general economic, financial, competitive, regulatory and other factors beyond our control. We cannot assure you that our business will be able to generate sufficient levels of cash from operations or that future borrowings or other financings will be available to us in an amount sufficient to enable us to service our indebtedness, satisfy our obligations under the Revenue Interest Obligation and fund our other liquidity needs. To the extent we are required to use cash from operations or the proceeds of any future financing to service our indebtedness and satisfy our obligations under the Revenue Interest Obligation instead of funding working capital, capital expenditures or other general corporate purposes, we will be less able to plan for, or react to, changes in our business, industry and in the economy generally. This will place us at a competitive disadvantage compared to our competitors that have less indebtedness.

In addition, the agreements governing our SWK Loan Facility contains, and any agreements evidencing or governing other future indebtedness may also contain, certain covenants that limit our ability to engage in certain transactions that may be in our long-term best interests. Subject to certain limited exceptions, these covenants limit our ability to, among other things:

- incur additional indebtedness;
- incur certain liens;
- pay dividends or make other distributions on equity interests;
- enter into agreements restricting their subsidiaries' ability to pay dividends;
- redeem, repurchase or refinance subordinated indebtedness;
- consolidate, merge or sell or otherwise dispose of their assets;
- make investments, loans, advances, guarantees and acquisitions;
- enter into transactions with affiliates;
- amend or modify their governing documents;
- amend or modify certain material agreements;
- alter the business conducted by them and their subsidiaries; and
- enter into sale and leaseback transactions.

In addition to these covenants, the agreement governing our SWK Loan Facility also contains two financial covenants, the first of which is measured quarterly, and requires us to achieve a specified minimum aggregate revenue (as defined therein) for the preceding 12-month period, and the second of which requires us to maintain a minimum liquidity (as defined therein) of the greater of $5.0 million and the sum of the operating burn (as defined therein) for the two prior consecutive fiscal quarters then ended. While we were in compliance with all covenants under the agreement as of December 31, 2022, there can be no guarantee that we will not breach these covenants in the future.

Our ability to comply with these covenants may be affected by events and factors beyond our control. In the event that we breach one or more covenants, our lenders may choose to declare an event of default and require that we immediately repay all amounts outstanding, terminate any commitment to extend further credit and foreclose on the collateral granted to them to collateralize such indebtedness. The occurrence of any of these events could have a material adverse effect on our business, financial condition and results of operations.

In addition, we may incur significant additional indebtedness in the future. Although the agreement governing our SWK Loan Facility contains restrictions on the incurrence of additional indebtedness by us, such restrictions are subject to a number of qualifications and exceptions, and the indebtedness incurred in compliance with these restrictions could be substantial. Also, these restrictions do not prohibit us from incurring obligations that do not constitute indebtedness as defined therein. To the extent that we incur additional indebtedness or such other obligations, the risks associated with our substantial indebtedness described above will increase.

Various events permit the lender under the SWK Loan Facility to terminate the agreement, following a cure period. Such events include, without limitation, a failure to timely pay interest or principal, insolvency, or an action by the FDA or such other material adverse event impacting the operations of Aziyo. If the lender were to terminate either the SWK Loan Facility, the lender may declare all or any portion of these obligations to become immediately due and payable.

Our future capital needs are uncertain and we may need to raise funds in the future, and such funds may not be available on acceptable terms or at all.

Our future capital needs are uncertain and, as such, we may seek to raise additional capital through equity offerings, debt financings, collaborations or other arrangements. Any future funding requirements will depend on many factors, including, among other things:

- continued patient, physician and market acceptance of our products;
- the scope, rate of progress and cost of our current and future pre-clinical and clinical studies;
- the cost of our research and development activities and the cost of commercializing new products or technologies;
- the cost and timing of expanding our sales and marketing capabilities;
- the cost of filing and prosecuting patent applications and maintaining, defending and enforcing our patent or other intellectual property rights;
- the cost of defending, in litigation or otherwise, any claims that we infringe, misappropriate or otherwise violate third-party patents or other intellectual property rights;
- the costs of defending against or damages payable (to the extent above the applicable insurance coverage), for example, in connection with claims involving the FiberCel Recall;
- the cost and timing of additional regulatory approvals or certifications;
- costs associated with any product recall;
- the effect of competing technological and market developments;
- the expenses we incur in manufacturing and selling our products;
- the costs of developing and commercializing new products or technologies;
- the extent to which we acquire or invest in products, technologies and businesses, although we currently have no commitments or agreements relating to any of these types of transactions;
- the costs of operating as a public company;
- unanticipated general, legal and administrative expenses; and
- the effects on any of the above of the current COVID-19 pandemic or any other pandemic, epidemic or outbreak of infectious disease.

In addition, our operating plan may change as a result of any number of factors, including those set forth above and other factors currently unknown to us, and we may need additional funds sooner than anticipated. Any additional equity or debt financing that we raise may contain terms that are not favorable to us or our stockholders. If we raise additional funds by selling additional shares of our common stock or other securities convertible (directly or indirectly) into or exercisable or exchangeable for shares of our common stock, the issuance of such securities will result in dilution to our stockholders. The price per share at which we sell additional shares of our common stock, or securities convertible into or exercisable or exchangeable for shares of our common stock, in future transactions may be higher or lower than

the price per share paid by you. Furthermore, investors purchasing any securities we may issue in the future may have rights superior to your rights as a holder of our common stock.

In addition, any future debt financing into which we enter may impose upon us covenants that restrict our operations, including limitations on our ability to incur liens or additional debt, pay dividends, repurchase our common stock, make certain investments and engage in certain merger, consolidation or asset sale transactions. If we raise additional funds through collaboration and other 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.

Furthermore, we cannot be certain that additional funding will be available to us on acceptable terms, if at all. If we do not have, or are not able to obtain, sufficient funds, we may have to delay development or commercialization of our products or license to third parties the rights to commercialize products or technologies that we would otherwise seek to commercialize. We also may have to reduce marketing, customer support or other resources devoted to our products or cease operations. Any of these factors could harm our business, financial condition and results of operations.

Security breaches, loss of or damage to data, information technology system failures and other disruptions could compromise sensitive information related to our business or our customers' patients, or prevent us from accessing critical information and expose us to liability, which could adversely affect our business and our reputation.

In the ordinary course of our business, we may become exposed to, or collect and store, sensitive data, including procedure-based information and legally protected health information, credit card, and other financial information, insurance information and other potentially personally identifiable information. We also store sensitive intellectual property and other proprietary business information. Regardless of any precautions we may take, our information technology ("IT") and infrastructure, and that of our technology partners and providers, may be vulnerable to attack, damage and interruption from computer viruses and malware (e.g. ransomware), malicious code, natural disasters, terrorism, war, telecommunication and electrical failures, hacking, cyberattacks, phishing attacks and other social engineering schemes, employee theft or misuse, human error, fraud, denial or degradation of service attacks, sophisticated nation-state and nation-state-supported actors or unauthorized access or use by persons inside our organization, or persons with access to systems inside our organization.

Attacks upon IT systems are increasing in their frequency, levels of persistence, sophistication and intensity, and are being conducted by sophisticated and organized groups and individuals with a wide range of motives and expertise. In addition to unauthorized access to or acquisition of personal information, confidential information, intellectual property or other sensitive information, such attacks could include the deployment of harmful malware and ransomware, and may use a variety of methods, including denial-of-service attacks, social engineering and other means, to attain such unauthorized access or acquisition or otherwise affect service reliability and threaten the confidentiality, integrity and availability of information. As a result of the COVID-19 pandemic, we may also face increased cybersecurity risks due to our reliance on internet technology and the number of our employees who are working remotely, which may create additional opportunities for cybercriminals to exploit vulnerabilities. Because the techniques used to obtain unauthorized access, disable or degrade service, or sabotage systems change frequently and often are not foreseeable or recognized until launched against a target, we may be unable to anticipate these techniques or to implement adequate preventative measures. We may also experience security breaches that may remain undetected for an extended period. Even if identified, we may be unable to adequately investigate or remediate incidents or breaches due to attackers increasingly using tools and techniques that are designed to circumvent controls, to avoid detection, and to remove or obfuscate forensic evidence. Any breakdowns or breaches of our systems, or resulting access, disclosure, or other loss of information, could significantly disrupt our business and result in legal claims or proceedings, liability under laws that protect the privacy of personal information, and damage to our reputation, any of which could have a material and adverse effect on our business, financial condition and results of operations.

We and certain of our service providers are from time to time subject to cyberattacks and security incidents. While we do not believe that we have experienced any significant system failure, accident or security breach to date, if such an event were to occur and result in the unauthorized disclosure of sensitive or confidential patient or employee data, it could result in negative publicity, legal liability and damage to our reputation. Unauthorized disclosure of personally identifiable information could also expose us to sanctions for violations of data privacy laws and regulations around the world.

Despite our security measures, there can be no assurance that our efforts will prevent breakdowns or breaches to our or our third-party providers' databases or systems, or any resulting unauthorized access to, or disclosure and use of, non-public or other legally protected information. Our general liability and cybersecurity insurance coverage may not cover all claims, continue to be available to us on reasonable terms or be sufficient in amount to cover one or more large claims. Additionally, the insurer may disclaim coverage as to any claim. The successful assertion of one or more large claims against us that exceed or are not covered by our insurance coverage or changes in our insurance policies, including premium increases or the imposition of large deductible or co-insurance requirements, could have a material adverse effect on our business, prospects, operating results and financial condition.

Our success depends on our ability to retain and motivate key management personnel and other employees and consultants, to attract, retain and motivate additional qualified personnel and to effectively navigate changes in our senior management team.

Our success depends to a significant extent on our ability to attract, retain and motivate key management personnel and other employees and consultants for our business, including scientific, technical and sales and marketing personnel. There is currently a shortage of skilled executives and other personnel in our industry, which is likely to continue. As a result, competition for skilled personnel is intense and the turnover rate can be high. We may not be able to attract and retain personnel on acceptable terms, given the competition among numerous regenerative medicine and other healthcare companies, for individuals with similar skill sets. Many of the companies that we compete against for qualified personnel have substantially greater financial and other resources and different risk profiles than we do. They may also provide more diverse opportunities, better chances for career advancement and/or more attractive compensation. Some of these characteristics may be more appealing to high quality candidates than what we can offer. Furthermore, in order to offer attractive compensation, we may need to increase the level of cash compensation that we pay to them, which will reduce funds available for research and development and support of our commercialization and sales growth objectives. In addition, any headcount reductions taken as part of cost saving initiatives and as our business strategy evolves may negatively impact our ability to attract qualified personnel in the future. There can be no assurance that we will have sufficient cash available to offer our employees and consultants attractive compensation or that we will realize any corresponding benefits from the payment of such compensation. We are also vulnerable to the risk that these individuals may take actions, either within or outside the scope of their duties, that intentionally or unintentionally tarnish our brand and reputation or otherwise adversely affect our business. We also cannot prevent our senior management team from terminating their employment with us. Losing the services of any member of our senior management team could materially harm our business until a suitable replacement is found, and such replacement may not have equal experience and capabilities. In addition, we do not maintain "key person" insurance policies on the lives of any of our management team or other employees. The inability to recruit or a loss of the services of any executive, key employee or consultant may impede the progress of our research, development, commercialization and sales growth objectives, which could have a material adverse effect on our business, financial condition, results of operations and our ability to grow our business.

In addition, we have recently had changes within our senior management team. These changes, and any other changes to our senior management team we experience in the future, subject us to a number of additional risks, including risks pertaining to the coordination of responsibilities and tasks, the creation of new management systems and processes, differences in management style, effects on corporate culture and the need for transfer of historical knowledge. If our management team does not work together harmoniously, efficiently allocate responsibilities between themselves and implement and abide by effective controls, our operations will be adversely affected.

Our sales into foreign markets expose us to risks associated with international sales and operations.

Though we have historically focused our market development and commercial activities primarily in the United States, we have obtained marketing registrations, developed commercial and distribution capabilities and are currently selling CanGaroo and our cardiovascular products in several countries outside the United States through commercial partnerships or independent sales agents. Our international sales subject us to additional risks as compared to those we face in the United States.

The sale and shipment of our products across international borders subject us to extensive U.S. and foreign governmental trade, import and export and customs regulations and laws, including but not limited to, the Export

Administration Regulations, which are administered by the Bureau of Industry and Security ("BIS") within the Department of Commerce, and economic and trade sanctions, which are administered by the Office of Foreign Assets Control ("OFAC") within the U.S. Department of the Treasury. These regulations limit our ability to market, sell, distribute or otherwise transfer our products or technology to prohibited countries, territories, or persons.

Compliance with these regulations and laws is costly, and failure to comply with applicable legal and regulatory obligations could adversely affect us in a variety of ways that include, but are not limited to, significant criminal, civil and administrative penalties, including imprisonment of individuals, monetary fines, denial of export privileges, seizure of shipments and restrictions on certain business activities. The failure to comply with applicable legal and regulatory obligations could also result in the disruption of our distribution and sales activities.

These risks may limit or disrupt our sales and commercialization efforts outside the United States, restrict the movement of funds or result in the deprivation of contractual rights or the taking of property by nationalization or expropriation without fair compensation. Operating in international markets also requires significant management attention and financial support, and, as a result, will divert these resources away from our other operations.

We are subject to anti-bribery, anti-corruption and anti-money laundering laws, including the U.S. Foreign Corrupt Practices Act, as well as export control laws, customs laws, sanctions laws and other laws governing our operations. If we fail to comply with these laws, we could be subject to civil or criminal penalties, other remedial measures and legal expenses, any of which would adversely affect our business, financial condition and results of operations.

We are subject to anti-corruption, anti-bribery, and other similar laws and regulations in various jurisdictions in which we operate, including the U.S. Foreign Corrupt Practices Act ("FCPA"), the U.K. Bribery Act 2010 ("Bribery Act"), and other anti-corruption laws and regulations. These laws generally prohibit us and our officers, directors, employees and business partners acting on our behalf, including agents, from corruptly offering, promising, authorizing or providing anything of value to obtain or retain business or otherwise obtain favorable treatment and require companies to maintain accurate books and records and a system of internal controls or adequate procedures to prevent bribery.

We are also subject to economic sanctions laws, export control laws and regulations, as well as customs regulations, in the various jurisdictions in which we operate, including those administered and enforced by OFAC, the U.S. Department of State, BIS, His Majesty's Treasury of the United Kingdom, the United Nations Security Council, the European Union (and its member states) and other relevant sanctions authorities. Such laws and regulations prohibit or restrict certain operations, investment decisions, and sales activities, including dealings with certain countries or territories, and with certain governments and designated persons. Investigations of alleged sanctions and export controls violations can be expensive and disruptive.

As our international operations increase, we expect to implement policies and procedures designed to promote compliance by us and our directors, officers, employees, representatives, consultants and agents with the FCPA, the Bribery Act and other anti-corruption laws, as well as economic sanctions and export controls. We cannot assure you, however, that any such policies and procedures will be sufficient or that directors, officers, employees, representatives, consultants and agents have not engaged, and will not engage, in conduct for which we may be held responsible, nor can we assure you that our business partners have not engaged, and will not engage, in conduct that could materially affect their ability to perform their contractual obligations to us or result in our being held liable for such conduct. Violations of the FCPA, Bribery Act, other anti-corruption laws, economic sanctions, export control laws and/or anti-money laundering and anti-terrorism laws or regulations may result in severe criminal or civil sanctions, and we may be subject to other liabilities, which could have a material adverse effect on our business, financial condition and results of operations.

Our officers, employees, independent contractors, principal investigators, consultants, commercial partners and independent sales agents may engage in misconduct or activities that are improper under other laws and regulations, which would create liability for us.

We are exposed to the risk that our officers, employees, independent contractors (including contract research organizations ("CROs")), principal investigators, consultants, commercial partners and independent sales agents may engage in fraudulent conduct or other illegal activity and/or may fail to disclose unauthorized activities to us. Misconduct

by these parties could include, but is not limited to, intentional, reckless and/or negligent failures to comply with the laws and regulations of the FDA and its foreign counterparts, including, but not limited to, those relating to the manufacture, processing, packing, holding, investigating or distributing in commerce of medical devices, biological products and/or HCT/Ps, requiring the reporting of true, complete and accurate information to such regulatory bodies (including any safety problems associated with the use of our products), and relating to the conduct of clinical studies and the protection of human research subject.

In particular, companies involved in the manufacture of medical products are subject to laws and regulations intended to ensure that medical products that will be used in patients are safe and effective, and specifically that they are not adulterated or contaminated, that they are properly labeled, and have the identity, strength, quality and purity that they are represented to possess. Further, companies involved in the research and development of medical products are subject to extensive laws and regulations intended to protect research subjects and ensure the integrity of data generated from clinical studies and of the regulatory review process. Any misconduct in any of these areas, whether by our own employees or by contractors, vendors, business associates, consultants or other entities acting as our agents, could result in regulatory sanctions, criminal or civil liability and serious harm to our reputation. 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 preventing such conduct, mitigating risks, or reducing the chance of governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. If any such investigations or other actions or lawsuits are instituted against us, those actions could have a significant impact on our business, financial condition and results of operations, including, without limitation, the imposition of significant fines and other sanctions that may materially impair our ability to run a profitable business. Even if we are successful in defending against the imposition of any such fines or other sanctions, we could be required to incur substantial legal fees and other costs, and management's attention will be diverted from our core business operations, either of which would negatively affect our business, financial condition and results of operations.

Our ability to use certain tax attributes to offset future income tax liabilities may be subject to limitations.

We have net operating losses and other tax attributes, including net operating loss carryforwards ("NOLs") for federal income tax purposes of approximately $86.9 million and state NOLs of approximately $26.4 million as of December 31, 2022. If not utilized, $17.7 million of our NOLs will begin to expire for federal income tax purposes beginning in 2036, and our state NOLs will expire beginning in 2030. Our ability to utilize our federal NOLs will depend on our future income, and there is a risk that our NOLs could expire unused and be unavailable to offset future income tax liabilities, which could adversely affect our operating results.

In addition, our ability to utilize our NOLs may be subject to an annual limitation under the Internal Revenue Code of 1986, as amended (the "Code"). In general, under Sections 382 and 383 of the Code, a corporation that undergoes an "ownership change" is subject to limitations on its ability to utilize its pre-change NOLs or tax credits to offset future taxable income. If we undergo an ownership change or have previously undergone an ownership change, our ability to utilize federal NOLs or tax credits could be limited by Sections 382 and 383 of the Code. Additionally, future changes in our stock ownership, many of which are outside of our control, could result in an ownership change under Sections 382 and 383 of the Code. Our state NOLs or credits may also be impaired under state tax law. Accordingly, we may not be able to utilize a material portion of our federal and state NOLs or credits. Our ability to utilize our NOLs or credits is conditioned upon our attaining profitability and generating U.S. federal and state taxable income. Valuation allowances have been provided for all deferred tax assets related to our federal and state NOLs.

In addition, other tax attributes, such as interest carryforwards, are also subject to various limits on their use under the Code. We have established valuation allowances for our interest carry forwards to reflect these limitations and their anticipated impact on our ability to utilize these tax attributes.

Changes in tax laws, unfavorable resolution of tax contingencies or exposure to additional income tax liabilities could have a material impact on our results of operations or financial condition.

We are subject to income taxes as well as non-income based taxes in the United States. We may from time to time be subject to tax audits in various jurisdictions. Tax authorities may disagree with certain positions we have taken and assess additional taxes. We regularly assess the likely outcomes of any tax audits to which we are subject in order to

determine the appropriateness of our tax provision and have established contingency reserves for material, known tax exposures. However, the calculation of such tax exposures involves the application of complex tax laws and regulations in many jurisdictions, as well as interpretations as to the legality under state aid rules of the EU of tax advantages granted in certain jurisdictions. Therefore, there can be no assurance that we will accurately predict the outcomes of any tax audits to which we may be subject or that issues raised by tax authorities will be resolved at a financial cost that does not exceed our related reserves and the actual outcomes of any such audit could have a material impact on our results of operations or financial condition.

Changes in tax laws and regulations, or their interpretation and application, in the jurisdictions where we are subject to tax, could materially impact our effective tax rate. For example, changes in tax law implemented by the tax reform legislation known as H.R. 1, commonly referred to as the Tax Cuts and Jobs Act (the "TCJA") in the United States became effective in 2018 and 2019, and we expect the U.S. Treasury to continue to issue future notices and regulations under the TCJA. Certain provisions of the TCJA and the regulations issued thereunder could have a significant impact on our future results of operations as could interpretations made by us in the absence of regulatory guidance and judicial interpretations. In addition, in 2018, we established valuation allowances against all deferred tax assets (including interest carry forwards) to reflect certain limitations on these assets and their anticipated impact on our ability to utilize these tax assets following the adoption of the TCJA.

Additionally, the U.S. Congress, government agencies in jurisdictions outside the United States where we do business and the Organization for Economic Co-operation and Development (the "OECD") have recently focused on issues related to the taxation of multinational corporations. One example is in the area of "base erosion and profit shifting," where profits are claimed to be earned for tax purposes in low-tax jurisdictions, or payments are made between affiliates from a jurisdiction with high tax rates to a jurisdiction with lower tax rates. The OECD has released several components of its comprehensive plan to create an agreed set of international rules for fighting base erosion and profit shifting. As a result, the tax laws in the United States and other countries, in which we do business, could change on a prospective or retroactive basis and any such changes could materially adversely affect our business, financial condition and results of operations.

As we conduct clinical studies designed to generate long-term data on some of our existing products, the data we generate may not be consistent with our existing data and may demonstrate less favorable safety or efficacy.

We are currently collecting and plan to continue collecting long-term clinical data regarding the quality, safety and effectiveness of some of our existing products. The clinical data collected and generated as part of these studies will further strengthen our clinical evaluation concerning safety and performance of these products. We believe that this additional data will help with the marketing of our products by providing surgeons and physicians with additional confidence in their long-term safety and efficacy. If the results of these clinical studies are negative, these results could reduce demand for our products and significantly reduce our ability to achieve expected net sales. We do not expect to undertake such studies for all of our products and will only do so in the future where we anticipate the benefits will outweigh the costs and risks. For these reasons, surgeons and physicians could be less likely to purchase our products than competing products for which longer-term clinical data are available. Also, we may not choose or be able to generate the comparative data that some of our competitors have or are generating and we may be subject to greater regulatory and product liability risks. If we are unable to or determine not to collect sufficient long-term clinical data supporting the quality, safety and effectiveness of our existing products, our business, financial condition and results of operations could be adversely affected.

Our estimates of market opportunity and forecasts of market and sales growth may prove to be inaccurate, and even if the markets in which we compete achieve the forecasted growth, our business could fail to grow at similar rates, if at all.

Market opportunity estimates and growth forecasts are inherently uncertain. Our estimates of the annual total addressable markets for our products are based on a number of internal and third-party estimates and assumptions, including, without limitation, the number of implantable electronic device procedures and orthopedic/spinal repair procedures, as well as the number of procedures using biologic products annually in the United States. While we believe our assumptions and the data underlying our estimates are reasonable, these assumptions and estimates may not be correct and the conditions supporting our assumptions or estimates may change at any time, thereby reducing the predictive

accuracy of these underlying factors. As a result, our estimates of the annual total addressable market for any of our products may prove to be incorrect. If the actual number of procedures, the price at which we are able to sell any of our products, or the annual total addressable market is smaller than we have estimated, it may impair our sales growth and have an adverse impact on our business, financial condition and results of operations.

Risks Related to Government Regulation

The regulatory approval, certification and clearance processes of the FDA and comparable foreign authorities and notified bodies are lengthy, time consuming and inherently unpredictable, and if we are ultimately unable to obtain regulatory approval or other marketing authorizations or certifications for our products and product candidates, our business will be substantially harmed.

The medical device and biologics industries are regulated extensively by governmental authorities, principally the FDA, the EU legislative bodies, and corresponding state and foreign regulatory agencies and authorities. The time required to obtain approval, clearance, certification of conformity or other marketing authorizations from the FDA, notified bodies in the EU, approved bodies in the UK, and comparable foreign authorities is unpredictable but can often take many years following the commencement of clinical studies and depends upon numerous factors, including the substantial discretion of the regulatory authorities. In addition, policies, regulations, or the type and amount of clinical data necessary to gain clearance, certification or approval may change during the course of a product candidate's clinical development and may vary among jurisdictions.

Before we can market or sell a new medical device or a new use of or a claim for or significant modification to an existing medical device in the United States, we must obtain either clearance from the FDA under Section 510(k) of the Federal Food, Drug, and Cosmetic Act (the "FDCA") or approval of an application for premarket approval, or PMA, unless an exemption applies. In the United States, we have obtained 510(k) premarket clearance from the FDA to market products such as our CanGaroo, VasCure, ProxiCor and Tyke products. In the 510(k) premarket clearance process, the FDA must determine that a proposed device is "substantially equivalent" to a device legally on the market, known as a "predicate" device, with respect to intended use, technology and safety and effectiveness, in order to clear the proposed device for marketing. Clinical data is sometimes required to support a finding of substantial equivalence. Under certain conditions, a medical device is required to be approved under a PMA before it may be legally marketed. The PMA pathway requires an applicant to demonstrate the safety and effectiveness of the device based, in part, on extensive data, including, but not limited to, technical, nonclinical, clinical study, manufacturing and labeling data. The PMA process is typically required for devices that are deemed to pose the greatest risk, such as life-sustaining, life-supporting or implantable devices. However, some devices are automatically subject to the PMA pathway regardless of the level of risk they pose because they have not previously been classified into a lower risk class by the FDA. Manufacturers of these devices may request that FDA review such devices in accordance with the *de novo* classification procedure, which allows a manufacturer whose novel device would otherwise require the submission and approval of a PMA prior to marketing to request down-classification of the device on the basis that the device presents low or moderate risk. If the FDA agrees with the down classification based on a *de novo* submission, the FDA will authorize the device for marketing. This device type can then be used as a predicate device for future 510(k) submissions.

The process of obtaining regulatory clearances or approvals, or completing the *de novo* classification process, to market a medical device can be costly and time consuming, and we may not be able to successfully obtain pre-market reviews on a timely basis, if at all. If the FDA requires us to go through a lengthier, more rigorous examination for our products than we expect, our product introductions or modifications could be delayed or canceled, which could cause our sales to decline. Further, even where a PMA is not required, we cannot assure you that we will be able to obtain 510(k) clearances with respect to such product candidates or modifications to previously cleared products.

Subject to the transitional provisions and to the extent we sell medical devices in EU member states, our products must comply with the general safety and performance requirements of the EU Medical Devices Regulation (Regulation (EU) No 2017/745). Compliance with these requirements is a prerequisite to be able to affix the European Conformity ("CE") mark to our products, without which they cannot be sold or marketed in the EU. All medical devices placed on the market in the EU must meet the general safety and performance requirements laid down in Annex I to the EU Medical Devices Regulation including the requirement that a medical device must be designed and manufactured in such a way

that, during normal conditions of use, it is suitable for its intended purpose. Medical devices must be safe and effective and must not compromise the clinical condition or safety of patients, or the safety and health of users and – where applicable – other persons, provided that any risks which may be associated with their use constitute acceptable risks when weighed against the benefits to the patient and are compatible with a high level of protection of health and safety, taking into account the generally acknowledged state of the art. To demonstrate compliance with the general safety and performance requirements, we must undergo a conformity assessment procedure, which varies according to the type of medical device and its (risk) classification. Except for low risk medical devices (Class I), where the manufacturer can self-assess the conformity of its products with the general safety and performance requirements (except for any parts which relate to sterility, metrology or reuse aspects), a conformity assessment procedure requires the intervention of a notified body. The notified body would typically audit and examine the technical file and the quality system for the manufacture, design and final inspection of our devices. If satisfied that the relevant product conforms to the relevant general safety and performance requirements, the notified body issues a certificate of conformity, which the manufacturer uses as a basis for its own declaration of conformity. The manufacturer may then apply the CE mark to the device, which allows the device to be placed on the market throughout the EU. If we fail to comply with applicable laws and regulations, we would be unable to affix the CE mark to our products, which would prevent us from selling them within the EU.

The aforementioned EU rules are generally applicable in the European Economic Area (“ EEA”) (which consists of the 27 EU member states plus Norway, Liechtenstein and Iceland). Non-compliance with the above requirements would also prevent us from selling our products in these three countries.

Since the end of the Brexit transition period on January 1, 2021, Great Britain (England, Scotland and Wales) has not been subject to EU laws, however under the terms of the Ireland/Northern Ireland Protocol, Northern Ireland continues to follow EU law. The EU laws that have been transposed into United Kingdom (“UK”) law through secondary legislation remain applicable in Great Britain. However, under the Retained EU Law (Revocation and Reform) Bill 2022, which is currently before the UK parliament, any retained EU law not expressly preserved and “assimilated” into domestic law or extended by ministerial regulations (to no later than June 23, 2026) will automatically expire and be revoked by December 31, 2023. In addition, new legislation such as the EU Medical Devices Regulation (Regulation (EU) No 2017/745) will not be applicable. The UK government has passed a new Medicines and Medical Devices Act 2021, which introduces delegated powers in favor of the Secretary of State or an ‘appropriate authority’ to amend or supplement existing regulations in the area of medicinal products and medical devices. This allows new rules to be introduced in the future by way of secondary legislation, which aims to allow flexibility in addressing regulatory gaps and future changes in the fields of human medicines, clinical trials and medical devices.

Since January 1, 2021, the Medicines and Healthcare Products Regulatory Agency (“MHRA”) has become the sovereign regulatory authority responsible for Great Britain. Following the end of the Brexit transition period, new regulations require all medical devices to be registered with the MHRA. From January 1, 2022, manufacturers based outside the UK need to appoint a UK responsible person that has a registered place of business in the UK to register devices with the MHRA.

On June 26, 2022, the MHRA published its response to a 10-week consultation on the post-Brexit regulatory framework for medical devices and diagnostics. MHRA seeks to amend the UK Medical Devices Regulations 2002 (which are based on EU legislation, primarily the EU Medical Devices Directive and the EU In Vitro Diagnostic Medical Devices Directive), in particular to create a new access pathway to support innovation, create an innovative framework for regulating software and artificial intelligence as medical devices, reform IVD regulation and foster sustainability through the reuse and remanufacture of medical devices. Regulations implementing the new regime were originally scheduled to come into force in July 2023, but have recently been postponed to July 2024. Devices bearing CE marks issued by EU notified bodies under the EU Medical Devices Regulation or EU Medical Devices Directive are now subject to transitional arrangements. In its consultation response, the MHRA indicated that the future UK regulations will allow devices certified under the EU Medical Devices Regulation to be placed on the market in Great Britain under the CE mark until either the certificate expires or for five years after the new regulations take effect, whichever is sooner. Devices certified under the EU Medical Devices Directive could continue to be placed on the market until either the certificate expires or for three years after the new regulations take effect, whichever is sooner. Following these transitional periods, it is expected that all medical devices will require a UK Conformity Assessed (“UKCA”) mark. Manufacturers may choose to use the UKCA mark on a voluntary basis until June 30, 2023. However, UKCA marking will not be recognized in the EU. The rules for

placing medical devices on the market in Northern Ireland, which is part of the UK, differ from those in the rest of the UK. Compliance with this legislation is a prerequisite to be able to affix the UKCA mark to our products, without which they cannot be sold or marketed in Great Britain.

Under the terms of the Ireland/Northern Ireland Protocol, Northern Ireland follows EU rules on medical devices and devices marketed in Northern Ireland require assessment according to the EU regulatory regime. Such assessment may be conducted by an EU notified body, in which case a CE mark is required before placing the device on the market in the EU or Northern Ireland. Alternatively, if a UK approved body conducts such assessment, a 'UKNI' mark is applied and the device may only be placed on the market in Northern Ireland and not the EU.

The EU-UK Trade and Cooperation Agreement ("TCA"), came into effect on January 1, 2021. The TCA does not specifically refer to medical devices, but does provide for cooperation and exchange of information in the area of product safety and compliance, including market surveillance, enforcement activities and measures, standardization related activities, exchanges of officials, and coordinated product recalls (or other similar actions). For medical devices that are locally manufactured but use components from other countries, the "rules of origin" criteria will need to be reviewed. Depending on which countries products will be ultimately sold in, manufacturers may start seeking alternative sources for components if this would allow them to benefit from no tariffs. The rules for placing medical devices on the Northern Ireland market will differ from those in Great Britain. These modifications may have an effect on the way we intend to conduct our business in these countries.

The FDA or any foreign regulatory agency or notified body can delay, limit or deny approval, certification or clearance of our product candidates or require us to conduct additional nonclinical or clinical testing or abandon a program for many reasons, including:

- the FDA or the applicable foreign regulatory agency or notified body's disagreement with the design or implementation of our clinical studies;
- negative or ambiguous results from our clinical studies or results that may not meet the level of statistical significance required by the FDA or comparable foreign regulatory agencies or notified body for approval or certification;
- serious and unexpected drug or device-related side effects experienced by participants in our clinical studies or by individuals using devices similar to our products or natural product candidates;
- our inability to demonstrate to the satisfaction of the FDA or the applicable foreign regulatory agency or notified body that our product candidates are safe and effective for their intended uses, or in the case of the 510(k) clearance process, that our product candidate is substantially equivalent to a predicate device;
- the FDA's or the applicable foreign regulatory agency or notified body's disagreement with the interpretation of data from pre-clinical or clinical studies;
- our inability to demonstrate the clinical and other benefits of our product candidates outweigh any safety or other perceived risks;
- the FDA's or the applicable foreign regulatory agency or notified body's requirement for additional pre-clinical studies or clinical studies;
- the FDA's or the applicable foreign regulatory agency or notified body's disagreement regarding the formulation, labeling or the specifications of our products or future product candidates;
- the FDA's or the applicable foreign regulatory agency's failure to approve the manufacturing processes or facilities of third-party manufacturers with which we contract; or

- the potential for approval or clearance policies or regulations of the FDA or the applicable foreign regulatory agencies or notified bodies to significantly change in a manner rendering our clinical data insufficient for approval.

Of the large number of products in development, only a small percentage successfully complete the FDA or foreign regulatory approval or certification processes and are commercialized. The lengthy approval, marketing authorization or certification process, as well as the unpredictability of future clinical study results, may result in our failing to obtain regulatory clearance, approval, certification or other marketing authorization to market our product candidates, which would significantly harm our business, financial condition and results of operations.

Even if we eventually complete clinical testing and receive approval or clearance of an FDA or foreign marketing application or certification for our product candidates, the FDA or the applicable foreign regulatory agency or notified body may grant clearance, certification, approval or other marketing authorization contingent on the performance of costly additional clinical studies, including post-market clinical studies. The FDA or the applicable foreign regulatory agency or notified body also may clear, approve or authorize for marketing a product candidate for a more limited indication or patient population than we originally requested, and the FDA or applicable foreign regulatory agency or notified body may not approve, certify or authorize the labeling that we believe is necessary or desirable for the successful commercialization of a product candidate. Any delay in obtaining, or inability to obtain, applicable regulatory clearance, certification, approval or other marketing authorization would delay or prevent commercialization of that product candidate and would materially adversely impact our business and prospects.

Our products may cause or contribute to adverse medical events or be subject to failures or malfunctions that we are required to report to the FDA, and if we fail to do so, we would be subject to sanctions that could harm our reputation, business, financial condition and results of operations. The discovery of serious safety issues with our products, or a recall of our products either voluntarily or at the direction of the FDA or another governmental authority, could have a negative impact on us.

Some of our marketed products are subject to Medical Device Reporting ("MDR") obligations, which require that we report to the FDA, the competent authorities of the EU member states or any other foreign regulatory authorities, any incident in which our products may have caused or contributed to a death or serious injury, or in which our products malfunctioned and, if the malfunction were to recur, it could likely cause or contribute to a death or serious injury. The timing of our obligation to report under the MDR regulations is triggered by the date we become aware of the adverse event as well as the nature of the event. We may fail to report adverse events of which we become aware within the prescribed timeframe. We may also fail to recognize that we have become aware of a reportable adverse event, especially if it is not reported to us as an adverse event or if it is an adverse event that is unexpected or removed in time from the use of our product. If we fail to comply with our reporting obligations, the FDA, or the competent authorities of the EU member states, could take action, including warning letters, untitled letters, administrative actions, criminal prosecution, imposition of civil monetary penalties, revocation of our device clearance or approval, seizure of our products or delay in clearance, certification or approval of future products.

The FDA, the competent authorities of the EU member states, and foreign regulatory authorities have the authority to require the recall of commercialized products in the event of material deficiencies or defects in design or manufacture of a product or in the event that a product poses an unacceptable risk to health. The FDA's authority to require a recall for a medical device must be based on a finding that there is reasonable probability that the device could cause serious injury or death. With respect to human cells, tissues, and cellular and tissue-based products ("HCT/Ps"), the FDA may also require a recall where the conditions of manufacture of the HCT/P do not provide adequate protections against risks of communicable disease transmission, or where the HCT/P is infected or contaminated so as to be a source of dangerous infections to humans. We may also choose to voluntarily recall a product if any material deficiency is found. A government-mandated or voluntary recall by us could occur as a result of an unacceptable risk to health, component failures, malfunctions, manufacturing defects, labeling or design deficiencies, packaging defects or other deficiencies or failures to comply with applicable regulations. Product defects or other errors may occur in the future.

In the EU, we must comply with the EU medical device vigilance system. Under this system, serious incidents and Field Safety Corrective Actions ("FSCAs") must be reported to the relevant authorities of the EU member states.

These reports will have to be submitted through Eudamed – once functional – and aim to ensure that, in addition to reporting to the relevant authorities of the EU member states, other actors such as the economic operators in the supply chain will also be informed. Until Eudamed is fully functional, the corresponding provisions of the EU Medical Devices Directive continue to apply. FSCAs must be communicated by the manufacturer or its legal representative to its customers and/or to the end users of the device through Field Safety Notices ("FSNs"). For similar serious incidents that occur with the same device or device type and for which the root cause has been identified or a FSCA implemented or where the incidents are common and well documented, manufacturers may provide periodic summary reports instead of individual serious incident reports. The aforementioned EU rules are generally applicable in the EEA.

Depending on the corrective action we take to redress a product's deficiencies or defects, the FDA or foreign regulatory authorities may require, or we may decide, that we will need to obtain new clearances, certifications or approvals for the device before we may market or distribute the corrected device. Seeking such clearances, certification or approvals may delay our ability to replace the recalled devices in a timely manner. Moreover, if we do not adequately address problems associated with our devices, we may face additional regulatory enforcement action, including FDA or foreign regulatory body warning letters, product seizure, injunctions, administrative penalties or civil or criminal fines.

Companies are required to maintain certain records of recalls and corrections, even if they are not reportable to the FDA or foreign regulatory bodies. We may initiate voluntary withdrawals or corrections for our products in the future that we determine do not require notification of the FDA or foreign regulatory bodies. If the FDA or foreign regulatory body disagrees with our determinations, it could require us to report those actions as recalls, and we may be subject to enforcement action. A future recall announcement could harm our reputation with customers, potentially lead to product liability claims against us and negatively affect our sales. Any corrective action, whether voluntary or involuntary, as well as defending ourselves in a lawsuit, will require the dedication of our time and capital, distract management from operating our business and may harm our reputation and financial results.

Modifications to our medical device products may require new 510(k) clearances or other marketing authorizations or certifications, and if we make modifications to such products without obtaining requisite marketing authorization, we may be required to cease marketing or recall the modified products until clearances or other marketing authorizations or certifications are obtained.

Any modification to a cleared or approved medical device that could significantly affect its safety or effectiveness, or that would constitute a major change in its intended use, design or manufacture, requires a new 510(k) clearance or, possibly, approval of a PMA. The FDA requires every manufacturer to make this determination in the first instance, but the FDA may review any manufacturer's decision. The FDA may not agree with our decisions regarding whether new clearances or approvals are necessary. We may make modifications or add features to any of our product candidates that are cleared under the 510(k) clearance process in the future that we believe do not require a new 510(k) clearance or approval of a PMA. If the FDA disagrees with our determination and requires us to submit new 510(k) notifications or PMA applications for modifications to our products for which we have concluded that new clearances or approvals are unnecessary, we may be required to cease marketing or to recall the modified product until we obtain clearance or approval, and we may be subject to significant regulatory fines or penalties. In addition, the FDA may not approve or clear our products for the indications that are necessary or desirable for successful commercialization or could require clinical studies to support any modifications. Any delay or failure in obtaining required clearances or approvals for such changes would adversely affect our ability to introduce new or enhanced products in a timely manner, which in turn would harm our future growth. Any of these actions would harm our operating results.

In the EU, devices lawfully placed on the market pursuant to the EU Medical Devices Directive prior to May 26, 2021 may generally continue to be made available on the market or put into service until at least the end of 2027, provided that the requirements of the transitional provisions are fulfilled. In particular, the certificate in question must still be valid and no substantial change must be made to the device as such a modification would trigger the obligation to obtain a new certification under the EU Medical Devices Regulation and therefore to have a notified body conducting a new conformity assessment of the devices. Once our devices will be certified under the EU Medical Devices Regulation, we must inform the notified body that carried out the conformity assessment of the medical devices that we market or sell in the EU and EEA of any planned substantial changes to our quality system or substantial changes to our medical devices that could affect compliance with the general safety and performance requirements laid down in Annex I to the EU Medical Devices

Regulation or cause a substantial change to the intended use for which the device has been CE marked. The notified body will then assess the planned changes and verify whether they affect the products' ongoing conformity with the EU Medical Devices Regulation. If the assessment is favorable, the notified body will issue a new certificate of conformity or an addendum to the existing certificate attesting compliance with the general safety and performance requirements and quality system requirements laid down in the Annexes to the EU Medical Devices Regulation. The notified body may disagree with our proposed changes and product introductions or modifications could be delayed or canceled, which could adversely affect our ability to grow our business.

The misuse or off-label use of our products may harm our reputation in the marketplace, result in injuries that lead to product liability suits or result in costly investigations, fines or sanctions by regulatory bodies if we are deemed to have engaged in the promotion of these uses, any of which could be costly to our business.

Our currently marketed products have been cleared by the FDA for specific indications. For example, our SimpliDerm product has been labeled for use to repair or replace damaged or inadequate integumental tissue, our CanGaroo Envelope is intended to securely hold an implantable electronic device to create a stable environment when implanted in the body and, in January 2021, we received CE certification for updated labeling of our CanGaroo envelope to allow for the addition of the antibiotic gentamicin in EU markets. We train our marketing personnel and direct sales force to not promote our devices for uses outside of the FDA-approved indications for use, known as "off-label uses." We cannot, however, prevent a physician from using our products off-label, when in the physician's independent professional medical judgment, he or she deems it appropriate. There may be increased risk of injury to patients if physicians attempt to use our products off-label. Furthermore, the use of our products for indications other than those authorized or certified by the FDA or by any foreign regulatory body or notified body may not effectively treat such conditions, which could harm our reputation in the marketplace among physicians and patients.

If the FDA or any foreign regulatory body determines that our promotional materials or training constitute promotion of an off-label use, it could request that we modify our training or promotional materials or subject us to regulatory or enforcement actions, including the issuance or imposition of an untitled letter, which is used for violators that do not necessitate a warning letter, injunction, seizure, civil fine or criminal penalties. It is also possible that other federal, state or foreign enforcement authorities might take action under other regulatory authority, such as false claims laws, if they consider our business activities to constitute promotion of an off-label use, which could result in significant penalties, including, but not limited to, criminal, civil and administrative penalties, damages, fines, disgorgement, exclusion from participation in government healthcare programs and the curtailment of our operations.

In addition, physicians may misuse our products or use improper techniques if they are not adequately trained, potentially leading to injury and an increased risk of product liability. If our devices are misused or used with improper technique, we may become subject to costly litigation by our customers or their patients. As described above, product liability claims could divert management's attention from our core business, harm our reputation, be expensive to defend and result in sizeable damage awards against us that may not be covered by insurance.

Failure to comply with post-marketing regulatory requirements could subject us to enforcement actions, including substantial penalties, and might require us to recall or withdraw a product from the market.

We are subject to ongoing and pervasive regulatory requirements governing, among other things, the manufacture, marketing, advertising, medical device reporting, sale, promotion, import, export, registration and listing of devices. For example, we must submit periodic reports to the FDA as a condition of receiving 510(k) clearances and other marketing authorizations. These reports include information about failures and certain adverse events associated with the device after its clearance. Failure to submit such reports, or failure to submit the reports in a timely manner, could result in enforcement action by the FDA. Following its review of the periodic reports, the FDA might ask for additional information or initiate further investigation.

The regulations to which we are subject are complex and have become more stringent over time. Regulatory changes could result in restrictions on our ability to continue or expand our operations, and higher than anticipated costs or lower than anticipated sales. Even after we have obtained the proper regulatory clearance to market a device, we have ongoing responsibilities under FDA regulations and applicable foreign laws and regulations. The FDA, state and foreign

regulatory authorities have broad enforcement powers. Our failure to comply with applicable regulatory requirements could result in enforcement action by the FDA, state or foreign regulatory authorities, which may include any of the following sanctions:

- untitled letters or warning letters;
- fines, injunctions, consent decrees and civil penalties;
- recalls, termination of distribution, administrative detention or seizure of our products;
- customer notifications or repair, replacement or refunds;
- operating restrictions or partial suspension or total shutdown of production;
- delays in or refusal to grant our requests for future clearances or approvals or foreign marketing authorizations or certification of new products, new intended uses or modifications to existing products;
- withdrawals or suspensions of our current 510(k) clearances, or certifications resulting in prohibitions on sales of our products;
- FDA refusal to issue certificates to foreign governments needed to export products for sale in other countries; and
- criminal prosecution.

Any of these sanctions could result in higher than anticipated costs or lower than anticipated sales and have a material adverse effect on our reputation, business, financial condition and results of operations.

In addition, the FDA may change its clearance policies, adopt additional regulations or revise existing regulations, or take other actions, which may prevent or delay clearance or approval of our future products under development or impact our ability to modify our currently cleared products on a timely basis. Such policy or regulatory changes could impose additional requirements upon us that could delay our ability to obtain new clearances or approvals, increase the costs of compliance or restrict our ability to maintain our clearances of our current products. For example, on February 23, 2022, the FDA issued a proposed rule to amend the QSR, which establishes current good manufacturing practice requirements for medical device manufacturers, to align more closely with the International Organization for Standardization standards. This proposal has not yet been finalized or adopted. Accordingly, it is unclear the extent to which this or any other proposals, if adopted, could impose additional or different regulatory requirements on us that could increase the costs of compliance or otherwise negatively affect our business.

Additionally, in September 2019, the FDA finalized guidance describing an optional "safety and performance based" premarket review pathway for manufacturers of "certain, well-understood device types" to demonstrate substantial equivalence under the 510(k) clearance pathway by showing that such device meets objective safety and performance criteria established by the FDA, thereby obviating the need for manufacturers to compare the safety and performance of their medical devices to specific predicate devices in the clearance process. The FDA is developing a list of device types appropriate for the "safety and performance based" pathway and will continue to develop product-specific guidance documents that identify the performance criteria for each such device type, as well as the testing methods recommended in the guidance documents, where feasible. The FDA may establish performance criteria for classes of devices for which we or our competitors seek or currently have received clearance, and it is unclear the extent to which such performance standards, if established, could impact our ability to obtain new 510(k) clearances or otherwise create competition that may negatively affect our business.

The FDA's and other regulatory authorities' and notified bodies' policies may change and additional government regulations may be promulgated that could prevent, limit or delay regulatory clearance or approval of our product

candidates. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained and we may not achieve or sustain profitability.

Our HCT/P products are subject to extensive government regulation, and our failure to comply with these requirements could cause our business to suffer.

In the United States, we sell human tissue-derived bone allografts, such as ViBone, Fiber VBM, and OsteGro V, which are referred to by the FDA as HCT/Ps. Certain HCT/Ps are regulated by the FDA solely under Section 361 of the PHSA and are referred to as "Section 361 HCT/Ps," while other HCT/Ps are subject to FDA's regulatory requirements applicable to medical devices or biologics. Section 361 HCT/Ps do not require 510(k) clearance, PMA approval, BLAs, or other premarket authorization from FDA before marketing. To be regulated as Section 361 HCT/Ps, these products must meet FDA's criteria to be considered "minimally manipulated" and intended for "homologous use," among other requirements. HCT/Ps that do not meet the criteria of Section 361 are regulated under Section 351 of the PHSA. HCT/Ps regulated as "351" HCT/Ps are subject to premarket review and approval by the FDA. We believe our HCT/Ps are regulated solely under Section 361 of the PHSA and, therefore, we have not sought or obtained 510(k) clearance, PMA approval, or licensure through a BLA. The FDA could disagree with our determination that our human tissue products are Section 361 HCT/Ps and could determine that these products are biologics requiring a BLA or medical devices requiring 510(k) clearance or PMA approval, and could require that we cease marketing such products and/or recall them pending appropriate clearance, approval or license from the FDA. For example, in public comments, the FDA has suggested that the use of human-derived acellular dermal matrices, such as SimpliDerm, may not be considered HCT/Ps when utilized in certain breast reconstruction procedures. As a result, we may be required to conduct clinical studies and/or seek approval of a PMA before we are able to market SimpliDerm for use in breast reconstruction.

Even though we believe that our HCT/Ps are not subject to premarket approval or review, HCT/Ps are subject to donor eligibility and screening, Good Tissue Practices, product labeling and post-market reporting requirements. If we or our suppliers fail to comply with these requirements, we could be subject to FDA enforcement action, including, for example, warning letters, fines, injunctions, product recalls or seizures and, in the most serious cases, criminal penalties.

The clinical study process is lengthy and expensive with uncertain outcomes. We have limited data and experience regarding the safety and efficacy of our products. Results of earlier studies may not be predictive of future clinical study results, or the safety or efficacy profile for such products.

Clinical testing is difficult to design and implement, can take many years, can be expensive and carries uncertain outcomes. The long-term effects of using our products in a large number of patients have not been studied, and the results of short-term clinical use of such products do not necessarily predict long-term clinical benefits or reveal long-term adverse effects.

The results of pre-clinical and clinical studies of our products conducted to date and ongoing or future studies of our current, planned or future products may not be predictive of the results of later clinical studies, and interim results of a clinical study do not necessarily predict final results. Our interpretation of data and results from our clinical studies do not ensure that we will achieve similar results in future clinical studies. In addition, pre-clinical and clinical data are often susceptible to various interpretations and analyses, and many companies that have believed their products performed satisfactorily in pre-clinical studies and earlier clinical studies have, nonetheless, failed to replicate results in later clinical studies. Products in later stages of clinical studies may fail to show the desired safety and efficacy despite having progressed through nonclinical studies and earlier clinical studies. Failure can occur at any stage of clinical testing. Our clinical studies may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical and non-clinical testing in addition to those we have planned.

The initiation and completion of any of clinical studies may be prevented, delayed or halted for numerous reasons. We may experience delays in our ongoing clinical studies for a number of reasons, which could adversely affect the costs, timing or successful completion of our clinical studies, including related to the following:

- we may be required to submit an investigational device exemption ("IDE"), application to the FDA, which must become effective prior to commencing certain human clinical studies of medical devices, and the FDA may reject our IDE application and notify us that we may not begin clinical studies;
- regulators and other comparable foreign regulatory authorities may disagree as to the design or implementation of our clinical studies;
- regulators and/or IRBs, or other reviewing bodies may not authorize us or our investigators to commence a clinical study or to conduct or continue a clinical study at a prospective or specific study site;
- we may not reach agreement on acceptable terms with prospective CROs and clinical study sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and study sites;
- clinical studies may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical studies or abandon product development programs;
- the number of subjects or patients required for clinical studies may be larger than we anticipate, enrollment in these clinical studies may be insufficient or slower than we anticipate, and the number of clinical studies being conducted at any given time may be high and result in fewer available patients for any given clinical study, or patients may drop out of these clinical studies at a higher rate than we anticipate;
- our third-party contractors, including those manufacturing products or conducting clinical studies on our behalf, may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner or at all;
- we might have to suspend or terminate clinical studies for various reasons, including a finding that the subjects are being exposed to unacceptable health risks;
- we may have to amend clinical study protocols or conduct additional studies to reflect changes in regulatory requirements or guidance, which we may be required to submit to an IRB and/or regulatory authorities for re-examination;
- regulators, IRBs or other parties may require or recommend that we or our investigators suspend or terminate clinical research for various reasons, including safety signals or noncompliance with regulatory requirements;
- the cost of clinical studies may be greater than we anticipate;
- clinical sites may not adhere to the clinical protocol or may drop out of a clinical study;
- we may be unable to recruit a sufficient number of clinical study sites;
- regulators, IRBs or other reviewing bodies may fail to approve or subsequently find fault with our manufacturing processes or facilities of third-party manufacturers with which we enter into agreement for clinical and commercial supplies, the supply of devices or other materials necessary to conduct clinical studies may be insufficient, inadequate or not available at an acceptable cost, or we may experience interruptions in supply;

- approval policies or regulations of the FDA, the EU legislative bodies or applicable foreign regulatory agencies may change in a manner rendering our clinical data insufficient for approval; and

- our current or future products may have undesirable side effects or other unexpected characteristics.

In addition, disruptions caused by the COVID-19 pandemic has increased and may increase the likelihood that we encounter such difficulties or delays in initiating, enrolling, conducting or completing our planned and ongoing clinical studies. Any of these occurrences may significantly harm our business, financial condition and prospects. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical studies may also ultimately lead to the denial of regulatory approval of our product candidates.

Patient enrollment in clinical studies and completion of patient follow-up depend on many factors, including the size of the patient population, the nature of the study protocol, the proximity of patients to clinical sites, the eligibility criteria for the clinical study, patient compliance, competing clinical studies and clinicians' and patients' perceptions as to the potential advantages of the product being studied in relation to other available therapies, including any new treatments that may be approved for the indications we are investigating. For example, patients may be discouraged from enrolling in our clinical studies if the study protocol requires them to undergo extensive post-treatment procedures or follow-up to assess the safety and efficacy of a product candidate, or they may be persuaded to participate in contemporaneous clinical studies of a competitor's product candidate. In addition, patients participating in our clinical studies may drop out before completion of the study or experience adverse medical events unrelated to our products. Delays in patient enrollment or failure of patients to continue to participate in a clinical study may delay commencement or completion of the clinical study, cause an increase in the costs of the clinical study and delays, or result in the failure of the clinical study.

Even if our future products are cleared or approved in the United States, commercialization of our products in foreign countries would require clearance or approval by regulatory authorities in those countries. Clearance or approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from, and greater than, those in the United States, including additional pre-clinical studies or clinical studies. Any of these occurrences could have an adverse effect on our business, financial condition and results of operations.

Disruptions at the FDA and other government agencies or notified bodies caused by funding shortages or global health concerns could hinder their ability to hire, retain or deploy key leadership and other personnel, or otherwise prevent new or modified products from being developed, cleared, certified or approved or commercialized in a timely manner or at all, which could negatively impact our business.

The ability of the FDA, foreign regulatory authorities and notified bodies to review and clear, certify or approve new products can be affected by a variety of factors, including government budget and funding levels, statutory, regulatory and policy changes, the FDA's, foreign regulatory authorities and notified bodies' ability to hire and retain key personnel and accept the payment of user fees and other events that may otherwise affect the FDA's, foreign regulatory authorities and notified bodies' ability to perform routine functions. Average review times at the FDA, foreign regulatory authorities and notified bodies' have fluctuated in recent years as a result. In addition, government funding of other government agencies that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable. Disruptions at the FDA, other agencies and notified bodies may also slow the time necessary for medical devices and biologics or modifications to be cleared or for approved medical devices and biologics to be reviewed and/or approved or certified by necessary government agencies, or notified bodies which would adversely affect our business. For example, over the last several years, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical FDA employees and stop critical activities.

Subsequently, in response to the global COVID-19 pandemic, the FDA postponed most inspections of domestic and foreign manufacturing facilities at various points. Even though the FDA has since resumed standard inspection operations of domestic facilities where feasible, the FDA has continued to monitor and implement changes to its inspectional activities to ensure the safety of its employees and those of the firms it regulates as it adapts to the evolving COVID-19 pandemic, and any resurgence of the virus or emergence of new variants may lead to further inspectional delays. Regulatory authorities outside the United States have adopted similar restrictions or other policy measures in response to the COVID-19 pandemic. If a prolonged government shutdown occurs, or if global health concerns continue

to prevent the FDA, other regulatory authorities or notified bodies from conducting their regular inspections, audits, reviews, or other regulatory activities, it could significantly impact the ability of the FDA, or other regulatory authorities and notified bodies to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

For instance, in the EU, notified bodies must be officially designated to certify products and services in accordance with the EU Medical Devices Regulation. While several notified bodies have been designated, the COVID-19 pandemic has significantly slowed down their designation process and the current designated notified bodies are facing a large amount of requests for (re)certification under the new regulation as a consequence of which notified body review times have lengthened significantly. This situation could impact our ability to grow our business in the EU and EEA.

We are subject to certain federal, state and foreign fraud and abuse laws, which, if violated, could subject us to substantial penalties. Additionally, any challenge to or investigation into our practices under these laws could cause adverse publicity and be costly to respond to, and thus could harm our business.

There are numerous U.S. federal and state, as well as foreign, laws pertaining to healthcare fraud and abuse, including anti-kickback, false claims and physician transparency laws. Our business practices and relationships with providers and hospitals are subject to scrutiny under these laws. The healthcare laws and regulations that may affect our ability to operate include:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons and entities from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce either the referral of an individual or furnishing or arranging for a good or service, for which payment may be made, in whole or in part, under federal healthcare programs, such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it to have committed a violation;

- the federal civil and criminal false claims laws, including the federal civil False Claims Act, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid or other federal healthcare programs that are false or fraudulent. Moreover, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act. Private individuals can bring False Claims Act “qui tam” actions, on behalf of the government and such individuals, commonly known as “whistleblowers,” may share in amounts paid by the entity to the government in fines or settlement. When an entity is determined to have violated the federal civil False Claims Act, the government may impose civil penalties, including treble damages, and exclude the entity from participation in Medicare, Medicaid and other federal healthcare programs;

- the federal Civil Monetary Penalties Law, which prohibits, among other things, offering or transferring remuneration to a federal healthcare beneficiary that a person knows or should know is likely to influence the beneficiary’s decision to order or receive items or services reimbursable by the government from a particular provider or supplier;

- the Health Insurance Portability and Accountability Act of 1996 (“HIPAA”), which created additional federal criminal statutes that prohibit, among other things, executing a scheme to defraud any healthcare benefit program and making false statements relating to healthcare matters. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it to have committed a violation;

- the federal Physician Sunshine Act, which requires certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or CHIP, to report annually to CMS, information related to payments and other transfers of value to physicians, which is defined broadly

to include doctors, dentists, optometrists, podiatrists and chiropractors, certain non-physician providers such as physician assistants and nurse practitioners, and teaching hospitals, and applicable manufacturers and GPOs, to report annually ownership and investment interests held by such physicians and their immediate family members. Manufacturers are required to submit annual reports to CMS and failure to do so may result in civil monetary penalties for all payments, transfers of value or ownership or investment interests not reported in an annual submission, and may result in liability under other federal laws or regulations. and

- analogous state and foreign law equivalents of each of the above federal laws, such as anti-kickback and false claims laws, which may apply to items or services reimbursed by any third-party payor, including commercial insurers or patients; state laws that require device companies to comply with the industry's voluntary compliance guidelines and the applicable compliance guidance promulgated by the federal government or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state laws that require device manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; and state laws related to insurance fraud in the case of claims involving private insurers.

These laws and regulations, among other things, constrain our business, marketing and other promotional activities by limiting the kinds of financial arrangements we may have with hospitals, physicians or other potential purchasers of our products, as well as independent sales agents and distributors. Due to the breadth of these laws, the narrowness of statutory exceptions and regulatory safe harbors available, and the range of interpretations to which they are subject, it is possible that some of our current or future practices might be challenged under one or more of these laws.

To enforce compliance with the healthcare regulatory laws, certain enforcement bodies have recently increased their scrutiny of interactions between healthcare companies and healthcare providers, which has led to a number of investigations, prosecutions, convictions and settlements in the healthcare industry. Responding to investigations can be time-and resource-consuming and can divert management's attention from the business. Additionally, as a result of these investigations, healthcare providers and entities may have to agree to additional compliance and reporting requirements as part of a consent decree or corporate integrity agreement. Any such investigation or settlement could increase our costs or otherwise have an adverse effect on our business. Even an unsuccessful challenge or investigation into our practices could cause adverse publicity, and be costly to respond to. If our operations are found to be in violation of any of the healthcare laws or regulations described above or any other healthcare regulations that apply to us, we may be subject to penalties, including administrative, civil and criminal penalties, damages, fines, exclusion from participation in government healthcare programs, such as Medicare and Medicaid, imprisonment, contractual damages, reputational harm, disgorgement and the curtailment or restructuring of our operations.

In addition, members of our management and companies with which they are affiliated or have been affiliated with in the past, have been, and may in the future be, involved in investigations, prosecutions, convictions or settlements in the healthcare industry. For example, Kevin Rakin, the chairman of our board of directors, was named as a defendant in United States ex rel. Webb v. Advanced BioHealing, Inc. ("ABH"), a whistleblower suit relating to sales methods employed by sales representatives of ABH, a biotechnology company for which Mr. Rakin served as its chief executive officer. All claims in the lawsuit were dismissed with prejudice pursuant to a settlement agreement, in which Mr. Rakin expressly denied that he engaged in any wrongful conduct, and Mr. Rakin agreed to pay to the United States $2.5 million. Any investigations, prosecutions, convictions or settlements involving members of our management and companies with which they are or have been affiliated may be detrimental to our reputation and could negatively affect our business, financial condition and results of operations.

Healthcare policy changes, including recently enacted legislation reforming the U.S. healthcare system, could harm our cash flows, financial condition and results of operations.

In March 2010, the ACA was enacted in the United States, which made a number of substantial changes in the way healthcare is financed by both governmental and private insurers. Among other ways in which it may impact our business, the ACA established a new Patient-Centered Outcomes Research Institute to oversee and identify priorities in comparative clinical effectiveness research in an effort to coordinate and develop such research, implemented payment system reforms, including a national pilot program on payment bundling to encourage hospitals, physicians and other

providers to improve the coordination, quality and efficiency of certain healthcare services through bundled payment models, and expanded the eligibility criteria for Medicaid programs.

Since its enactment, there have been judicial, U.S. Congressional and executive branch challenges to certain aspects of the ACA. On June 17, 2021, the U.S. Supreme Court dismissed the most recent judicial challenge to the ACA brought by several states without specifically ruling on the constitutionality of the ACA. Thus, the ACA will remain in effect in its current form. Further, prior to the U.S. Supreme Court ruling, President Biden issued an executive order that initiated a special enrollment period for purposes of obtaining health insurance coverage through the ACA marketplace from February 15, 2021 through August 15, 2021. The executive order instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the ACA.

In addition, other legislative changes have been proposed and adopted since the ACA was enacted. On August 2, 2011, the Budget Control Act of 2011 was signed into law, which, among other things, reduced Medicare payments to providers by 2% per fiscal year, effective on April 1, 2013 and, due to subsequent legislative amendments to the statute, was to remain in effect through 2030, with the exception of a temporary suspension from May 1, 2020 through March 31, 2022, unless additional Congressional action is taken. In addition, on January 2, 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, reduced Medicare payments to several providers, including hospitals, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. In addition, the Medicare Access and CHIP Reauthorization Act of 2015 enacted on April 16, 2015, repealed the formula by which Medicare made annual payment adjustments to physicians and replaced the former formula with fixed annual updates and a new system of incentive payments began in 2019 that are based on various performance measures and physicians' participation in alternative payment models such as accountable care organizations.

We expect additional state, federal and foreign healthcare reform measures to be adopted in the future, any of which could limit reimbursement for healthcare products and services, which could result in reduced demand for our products or additional pricing pressure.

Actual or perceived failure to comply with data protection laws and regulations could lead to government enforcement actions (which could include civil or criminal penalties), private litigation and/or adverse publicity and could negatively affect our operating results and business.

We and our commercial partners, independent sales agents, suppliers and other business partners may be subject to federal, state and foreign data protection laws and regulations (i.e., laws and regulations that address data privacy and security). In the United States, numerous federal and state laws and regulations govern the collection, use, disclosure and protection of health-related and other personal information could apply to our operations or the operations of our partners. For example, HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, and regulations implemented thereunder, or collectively HIPAA, imposes privacy, security and breach notification obligations. We may obtain health information from third parties (including research institutions from which we obtain clinical study data) that are subject to privacy and security requirements under HIPAA. While we do not believe that we are currently acting as a covered entity or business associate under HIPAA and thus are not directly regulated under HIPAA, any person may be prosecuted under HIPAA's criminal provisions either directly or under aiding-and-abetting or conspiracy principles. Consequently, depending on the facts and circumstances, we could be subject to criminal penalties if we knowingly obtain, use, or disclose individually identifiable health information maintained by a HIPAA-covered entity in a manner that is not authorized or permitted by HIPAA.

In addition, the California Consumer Privacy Act("CCPA"), became effective on January 1, 2020. The CCPA gives California residents expanded rights to access and delete their personal information, opt out of certain personal information sharing and receive detailed information about how their personal information is used by requiring covered companies to provide new disclosures to California consumers (as that term is broadly defined) and provide such consumers new ways to opt out of certain sales of personal information. The CCPA provides for civil penalties for violations, as well as a private right of action for data breaches that has increased the likelihood of, and risks associated with data breach litigation. Although there are limited exemptions for certain health-related information, including certain

clinical study data, the CCPA may increase our compliance costs and potential liability. Further the California Privacy Rights Act, or the CPRA, generally went into effect on January 1, 2023, and significantly amends the CCPA. The CPRA imposes additional data protection obligations on covered businesses, including additional consumer rights processes, limitations on data uses, new audit requirements for higher risk data, and opt outs for certain uses of sensitive data. It also creates a new California data protection agency authorized to issue substantive regulations and could result in increased privacy and information security enforcement. Additional compliance investment and potential business process changes may be required. Similar laws have passed in Virginia, Connecticut, Utah and Colorado, and have been proposed in other states and at the federal level, reflecting a trend toward more stringent privacy legislation in the United States. The enactment of such laws could have potentially conflicting requirements that would make compliance challenging. In the event that we are subject to or affected by HIPAA, the CCPA, the CPRA or other domestic privacy and data protection laws, any liability from failure to comply with the requirements of these laws could adversely affect our financial condition.

Furthermore, the Federal Trade Commission (FTC) and many state Attorneys General continue to enforce federal and state consumer protection laws against companies for online collection, use, dissemination and security practices that appear to be unfair or deceptive. For example, according to the FTC, failing to take appropriate steps to keep consumers' personal information secure can constitute unfair acts or practices in or affecting commerce in violation of Section 5(a) of the Federal Trade Commission Act. The FTC expects a company's data security measures to be reasonable and appropriate in light of the sensitivity and volume of consumer information it holds, the size and complexity of its business, and the cost of available tools to improve security and reduce vulnerabilities.

In Europe, the European Union General Data Protection Regulation, or GDPR went into effect in May 2018 and imposes strict requirements for processing the personal data of individuals within the EEA. Failure to comply with the requirements of GDPR and the applicable national data protection and marketing laws may result in fines of up to €20,000,000 or up to 4% of the total worldwide annual turnover of the preceding financial year, whichever is higher, and other administrative penalties as well as individual claims for compensation. In addition to the foregoing, a breach of the GDPR could result in regulatory investigations, reputational damage, orders to cease/ change our processing of our data and/or enforcement notices. We may also face civil claims including representative actions and other class action type litigation (where individuals have suffered harm), potentially amounting to significant compensation or damages liabilities, as well as associated costs, diversion of internal resources, and reputational harm.

The GDPR also imposes strict rules on the transfer of personal data out of the EEA, to the United States and other third countries that have not been found to provide adequate protection to such personal data. Recent legal developments in Europe have created complexity and uncertainty regarding transfers of personal data from the EEA to the United States, e.g. on July 16, 2020, the Court of Justice of the European Union, or the "CJEU," invalidated the EU-U.S. Privacy Shield Framework, for purposes of international transfers and imposed further restrictions on the use of standard contractual clauses, or SCCs. In March 2022, the US and EU announced a new regulatory regime intended to replace the invalidated regulations; however, this new EU-US Data Privacy Framework has not been implemented beyond an executive order signed by President Biden on October 7, 2022 on Enhancing Safeguards for United States Signals Intelligence Activities. European court and regulatory decisions subsequent to the CJEU decision of July 16, 2020 have taken a restrictive approach to international data transfers. As supervisory authorities issue further guidance on personal data export mechanisms, including circumstances where the SCCs cannot be used, and/or start taking enforcement action, we could suffer additional costs, complaints and/or regulatory investigations or fines, and/or if we are otherwise unable to transfer personal data between and among countries and regions in which we operate, it could affect the manner in which we provide our services, the geographical location or segregation of our relevant systems and operations, and could adversely affect our financial results.

From January 1, 2021, we have been subject to the GDPR and also the UK GDPR, which, together with the amended UK Data Protection Act 2018, retains the GDPR in UK national law. The UK GDPR mirrors the fines under the GDPR, e.g. fines up to the greater of €20 million (£17.5 million) or 4% of global turnover. As we continue to expand into other foreign countries and jurisdictions, we may be subject to additional laws and regulations that may affect how we conduct business.

Compliance with U.S. and foreign privacy and security laws, rules and regulations could require us to take on more onerous obligations in our contracts, require us to engage in costly compliance exercises, restrict our ability to

collect, use and disclose data, or in some cases, impact our ability, or the ability of our commercial partners, independent sales agents, suppliers or other business partners, to operate in certain jurisdictions. Each of these constantly evolving laws can be subject to varying interpretations. Failure to comply with U.S. and foreign data protection laws and regulations could result in government investigations and enforcement actions (which could include civil or criminal penalties), fines, private litigation and/or adverse publicity and could negatively affect our operating results and business. Moreover, patients about whom we or our partners obtain information, as well as the providers who share this information, may contractually limit our ability to use and disclose the information. Claims that we have violated individuals' privacy rights, failed to comply with data protection laws, or breached our contractual obligations, even if we are not found liable, could be expensive and time-consuming to defend and could result in adverse publicity that could have a material and adverse effect on our business, financial condition and results of operations.

Risks Related to Intellectual Property

If we are unable to obtain, maintain and adequately protect our intellectual property rights, our competitive position could be harmed or we could be required to incur significant expenses to enforce or defend our rights.

Our commercial success will depend in part on our success in obtaining and maintaining issued patents, trademarks and other intellectual property rights in the United States and elsewhere and protecting our proprietary technology. If we do not adequately protect our intellectual property and proprietary technology, competitors may be able to use our technologies or the goodwill we have acquired in the marketplace and erode or negate any competitive advantage we may have, which could harm our business and ability to achieve profitability.

Some of our intellectual property rights depend on licensing agreements with third parties, and our patent coverage includes protection provided by licensed patents. If in the future we no longer have rights to one or more of these licensed patents, our patent coverage may be compromised, which in turn could adversely affect our ability to protect our products and defend against competitors.

We have sought to protect our proprietary position by filing patent applications in the United States and abroad related to our products that we view as important to our business. This process is expensive and time-consuming, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. In addition, we cannot provide any assurances that any of our patents have, or that any of our pending patent applications that mature into issued patents will include, claims with a scope sufficient to protect our existing products, any enhancements we may develop to our existing products or any new products we may develop or acquire and introduce in the future. We, or our licensors, may fail to identify patentable aspects of inventions made in the course of development and commercialization activities before it is too late to obtain patent protection on them. Therefore, we may miss potential opportunities to strengthen our patent position. Other parties may have developed technologies that may be related or competitive to our system, may have filed or may file patent applications and may have received or may receive patents that overlap or conflict with our patent applications, either by claiming the same methods or devices or by claiming subject matter that could dominate our patent position.

The patent positions of regenerative medicine companies, including our patent position, may involve complex legal, scientific and factual questions, and, therefore, the scope, validity, ownership and enforceability of any patent claims that we may obtain cannot be predicted with certainty. Patents, if issued, may be challenged, deemed unenforceable, narrowed, invalidated or circumvented. Proceedings challenging our patents could result in either loss of the patent or denial of the patent application or loss or reduction in the scope of one or more of the claims of the patent or patent application. In addition, such proceedings may be costly. Thus, any patents that we currently own or may own may not provide any protection against competitors. Furthermore, an adverse decision in an interference proceeding can result in a third party receiving the patent right sought by us, which in turn could affect our ability to commercialize our products. In recent years, patent rights have been the subject of significant litigation. Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of our owned or licensed patents or narrow the scope of our patent protection.

Though an issued patent is presumed valid and enforceable, its issuance is not conclusive as to its inventorship, scope, validity or enforceability, and it may not provide us with adequate proprietary protection or competitive advantages

against competitors with similar products. Competitors could attempt to replicate some or all of the competitive advantages we derive from our development efforts, willfully infringe, misappropriate or otherwise violate our intellectual property rights, design around our patents or develop and obtain patent protection for more effective technologies, designs or methods.

CanGaroo and SimpliDerm are the only current products covered by issued patents. We rely on unpatented trade secrets and know-how for several of our current products to develop and maintain our competitive position. However, trade secrets and know-how can be difficult to protect and enforce against third parties. Accordingly, we cannot be certain that these intellectual property rights will provide us with adequate protection or enable us to prevent third parties from developing or commercializing competitive products.

We may be unable to prevent the unauthorized disclosure or use of our technical knowledge or trade secrets by consultants, suppliers, vendors, current and former employees, distributors, commercial partners or independent sales agents. The laws of some foreign countries do not protect our proprietary rights to the same extent as the laws of the United States, and we may encounter significant problems in protecting our proprietary rights in these countries.

Our ability to enforce our patent rights depends on our ability to detect infringement. It may be difficult to detect infringers who do not advertise the components that are used in their products. Moreover, it may be difficult or impossible to obtain evidence of infringement in a competitor's or potential competitor's product. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if we were to prevail, may not be commercially meaningful.

In addition, proceedings to enforce or defend our patents could put our patents at risk of being invalidated, held unenforceable or interpreted narrowly, which could limit our ability to stop or prevent us from stopping others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology and products. Such proceedings could provoke third parties to assert claims against us, including that some or all of the claims in one or more of our patents are invalid or otherwise unenforceable. If any of the patents covering our products are narrowed, invalidated or found unenforceable, or if a court found that valid, enforceable patents held by third parties covered one or more of our products, our competitive position could be harmed or we could be required to incur significant expenses to enforce or defend our rights.

The degree of future protection for our proprietary rights is uncertain, and we cannot ensure that:

- any of our patents, or any of our pending patent applications, if issued, will include claims having a scope sufficient to protect our products;
- any of our pending patent applications will issue as patents;
- we will be able to successfully commercialize our products on a substantial scale, if approved, before the relevant patents we currently have, or may have, expire;
- we were the first to conceive and reduce to practice the inventions covered by each of our patents and pending patent applications;
- we were the first to file patent applications for these inventions;
- others will not develop similar or alternative technologies that do not infringe, misappropriate or otherwise violate our owned or licensed patents and other intellectual property rights;
- any of our patents will ultimately be found to be valid and enforceable;
- ownership of our patents or patent applications will not be challenged by third parties;

- any patents issued to us will provide a basis for an exclusive market for our commercially viable products, will provide us with any competitive advantages or will not be challenged by third parties;

- our competitors will not conduct research and development activities in countries where we do not have patent rights, or in countries where research and development safe harbor laws exist, and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;

- we will develop additional proprietary technologies or products that are separately patentable; or

- our commercial activities or products will not infringe, misappropriate or otherwise violate the patents and other intellectual property rights of others.

- Should any of these events occur, they could have a material and adverse effect on our business, financial condition and results of operations.

We may not enter into invention assignment and confidentiality agreements with all of our employees and contractors and such agreements could be ineffective or breached.

We rely, in part, upon unpatented trade secrets, unpatented know-how and continuing technological innovation to develop and maintain our competitive position, which we seek to protect, in part, by confidentiality agreements with our employees, consultants, independent sales agents, collaborators and third-party vendors. We also seek to enter agreements with our employees and consultants that obligate them to assign any inventions created during their work for us to us and have non-compete agreements with some, but not all, of our consultants. However, we may not obtain these agreements in all circumstances and the assignment of intellectual property under such agreements may not be self-executing. If the employees, consultants or collaborators that are parties to these agreements breach or violate their respective terms, we may not have adequate remedies for any such breach or violation. It is possible that technology relevant to our business will be independently developed by a person that is not a party to such an agreement. Furthermore, if the employees and consultants who are parties to these agreements breach or violate the terms of these agreements, we may not have adequate remedies for any such breach or violation, and we could lose our trade secrets through such breaches or violations. Further, our trade secrets could otherwise become known or be independently discovered by our competitors. Any of the foregoing could have a material and adverse effect on our business, financial condition and results of operations.

The patent protection we obtain for our products may not be sufficient enough to provide us with any competitive advantage or our patents may be challenged.

Our owned and licensed patents and pending patent applications, if issued, may not provide us with any meaningful protection or prevent competitors from designing around our patent claims to circumvent our patents by developing similar or alternative technologies or products in a non-infringing manner. For example, a third party may develop a competitive product that provides benefits similar to one or more of our products but falls outside the scope of our patent protection or license rights. If the patent protection provided by the patents and patent applications we hold or pursue with respect to our products is not sufficiently broad to impede such competition, our ability to successfully commercialize our products could be negatively affected, which would harm our business.

It is possible that defects of form in the preparation or filing of our patents or patent applications may exist, or may arise in the future, for example with respect to proper priority claims, inventorship, claim scope, or requests for patent term adjustments. If we or our collaborators or licensors, fail to establish, maintain or protect such patents and other intellectual property rights, such rights may be reduced or eliminated. If our collaborators or licensors are not fully cooperative or disagree with us as to the prosecution, maintenance or enforcement of any patent rights, such patent rights could be compromised. If there are material defects in the form, preparation, prosecution or enforcement of our patents or patent applications, such patents may be invalid and/or unenforceable, and such applications may never result in valid and enforceable patents. Any of these outcomes could impair our ability to prevent competition from third parties, which may have an adverse impact on our business.

Pending patent applications cannot be enforced against third parties practicing the technology claimed in such applications unless and until a patent issues from such applications. Assuming the other requirements for patentability are met, currently, the first to file a patent application is generally entitled to the patent. However, prior to March 16, 2013, in the United States, the first to invent was entitled to the patent. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are not published until 18 months after filing, or in some cases not at all. Therefore, we cannot be certain that we were the first to make the inventions claimed in our patents or pending patent applications, or that we were the first to file for patent protection of such inventions. Similarly, we cannot be certain that parties from whom we do or may license or purchase patent rights were the first to make relevant claimed inventions, or were the first to file for patent protection for them. If third parties have filed prior patent applications on inventions claimed in our patents or applications that were filed on or before March 15, 2013, an interference proceeding in the United States can be initiated by such third parties to determine who was the first to invent any of the subject matter covered by the patent claims of our applications. If third parties have filed such prior applications after March 15, 2013, a derivation proceeding in the United States can be initiated by such third parties to determine whether our invention was derived from theirs.

Moreover, because the issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, our owned and licensed patents or pending patent applications may be challenged in the courts or patent offices in the United States and abroad. There is no assurance that all of the potentially relevant prior art relating to our patents and patent applications has been found. If such prior art exists, it may be used to invalidate a patent, or may prevent a patent from issuing from a pending patent application. For example, such patent filings may be subject to a third-party submission of prior art to the U.S. Patent and Trademark Office (the "USPTO") or to other patent offices around the world. Alternately or additionally, we may become involved in post-grant review procedures, oppositions, derivation proceedings, ex parte reexaminations, inter partes review, supplemental examinations or interference proceedings or challenges in district court, in the United States or in various foreign patent offices, including both national and regional, challenging patents or patent applications in which we have rights, including patents on which we rely to protect our business. In addition, if we seek to enforce our patents against third parties, third parties may initiate such challenges in response. An adverse determination in any such challenges may result in loss of the patent or in patent or patent application claims being narrowed, invalidated or held unenforceable, in whole or in part, or in denial of the patent application or loss or reduction in the scope of one or more claims of the patent or patent application, any of which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology and products. In addition, given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. Any of the foregoing could have a material and adverse effect on our business, financial condition and results of operations.

Litigation or other proceedings or third-party claims of intellectual property infringement, misappropriation or other violations could require us to spend significant time and money, prevent us from selling our products and adversely affect our stock price.

Our commercial success will depend in part on not infringing, misappropriating or otherwise violating the patents or other proprietary rights of third parties. Significant litigation regarding patent rights occurs in our industry. Our competitors in both the United States and abroad, many of which have substantially greater resources and have made substantial investments in patent portfolios and competing technologies, may have applied for or obtained or may in the future apply for and obtain, patents that will prevent, limit or otherwise interfere with our ability to make, use and sell our products. We do not always conduct independent reviews of patents issued to third parties. In addition, patent applications in the United States and elsewhere can be pending for many years before issuance, or unintentionally abandoned patents or applications can be revived, so there may be applications of others now pending or recently revived patents of which we are unaware. These applications may later result in issued patents, or the revival of previously abandoned patents, that will prevent, limit or otherwise interfere with our ability to make, use or sell our products. Third parties may, in the future, assert claims that we are employing their proprietary technology without authorization, including claims from competitors or from non-practicing entities that have no relevant product sales and against whom our own patent portfolio may have no deterrent effect. As we continue to commercialize our products in their current or updated forms, launch new products and enter new markets, we expect competitors may claim that one or more of our products infringe, misappropriate or otherwise violate their intellectual property rights as part of business strategies designed to impede our successful

commercialization and entry into new markets. The large number of patents, the rapid rate of new patent applications and issuances, the complexities of the technology involved and the uncertainty of litigation may increase the risk of business resources and management's attention being diverted to patent litigation. We may in the future receive letters or other threats or claims from third parties inviting us to take licenses under, or alleging that we infringe, their patents.

Moreover, we may become party to future adversarial proceedings regarding our patent portfolio or the patents of third parties. Such proceedings could include supplemental examination or contested post-grant proceedings, such as review, reexamination, inter parties review, interference or derivation proceedings before the USPTO and challenges in U.S. District Court. Patents may be subjected to opposition, post-grant review or comparable proceedings lodged in various foreign, both national and regional, patent offices. The legal threshold for initiating litigation or contested proceedings may be low, so that even lawsuits or proceedings with a low probability of success might be initiated. Litigation and contested proceedings can also be expensive and time-consuming, and our adversaries in these proceedings may have the ability to dedicate substantially greater resources to prosecuting these legal actions than we can. We may also occasionally use these proceedings to challenge the patent rights of others. We cannot be certain that any particular challenge will be successful in limiting or eliminating the challenged patent rights of the third party.

Any lawsuits resulting from such allegations could subject us to significant liability for damages and/or invalidate our proprietary rights. Any potential intellectual property litigation also could force us to do one or more of the following:

- stop making, selling or using products or technologies that allegedly infringe, misappropriate or otherwise violate the asserted intellectual property;
- lose the opportunity to license our technology to others or to collect royalty payments based upon successful protection and assertion of our intellectual property rights against others;
- incur significant legal expenses;
- pay substantial damages or royalties to the party whose intellectual property rights we may be found to be infringing, misappropriating or otherwise violating;
- pay the attorney's fees and costs of litigation to the party whose intellectual property rights we may be found to be infringing, misappropriating or otherwise violating;
- redesign those products that contain the allegedly infringing intellectual property, which could be costly, disruptive and infeasible; and
- attempt to obtain a license to the relevant intellectual property from third parties, which may not be available on reasonable terms or at all, or from third parties who may attempt to license rights that they do not have.

Any litigation or claim against us, even those without merit, may cause us to incur substantial costs, and could place a significant strain on our financial resources, divert the attention of management from our core business and harm our reputation. If we are found to infringe, misappropriate or otherwise violate the intellectual property rights of third parties, we could be required to pay substantial damages (possibly treble damages) and/or substantial royalties and could be prevented from selling our products unless we obtain a license or are able to redesign our products to avoid infringement, misappropriation or violation. Any such license may not be available on reasonable terms, if at all, and there can be no assurance that we would be able to redesign our products in a way that would not infringe, misappropriate or otherwise violate the intellectual property rights of others. We could encounter delays in product introductions while we attempt to develop alternative methods or products. If we fail to obtain any required licenses or make any necessary changes to our products or technologies, we may have to withdraw existing products from the market or may be unable to commercialize one or more of our products.

In addition, we generally indemnify our customers with respect to infringement by our products of the proprietary rights of third parties. Third parties may assert infringement claims against our customers. These claims may require us to

initiate or defend protracted and costly litigation on behalf of our customers, regardless of the merits of these claims. If any of these claims succeed or settle, we may be forced to pay damages or settlement payments on behalf of our customers or may be required to obtain licenses for the products they use. If we cannot obtain all necessary licenses on commercially reasonable terms, our customers may be forced to stop using our products.

We may not have sufficient resources to bring these actions to a successful conclusion. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the market price of shares of our Class A common stock. Any of the foregoing could have a material and adverse effect on our business, financial condition and results of operations.

If we are unable to protect the confidentiality of our trade secrets, our business and competitive position could be harmed.

In addition to patent protection, we also rely upon copyright and trade secret protection, as well as non-disclosure agreements and invention assignment agreements with our employees, consultants, independent sales agents and other third parties, to protect our confidential and proprietary information. In addition to contractual measures, we try to protect the confidential nature of our proprietary information using commonly accepted physical and technological security measures. Such measures may not, for example, in the case of misappropriation of a trade secret by an employee or third party with authorized access, provide adequate protection for our proprietary information. Our security measures may not prevent an employee or consultant from misappropriating our trade secrets and providing them to a competitor, and recourse we take against such misconduct may not provide an adequate remedy to protect our interests fully. Unauthorized parties may also attempt to copy or reverse engineer certain aspects of our products that we consider proprietary. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret can be difficult, expensive and time-consuming, and the outcome is unpredictable. Even though we use commonly accepted security measures, trade secret violations are often a matter of state law, and the criteria for protection of trade secrets can vary among different jurisdictions. In addition, trade secrets may be independently developed by others in a manner that could prevent legal recourse by us. If any of our confidential or proprietary information, such as our trade secrets, were to be disclosed or misappropriated, or if any such information was independently developed by a competitor, it could have a material and adverse effect on our business, financial condition and results of operations.

We may be unable to enforce our intellectual property rights throughout the world.

Obtaining, maintaining and enforcing intellectual property rights is expensive and it is cost prohibitive to do so throughout the world. Accordingly, we may determine not to obtain, maintain or enforce intellectual property rights in certain jurisdictions. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as the laws of the United States. Many companies have encountered significant problems in protecting and defending intellectual property rights in certain foreign jurisdictions. This could make it difficult for us to stop infringement of our foreign patents, if obtained, or the misappropriation or other violation of our other intellectual property rights. For example, some foreign countries have compulsory licensing laws under which a patent owner must grant licenses to third parties. In addition, some countries limit the enforceability of patents against third parties, including government agencies or government contractors. In these countries, patents may provide limited or no benefit. Patent protection must ultimately be sought on a country-by-country basis, which is an expensive and time-consuming process with uncertain outcomes. Accordingly, we may choose not to seek patent protection in certain countries, and we will not have the benefit of patent protection in such countries.

Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business. Accordingly, our efforts to protect our intellectual property rights in such countries may be inadequate. In addition, changes in the law and legal decisions by courts in the United States and foreign countries may affect our ability to obtain adequate protection for our technology and the enforcement of our intellectual property. Any of the foregoing could have a material and adverse effect on our business, financial condition and results of operations.

Third parties may assert ownership or commercial rights to inventions we develop.

Third parties may in the future make claims challenging the inventorship or ownership of our intellectual property. We have written agreements with collaborators that provide for the ownership of intellectual property arising from our collaborations. In addition, we may face claims by third parties that our agreements with employees, contractors or consultants obligating them to assign intellectual property to us are ineffective or in conflict with prior or competing contractual obligations of assignment, which could result in ownership disputes regarding intellectual property we have developed or will develop and interfere with our ability to capture the commercial value of such intellectual property. Litigation may be necessary to resolve an ownership dispute, and if we are not successful, we may be precluded from using certain intellectual property or may lose our exclusive rights in such intellectual property. Either outcome could harm our business and competitive position. Any of the foregoing could have a material and adverse effect on our business, financial condition and results of operations.

Third parties may assert that our employees or consultants have wrongfully used or disclosed confidential information or misappropriated trade secrets.

We employ individuals who previously worked with other companies, including our competitors or potential competitors. Although we try to ensure that our employees and consultants do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or our employees, consultants or independent contractors have inadvertently or otherwise used or disclosed intellectual property or personal data, including trade secrets or other proprietary information, of a former employer or other third party. Litigation may be necessary to defend against these claims. If we fail in defending any such claims or settling those claims, in addition to paying monetary damages or a settlement payment, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees. Any of the foregoing could have a material and adverse effect on our business, financial condition and results of operations.

Recent changes in U.S. patent laws may limit our ability to obtain, defend and/or enforce our patents.

Recent patent reform legislation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents. The Leahy-Smith America Invents Act, or the Leahy-Smith Act, includes a number of significant changes to U.S. patent law. These include provisions that affect the way patent applications are prosecuted and also affect patent litigation. The USPTO recently developed new regulations and procedures to govern administration of the Leahy-Smith Act, and many of the substantive changes to patent law associated with the Leahy-Smith Act, and in particular, the first to file provisions, which became effective on March 16, 2013, could affect us. The first to file provisions limit the rights of an inventor to patent an invention if the inventor was not the first to file an application for patenting that invention, even if such invention was the first invention. Accordingly, it is not clear what, if any, impact the Leahy-Smith Act will have on the operation of our business. This will require us to be cognizant going forward of the timing from invention to filing of a patent application and be diligent in filing patent applications, but circumstances could prevent us from promptly filing patent applications on our inventions.

In addition, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the enforcement and defense of our issued patents. For example, the Leahy-Smith Act provides that an administrative tribunal known as the Patent Trial and Appeals Board (the “PTAB”) provides a venue for challenging the validity of patents at a cost that is much lower than district court litigation and on timelines that are much faster. This applies to all of our U.S. patents, even those issued before March 16, 2013. Furthermore, because of a lower evidentiary standard in USPTO proceedings compared to the evidentiary standard in U.S. federal courts necessary to invalidate a patent claim, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action. Although it is not clear what, if any, long-term impact the PTAB proceedings will have on the operation of our business, patent challenge proceedings before the PTAB since its inception in 2013 have resulted in the invalidation of many U.S. patent claims. The availability of the PTAB as a lower-cost, faster and potentially more potent tribunal for challenging patents could increase the likelihood that our own patents will be challenged, thereby increasing the uncertainties and costs of maintaining and enforcing them. Any failure by us to adequately address the uncertainties and costs surrounding recent patent legislation could have a material and adverse effect on our business, financial condition and results of operations.

Outside of the United States we cannot be certain that any country's patent or trademark office will not implement new rules that could seriously affect how we draft, file, prosecute and maintain patents, trademarks and patent and trademark applications.

We cannot be certain that the patent or trademark offices of countries outside the United States will not implement new rules that increase costs for drafting, filing, prosecuting and maintaining patents, trademarks and patent and trademark applications or that any such new rules will not restrict our ability to file for patent or trademark protection. For example, we may elect not to seek patent protection in some jurisdictions or for some drug candidates in order to save costs. We may be forced to abandon or return the rights to specific patents due to a lack of financial resources.

For example, the impact of the withdrawal of the U.K. from the EU will not be known for some time, which could lead to a period of uncertainty relating to our ability to obtain and maintain patents and trademarks in the U.K. In 2012, the European Patent Package, or EU Patent Package, regulations were passed with the goal of providing for a single pan-European Unitary Patent, and a new European Unified Patent Court, or UPC, for litigation of European patents. It is possible that implementation of the EU Patent Package will occur in the first half of 2023. If the EU Patent Package is ratified and in effect, all European patents, including those issued prior to ratification, would by default automatically fall under the jurisdiction of the UPC and allow for the possibility of obtaining pan-European injunctions. Under the EU Patent Package as currently proposed, once the UPC is established, patent holders are permitted to "opt out" of the UPC on a patent-by-patent basis during an initial seven year period after the EU Patent Package is ratified. Owners of traditional European patent applications who receive notice of grant after the EU Patent Package is ratified could either accept a Unitary Patent or validate the patent nationally and file an opt-out demand. The EU Patent Package may increase the uncertainties and costs surrounding the enforcement or defense of our issued European patents and pending applications. The full impact on future European patent filing strategy and the enforcement or defense of our issued European patents in member states and/or the UPC is not known.

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

Periodic maintenance and annuity fees on any issued patent are due to be paid to the USPTO and European and other patent agencies over the lifetime of a patent. In addition, the USPTO and European and other patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. While an inadvertent failure to make payment of such fees or to comply with such provisions can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which such noncompliance will result in the abandonment or lapse of the patent or patent application, and the partial or complete loss of patent rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of a patent or patent application include failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents within prescribed time limits. If we or our licensors fail to maintain the patents and patent applications covering our product candidates or if we or our licensors otherwise allow our patents or patent applications to be abandoned or lapse, our competitors might be able to enter the market, which would hurt our competitive position, could impair our ability to successfully commercialize our product candidates in any indication for which they are approved, and could have a material and adverse effect on our business, financial condition and results of operations.

In addition, any of the intellectual property rights that we own or license that are developed through the use of U.S. government funding will be subject to additional federal regulations. Pursuant to the Bayh-Dole Act of 1980 (the "Bayh-Dole Act"), the government will receive a license under inventions developed under a government-funded program and may require us to manufacture products embodying such inventions in the United States. Under certain circumstances, the government may also claim ownership in such inventions or compel us to license them to third parties. Any failure by us to comply with federal regulations regarding intellectual property rights that were developed through the use of U.S. government funding could have a material and adverse effect on our business, financial condition and results of operations.

If we do not obtain patent term extension in the United States under the Hatch-Waxman Amendments and in foreign countries under similar legislation, thereby potentially extending the term of marketing exclusivity for our product candidates, our business may be materially harmed.

Patents have a limited lifespan. In the United States, if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest U.S. non-provisional filing date. Various extensions may be available, but the life of a patent, and the protection it affords, is limited. Even if patents covering our product candidates are obtained, once the patent life has expired for a product, we may be open to competition from competitive products. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

In the United States, a patent that covers an FDA-approved drug, biologic or medical device may be eligible for a term extension designed to restore the period of the patent term that is lost during the premarket regulatory review process conducted by the FDA. Depending upon the timing, duration and conditions of FDA marketing approval of our product candidates, we may be able to extend the term of a patent covering each product candidate under the Drug Price Competition and Patent Term Restoration Act of 1984, referred to as the Hatch-Waxman Amendments and similar legislation in the European Union. The Hatch-Waxman Amendments permit a patent term extension of up to five years for a patent covering an approved product as compensation for effective patent term lost during product development and the FDA regulatory review process. However, we may not receive an extension if we fail to apply within applicable deadlines, fail to apply prior to expiration of relevant patents or otherwise fail to satisfy applicable requirements. Moreover, the length of the extension could be less than we request. A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, and only claims covering such approved product, a method for using it or a method for manufacturing it may be extended. In the European Union, our product candidates may be eligible for term extensions based on similar legislation. If we are unable to obtain patent term extension or the term of any such extension is less than we request, the period during which we can enforce our patent rights for that product will be shortened and our competitors may obtain approval to market competing products sooner. As a result, our revenue from applicable products could be reduced, possibly materially.

Further, under certain circumstances, patent terms covering our products or product candidates may be extended for time spent during the pendency of the patent application in the USPTO (referred to as Patent Term Adjustment ("PTA")). The laws and regulations underlying how the USPTO calculates the PTA is subject to change and any such PTA granted by the USPTO could be challenged by a third-party. If we do not prevail under such a challenge, the PTA may be reduced or eliminated, resulting in a shorter patent term, which may negatively impact our ability to exclude competitors. Because PTA added to the term of patents covering products has particular value, our business may be adversely affected if the PTA is successfully challenged by a third party and our ability to exclude competitors is reduced or eliminated. Any of the foregoing could have a material and adverse effect on our business, financial condition and results of operations.

We depend on certain technologies that are licensed to us. We do not control the intellectual property rights covering these technologies, and any loss of our rights to these technologies or the rights licensed to us could prevent us from selling our products and adversely impact our business.

We are a party to license agreements under which we are granted rights to intellectual property that is important to our business, and we may need to enter into additional license agreements in the future. We rely on these licenses in order to be able to use and sell various proprietary technologies that are material to our business, as well as technologies we intend to use in our future commercial activities. For example, we expect that we will be dependent on our licensing arrangements with Cook Biotech, relating to CanGaroo and our cardiovascular products. Our rights to use these technologies and the inventions claimed in the licensed patents are subject to the continuation of and our compliance with the terms of those license agreements. Our existing license agreements impose, and we expect that future license agreements will also impose on us, various diligence obligations, milestone payments, royalties and other obligations. If we fail to comply with our obligations under these agreements, or if we are subject to a bankruptcy proceeding, the licensor may have the right to terminate the license, in which case we would not be able to market products covered by the license, which would adversely affect our business, financial condition and results of operations.

As we have done previously, we may need to obtain additional licenses from third parties in order to advance our research or allow commercialization of our products and technologies. The in-licensing and acquisition of third-party intellectual property is a competitive area, and a number of more established companies are also pursuing strategies to in-license or acquire third-party intellectual property rights that we may consider attractive or necessary. These established companies may have a competitive advantage over us due to their size, cash resources and greater clinical development and commercialization capabilities. Furthermore, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. Accordingly, we may not be able to obtain any of these licenses on commercially reasonable terms or at all. Even if we are able to obtain a license, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. In the event that we are not able to acquire a license, we may be required to expend significant time and resources to develop or license replacement technology. If we are unable to do so, we may be unable to develop or commercialize the affected products and technologies, which could materially harm our business. In addition, the third parties owning such intellectual property rights could seek either an injunction prohibiting our sales, or, with respect to our sales, an obligation on our part to pay royalties or other forms of compensation and damages.

In some cases, we may not have the right to control the prosecution, maintenance or filing of the patents that are licensed to us, or the enforcement of these patents against infringement by third parties. Some of our patents and patent applications were not filed by us, but were either acquired by us or are licensed from third parties. Thus, these patents and patent applications were not drafted by us, and we did not control or have any input into the prosecution of these patents and patent applications prior to our acquisition of, or our entry into a license with respect to, such patents and patent applications. We cannot be certain that the drafting or prosecution of these patents and patent applications will result or has resulted in valid and enforceable patents. Further, since we do not always retain complete control over our ability to enforce our licensed patent rights against third-party infringement, we cannot be certain that our licensor will elect to enforce these patents to the extent that we would choose to do so, or in a way that will ensure that we retain the rights we currently have under the applicable license agreement. If our licensor fails to properly enforce the patents subject to our license agreement in the event of third-party infringement, our ability to retain our competitive advantage with respect to the applicable products may be materially and adversely affected.

Licensing of intellectual property is an important part of our business and involves complex legal, business and scientific issues. Disputes may arise between us and our licensors regarding intellectual property that is subject to a license agreement, including, with respect to, among other things:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- whether our licensor had the right to grant the rights granted to us under the license agreement;
- whether and the extent to which our technology and processes infringe, misappropriate or otherwise violate intellectual property of the licensor that is not subject to the license agreement;
- our right to sublicense patent and other rights to third parties under collaborative development relationships;
- our involvement in the prosecution and enforcement of the licensed patents and our licensor’s overall patent enforcement strategy;
- our diligence obligations with respect to the use of the licensed technology in relation to our development and commercialization of our products and technologies, and what activities satisfy those diligence obligations;
- the ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us and our partners; and
- the amounts of royalties, milestones or other payments due under the license agreement.

In addition, we may become the owner of intellectual property that was obtained through assignments, which may be subject to re-assignment back to the original assignor upon our failure to prosecute or maintain such intellectual property, upon our breach of the agreement pursuant to which such intellectual property was assigned, or upon our bankruptcy.

The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant intellectual property or technology, or increase what we believe to be our financial or other obligations under the relevant agreement. If disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on acceptable terms, or if intellectual property is re-assigned back to the original assignor, we may be unable to successfully develop and commercialize or continue selling products that utilize the affected intellectual property, any of which could impair our ability to execute our growth strategy and could have a material and adverse effect on our business, financial condition and results of operations.

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

We have not yet registered certain of our trademarks in all of our potential markets. If we apply to register these and other trademarks in the United States and other countries, our applications may not be allowed for registration in a timely fashion or at all, and our registered trademarks may not be maintained or enforced. In addition, the registered or unregistered trademarks or trade names that we own may be challenged, infringed, circumvented, declared generic, lapsed or determined to be infringing on or dilutive of other marks. We may not be able to protect our rights in these trademarks and trade names, which we need in order to build name recognition. In addition, third parties may file for registration of trademarks similar or identical to our trademarks, thereby impeding our ability to build brand identity and possibly leading to market confusion. If they succeed in registering or developing common law rights in such trademarks, and if we are not successful in challenging such rights, we may not be able to use these trademarks to develop brand recognition of our technologies, products or services. In addition, there could be potential trade name or trademark infringement claims brought by owners of other registered trademarks or trademarks that incorporate variations of our registered or unregistered trademarks or trade names. Further, we may in the future enter into agreements with owners of such third party trade names or trademarks to avoid potential trademark litigation which may limit our ability to use our trade names or trademarks in certain fields of business.

In addition, opposition or cancellation proceedings may in the future be filed against our trademark applications and registrations, and our trademarks may not survive such proceedings. In addition, third parties may file first for our trademarks in certain countries. If they succeed in registering such trademarks, and if we are not successful in challenging such third party rights, we may not be able to use these trademarks to market our products in those countries. If we do not secure registrations for our trademarks, we may encounter more difficulty in enforcing them against third parties than we otherwise would. If we are unable to establish name recognition based on our trademarks and trade names, we may not be able to compete effectively, which could have a material adverse effect on our business, financial condition, results of operations and prospects.

Risks Related to Our Common Stock

We expect that the price of our Class A common stock will fluctuate substantially and you may not be able to sell the shares you purchase at or above the price you paid for such shares.

The market price of our Class A common stock is likely to be highly volatile and may fluctuate substantially due to a variety of factors, many of which are outside of our control, including, among other things:

- the volume and timing of sales of our products;
- the introduction of new products or product enhancements by us or others in our industry;
- disputes or other developments with respect to our or others' intellectual property rights;

- our ability to develop, obtain regulatory clearance or approval for, and market new and enhanced products on a timely basis, including our CanGaroo RM;
- changes or proposed changes in laws or regulations or differing interpretations or enforcement thereof affecting our business;
- product liability claims, other litigation or regulatory investigations;
- annual or quarterly variations in our results of operations or those of others in our industry, or results of operations that otherwise vary from those expected by securities analysts and investors;
- publications, reports or other media exposure of our products or those of others in our industry, or of our industry generally;
- announcements by us or others in our industry, or by our or their respective suppliers, distributors or other business partners, regarding, among other things, significant contracts, price reductions, capital commitments or other business developments, the entry into or termination of strategic transactions or relationships, securities offerings or other financing initiatives, and public reaction thereto;
- additions or departures of key management personnel;
- changes in governmental regulations or in reimbursement;
- changes in earnings estimates or recommendations by securities analysts, or other changes in investor perceptions of the investment opportunity associated with our Class A common stock relative to other investment alternatives;
- the development and sustainability of an active trading market for our Class A common stock;
- general market conditions and other factors, including factors unrelated to our operating performance or the operating performance of our competitors; and
- other factors discussed in Part I, Item 1A. “Risk Factors” of this Annual Report.

In recent years, the stock markets generally have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of those companies, including, as a result of the pandemic related to COVID-19 including variants and resurgences. Broad market and industry factors may significantly affect the market price of our Class A common stock, regardless of our actual operating performance. If the market price of shares of our Class A common stock does not ever exceed the price you paid for your shares, you may not realize any return on your investment in us and may lose some or all of your investment.

In addition, in the past, class action litigation has often been instituted against companies whose securities have experienced periods of volatility in market price. Securities litigation brought against us following volatility in our stock price, regardless of the merit or ultimate results of such litigation, could result in substantial costs, which would hurt our financial condition and operating results and divert management’s attention and resources away from our business.

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

As of December 31, 2022, our principal stockholder, HighCape Partners L.P. and its affiliates, held approximately 47.3% of our outstanding Class A common stock. As a result, HighCape Partners L.P. and its affiliates are able to significantly influence the management and affairs of our company and the outcome of most matters requiring stockholder approval, including the election of directors and approval of significant corporate transactions. The interests of these

stockholders may not be the same as or may even conflict with your interests. For example, these stockholders could attempt to delay or prevent a change in control of the company, even if such change in control would benefit our other stockholders, thereby depriving our other stockholders of an opportunity to receive a premium for their common stock as part of a sale of the company or our assets. Conversely, these stockholders may pursue acquisitions, divestitures and other transactions that, in their judgment, could enhance the value of their investment, even though such transactions might involve risks to you. Even in the absence of any actual conflict of interest, the degree of control possessed by these stockholders may affect the prevailing market price of our Class A common stock due to investors' perceptions that such conflicts of interest may exist or arise. As a result, this concentration of ownership may not be in the best interests of our other stockholders and may impair your ability to realize any return on your investment in us and may impair your ability to avoid losing some or all of your investment.

A significant portion of our total outstanding shares are eligible to be sold into the market in the near future, which could cause the market price of our Class A common stock to drop significantly, even if our business is doing well.

Sales of a substantial number of shares of our outstanding Class A common stock in the public market could occur at any time. In addition, conversions of a substantial number of shares of our outstanding Class B common stock into Class A common stock and sales of such converted shares of our Class A common stock in the public market could occur at any time. These sales, or the perception in the market that the holders of a large number of such shares intend to sell shares, could reduce the market price of our Class A common stock.

As of December 31, 2022, we had outstanding approximately 11.8 million shares of Class A common stock, of which 6.2 million shares of our Class A common stock were freely tradable without restriction or further registration under the Securities Act of 1933, as amended (the "Securities Act"), by persons other than our "affiliates," as that term is defined under Rule 144 of the Securities Act and approximately 5.6 million shares were held by our affiliates and eligible for resale subject to volume, manner of sale and other limitations under Rule 144. Additionally, we had outstanding approximately 4.3 million shares of Class B common stock which may be converted on a one to one basis into shares of Class A common stock, of which all were freely tradable and held by persons other than our "affiliates."

Moreover, as of the date of this Annual Report, several of our affiliates have rights, subject to conditions and limitations, to require us to file registration statements covering up to approximately 4.5 million of their shares or to include such shares in registration statements that we may file for ourselves or other stockholders. We have also registered shares of our Class A common stock issued and available for issuance under our equity compensation plans, which can be freely sold in the public market, subject to vesting requirements and volume limitations applicable to affiliates.

If these shares are sold, or if it is perceived that they will be sold, in the public market, or when we are required to register the sale of our stockholders' remaining shares of our Class A common stock, the trading price of our Class A common stock could decline. A decline in the trading price of our Class A common stock might impede our ability to raise capital through the issuance of additional shares of our Class A common stock or other equity securities and may impair your ability to sell shares of our Class A common stock at a price higher than the price you paid for them or at all.

The dual class structure of our common stock and the option of the holders of shares of our Class B common stock to convert into shares of our Class A common stock may limit your ability to influence corporate matters.

Our Class A common stock has one vote per share, while our Class B common stock is non-voting. Nonetheless, each share of our Class B common stock may be converted at any time into one share of Class A common stock at the option of its holder, subject to the limitations provided for in our certificate of incorporation that prohibit the conversion of our Class B common stock into shares of Class A common stock to the extent that, upon such conversion, such holder would beneficially own in excess of 4.9% of any class of our securities registered under the Exchange Act. Consequently, if holders of Class B common stock exercise their option to make this conversion, such exercise will have the effect of increasing the relative voting power of those prior holders of our Class B common stock (subject to the ownership limitation described in the previous sentence) and increasing the number of outstanding shares of our voting common stock, and correspondingly decreasing the relative voting power of the current holders of our Class A common stock,

which may limit your ability to influence corporate matters. Because our Class B common stock is generally non-voting, stockholders who own more than 10% of our common stock overall but 10% or less of our Class A common stock will not be required to report changes in their ownership from transactions in our Class B common stock pursuant to Section 16(a) of the Exchange Act and would not be subject to the short-swing profit provisions of Section 16(b) of the Exchange Act.

You may be diluted by the future issuance of additional common stock in connection with our incentive plans, acquisitions or otherwise.

As of December 31, 2022, we had 188,176,555 shares of Class A common stock authorized but unissued and 15,686,594 shares of Class B common stock authorized but unissued. We are authorized under our certificate of incorporation to issue these shares of common stock and other securities convertible into or exercisable or exchangeable for shares of our common stock for the consideration and on the terms and conditions established by our board of directors in its sole discretion, whether in connection with acquisitions or otherwise. As of December 31, 2022, we had a total of 1,864,739 shares of our Class A common stock issuable upon the exercise of outstanding options under our 2015 Stock Option/Stock Issuance Plan, as amended (the "2015 Plan") and our 2020 Incentive Award Plan (the "2020 Plan") at a weighted average exercise price of $9.41 per share, 723,793 of which were vested as of such date, 192,070 shares of Class A common stock issuable upon the settlement of RSUs granted under our 2020 Plan to several of our executive officers, employees and consultants, 656,689 additional shares of our Class A common stock reserved for future issuance under our 2020 Plan, not including the additional shares of Class A common stock that will be reserved for future issuance under our 2020 Plan pursuant to provisions in the 2020 Plan that automatically increase the number of shares of our Class A common stock reserved for future issuance thereunder, and 279,345 shares of our Class A common stock available for future issuance under our 2020 Employee Stock Purchase Plan (the "2020 ESPP"), not including the additional shares of Class A common stock that will be reserved for future issuance under our 2020 ESPP pursuant to provisions in the 2020 ESPP that automatically increase the number of shares of our Class A common stock reserved for future issuance thereunder. Additionally, as of December 31, 2022, we had a warrant to purchase up to 187,969 shares of our Class A common stock issued to the lender under the SWK Loan Facility that was outstanding. Any additional shares of common stock that we issue, including under our 2020 Plan, 2020 ESPP or other equity incentive plans that we may adopt in the future, or as a result of any exercise of the warrant, would dilute the percentage ownership and voting power held by investors who purchase our common stock. In the future, we may also issue additional securities if we need to raise capital, including, but not limited to, in connection with acquisitions, which could constitute a material portion of our then-outstanding shares of our common stock.

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

We are an "emerging growth company," as defined in the JOBS Act, and a "smaller reporting company," as defined in Rule 12b-2 under the Exchange Act. Emerging growth companies and smaller reporting companies may take advantage of certain exemptions from various reporting requirements that are applicable to other publicly-traded entities that are not emerging growth companies or smaller reporting companies.

With respect to emerging growth companies, these exemptions include:

- the option to present only two years of audited financial statements , in addition to any required unaudited interim financial statements, with a correspondingly reduced Management's Discussion and Analysis of Financial Condition and Results of Operations;

- not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act;

- not being required to comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements (i.e., an auditor discussion and analysis);

- not being required to submit certain executive compensation matters to stockholder advisory votes, such as "say-on-pay," "say-on-frequency" and "say-on-golden parachutes"; and

- not being required to disclose certain executive compensation related items such as the correlation between executive compensation and performance and comparisons of the chief executive officer's compensation to median employee compensation.

We have elected to take advantage of certain of these reduced disclosure obligations and may elect to take advantage of other reduced reporting requirements in the future. As a result, the information that we provide to our stockholders may be different than the information you might receive from other public reporting companies in which you hold equity interests. In addition, the JOBS Act permits emerging growth companies to delay adopting new or revised accounting standards until such time as those standards apply to private companies. We have elected to use this extended transition period for complying with new or revised accounting standards until the earlier of the date we (i) are no longer an emerging growth company or (ii) affirmatively and irrevocably opt out of the extended transition period provided in the JOBS Act. As a result, our consolidated financial statements and the reported results of operations contained therein may not be directly comparable to those of other public companies. We cannot predict whether investors will find our common stock less attractive because of our reliance on these exemptions. If some investors do find our common stock less attractive, there may be a less active trading market for our Class A common stock and our stock price may be reduced or more volatile.

We will remain an emerging growth company, and will be able to take advantage of the foregoing exemptions, until the earliest of: (i) the last day of the first fiscal year in which our annual gross revenues are $1.235 billion or more; (ii) the last day of 2025; (iii) the date that we become a "large accelerated filer" as defined in Rule 12b-2 under the Exchange Act, which would occur if the market value of our common equity held by non-affiliates is $700 million or more as of the last business day of our most recently completed second fiscal quarter; or (iv) the date on which we have issued more than $1.0 billion in non-convertible debt securities during the previous three years.

Even after we cease to be an emerging growth company, we will still be a smaller reporting company until such time as (i) we determine that the market value of the voting and non-voting shares held by non-affiliates is $250 million or more but less than $700 million as of the last business day of our second fiscal quarter and our annual revenues are $100 million or more during our most recently completed fiscal year, or (ii) the market value of the voting and non-voting shares held by non-affiliates is $700 million or more measured on 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, including reduced financial and executive compensation disclosure. In addition, even if we cease to be an emerging growth company, we will remain exempt from the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act provided we do not qualify as an "accelerated filer" as defined in Rule 12b-2 under the Exchange Act, which would occur if our annual revenue was $100 million or more during our most recently completed fiscal year and the market value of our common equity held by non-affiliates is $75 million or more as of the last business day of our most recently completed second fiscal quarter, and only after we have been subject to the reporting requirements of the Exchange Act for a period of at least 12 calendar months.

We will continue to incur increased costs as a result of operating as a public company, and our management is required to devote substantial time to new compliance initiatives and corporate governance practices.

As a public company, and particularly after we are no longer an emerging growth company, we incur and will continue to incur significant legal, accounting and other expenses. The Sarbanes-Oxley Act, the Dodd-Frank Wall Street Reform and Consumer Protection Act, the listing requirements of The Nasdaq Global Market and other applicable securities rules and regulations impose various requirements on public companies, including establishment and maintenance of effective disclosure and financial controls and corporate governance practices. Our management and other personnel need to devote a substantial amount of time to these compliance initiatives, which has and we expect will continue to divert their attention away from our core business operations and revenue-producing activities. Moreover, these rules and regulations has and will continue to increase our legal and financial compliance costs and make some activities more time-consuming and costly. For example, these rules and regulations make it more difficult and more

expensive for us to obtain director and officer liability insurance, which requires us to incur substantially higher costs to obtain the same or similar coverage or accept reduced policy limits and coverage, which in turn could also make it more difficult for us to attract and retain qualified individuals to serve on our board of directors and as our executive officers.

We cannot predict or estimate the amount of additional costs we may incur or the timing of such costs. These rules and regulations are often subject to varying interpretations, in many cases due to their lack of specificity, and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices. In addition, if we fail to comply with these rules and regulations, we could be subject to a number of penalties, including the delisting of our Class A common stock, fines, sanctions or other regulatory action or civil litigation.

Failure to comply with requirements to design, implement and maintain effective internal control over financial reporting could have a material adverse effect on our business and stock price.

As a public company, we are required to evaluate our internal control over financial reporting in a manner that meets the standards of publicly traded companies required by Section 404(a) of the Sarbanes-Oxley Act, or Section 404.

As a public company, we have significant requirements for enhanced financial reporting and internal controls. The process of designing, implementing and maintaining effective internal controls is a continuous effort that will require us to anticipate and react to changes in our business and the economic and regulatory environments. In this regard, we will need to continue to dedicate internal resources, potentially engage outside consultants, adopt a detailed work plan to assess and document the adequacy of internal control over financial reporting, continue steps to improve control processes as appropriate, validate through testing whether such controls are functioning as documented, and implement a continuous reporting and improvement process for internal control over financial reporting. If we are unable to establish or maintain appropriate internal financial reporting controls and procedures, it could cause us to fail to meet our reporting obligations on a timely basis, result in material misstatements in our consolidated financial statements and adversely affect our operating results. In addition, we are required, pursuant to Section 404, to furnish a report by our management on, among other things, the effectiveness of our internal control over financial reporting. This assessment must include disclosure of any material weaknesses identified by our management in our internal control over financial reporting. The rules governing the standards that must be met for our management to assess our internal control over financial reporting are complex and require significant documentation and testing. Testing and maintaining internal controls may divert our management's attention from other matters that are important to our business. In addition, once we are no longer an emerging growth company, provided we then qualify as an "accelerated filer" as defined in Rule 12b-2 under the Exchange Act, we will be required to include in the annual reports that we file with the SEC an attestation report on our internal control over financial reporting issued by our independent registered public accounting firm.

In connection with the implementation of the necessary procedures and practices related to internal control over financial reporting, we may identify deficiencies that we may not be able to remediate in time to meet the deadline imposed by the Sarbanes-Oxley Act for compliance with the requirements of Section 404. In addition, we may encounter problems or delays in completing the remediation of any deficiencies identified by our independent registered public accounting firm in connection with the issuance of their attestation report. Our testing, or the 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. Any material weaknesses could result in a material misstatement of our annual or quarterly consolidated financial statements or disclosures that may not be prevented or detected.

Furthermore, we may not be able to conclude, on an ongoing basis, that we have effective internal control over financial reporting in accordance with Section 404, or our independent registered public accounting firm may not be able to issue an unqualified attestation report once we become subject to the corresponding requirement under Section 404. If either we are unable to conclude that we have effective internal control over financial reporting or our independent registered public accounting firm is unable to provide us with an unqualified report, investors could lose confidence in our reported financial information, which could have a material adverse effect on the trading price of our Class A common stock.

Provisions in our certificate of incorporation and bylaws and under Delaware law could make an acquisition of our company, which may be beneficial to our stockholders, more difficult and may prevent attempts by our stockholders to replace or remove our current management.

Provisions in our certificate of incorporation and our bylaws may discourage, delay or prevent a merger, acquisition or other change in control of our company that stockholders may consider favorable, including transactions in which you might otherwise receive a premium for your shares. These provisions could also limit the price that investors might be willing to pay in the future for shares of our common stock, thereby depressing the market price of our Class A common stock. In addition, because our board of directors is responsible for appointing the members of our management team, 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. Among other things, these provisions include those establishing:

- a classified board of directors with three-year staggered terms, which may delay the ability of stockholders to change the membership of a majority of our board of directors;
- no cumulative voting in the election of directors, which limits the ability of minority stockholders to elect director candidates;
- the exclusive right of our board of directors to elect a director to fill a vacancy created by the expansion of the board of directors or the resignation, death or removal of a director, which prevents stockholders from filling vacancies on our board of directors;
- the ability of our board of directors to authorize the issuance of shares of preferred stock and to determine the terms of those shares, including preferences and voting rights, without stockholder approval, which could be used to significantly dilute the ownership of a hostile acquirer;
- the ability of our board of directors to alter our bylaws without obtaining stockholder approval;
- the required approval of the holders of at least two-thirds of the shares entitled to vote at an election of directors to adopt, amend or repeal our bylaws or repeal the provisions of our certificate of incorporation regarding the election and removal of directors;
- a prohibition on stockholder action by written consent, which forces stockholder action to be taken at an annual or special meeting of our stockholders;
- the requirement that a special meeting of stockholders may be called only by the chairman of the board of directors, the chief executive officer, the president or the board of directors, which may delay the ability of our stockholders to force consideration of a proposal or to take action, including the removal of directors; and
- advance notice procedures that stockholders must comply with in order to nominate candidates to our board of directors or to propose matters to be acted upon at a stockholders' meeting, which may discourage or deter a potential acquirer from conducting a solicitation of proxies to elect the acquirer's own slate of directors or otherwise attempting to obtain control of us.

Moreover, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the General Corporation Law of the State of Delaware (the "DGCL"), which prohibits a person who owns in excess of 15% of our outstanding voting stock from merging or combining with us for a period of three years after the date of the transaction in which the person acquired in excess of 15% of our outstanding voting stock, unless the merger or combination is approved in a prescribed manner.

Our certificate of incorporation designates specific courts as the exclusive forum for certain litigation that may be initiated by our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees.

Our certificate of incorporation provides that, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware will be the exclusive forum for (i) any derivative action or proceeding brought on our behalf, (ii) any action asserting a claim of breach of a fiduciary duty or other wrongdoing by any of our directors, officers, employees or agents to us or our stockholders, (iii) any action asserting a claim arising pursuant to any provision of the DGCL or our certificate of incorporation or bylaws, (iv) any action to interpret, apply, enforce or determine the validity of our certificate of incorporation or bylaws or (v) any action asserting a claim governed by the internal affairs doctrine; provided that, the exclusive forum provision will not apply to suits brought to enforce any liability or duty created by the Securities Act, the Exchange Act, the rules and regulations thereunder or any other claim for which the federal courts have exclusive jurisdiction; and provided further that, if and only if the Court of Chancery of the State of Delaware dismisses any such action for lack of subject matter jurisdiction, such action may be brought in another state or federal court sitting in the State of Delaware. Our certificate of incorporation further provides that, unless we consent in writing to the selection of an alternative forum, the federal district courts of the United States of America shall, to the fullest extent permitted by law, be the sole and exclusive forum for the resolution of any complaint asserting a cause of action arising under the Securities Act. Any person or entity purchasing or otherwise acquiring any interest in shares of our capital stock shall be deemed to have notice of and to have consented to the provisions of our certificate of incorporation described above.

We believe these provisions benefits us by providing increased consistency in the application of Delaware law by chancellors particularly experienced in resolving corporate disputes and in the application of the Securities Act by federal judges, as applicable, efficient administration of cases on a more expedited schedule relative to other forums and protection against the burdens of multi-forum litigation. However, these 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 or agents, which may discourage such lawsuits against us and our directors, officers and other employees and agents.

Because we do not anticipate paying any cash 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 cash 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. As a result, capital appreciation, if any, of our common stock would be your sole source of gain on an investment in our common stock for the foreseeable future.

We could be subject to securities class action litigation.

In the past, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for us because medical device companies have experienced significant stock price volatility in recent years. If we face such litigation, it could result in substantial costs and a diversion of management's attention and resources, which could harm our business.

General Risk Factors

Changes in accounting standards and subjective assumptions, estimates and judgments by management related to complex accounting matters could significantly affect our business, financial condition and results of operations.

U.S. GAAP, and related accounting pronouncements, implementation guidelines and interpretations with regard to a wide range of matters that are relevant to our business are highly complex. These matters include, but are not limited to, revenue recognition, leases, income taxes, impairment of goodwill and long-lived assets and stock-based compensation. Changes in these rules, guidelines or interpretations could significantly change our reported or expected financial performance or financial condition.

In addition, the preparation of financial statements in conformity with GAAP requires management to make assumptions, estimates and judgments that affect the amounts reported in our consolidated financial statements and accompanying notes. We base our estimates and judgments on historical experience and on various other assumptions that we believe to be reasonable under the circumstances. The results of these estimates form the basis for making judgments about the carrying values of assets, liabilities and equity, and the amount of net sales and expenses that are not readily apparent from other sources. Our operating results may be adversely affected if our assumptions change or if actual circumstances differ from those in our assumptions, which could cause our operating results to fall below the expectations of securities analysts and investors, resulting in a decline in our stock price.

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

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

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

If our operating and financial performance in any given period does not meet the guidance we provide to the public, the market price of our Class A common stock may decline.

We may, but are not obligated to, continue to provide public guidance on our expected operating and financial results for future periods. Any such guidance will be comprised of forward-looking statements subject to certain risks and uncertainties similar to those described in this Annual Report and any additional risks and uncertainties described from time to time in our public filings or other public statements. Our actual results may not always be in line with or exceed any guidance we have provided, especially in times of economic uncertainty. There can be no assurance that we will continue to issue public guidance in the future. If, in the future, we provide guidance, and our operating and/or financial results for a particular period do not meet such guidance or the expectations of investment analysts, or if we reduce, withdraw or otherwise change our guidance for future periods, or stop providing guidance, the market price of our Class A common stock will likely decline.

If securities or industry analysts do not publish research or reports about our business, or if they issue an adverse or misleading opinion regarding our Class A common stock, our stock price and trading volume would likely decline.

The trading market for our Class A common stock will be influenced by the research and reports that industry or securities analysts publish about us and our business. We do not control these analysts. We may be slow to attract research coverage and the analysts, who publish information about our Class A common stock, may have had relatively little experience with us or our industry, which could affect their ability to accurately forecast our results and could make it more likely that we fail to meet their estimates. If no or few securities or industry analysts commence coverage of us, the trading price for our stock would be negatively impacted. In the event we obtain securities or industry analyst coverage, if any of the analysts who cover us issue an adverse or misleading opinion regarding us, our business model, our financial performance, our stock price or otherwise, our stock price would likely decline. If one or more of these analysts ceases coverage of us or fails to publish reports on us regularly, we could lose visibility in the financial markets, which in turn could cause our stock price or trading volume to decline and result in the loss of all or a part of your investment in us.

Item 1B. Unresolved Staff Comments.

None.

Item 2. Properties.

Our principal executive office is located in Silver Spring, Maryland, where we lease approximately 5,052 square feet of office and laboratory space under a lease that expires in May 2023. We also occupy approximately 12,888 square feet of manufacturing and office space in Roswell, Georgia under a lease that expires in July 2023, approximately 36,173 square feet of manufacturing, laboratory and office space in Richmond, California under a lease that expires in November 2025, and limited square footage for administrative space in San Diego, California that expires in March 2023. We expect to renew all of our leases that expire in 2023. We believe that our facilities are sufficient to meet our current needs and that suitable additional space will be available as and when needed.

Item 3. Legal Proceedings.

From time to time, we may be involved in claims and proceedings arising in the course of our business. The outcome of any such claims or proceedings, regardless of the merits, is inherently uncertain. For information about legal proceedings in which we are involved, see Note 17 to the consolidated financial statements included elsewhere in this Annual Report.

Item 4. Mine Safety Disclosure.

Not applicable.

PART II

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

Market Information

Our Class A common stock is traded on The Nasdaq Stock Market under the symbol "AZYO."

Stockholders

As of March 6, 2023, there were approximately 16 holders of record of our Class A common stock and two holders of record of our Class B common stock. This number does not include "street name" or beneficial holders, whose shares are held of record by banks, brokers, financial institutions and other nominees.

Dividend Policy

We have never declared or paid any cash dividends on our capital stock. We intend to retain future earnings, if any, to finance the operation and expansion of our business and do not anticipate paying any cash dividends in the foreseeable future. Any future determination related to our dividend policy will be made at the discretion of our board of directors after considering our financial condition, results of operations, capital requirements, business prospects and other factors the board of directors deems relevant, and subject to the restrictions contained in any future financing instruments. In addition, our ability to pay cash dividends is currently restricted by the terms of the agreements governing our SWK Loan Facility.

Equity Compensation Plans

The information required by Item 5 regarding equity compensation plans is incorporated herein by reference to Part III, Item 11 in this Annual Report.

Recent Sales of Unregistered Securities

None.

Purchases of Equity Securities by the Issuer or Affiliated Purchasers

None.

Item 6. [Reserved]

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

The following discussion and analysis should be read in conjunction with our consolidated financial statements and the related notes included elsewhere in this Annual Report. This discussion contains forward-looking statements reflecting our current expectations, estimates, plans and assumptions concerning events and financial trends that involve risks and may affect our future operating results and financial position. Actual results and the timing of events may differ materially from those contained in these forward-looking statements due to a number of factors, including those discussed in the sections entitled "Forward-Looking Statements," "Risk Factors Summary" and in Part I, Item 1A. "Risk Factors" of this Annual Report.

Overview

We are a commercial-stage regenerative medicine company focused on creating the next generation of differentiated products and improving outcomes in patients undergoing surgery. We seek to leverage our unique understanding of biologics to improve the interaction between medical devices and patients, with the goal of reducing complications and improving healing. From our proprietary tissue processing platforms, we have developed a portfolio of advanced regenerative medical products that are designed to mimic the healing response of natural biological material. Our proprietary products are designed to address the device protection, women's health, orthobiologics and cardiovascular markets, which represented a combined $3 billion market opportunity in the United States in 2019. To expand our commercial reach, we have commercial relationships with major medical device companies, such as Boston Scientific, Biotronik and beginning in March 2023, Sientra, to promote and sell some of our products. We believe our focus on our unique regenerative medicine platforms will ultimately maximize our probability of continued clinical and commercial success and will create a long-term competitive advantage for us.

We estimate that, over the past two years, approximately two million patients per year in the United States were implanted with either medical devices, such as pacemakers, defibrillators, neuro-stimulators, spinal fusion and trauma fracture hardware or tissue expanders for breast reconstruction. This number has been driven by advances in medical device technologies, reimbursement models focused on patient outcomes, and an aging population with a growing incidence of comorbidities, including diabetes, obesity and cardiovascular and peripheral vascular diseases. These comorbidities can exacerbate various immune responses and contribute to other complications upon device implant.

Our products are targeted to address unmet clinical needs with the goal of promoting healthy tissue formation and avoiding complications associated with medical device implants, such as infection, scar-tissue formation, capsular contraction, erosion, migration, non-union of implants and implant rejection. We have leading products in each of our four priority markets: device protection, cardiovascular, orthobiologics and women's health. In device protection, we sell the only biological envelope, protected by a global patent portfolio, that forms a natural, systemically vascularized pocket for holding implanted electronic devices. In cardiovascular, we sell our SIS ECM for use as an intracardiac and vascular patch. In orthobiologics, we have a proprietary processing technology for manufacturing a comprehensive portfolio of bone regenerative products designed to promote the body's ability to regenerate healthy bone, osteogenesis, while decreasing cell apoptosis, or programmed cell death. In women's health, we have a patented cell removal technology that produces undamaged extracellular dermal matrices with superior handling, designed to promote faster healing and reduce inflammation. In pre-clinical and clinical studies, our products have supported and, in some cases, accelerated tissue healing, and thereby improved patient outcomes.

We process all of our products at our two manufacturing facilities in Roswell, Georgia and Richmond, California, and stock inventory of raw materials, supplies and finished goods at those locations. We rely on a single or limited number of suppliers for certain raw materials and supplies. Except for the porcine tissue supplier of our raw materials for our CanGaroo and cardiovascular products, which is Cook Biotech, we generally have no long-term supply agreements with our suppliers, as we obtain supplies on a purchase order basis. Specifically, we acquire donated human tissue directly through tissue procurement firms engaged by us. Our product are shipped either directly to hospital customers or through distribution channels.

We have incurred significant operating losses since our inception. We incurred a net loss of $32.9 million and $24.8 million for the years ended December 31, 2022 and 2021, respectively. Our accumulated deficit as of December 31, 2022 was $138.0 million.

We expect to continue to incur significant expenses and operating losses for the foreseeable future as we expand our product development and clinical and research activities. In addition, we expect to continue to incur additional costs and expenses associated with operating as a public company.

Our ability to achieve profitability will depend on our ability to generate sales from existing or new products sufficient to exceed our ongoing operating expenses and capital requirements. Because of the numerous risks and uncertainties affecting product sales and our ongoing commercialization and product development efforts, including our ability to obtain FDA clearance for the next generation of our flagship CanGaroo product, CanGaroo RM and successfully commercialize this product, we are unable to predict with any certainty whether we will be able to increase sales of our products or the timing or amount of ongoing expenditures we will be required to incur. Accordingly, even if we are able to increase sales of our products, we may not become profitable.

In order to mitigate the current and potential future liquidity issues caused by the matters noted above, we may seek to raise capital through the issuance of common stock, restructure our Revenue Interest Obligation, or pursue asset sale or other transactions. However, such transactions may not be successful and we may not be able to raise additional equity, refinance or restructure our debt instruments, or sell assets on acceptable terms, or at all. As such, based on our current operating plans, we believe there is uncertainty as to whether our future cash flows along with our existing cash, issuances of additional equity and cash generated from expected future sales will be sufficient to meet our anticipated operating needs through twelve months from the financial statement issuance date. Due to these factors, there is substantial doubt about our ability to continue as a going concern within one year after the issuance of the financial statements.

Impact of COVID-19

As a result of the COVID-19 pandemic, the number of procedures performed using our products has intermittently decreased, as governmental authorities in the United States have recommended, and in certain cases required, that elective, specialty and other non-emergency procedures and appointments be suspended or canceled in order to avoid patient exposure to medical environments and the risk of potential infection with COVID-19, and to focus limited resources and personnel capacity on the treatment of COVID-19 patients. These measures and challenges will likely continue for the duration of the pandemic, which is uncertain, and may reduce our net sales in the future and negatively impact our business, financial condition and results of operations while the pandemic continues. In addition, numerous state and local jurisdictions, including those where our facilities are located, imposed, and others in the future may impose or re-impose, “shelter-in-place” orders, quarantines, executive orders and similar government orders and restrictions for their residents to control the spread of COVID-19. The extent to which the COVID-19 pandemic impacts our future financial condition and results of operations will depend on future events and developments, which are highly uncertain and cannot be predicted, including the severity and spread of the disease and the effectiveness of actions to contain the disease or treat its impact, among others. As new information regarding COVID-19 continues to emerge, and, as variants of COVID-19 emerge, it is difficult to predict the degree to which this disease will continue to affect our business.

FiberCel Recall

On June 2, 2021, we issued a voluntary recall pertaining to a single donor lot of our FiberCel Fiber Viable Bone Matrix, a bone repair product formerly distributed by Medtronic, after learning of post-surgical infections reported in

several patients treated with the product, including some patients that tested positive for tuberculosis. Since the voluntary recall, we have settled 26 lawsuits relating to FiberCel for a total of approximately $7.3 million and settled and paid 11 of these lawsuits for a total cash outlay of $3.6 million. For the remaining 81 cases for which settlements have not been reached, we estimated a probable loss related to each case and have recorded a liability at an estimated amount of $13.7 million for a total estimated liability at December 31, 2022 of $17.4 million, which is recorded as Contingent Liability for FiberCel Litigation in the accompanying consolidated balance sheets included in this Annual Report. As of December 31, 2022, we have recorded insurance receivables of $13.8 million on our balance sheet in respect of our insurance coverage for the FiberCel Litigation product liability losses.

For an update on the legal proceedings related to the FiberCel Recall, see Part I, Item 3, “Legal Proceedings” and Note 16 to the consolidated financial statements included elsewhere in this Annual Report.

Defending any current or future claims, proceedings or lawsuits, regardless of merit, could be costly, divert management attention and result in adverse publicity, which could result in the withdrawal of, or reduced acceptance of, our products in the market. If we cannot successfully defend against product liability claims, we could incur substantial liability and costs. Additionally, following the public announcement of our voluntary recall, there has been various media coverage surrounding the recall and patients impacted. Such negative publicity related to the perceived quality and safety of our products could affect our brand image, decrease confidence in our products or have an adverse effect on our ability to retain existing and attract new customers, suppliers and distribution partners, any one of which could result in decreased revenue, having an adverse effect on our business, financial condition and operating results.

Components of Our Results of Operations

Net Sales

We recognize revenue on the sale of our products. Our device protection and cardiovascular products are sold to hospitals and other healthcare facilities primarily through our direct sales force, commercial partners or independent sales agents. Our women’s health product, SimpliDerm, is sold directly to hospitals and other healthcare facilities through independent sales agents. Our orthobiologics products are sold through commercial partners. Our contract manufacturing products are sold directly to corporate customers. Gross to net sales adjustments include sales returns and prompt payment and volume discounts.

Expenses

In recent years, we have incurred significant costs in the operation of our business. We expect that our recurring operating costs will largely stabilize, or increase at modest rates, in the near future through the identification of efficiencies as we grow. We may, however, still experience more significant expense increases as we expand our product development and clinical and research activities. As a result, we will need to generate significant net sales in order to achieve profitability. Below is a breakdown of our main expense categories and the related expenses incurred in each category:

Costs of Goods Sold

Our cost of goods sold relate to purchased raw materials and the processing and conversion costs of such raw materials consisting primarily of salaries and benefits, supplies, quality control testing and the manufacturing overhead incurred at our processing facilities in Richmond, California and Roswell, Georgia. Both facilities have additional capacity, which if utilized, would further leverage our fixed overhead. Cost of goods sold also includes the amortization of intangibles generated from the CorMatrix Acquisition in 2017.

Sales and Marketing Expenses

Sales and marketing expenses are primarily related to our direct sales force, consisting of salaries, commission compensation, fringe benefits, meals and other expenses. Auto and travel costs have also historically contributed to sales and marketing expenses, albeit to a lesser extent due to the COVID-19 pandemic. Outside of our direct sales force, we incur significant expenses relating to commissions to our CanGaroo commercial partners and independent sales agents.

Additionally, this expense category includes distribution costs as well as market research, trade show attendance, advertising and public relations related to our products, and customer service expenses.

General and Administrative Expenses

General and administrative ("G&A") expenses consist primarily of compensation, consulting, legal, human resources, information technology, accounting, insurance and general business expenses. Our G&A expenses have increased as a result of operating as a public company, especially as a result of hiring additional personnel and incurring greater director and officer insurance premiums, greater investor relations costs, and additional costs associated with accounting, legal, tax-related and other services associated with maintaining compliance with exchange listing and SEC requirements.

Research and Development Expenses

Research and development ("R&D") expenses consist primarily of salaries and fringe benefits, laboratory supplies, clinical studies and outside service costs. Our product development efforts primarily relate to new offerings in support of the orthobiologics market and activities associated with the development of CanGaroo RM, our CanGaroo Envelope with antibiotics. Our future R&D expenses may increase as a result of additional work required to address the FDA's questions in the NSE letter we recently received regarding our CanGaroo RM. We also conduct clinical studies to validate the performance characteristics of our products and to capture patient data necessary to support our commercial efforts.

FiberCel Litigation Costs

FiberCel litigation costs consist primarily of legal fees and the estimated costs to resolve the outstanding FiberCel litigation cases offset by the estimated amounts recoverable under insurance, indemnity and contribution agreements for such costs.

Results of Operations

Comparison of the Years Ended December 31, 2022 and 2021

	Year Ended December 31,				Change 2021 / 2022	
	2022		2021			
(in thousands, except percentages)	Amount	% of Net Sales	Amount	% of Net Sales	$	%
Net sales	$ 49,187	100.0 %	$ 47,390	100.0 %	$ 1,797	3.8 %
Cost of goods sold	29,965	60.9 %	28,368	59.9 %	1,597	5.6 %
Gross profit	19,222	39.1 %	19,022	40.1 %	200	1.1 %
Sales and marketing	20,195	41.1 %	18,825	39.7 %	1,370	7.3 %
General and administrative	16,627	33.8 %	13,687	28.9 %	2,940	21.5 %
Research and development	8,940	18.2 %	9,266	19.6 %	(326)	(3.5)%
FiberCel litigation costs	5,200	10.6 %	276	0.6 %	4,924	NM
Total operating expenses	50,962	103.6 %	42,054	88.7 %	8,908	21.2 %
Loss from operations	(31,740)	(64.5)%	(23,032)	(48.6)%	(8,708)	(37.8)%
Interest expense	5,282	10.7 %	5,324	11.2 %	(42)	(0.8)%
Other income, net	(4,159)	(8.5)%	(3,579)	(7.6)%	(580)	NM
Loss before provision of income taxes	(32,863)	(66.8)%	(24,777)	(52.3)%	(8,086)	(32.6)%
Income tax expense	34	0.1 %	55	0.1 %	(21)	(38.2)%
Net loss	**$ (32,897)**	**(66.9)%**	**$ (24,832)**	**(52.4)%**	**$ (8,065)**	**(32.5)%**

NM = not meaningful

Net Sales

Net sales information for our products is summarized as follows:

	Year Ended December 31,					
	2022		2021		Change 2021 / 2022	
(in thousands, except percentages)	Amount	% of Net Sales	Amount	% of Net Sales	$	%
Products:						
Device protection	$ 9,093	18.5 %	$ 7,902	16.7 %	$ 1,191	15.1 %
Women's health	7,474	15.2 %	5,046	10.6 %	2,428	48.1 %
Orthobiologics	25,338	51.5 %	26,934	56.8 %	$ (1,596)	(5.9)%
Cardiovascular	7,282	14.8 %	7,508	15.8 %	$ (226)	(3.0)%
Total Net Sales	**$ 49,187**	**100.0 %**	**$ 47,390**	**100.0 %**	**$ 1,797**	**3.8 %**

Total net sales increased $1.8 million, or 3.8%, to $49.2 million in the year ended December 31, 2022 compared to $47.4 million in the year ended December 31, 2021. With respect to the individual product segments, the increase in the net sales of both our device protection and women's health products were primarily attributable to volume growth in the respective segment. The net sales in the orthobiologics segment decreased between the years as a result of the discontinuation of sales to Medtronic in June 2021 following our recall. Excluding the $4.9 million of Medtronic sales from the year ended December 31, 2021, our net sales of orthobiologic products increased $3.3 million between the years primarily due to increased sales from several contract manufacturing customers. Net sales of our cardiovascular products were relatively flat between the years.

Cost of Goods Sold

Cost of goods sold and gross margin percentage information for our products is summarized as follows:

	Year Ended December 31,					
	2022		2021		Change 2021 / 2022	
(in thousands, except percentages)	Amount	Gross Margin %	Amount	Gross Margin %	$	%
Products:						
Device protection	$ 2,979	67.2 %	$ 2,141	72.9 %	$ 838	(5.7)%
Women's health	4,337	42.0 %	4,132	18.1 %	205	23.9 %
Orthobiologics	17,755	29.9 %	17,192	36.2 %	563	(6.2)%
Cardiovascular	1,497	79.4 %	1,507	79.9 %	(10)	(0.5)%
Cost of goods sold, excluding intangible asset amortization	26,568	46.0 %	24,972	47.3 %	1,596	(1.3)%
Intangible asset amortization expense	3,397	(6.9)%	3,396	(7.2)%	1	0.3 %
Total Cost of Goods Sold	**$ 29,965**	**39.1 %**	**$ 28,368**	**40.1 %**	**$ 1,596**	**(1.1)%**

Total cost of goods sold increased $1.6 million to $30.0 million in the year ended December 31, 2022 compared to $28.4 million in the year ended December 31, 2021 primarily due to an increase in total net sales. Gross margin was 39.1% in the year ended December 31, 2022 compared to 40.1% in the year ended December 31, 2021. Gross margin, excluding intangible asset amortization, was 46.0% in the year ended December 31, 2022 compared to 47.3% in the year ended December 31, 2021. With respect to the individual product segments, the gross margin of device protection declined slightly in the year ended December 31, 2022 compared to the year ended December 31, 2021 due to operational inefficiencies in the current year causing minor increases to the cost of the product. The gross margin of women's health products increased significantly in the current year due to non-recurring inventory writedowns in the prior year on certain slow moving product sizes which caused reductions in the prior years' gross margin. The current year decrease in gross margin of the orthobiologics products was primarily due to a shift in product mix as the contracted services component of

this segment, which have lower margins than our other products, experienced sales growth in the year ended December 31, 2022. Gross margin on our cardiovascular products was relatively flat between years.

Operating Expenses

Sales and Marketing

Sales and marketing expenses increased $1.4 million, or 7.3%, to $20.2 million in the year ended December 31, 2022 compared to $18.8 million in the year ended December 31, 2021. The increase was primarily the result of increases in commissions paid to independent sales agents due to sales growth in our women's health products and higher stock-based compensation. As a percentage of net sales, sales and marketing expenses grew to 41.1% in the year ended December 31, 2022 from 39.7% in the year ended December 31, 2021 primarily due to increases in our commission-based revenue streams.

General and Administrative

G&A expenses increased $2.9 million, or 21.5%, to $16.6 million in the year ended December 31, 2022 compared to $13.7 million in the year ended December 31, 2021. The increase in G&A expenses was primarily due to certain non-recurring charges associated with legal fees on various corporate matters and the Chief Executive Officer transition described in Note 4 to the consolidated financial statements included elsewhere in this Annual Report. As a percentage of net sales, G&A expenses rose to 33.8% in the year ended December 31, 2022 from 28.9% in the year ended December 31, 2021.

Research and Development

R&D expenses decreased $0.4 million, or 3.5%, to $8.9 million in the year ended December 31, 2022 compared to $9.3 million in the year ended December 31, 2021. The decline in R&D expenses was largely attributable to the lessening of work needed to finalize the development and testing of our CanGaroo Envelope with antibiotics. We continue to focus our R&D efforts on the development of our pipeline products.

FiberCel Litigation Costs

FiberCel litigation costs increased to $5.2 million in the year ended December 31, 2022 compared to $0.3 million in the year ended December 31, 2021. The increase in expense was primarily due to the settlements reached in a significant number of FiberCel Litigation cases in the year ended December 31, 2022 as well as the estimation of contingent liabilities for the unsettled cases. The total of such settlement and estimated settlement values was recorded (net of estimated insurance, indemnity and contribution agreement recoveries) in the year ended December 31, 2022. See further discussion in Note 17 to consolidated financial statements included elsewhere in this Annual Report.

Interest Expense

Interest expense was approximately $5.3 million in both the years ended December 31, 2022 and December 31, 2021. While there was essentially no fluctuation between years, we had lower draws on our formerly outstanding MidCap Credit Facility and lower outstanding principal on our formerly outstanding MidCap Loan Facility, which reductions in interest expense were offset by increased principal outstanding and higher interest rates on the SWK Credit Facility which commenced in August 2022 upon consummation of our debt refinancing. See " - Liquidity and Capital Resources - Credit Facilities" below for a further discussion of these debt agreements and Note 9 to the consolidated financial statements included elsewhere in this Annual Report.

Other Income, net

Other income, net was approximately $4.2 million in the year ended December 31, 2022 and was primarily attributable to the $5.0 million gain on the revaluation of our Revenue Interest Obligation to Ligand. See Note 11 to the consolidated financial statements included elsewhere in this Annual Report for additional information. Such gain was

offset by other expense related to our debt refinancing in August 2022 and the associated prepayment fees, payment of unaccrued exit fees and the write-off of unamortized deferred financing costs, which collectively resulted in a loss of $1.2 million. Such loss was offset by other income of $0.4 million related to the forgiveness of interest accrued on the promissory note to a tissue supplier upon repayment of such note in August 2022. See Note 9 to the accompanying consolidated financial statements included elsewhere in this Annual Report for further discussion of these transactions.

Other income, net was approximately $3.6 million in the year ended December 31, 2021. Such other income relates to the forgiveness of our promissory note with Silicon Valley Bank under the Paycheck Protection Program of the CARES Act in the amount of approximately $3.0 million and our receipt of $550,000 in satisfaction of a 2018 settlement with KeraLink. For further discussion on these items, see Notes 9 and 18 to the consolidated financial statements included elsewhere in this Annual Report.

Non-GAAP Financial Measures

In this Part II. Item 7. “Management’s Discussion and Analysis of Financial Condition and Results of Operations” of the Annual Report, we present our gross margin, excluding intangible asset amortization. We calculate gross margin, excluding intangible asset amortization, as gross profit, excluding amortization expense relating to intangible assets we acquired in the CorMatrix Acquisition, divided by net sales. Gross margin, excluding intangible asset amortization, is a supplemental measure of our performance, is not defined by or presented in accordance with U.S. generally accepted accounting principles (“GAAP”), has limitations as an analytical tool and should not be considered in isolation or as an alternative to our GAAP gross margin, gross profit or any other financial performance measure presented in accordance with GAAP. We present gross margin, excluding intangible asset amortization, because we believe that it provides meaningful supplemental information regarding our operating performance by removing the impact of amortization expense, which is not indicative of our overall operating performance. We believe this provides our management and investors with useful information to facilitate period-to-period comparisons of our operating results. Our management uses this metric and the results of the segments in assessing the health of our business and our operating performance, and we believe investors’ understanding of our operating performance is similarly enhanced by our presentation of this metric.

Although we use gross margin, excluding intangible asset amortization, as described above, this metric has limitations as an analytical tool and should not be considered in isolation or as a substitute for financial information presented in accordance with GAAP. In addition, other companies, including companies in our industry, may use other measures to evaluate their performance, which could reduce the usefulness of this non-GAAP financial measure as a tool for comparison.

The following table presents a reconciliation of our gross margin, excluding intangible asset amortization, for the years ended December 31, 2022 and 2021 to the most directly comparable GAAP financial measure, which is our GAAP gross margin (in thousands).

	Year Ended December 31,	
	2022	2021
Net sales	$ 49,187	$ 47,390
Cost of goods sold	29,965	28,368
Gross profit	19,222	19,022
Intangible asset amortization expense	3,397	3,396
Gross profit, excluding intangible asset amortization	$ 22,619	$ 22,418
Gross margin	39.1 %	40.1 %
Gross margin, excluding intangible asset amortization	46.0 %	47.3 %

Seasonality

Historically, we have experienced seasonality in our first and fourth quarters, and we expect this trend to continue. We have experienced and may in the future experience higher sales in the fourth quarter as a result of hospitals in the United States increasing their purchases of our products to coincide with the end of their budget cycles. Satisfaction of

patient deductibles throughout the course of the year also results in increased sales later in the year, once patients have paid their annual insurance deductibles in full, which reduces their out-of-pocket costs. Conversely, our first quarter generally has lower sales than the preceding fourth quarter as patient deductibles are re-established with the new year, which increases their out-of-pocket costs.

Liquidity and Capital Resources

As of December 31, 2022, we had cash and restricted cash of approximately $17.0 million. Since inception, we have financed our operations primarily through private placements of our convertible preferred stock, amounts borrowed under our credit facilities, sales of our products and sales of our common stock. Our historical cash outflows have primarily been associated with acquisition and integration, manufacturing and administrative costs, research and development, clinical activity and investing in our commercial infrastructure through our direct sales force and our commercial partners in order to expand our presence and to promote awareness and adoption of our products. As of December 31, 2022, our accumulated deficit was $138.0 million.

On October 13, 2020, in connection with our IPO, we issued and sold 2,941,176 shares of common stock, consisting of 2,205,882 shares of Class A common stock and 735,294 shares of Class B common stock, at a price to the public of $17.00 per share, resulting in net proceeds to us of approximately $43.0 million, after deducting the underwriting discount of approximately $3.5 million and offering expenses of approximately $3.5 million. Additionally, in December 2021, we closed on a private investment in public equity (PIPE) financing, thereby receiving net proceeds of approximately $13.8 million, after deducting offering costs. The PIPE investors purchased an aggregate of 2,122,637 shares of the Company's Class A common stock and an aggregate of 1,179,244 shares of the Company's Class B common stock (which are convertible on a one-for-one basis into shares of Class A common stock), in each case, at a price of $4.24 per share. Furthermore, in December 2022, we issued and sold 2,350,000 shares our Class A common stock at a price to the public of $4.75 per share in a registered underwritten offering, resulting in net proceeds to us of approximately $10.2 million, after deducting underwriting discounts and offering expenses.

We expect our losses to continue for the foreseeable future and these losses will continue to have an adverse effect on our financial position. Because of the numerous risks and uncertainties associated with our commercialization and development efforts, including our ability to obtain FDA clearance for the next generation of our flagship CanGaroo product, CanGaroo RM and successfully commercialize this product, we are unable to predict when we will become profitable, and we may never become profitable. Our inability to achieve and then maintain profitability would negatively affect our business, financial condition, results of operations and cash flows.

In order to mitigate the current and potential future liquidity issues caused by the matters noted above, we may seek to raise capital through the issuance of common stock, restructure our Revenue Interest Obligation, or pursue asset sale or other transactions. However, such transactions may not be successful and we may not be able to raise additional equity, refinance our debt instruments, or sell assets on acceptable terms, or at all. As such, based on our current operating plans, we believe there is uncertainty as to whether our future cash flows along with our existing cash, availability under the SWK Loan Facility (described below under "—Credit Facilities"), issuances of additional equity and cash generated from expected future sales will be sufficient to meet our anticipated operating needs through twelve months from the financial statement issuance date. Due to these factors, there is substantial doubt about our ability to continue as going concern within one year after the issuance of the financial statements.

Cash Flows for the Years Ended December 31, 2022 and 2021

	Year Ended December 31,	
	2022	2021
	(in thousands)	
Net cash used in:		
Operating activities	$ (21,434)	$ (15,446)
Investing activities	(540)	(369)
Financing activities	8,535	6,711
Net decrease in cash	**$ (13,439)**	**$ (9,104)**

Net Cash Used in Operating Activities

Net cash used in operating activities for the year ended December 31 2022 was $21.4 million compared to $15.4 million for the year ended December 31, 2021. The year-over-year increase was primarily due to a gain on extinguishment of debt in the year ended December 31, 2021 versus a loss experienced in the year ended December 31, 2022. Additionally, due to timing, accounts payable increases in the current period increased cash and offset a portion of the cash used in operating cash activities when compared to the prior period.

Net Cash Used in Investing Activities

Net cash used in investing activities for the year ended December 31, 2022 was $0.5 million and approximately $0.4 million for the year ended December 31, 2021. In both periods, the use of cash related to the purchase of property and equipment, the majority of which are used in the production activities of our Richmond, California facility.

Net Cash Provided by Financing Activities

Net cash provided by financing activities for the year ended December 31, 2022 totaled $8.5 million compared to $6.7 million of cash provided by financing activities for the year ended December 31, 2021. The year-over-year net increase was caused primarily by the net cash infusion from the proceeds of the August 2022 debt refinancing, less all debt repayments and refinancing costs incurred during the year ended December 31, 2022 offset by the lower equity raise in the year ended December 31, 2022 as compared to the year ended December 31, 2021.

Credit Facilities

General

On August 10, 2022 (the “Closing Date”), we entered into a senior secured term loan facility with SWK Funding LLC, as agent, and other lenders party thereto (as amended and modified subsequent to the Closing Date, the “SWK Loan Facility”) for an aggregate principal amount of $25 million. An initial draw of $21 million drawn was made on the Closing Date with the additional $4 million drawn on December 14, 2022 upon satisfaction of the amended terms enabling such receipt. The SWK Loan Facility also allows for the establishment of a separate, new asset-based revolving loan facility of up to $8 million, which had not been entered into to date. We used $16 million of the proceeds of the SWK Loan Facility to pay all outstanding obligations on the formerly outstanding MidCap Loan Facility and MidCap Credit Facility. Such payment included (i) $12.8 million to repay all outstanding principal and accrued interest on the MidCap Loan Facility, (ii) $1.7 million to pay the prepayment and exit fees on the MidCap Loan Facility and (iii) $1.5 million to repay the outstanding balance, accrued interest and exit fees on the MidCap Credit Facility. As of December 31, 2022, we had $24.3 million of indebtedness outstanding under our SWK Loan Facility, with such balance being net of $1.0 million of unamortized discount and deferred financing costs, but increased by capitalized PIK Interest (as defined below) in November 2022 of $0.3 million.

Interest Rates

All of the SWK Loan Facility borrowings take the form of Secured Overnight Financing Rate ("SOFR") loans and will bear interest at a rate per annum equal to the sum of an applicable margin of (i) 7.75% and the "Term SOFR Rate" (based upon an interest period of 3 months), or (ii) if we have elected the PIK Interest option (as defined below), 4.75% and the "Term SOFR Rate." We may elect a portion of the interest due, to be paid in-kind at a rate per annum of 4.5% ("PIK Interest"), and such election may be made (x) until November 15, 2024 if certain profitability and regulatory conditions ("Extension Conditions") have not been met, or until November 17, 2025 if such conditions have been satisfied. The "Term SOFR Rate" is subject to a floor of 2.75%.

Mandatory Prepayments

The SWK Loan Facility Agreement requires certain mandatory prepayments, subject to certain exceptions, with: (1) 100% of any net casualty proceeds in excess of $250,000 and (2) for non-ordinary course asset sales, an amount equal to the difference between (x) the proportion of divested gross profit (as defined in the SWK Loan Facility Agreement) to the Company's total gross profit (as defined in the SWK Loan Facility Agreement) multiplied by the outstanding loans under the SWK Loan Facility, and (y) the difference between $1,000,000 and the aggregate sale proceeds of any assets previously sold during the fiscal year. No such mandatory prepayments were required during the year ended December 31, 2022.

Optional Prepayment

The SWK Loan Facility Agreement also includes an exit fee equal to: (i) if such prepayment occurs prior to the first anniversary of the Closing Date, 2% of the aggregate principal amount funded prior to the termination plus remaining unpaid interest payments scheduled to be paid during the first year of the loan or (ii) if such prepayment occurs after the first anniversary of the Closing Date but prior to the second anniversary of the Closing Date, 2% of the aggregate principal amount funded prior to termination.

Amortization and Final Maturity

The SWK Loan Facility matures on August 10, 2027 and accrues interest, payable quarterly in arrears. Principal amortization of the SWK Loan Facility starts on November 15, 2024, which amortization may be extended to November 17, 2025 if the Extension Conditions (as defined in the SWK Loan Facility Agreement) have been satisfied. Principal payments during the amortization period will be limited based on revenue-based caps. As of December 31, 2022, quarterly principal payments are scheduled to begin on November 15, 2024, in an amount equal to 5% of the Initial Term Loan with the balance paid at maturity.

Security

All obligations under the SWK Loan Facility are, and any future guarantees of those obligations will be, secured by, among other things, and in each case subject to certain exceptions, a first priority lien on and security interest in, upon, and to all of our assets, whether now owned or hereafter acquired, wherever located.

Covenants and Other Matters

The SWK Loan Facility Agreement that governs the SWK Loan Facility contains a number of covenants that, among other things and subject to certain exceptions, restrict our ability to:

- incur additional indebtedness;
- incur certain liens;
- pay dividends or make other distributions on equity interests;

- redeem, repurchase or refinance subordinated indebtedness;
- consolidate, merge or sell or otherwise dispose of their assets;
- make investments, loans, advances, guarantees and acquisitions;
- enter into transactions with affiliates;
- amend or modify their governing documents;
- amend or modify certain material agreements; and
- alter the business conducted by them and their subsidiaries.

In addition, the SWK Loan Facility Agreement contains two financial covenants. The first covenant, which is measured quarterly, requires us to achieve a specified Minimum Aggregate Revenue (as defined in the SWK Loan Facility Agreement) for the preceding 12-month period. The second covenant requires us to maintain a minimum liquidity (as defined in the SWK Loan Facility Agreement) of $5.0 million until December 16, 2022 and thereafter, the greater of (a) $5.0 million and (b) the sum of the operating cash burn (as defined in the SWK Loan Facility Agreement) for the two prior consecutive fiscal quarters then ended (the "Liquidity Covenant").

The SWK Loan Facility Agreement contains events of default, including, most significantly, a failure to timely pay interest or principal, insolvency, or an action by the FDA or such other material adverse event impacting the operations of Aziyo. As of December 31, 2022, we were in compliance with the financial covenant and all other covenants.

Supplier Promissory Note

During 2017, we restructured certain of our liabilities with a tissue supplier and entered into an unsecured promissory note bearing interest at 5%. In both 2022 and 2021, no payments were made on the promissory note because the Company's senior lender restricted payment of the amounts due. The Company used $1.4 million of the proceeds from the SWK Loan Facility to repay the remaining balance on the promissory note; however the accrued interest on the promissory note was forgiven by the lender. Such forgiveness resulted in a gain to the Company of approximately $0.4 million which has been recorded as other income, net in the accompanying consolidated statements of operations for the year ended December 31, 2022 included elsewhere in this Annual Report.

PPP Loan

In May 2020, we entered into a promissory note with Silicon Valley Bank, or SVB, under the Paycheck Protection Program of the CARES Act pursuant to which SVB agreed to make a loan to us in the amount of approximately $3.0 million. The PPP Loan bears interest at a rate of 1.0% per annum with monthly principal and interest payments beginning in March 2021 and ending on the maturity date of May 7, 2022; however such repayment commencement was deferred by the U.S. Small Business Administration while they evaluated our forgiveness application. In June 2021, we were notified by the U.S. Small Business Administration that the entire balance of our PPP Loan and all related accrued interest was forgiven. Such forgiveness resulted in a gain to us of approximately $3.0 million which has been recorded as other income, net in the accompanying consolidated statements of operations for the year ended December 31, 2021.

Funding Requirements

We expect to continue to incur significant expenses and operating losses for the foreseeable future as we expand our product development and clinical and research activities. In addition, we expect to continue to incur significant costs and expenses associated with operating as a public company.

As of December 31, 2022, we had $24.3 million of indebtedness outstanding, consisting of $25.3 million outstanding under our SWK Loan Facility (net of $1.0 million of unamortized discount and deferred financing costs). In addition, as further described in Note 10 to the consolidated financial statements included elsewhere in this Annual Report, we are party to a royalty agreement with Ligand Pharmaceuticals Incorporated ("Ligand") pursuant to which we assumed a restructured, long-term obligation to Ligand (the "Revenue Interest Obligation"), that requires us to pay Ligand 5.0% of future sales of the products we acquired from CorMatrix (as well as products substantially similar to those products), subject to annual minimum payments of $2.75 million. Furthermore, a $5.0 million payment will be due to Ligand if cumulative sales of these products exceed $100 million and a second $5.0 million will be due if cumulative sales exceed $300 million during the ten-year term of the agreement which expires on May 31, 2027. We are currently forecasting that the initial $5.0 million milestone payment will become payable in mid-2023.

If our available cash balances and cash flow from operations, if any, are insufficient to satisfy our liquidity requirements, we may seek to raise additional capital through equity offerings, debt financings, or asset sale or other transactions. However, such transactions may not be successful and we may not be able to raise additional equity or debt, or sell or license assets on acceptable terms, or at all. We may also consider raising additional capital in the future to expand our business, pursue strategic investments or take advantage of financing opportunities. Our present and future funding requirements will depend on many factors, including, among other things:

- continued patient, physician and market acceptance of our products;
- the scope, rate of progress and cost of our current and future pre-clinical and clinical studies;
- the cost of our research and development activities and the cost and timing of commercializing new products or technologies;
- the cost and timing of expanding our sales and marketing capabilities;
- the cost of filing and prosecuting patent applications and maintaining, defending and enforcing our patent or other intellectual property rights;
- the cost of defending, in litigation or otherwise, any claims that we infringe, misappropriate or otherwise violate third-party patents or other intellectual property rights;
- the costs of defending against or the damages payable in connection with the FiberCel Litigation and any future litigation that we may be subject to (to the extent above the applicable insurance coverage);
- the cost and timing of additional regulatory approvals;
- costs associated with any product recall that may occur;
- the effect of competing technological and market developments;
- the expenses we incur in manufacturing and selling our products;
- the extent to which we acquire or invest in products, technologies and businesses, although we currently have no commitments or agreements relating to any of these types of transactions;
- the costs of operating as a public company;
- unanticipated general, legal and administrative expenses; and
- the effects on any of the above of the current COVID-19 pandemic or any other pandemic, epidemic or outbreak of infectious disease.

In addition, our operating plans may change as a result of any number of factors, including those set forth above and other factors currently unknown to us, and we may need additional funds sooner than anticipated. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest may be materially diluted, and the terms of such securities could include liquidation or other preferences that adversely affect your rights as a common stockholder. Debt financing, if available, may involve agreements that include restrictive covenants that limit our ability to take specific actions, such as incurring additional debt, making capital expenditures, creating liens, redeeming shares of our common stock and/or declaring dividends. If we raise funds through collaborations, licensing agreements or other strategic alliances, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates, or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings or other arrangements when needed, we may be required to delay the development or commercialization of our products, license to third parties the rights to commercialize products or technologies that we would otherwise seek to commercialize and reduce marketing, customer support or other resources devoted to our products or cease operations. See our "Risk Factors — Risks Related to Our Business — *Our future capital needs are uncertain and we may need to raise funds in the future, and such funds may not be available on acceptable terms or at all*."

Based on our current operating plans, we believe there is uncertainty as to whether our future cash flows along with our existing cash, issuances of additional equity and cash generated from expected future sales will be sufficient to meet our anticipated operating needs through twelve months from the financial statement issuance date. Due to these factors, there is substantial doubt about our ability to continue as going concern within one year after the issuance of the financial statements.

Off-Balance Sheet Arrangements

As of December 31, 2022, we did not have any off-balance sheet arrangements, as defined under SEC Regulation S-K Item 303(a)(4)(ii).

Critical Accounting Policies and Significant Judgments and Estimates

The preparation of financial statements in conformity with U.S. GAAP requires that management 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 financial statements and the amounts of revenues and expenses reported during the period. On an ongoing basis, management evaluates these estimates and judgments, including those related to revenue, inventory valuation, valuation of intangibles, revenue interest obligation and stock-based compensation. Actual results may differ from those estimates. We have identified the following critical accounting policies:

Revenue Recognition

We enter into contracts to sell and distribute products to healthcare providers or commercial partners, or are produced and sold under contract manufacturing arrangements with corporate customers which are billed under ship and bill contract terms. Revenue is recognized when we have met our performance obligations pursuant to our contracts with our customers in an amount that we expect to be entitled to in exchange for the transfer of control of the products and services to our customers. For all net sales, we have no further performance obligations and revenue is recognized when control transfers which occurs either when: i) the product is shipped via common carrier; or ii) the product is delivered to the customer or distributor, in accordance with the terms of the agreement.

A portion of our product revenue is generated from consigned inventory maintained at hospitals, and from inventory physically held by our direct sales representatives. For these types of products sales, we retain control until the product has been used or implanted, at which time revenue is recognized.

We have elected to account for shipping and handling activities as a fulfillment cost rather than a separate performance obligation. Amounts billed to customers for shipping and handling are included as part of the transaction price and recognized as revenue when control of the underlying products is transferred to the customer. The related shipping and freight charges incurred by us are included in sales and marketing costs.

Contracts with customers state the final terms of the sale, including the description, quantity, and price of each implant distributed. The payment terms and conditions in our contracts vary; however, as a common business practice, payment terms are typically due in full within 30 to 60 days of delivery. We, at times, extend volume discounts to customers. We permit returns of our products in accordance with the terms of contractual agreements with customers.

Inventory Valuation

Inventories, consisting of purchased materials, direct labor and manufacturing overhead, are stated at the lower of cost or net realizable value, with cost determined using the average cost method. Inventory write-downs for unprocessed and certain processed donor tissue are recorded based on the estimated amount of inventory that will not pass the quality control process based on historical data. At each balance sheet date, we also evaluate inventories for excess quantities, obsolescence or shelf life expiration. This evaluation includes analysis of our current and future strategic plans, historical sales levels by product, projections of future demand, the risk of technological or competitive obsolescence for products, general market conditions and a review of the shelf life expiration dates for products. To the extent that management determines there is excess or obsolete inventory or quantities with a shelf life that is too near its expiration for us to reasonably expect that we can sell those products prior to their expiration, we adjust the carrying value of the inventory to its estimated net realizable value.

Due to the judgmental nature of inventory valuation, we may from time to time be required to adjust our assumptions as processes change and as we gain better information. Although we continue to refine the assumptions, described above, on which we base our estimates, we cannot be sure that our estimates are accurate indicators of future events. Accordingly, future adjustments may result from refining these estimates. Such adjustments may be significant.

Valuation of Purchased Intangible Assets

Purchased intangible assets with finite lives are carried at acquired fair value, less accumulated amortization. Amortization is computed over the estimated useful lives of the respective assets. We periodically evaluate the period of amortization for purchased intangible assets to determine whether current circumstances warrant revised estimates of useful lives. We review our purchased intangible assets for impairment whenever events or changes in circumstances indicate the carrying value of an asset may not be recoverable. Recoverability is measured by a comparison of the carrying amount to the net undiscounted cash flows expected to be generated by the asset. Impairment exists when the carrying value of our asset exceeds the related estimated undiscounted future cash flows expected to be derived from the asset. If impairment exists, the carrying value of that asset is adjusted to its fair value. A discounted cash flow analysis is used to estimate an asset’s fair value, using assumptions that market participants would apply. An impairment loss would be recorded for the excess of net carrying value over the fair value of the asset impaired. The results of impairment tests are subject to management’s estimates and assumptions of projected cash flows and operating results. Changes in assumptions or market conditions could result in a change in estimated future cash flows and could result in a lower fair value and therefore an impairment, which could impact reported results.

Revenue Interest Obligation

In 2017, we completed an asset purchase agreement with CorMatrix and acquired all of the CorMatrix commercial assets and related intellectual property. As part of this acquisition, we entered into a royalty agreement with Ligand pursuant to which we assumed the Revenue Interest Obligation, with an estimated present value on the acquisition date of $27.7 million. The terms of the Revenue Interest Obligation require us to pay Ligand 5% of future sales of the products we acquired in the CorMatrix acquisition, subject to certain annual minimum payments. Furthermore, a $5.0 million payment will be due to Ligand if cumulative sales of the acquired products exceed $100 million and a second $5.0 million will be due if cumulative sales exceed $300 million during the ten-year term of the agreement which expires on May 31, 2027.

We have estimated the fair value of the Revenue Interest Obligation, including contingent milestone payments and estimated sales-based payments, based on assumptions related to future sales of the acquired products. At each reporting period, the value of the Revenue Interest Obligation is re-measured based on current estimates of the net present value of future payments, with changes to be recorded in the consolidated statements of operations. In connection with our

estimation at December 31, 2022, it was determined that the estimated future payments, discounted at the original discount rate, had decreased since the prior estimates. Such decrease was primarily the result of anticipated changes to our strategic partnerships relative to sales of both our CanGaroo and cardiovascular product lines that will impact the timing and extent of such sales and, thereby, will reduce expected future payments to Ligand. The change to estimated future payments yielded a reduction to the total Revenue Interest Obligation of approximately $5.0 million for the year ended December 31, 2022 with such amount recognized as a gain in Other income, net in our consolidated statement of operations. There was no change to estimated future payments during the year ended December 31, 2021 and thus, no re-measurement gain or loss was recognized. The estimation of future sales and the possible attainment of sales milestones is subject to significant judgment. Different judgments would yield different valuations of the Revenue Interest Obligation and these differences could be significant.

Contingent Liability for FiberCel Litigation

We review every lawsuit and claim and are in contact with outside counsel on an ongoing basis in determining our Contingent Liability for FiberCel Litigation. An accrual is established for each lawsuit and claim, when appropriate, based on the nature of each such lawsuit or claim. The provision for FiberCel Litigation claims are based upon many factors, which vary for each case. These factors include (i) the extent of the injuries incurred, (ii) recent experience on settled claims, (iii) settlement offers made to the other parties to the litigation and (iv) any other factors that may have a material effect on the estimated liability. While we believe our estimated liability to be reasonable, the actual loss amounts are highly variable and turn on a case-by-case analysis of the relevant facts. As such, actual settlement amounts may differ from our estimates and such differences may be material.

Stock-Based Compensation

Compensation costs associated with stock option awards and other forms of equity compensation are measured at the grant-date fair value of the awards and recognized over the requisite vesting period of the awards on a straight-line basis.

Our policy is to grant stock options at an exercise price equal to 100% of the market value of a share of common stock at closing on the date of the grant. Our stock options generally have seven to ten year contractual terms and vest over a four-year period from the date of grant. We use the Black-Scholes model to value our time-vested stock option grants. The fair value of stock options is determined on the grant date using assumptions for the estimated fair value of the underlying common stock, expected term, expected volatility, dividend yield and the risk-free interest rate. Before the completion of our IPO, our board of directors determined the fair value of common stock considering the state of the business, input from management, third party valuations and other considerations. We use the simplified method for estimating the expected term used to determine the fair value of options. Until our IPO in October 2020, there had been no public market for our common stock and thus, we lacked company-specific historical and implied volatility information. As a result, we estimate the expected volatility primarily based on the historical volatility of comparable companies in the industry whose share prices are publicly available and expect to continue to do so until such time as we have adequate historical data regarding the volatility of our own traded share price. We use a zero-dividend yield assumption as we have not paid dividends since inception nor do we anticipate paying dividends in the future. The risk-free interest rate approximates recent U.S. Treasury note auction results with a similar life to that of the option.

For our performance-based stock option grants which vest upon the achievement of specified market conditions, we used the Monte Carlo simulation model to calculate the grant-date fair value. This model simulates the probabilities of the potential outcomes of our future stock prices over the performance period to determine a fair value. Under this simulation model, our key assumptions relate to the risk-free interest rate and equity volatility based on consideration of our historical trading volatility as well as the observed equity volatility of other publicly-traded life sciences companies.

The period expense for all of our stock options is recognized on a straight-line basis over the requisite service period for the entire award. Different assumptions relative to the fair valuation of our stock options would result in a different period expense and such differences may be material.

JOBS Act

Section 107 of the JOBS Act permits us, as an "emerging growth company," to take advantage of an extended transition period for adopting new or revised accounting standards until those standards would otherwise apply to private companies. We have elected to avail ourselves of this exemption and, as a result, for so long as we remain an emerging growth company, unless we subsequently choose to affirmatively and irrevocably opt out of the extended transition period, 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. Section 107 of the JOBS Act provides that we can elect to opt out of the extended transition period at any time, which election is irrevocable.

We will remain an emerging growth company, and will be able to take advantage of the foregoing exemptions, until the earliest of: (i) the last day of the first fiscal year in which our annual gross revenues are $1.235 billion or more; (ii) the last day of 2025; (iii) the date that we become a "large accelerated filer" as defined in Rule 12b-2 under the Exchange Act, which would occur if the market value of our common equity held by non-affiliates is $700 million or more as of the last business day of our most recently completed second fiscal quarter; or (iv) the date on which we have issued more than $1.0 billion in non-convertible debt securities during the previous three years.

Recently Issued Accounting Pronouncements

See Note 3, "Recently Issued Accounting Standards," to our audited consolidated financial statements included elsewhere in this Annual Report for information regarding recently issued accounting pronouncements.

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

We are exposed to market risks in the ordinary course of our business, including risks relating to changes in interest rates, foreign currency and inflation. The following discussion provides additional information regarding these risks.

Interest Rate Risk

Our primary exposure to market risk relates to changes in interest rates. Borrowings under our SWK Loan Facility bears interest at variable rates, subject to an interest rate floor. Interest rate risk is highly sensitive due to many factors, including U.S. monetary and tax policies, U.S. and international economic factors and other factors beyond our control. A hypothetical 10% relative change in interest rates to our variable rate indebtedness outstanding during the years ended December 31, 2022 or 2021 would not have had a material effect on our financial statements. We do not currently engage in hedging transactions to manage our exposure to interest rate risk.

Credit Risk

As of December 31, 2022, our cash and cash equivalents were maintained with one financial institution in the United States. While our deposit accounts are insured up to the legal limit, the balances we maintain may, at times, exceed this insured limit. As of December 31, 2022 we maintained $17.8 million in bank deposit accounts that are in excess of the federally insured limit in one federally insured financial institution. The Company has not experienced any losses in such accounts.

Our accounts receivable relate to sales to customers. To minimize credit risk, ongoing credit evaluations of all customers' financial condition are performed. Two customers represented 10% or more of our accounts receivable as of December 31, 2022.

Foreign Currency Risk

Our business is primarily conducted in U.S. dollars. Any transactions that may be conducted in foreign currencies are not expected to have a material effect on our financial condition, results of operations or cash flows. As we grow our operations, our exposure to foreign currency risk could become more significant.

Inflation Risk

Inflationary factors, such as increases in our cost of goods sold or other operating expenses, may adversely affect our operating results. While it is difficult to accurately measure the impact of inflation due to the imprecise nature of the estimates required, we do not believe inflation had a material effect on our financial condition or results of operations during the years ended December 31, 2022 and 2021. We cannot assure you, however, that we will be able to increase the selling prices of our products or reduce our operating expenses in an amount sufficient to offset the effects future inflationary pressures may have on our gross margin. Accordingly, we cannot assure you that our financial condition and results of operations will not be materially impacted by inflation in the future.

Item 8. Financial Statements and Supplementary Data.

The financial statements required to be filed pursuant to this Item 8 are appended to this Annual Report and are incorporated herein by reference.

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

None.

Item 9A. Controls and Procedures.

Limitations on Effectiveness of Controls and Procedures

In designing and evaluating our disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives. In addition, the design of disclosure controls and procedures must reflect the fact that there are resource constraints and that management is required to apply judgment in evaluating the benefits of possible controls and procedures relative to their costs.

Evaluation of Disclosure Controls and Procedures

The Company's management has evaluated, with the participation of our principal executive officer and our principal financial officer, the effectiveness of our disclosure controls and procedures (as defined in Rule 13a-15(e) and 15d-15(e) under the Exchange Act) as of the end of the period covered by this Annual Report. Based on this evaluation, management concluded that the Company's disclosure controls and procedures were effective at the reasonable assurance level as of December 31, 2022.

Management's Annual Report on Internal Control Over Financial Reporting

Our management, with the participation of our principal executive officer and our principal financial officer, is responsible for establishing and maintaining adequate internal control over financial reporting as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act. Our management conducted an assessment of the effectiveness of our internal control over financial reporting based on the criteria set forth in "Internal Control–Integrated Framework (2013)" issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on this assessment, management concluded that, as of December 31, 2022, our internal control over financial reporting was effective.

Attestation Report of the Registered Public Accounting Firm

Our independent registered accounting firm will not be required to opine on the effectiveness of our internal control over financial reporting pursuant to Section 404 of Sarbanes-Oxley Act of 2002 until we are no longer an "emerging growth company" as defined in the JOBS Act.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the three months ended December 31, 2022 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information.

We are reporting the following information in lieu of reporting on a Current Report on Form 8-K under Item 5.02 Departure of Directors or Certain Officers; Election of Directors; Appointment of Certain Officers; Compensatory Arrangements of Certain Officers.

On March 20, 2023, Thomas Englese, the Company's Chief Commercial Officer, was informed that his position was being eliminated in connection with the Company's headcount reduction. In connection with the foregoing, on March 22, 2023 Mr. Englese and the Company entered into a separation agreement (the "Englese Separation Agreement"), pursuant to which Mr. Englese will cease serving as the Company's Chief Commercial Officer and an employee of the Company effective March 24, 2023 (the "Separation Date"). During the period beginning on the Separation Date and ending on October 8, 2023 (the "Transition Period"), Mr. Englese has agreed to assist completing strategic partnerships in process, advising on strategic decisions impacting the sales organization and mentoring the new head of sales.

Under the terms of the Englese Separation Agreement, subject to Mr. Englese's non-revocation of a release of claims, continued compliance with the restrictive covenants set forth in his employment agreement, and compliance with the terms of the Englese Separation Agreement, (i) Mr. Englese will receive the severance payments and benefits payable in connection with a termination without cause under his employment agreement as currently in effect, (ii) Mr. Englese will remain eligible to receive an annual bonus for the 2022 fiscal year, (iii) all of the outstanding equity awards that Mr. Englese received under the Aziyo Biologics, Inc. 2020 Incentive Award Plan (the "2020 Equity Plan") and the Aziyo Biologics, Inc. 2015 Stock Option/Stock Issuance Plan will remain outstanding and continue to vest on their original vesting dates during the Transition Period and (iv) all of the restricted stock units awarded to Mr. Englese pursuant to the 2020 Equity Plan that remain outstanding and unvested as of the last day of the Transition Period will accelerate and vest in full on the last day of the Transition Period.

The forgoing description of the Englese Separation Agreement is qualified in its entirety by the full text of the Englese Separation Agreement, which is filed as Exhibit 10.15 hereto and is incorporated herein by reference.

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections

Not applicable.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

INFORMATION ABOUT OUR DIRECTORS & EXECUTIVE OFFICERS

The following information with respect to our Board of Directors (the "Board") and executive officers is presented as of March 21, 2023:

Name	Age	Position at Azyo Biologics	Principal Employment
C. Randal Mills, Ph.D.	51	Chief Executive Officer and President, and Director	Same
Matthew Ferguson	55	Chief Financial Officer	Same
Michelle Williams, Ph.D.	49	Chief Scientific Officer	Same
Thomas Englese(1)	48	Chief Commercial Officer	Same
David Colpman	61	Director	Former Managing Partner of Colpman Consulting Ltd., a business development consultancy
Maybelle Jordan	57	Director	Chief Strategy Officer at Deerfield Device Design and Development Catalyst, a medical technology incubator
Brigid A. Makes	67	Director	Chief Financial Officer at Vivani Medical, Inc., a biopharmaceutical company
Kevin Rakin	62	Director	Co-founder and General Partner at HighCape Partners, an investment fund
W. Matthew Zuga	57	Director	Chief Financial Officer and Chief Business Officer at Acumen Pharmaceuticals, Inc., a biotechnology company

(1) Mr. Englese will cease to be an employee and an executive officer of the Company effective March 24, 2023 and has agreed to provide advisory services to the Company until October 8, 2023. See Part II, Item 9B. “Other Information.”

The information required by this Item is incorporated herein by reference to the information that will be contained in our proxy statement related to our annual meeting of stockholders to be held in 2023 (the “2023 Annual Meeting of Stockholders”), which we intend to file with the SEC within 120 days of the year ended December 31, 2022.

Item 11. Executive Compensation.

The information required by this Item is incorporated herein by reference to the information that will be contained in our proxy statement related to the 2023 Annual Meeting of Stockholders, which we intend to file with the SEC within 120 days of the year ended December 31, 2022.

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

Equity Compensation Plan Information

The following table provides information on our equity compensation plans as of December 31, 2022.

Plan Category	Number of Securities to be Issued Upon Exercise of Outstanding Options, Warrants and Rights (a)	Weighted Average Exercise Price of Outstanding Options, Warrants and Rights (b)	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a)) (c)
Equity Compensation Plans Approved by Stockholders			
2015 Plan (1)	233,464	$ 6.28 (4)	—
2020 Plan (2)	1,823,345	$ 9.86 (4)	656,689
ESPP (3)	—	—	279,345
Equity Compensation Plans Not Approved by Stockholders	—	—	—
Total	2,056,809	$ 9.41	936,034

(1) In connection with our IPO, we adopted the Aziyo Biologics, Inc. 2020 Incentive Award Plan (the "2020 Plan") and, as of the consummation of our IPO, ceased making grants or awards under the Aziyo Biologics, Inc. 2015 Stock Option/Stock Issuance Plan (the "2015 Plan"). To the extent stock options outstanding under the 2015 Plan are forfeited, lapse unexercised or are settled in cash, the shares of Class A common stock subject to the stock options will be available for future issuance under the 2020 Plan.

(2) 1,685,962 shares of Class A common stock were initially available for issuance under the 2020 Plan. The number of shares of Class A common stock available for issuance under the 2020 Plan automatically increases on each January 1, until and including January 1, 2030, by an amount equal to the lesser of (A) 4% of the shares of Class A common stock outstanding (on an as-converted basis) on the last day of the immediately preceding fiscal year and (B) such smaller number of shares of Class A common stock as determined by our board of directors (but no more than 1,636,000 shares of Class A common stock may be issued upon the exercise of incentive stock options). In addition, the shares reserved for issuance under the 2020 Plan will also include shares reserved but not issued under the 2015 Plan.

(3) The number of shares of Class A common stock available for issuance under the ESPP automatically increases on each January 1, until and including January 1, 2030, by an amount equal to the lesser of (A) 1% of the shares of Class A and Class B common stock outstanding on the last day of the immediately preceding fiscal year and (B) such smaller number of shares of Class A common stock as determined by our board of directors.

(4) The calculation of the weighted average exercise price does not include outstanding equity awards that are received or exercised for no consideration.

The other information required by this Item is incorporated herein by reference to the information that will be contained in our proxy statement related to the 2023 Annual Meeting of Stockholders, which we intend to file with the SEC within 120 days of the year ended December 31, 2022.

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

The information required by this Item is incorporated herein by reference to the information that will be contained in our proxy statement related to the 2023 Annual Meeting of Stockholders, which we intend to file with the SEC within 120 days of the year ended December 31, 2022.

Item 14. Principal Accountant Fees and Services.

The information required by this Item is incorporated herein by reference to the information that will be contained in our proxy statement related to the 2023 Annual Meeting of Stockholders, which we intend to file with the SEC within 120 days of the year ended December 31, 2022.

PART IV

Item 15. Exhibits and Financial Statement Schedules.

(a)(1) Financial Statements

The Consolidated Financial Statements are included on pages F-2 through F-24 attached hereto and are filed as part of this Annual Report. See Index to Consolidated Financial Statements on page F-1.

(a)(2) Financial Statement Schedules

All financial statement schedules have been omitted because they are not applicable, not required or the information required is shown in the financial statements or the notes thereto.

(a)(3) Exhibits

The following is a list of exhibits filed as part of this Annual Report.

Exhibit Number	Description	Form	File No.	Exhibit	Filing Date	Filed/Furnished Herewith
3.1	Restated Certificate of Incorporation of Aziyo Biologics, Inc.	8-K	001-39577	3.1	10/13/2020	
3.2	Amended and Restated Bylaws of Aziyo Biologics, Inc.	8-K	001-39577	3.2	10/13/2020	
4.1	Second Amended and Restated Investor Rights Agreement, dated as of September 14, 2020, among the Registrant and the investors named therein	S-1	333-248788	4.1	09/14/2020	
4.2	Specimen stock certificate evidencing the shares of Class A common stock	S-1	333-248788	4.2	09/14/2020	
4.3	Specimen stock certificate evidencing the shares of Class B common stock	S-1/A	333-248788	4.3	09/30/2020	

Exhibit Number	Description	Form	File No.	Exhibit	Filing Date	Filed/Furnished Herewith
4.4	Warrant to Purchase Stock, issued on August 10, 2022, by Aziyo Biologics, Inc.to SWK Funding LLC.	8-K	001-39577	4.1	8/15/2022	
4.5	Description of Securities	10-K	001-39577	4.4	03/15/2021	
10.1	Registration Rights Agreement, dated December 5, 2021, by and among Aziyo Biologics, Inc. and the Investors named therein.	8-K	001-39577	10.2	12/08/2021	
10.2	Royalty Agreement, dated as of May 31, 2017, by and between Aziyo Med, LLC and Ligand Pharmaceuticals Incorporated	S-1	333-248788	10.14	09/14/2020	
10.3	License Agreement, dated as of May 31, 2017, by and between Cook Biotech Incorporated and Aziyo Med, LLC	S-1	333-248788	10.16	09/14/2020	
10.4	December 2017 Amendment to License Agreement, dated as of December 21, 2017, by and between Cook Biotech Incorporated and Aziyo Med, LLC	S-1	333-248788	10.17	09/14/2020	
10.5†	Aziyo Biologics, Inc. 2015 Stock Option/Stock Issuance Plan (as amended)	S-1	333-248788	10.1	09/14/2020	
10.6†	Aziyo Biologics, Inc. 2020 Incentive Award Plan and form of stock option agreements thereunder					*

Exhibit Number	Description	Form	File No.	Exhibit	Filing Date	Filed/Furnished Herewith
10.7†	Form of Restricted Stock Unit Award Agreement (approved August 2022)	10-Q	001-39577	10.4	11/14/2022	
10.8†	Form of Restricted Stock Unit Award Agreement (approved October 2020)					*
10.9†	Aziyo Biologics, Inc. Non-Employee Director Compensation Program	S-1/A	333-248788	10.3	09/30/2020	
10.10†	Aziyo Biologics, Inc. 2020 Employee Stock Purchase Plan	S-1/A	333-248788	10.4	09/30/2020	
10.11†	Amended and Restated Employment Agreement, by and between the Registrant and Ronald Lloyd, dated as of September 30, 2021	S-1/A	333-248788	10.6	09/30/2020	
10.12†	Separation and Release of Claims Agreement, dated June 21, 2022, by and between Ronald Lloyd and Aziyo Biologics, Inc.	8-K	001-39577	10.1	6/21/2022	
10.13†	Employment Agreement, dated June 21, 2022, by and between C. Randal Mills, Ph.D. and Aziyo Biologics, Inc.	8-K	001-39577	10.2	6/21/2022	
10.14†	Amended and Restated Employment Agreement, dated December 23, 2022, by and between Aziyo Biologics, Inc. and Thomas Englese	8-K	001-39577	10.2	12/30/2022	

Exhibit Number	Description	Form	File No.	Exhibit	Filing Date	Filed/Furnished Herewith
10.15†	Letter Agreement, dated as of March 22, 2023, by and between Aziyo Biologics, Inc. and Thomas Englese					*
10.16†	Amended and Restated Employment Agreement, dated December 23, 2022, by and between Aziyo Biologics, Inc. and Matthew Ferguson	8-K	001-39577	10.1	12/30/2022	
10.17†	Form of Indemnification Agreement for Directors and Officers	S-1/A	333-248788	10.12	09/30/2020	
10.18#	Credit Agreement, dated as of August 10, 2022, between Aziyo Biologics, Inc. and SWK Funding LLC, as Agent and the Lenders from time to time party thereto	8-K	001-39577	10.1	8/15/2022	
10.19	Amendment Letter, dated as of October 9, 2022 to Credit Agreement, dated as of August 10, 2022, between Aziyo Biologics, Inc. and SWK Funding LLC, as Agent and the Lenders from time to time party thereto	8-K	001-39577	10.1	10/13/2022	

Exhibit Number	Description	Form	File No.	Exhibit	Filing Date	Filed/Furnished Herewith
10.20	Amendment Letter, dated as of November 10, 2022 to Credit Agreement, dated as of August 10, 2022, between Aziyo Biologics, Inc. and SWK Funding LLC, as Agent and the Lenders from time to time party thereto (as amended by the Amendment Letter dated as of October 9, 2022)	10-Q	001-39577	10.3	11/14/2022	
10.21	Amendment Letter, dated as of November 21, 2022, to the Credit Agreement, dated as of August 10, 2022, among Aziyo Biologics, Inc., SWK Funding LLC, as Agent, and the Lenders from time to time party thereto (as amended).	8-K	001-39577	10.1	11.28	
10.22	Amendment Letter, dated as of November 30, 2022, to the Credit Agreement, dated as of August 10, 2022, among Aziyo Biologics, Inc., SWK Funding LLC, as Agent, and the Lenders from time to time party thereto (as amended).	8-K	001-39577	10.1	12/5/2022	
21.1	Subsidiaries of Aziyo Biologics, Inc.	10-K	001-39577	21.1	03/8/2022	
23.1	Consent of PricewaterhouseCoopers LLP					*

Exhibit Number	Description	Form	File No.	Exhibit	Filing Date	Filed/Furnished Herewith
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.					**
101.INS	Inline XBRL Instance Document - the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document					*
101.SCH	Inline XBRL Taxonomy Extension Schema Document					*

Exhibit Number	Description	Form	File No.	Exhibit	Filing Date	Filed/Furnished Herewith
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document					*
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document					*
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document					*
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document					*
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101)					*

* Filed herewith.

** Furnished herewith.

† Denotes a management contract or compensation plan or arrangement.

Annexes, schedules and exhibits have been omitted pursuant to Item 601(a)(5)(b)(2) of Regulation S-K. The Registrant hereby agrees to furnish supplementally a copy of any omitted annex, schedule or exhibit to the SEC upon request.

Item 16. Form 10-K Summary.

None.

SIGNATURES

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

Aziyo Biologics, Inc.

Date: March 23, 2023

By: /s/ C. RANDAL MILLS, PH.D.
C. Randal Mills
President and Chief Executive Officer
(Principal Executive Officer)

Date: March 23, 2023

/s/ MATTHEW FERGUSON
Matthew Ferguson
Chief Financial Officer
(Principal Financial Officer and Principal Accounting Officer)

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

Name	Title	Date
/s/C. Randal Mills, Ph.D. C. Randal Mills	President, Chief Executive Officer and Director *(principal executive officer)*	March 23, 2023
/s/Matthew Ferguson Matthew Ferguson	Chief Financial Officer *(principal financial officer and principal accounting officer)*	March 23, 2023
/s/Kevin Rakin Kevin Rakin	Chairperson of the Board of Directors	March 23, 2023
/s/W. Matthew Zuga W. Matthew Zuga	Director	March 23, 2023
/s/Maybelle Jordan Maybelle Jordan	Director	March 23, 2023
/s/David Colpman David Colpman	Director	March 23, 2023
/s/Brigid A. Makes Brigid A. Makes	Director	March 23, 2023

AZIYO BIOLOGICS, INC.

INDEX TO FINANCIAL STATEMENTS

Report of Independent Registered Public Accounting Firm

To the Board of Directors and Stockholders of Aziyo Biologics, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Aziyo Biologics, Inc. and its subsidiaries (the "Company") as of December 31, 2022 and 2021, and the related consolidated statements of operations, of changes in stockholders' equity (deficit) and of cash flows for the years then ended, including the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2022 and 2021, and the results of its operations and its cash flows for the years then ended in conformity with accounting principles generally accepted in the United States of America.

Substantial Doubt About the Company's Ability to Continue as a Going Concern

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 2 to the consolidated financial statements, the Company has generated recurring losses from operations and is expected to incur cash outflows from operating activities that raise substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 2. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Change in Accounting Principle

As discussed in Note 2 to the consolidated financial statements, the Company changed the manner in which it accounts for leases in 2022.

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

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

/s/ *PricewaterhouseCoopers LLP*

Baltimore, Maryland
March 23, 2023

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

AZIYO BIOLOGICS, INC.
CONSOLIDATED BALANCE SHEETS
(In Thousands, Except for Share and Per Share Data)

	December 31, 2022	December 31, 2021
Assets		
Current assets:		
Cash	$ 16,989	$ 30,393
Restricted cash	—	35
Accounts receivable, net	6,830	5,996
Inventory	10,052	9,554
Receivables of FiberCel litigation costs	13,813	—
Prepaid expenses and other current assets	3,015	1,450
Total current assets	50,699	47,428
Property and equipment, net	1,403	1,200
Intangible assets, net	15,069	18,466
Operating lease right-of-use assets and other	1,670	76
Total assets	**$ 68,841**	**$ 67,170**
Liabilities and Stockholders' Equity (Deficit)		
Current liabilities:		
Accounts payable	$ 2,328	$ 1,582
Accrued expenses	10,103	6,375
Payables to tissue suppliers	3,152	2,467
Current portion of long-term debt	—	8,059
Current portion of revenue interest obligation	8,990	2,750
Revolving line of credit	—	4,763
Contingent liability for FiberCel litigation	17,360	—
Current operating lease liabilities and other	682	5
Total current liabilities	42,615	26,001
Long-term debt	24,260	10,410
Long-term revenue interest obligation	5,916	16,540
Long-term operating lease liabilities	956	—
Other long-term liabilities	127	698
Total liabilities	73,874	53,649
Commitments and contingencies (Note 17)		
Stockholders' equity (deficit):		
Class A Common stock, $0.001 par value, 200,000,000 shares authorized as of December 31, 2022 and December 31, 2021, and 11,823,445 and 9,245,146 shares issued and outstanding, as of December 31, 2022 and December 31, 2021, respectively	12	9
Class B Common stock, $0.001 par value, 20,000,000 shares authorized, as of December 31, 2022 and December 31, 2021 and 4,313,406 issued and outstanding as of December 31, 2022 and December 31, 2021	4	4
Additional paid-in capital	132,939	118,599
Accumulated deficit	(137,988)	(105,091)
Total stockholders' equity (deficit)	(5,033)	13,521
Total liabilities and stockholders' equity (deficit)	**$ 68,841**	**$ 67,170**

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

AZIYO BIOLOGICS, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS
(In Thousands, Except Share and Per Share Data)

	Year Ended December 31,	
	2022	**2021**
Net sales	$ 49,187	$ 47,390
Cost of goods sold	29,965	28,368
Gross profit	19,222	19,022
Sales and marketing	20,195	18,825
General and administrative	16,627	13,687
Research and development	8,940	9,266
FiberCel litigation costs, net	5,200	276
Total operating expenses	50,962	42,054
Loss from operations	(31,740)	(23,032)
Interest expense	5,282	5,324
Other income, net	(4,159)	(3,579)
Loss before provision for income taxes	(32,863)	(24,777)
Income tax expense	34	55
Net loss	**$ (32,897)**	**$ (24,832)**
Net loss per share - basic and diluted	**$ (2.38)**	**$ (2.38)**
Weighted average common shares outstanding - basic and diluted	13,832,887	10,444,767

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

AZIYO BIOLOGICS, INC.
CONSOLIDATED STATEMENT OF CHANGES IN STOCKHOLDERS' EQUITY (DEFICIT)
(In Thousands, Except Share and Per Share Data)

	Class A Common Stock		Class B Common Stock				
	Number of Shares	Amount	Number of Shares	Amount	Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity (Deficit)
Balance, December 31, 2020	**7,091,960**	**$ 7**	**3,134,162**	**$ 3**	**$ 101,080**	**$ (80,259)**	**$ 20,831**
Proceeds from stock option exercises	3,305	—	—	—	26	—	26
Proceeds from sale of common stock through Employee Stock Purchase Plan	27,244	—	—	—	208	—	208
Issuance of common stock through private placement, net of issuance costs of $247	2,122,637	2	1,179,244	1	13,750	—	13,753
Stock-based compensation	—	—	—	—	3,535	—	3,535
Net loss	—	—	—	—	—	(24,832)	(24,832)
Balance, December 31, 2021	**9,245,146**	**$ 9**	**4,313,406**	**$ 4**	**$ 118,599**	**$ (105,091)**	**$ 13,521**
Proceeds from stock option exercises	13,887	—	—	—	78	—	78
Additional issuance costs in connection with private placement	—	—	—	—	(110)	—	(110)
Proceeds from sale of common stock through Employee Stock Purchase Plan	74,408	—	—	—	317	—	317
Proceeds from sale of common stock in secondary public offering, net of issuance costs of $966	2,350,000	3	—	—	10,196	—	10,199
Vesting of restricted stock units, net of shares withheld and taxes paid	140,004	—	—	—	(395)	—	(395)
Issuance of warrants in connection with debt financing	—	—	—	—	607	—	607
Stock-based compensation	—	—	—	—	3,647	—	3,647
Net loss	—	—	—	—	—	(32,897)	(32,897)
Balance, December 31, 2022	**11,823,445**	**$ 12**	**4,313,406**	**$ 4**	**$ 132,939**	**$ (137,988)**	**$ (5,033)**

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

AZIYO BIOLOGICS, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS
(In Thousands)

	Year Ended December 31,	
	2022	2021
Net loss	$ (32,897)	$ (24,832)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	3,733	3,730
(Gain) loss on extinguishment of debt	311	(3,029)
(Gain) on revaluation of revenue interest obligation	(4,962)	—
Amortization of deferred financing costs and debt discount	115	121
Interest expense recorded as additional revenue interest obligation or long-term debt	2,908	2,654
Stock-based compensation	3,647	3,535
Changes in operating assets and liabilities:		
Accounts receivable	(834)	1,170
Inventory	(498)	563
Receivables of FiberCel litigation costs	(13,813)	—
Prepaid expenses and other	(1,526)	1,442
Accounts payable and accrued expenses	4,908	(420)
Obligations to tissue suppliers	685	172
Contingent liability for FiberCel litigation	17,360	—
Deferred revenue and other liabilities	(571)	(552)
Net cash used in operating activities	**(21,434)**	**(15,446)**
INVESTING ACTIVITIES:		
Expenditures for property, plant and equipment	(540)	(369)
Net cash used in investing activities	**(540)**	**(369)**
FINANCING ACTIVITIES:		
Proceeds from public offering or private placement, net of offering costs	10,089	13,753
Net borrowings (repayments) under revolving line of credit	(4,763)	(1,751)
Proceeds from stock option exercises	78	26
Proceeds from long-term debt	25,000	—
Deferred financing costs	(468)	—
Repayments of long-term debt	(18,615)	(2,778)
Costs related to the extinguishment of debt	(633)	—
Payments on revenue interest obligation	(2,075)	(2,747)
Payments for taxes upon vesting of restricted stock units	(395)	—
Proceeds from sales of common stock through Employee Stock Purchase Plan	317	208
Net cash provided by financing activities	**8,535**	**6,711**
Net decrease in cash and restricted cash	**(13,439)**	**(9,104)**
Cash and restricted cash, beginning of period	**30,428**	**39,532**
Cash and restricted cash, end of period	**$ 16,989**	**$ 30,428**
Supplemental Cash Flow and Non-Cash Financing Activities Disclosures:		
Cash paid for interest	$ 5,480	$ 4,984
Fair value of warrants issued	$ 607	$ —
Forgiveness of SBA PPP loan	$ -	$ 3,029

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

AZIYO BIOLOGICS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Note 1. Organization and Description of Business

Aziyo Biologics, Inc. (together with its consolidated subsidiaries, "Aziyo" or the "Company") is a regenerative medicine company, with a focus on patients receiving implantable medical devices. The Company has developed a portfolio of regenerative products using both human and porcine tissue that are designed to be as close to natural biological material as possible. Aziyo's portfolio of products span the device protection, women's health, orthobiologics and cardiovascular markets. These products are primarily sold to healthcare providers or commercial partners. The Company also sells human tissue products under contract manufacturing and certain other arrangements with corporate customers.

Note 2. Summary of Significant Accounting Policies

Basis of Presentation and Liquidity

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

The consolidated financial statements include the accounts of the Company and its wholly-owned subsidiaries. Intercompany accounts and transactions have been eliminated in consolidation.

In accordance with Accounting Standards Update ("ASU") 2014-15, *Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern (Subtopic 205-40)*, the Company has evaluated whether there are conditions and events, considered in the aggregate, that raise substantial doubt about the Company's ability to continue as a going concern within one year after the date that the consolidated financial statements are issued. For the year ended December 31, 2022, the Company incurred a net loss of $32.9 million, and as of December 31, 2022, the Company had an accumulated deficit of $138.0 million. In addition, during the year ended December 31, 2022, the Company used $21.4 million of cash in operating activities, and expects to continue to incur cash outflows in 2023. Because of the numerous risks and uncertainties associated with the Company's commercialization and development efforts, the Company is unable to predict when it will become profitable, and it may never become profitable. The Company's inability to achieve and then maintain profitability would negatively affect its business, financial condition, results of operations and cash flows.

In order to mitigate the current and potential future liquidity issues caused by the matters noted above, the Company may seek to raise capital through the issuance of common stock or debt, restructure its Revenue Interest Obligation (as such term is defined, and further described, in Note 10), or pursue asset sale or other transactions. However, such transactions may not be successful and the Company may not be able to raise additional equity or debt, restructure its Revenue Interest Obligation, or sell or license assets on acceptable terms, or at all. As such, based on its current operating plans, the Company believes there is uncertainty as to whether its future cash flows along with its existing cash, issuances of additional equity and cash generated from expected future sales will be sufficient to meet the Company's anticipated operating needs through twelve months from the financial statement issuance date. Due to these factors, there is substantial doubt about the Company's ability to continue as a going concern within one year after the issuance of the financial statements.

The accompanying consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty. That is, the accompanying financial statements have been prepared assuming that the Company will continue as a going concern, which contemplates continuity of operations, realization of assets, and satisfaction of liabilities in the ordinary course of business.

Reclassifications

Certain reclassifications have been made to prior year amounts to conform to current year financial statement presentation. The reclassifications relate to the separate presentation of prior year costs related to the FiberCel Litigation.

Such costs were formerly shown as a component of general and administrative expenses in the accompanying consolidated statements of operations.

Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Estimates and assumptions relating to inventories, receivables, long-lived assets, the valuation of stock-based awards, the valuation of the revenue interest obligation, the contingent liability for the FiberCel Litigation and deferred income taxes are made at the end of each financial reporting period by management. Management continually re-evaluates its estimates, judgments and assumptions, and management's evaluation could change. Actual results could differ from those estimates.

Impact of COVID-19

The Company continues to closely monitor the impact of the COVID-19 pandemic and its variants on its business. In March 2020, the World Health Organization declared COVID-19 a global pandemic and recommended various containment and mitigation measures worldwide. Since that time, the number of procedures performed using the Company's products has intermittently decreased, as governmental authorities in the United States have recommended, and in certain cases required, that elective, specialty and other non-emergency procedures and appointments be suspended or canceled in order to avoid patient exposure to medical environments and the risk of potential infection with COVID-19, and to focus limited resources and personnel capacity on the treatment of COVID-19 patients. As a result, beginning in March 2020, a significant number of procedures using the Company's products have intermittently been postponed or cancelled, which has negatively impacted sales of its products. These measures and challenges will likely continue for the duration of the pandemic, which is uncertain, and may reduce the Company's net sales in the future and negatively impact its business, financial condition and results of operations while the pandemic continues.

Net Loss per Share

Our common stock has a dual class structure, consisting of Class A common stock, $0.001 par value per share (the “Class A common stock) and Class B common stock, $0.001 par value per share (the “Class B common stock). Other than voting rights, the Class B common stock has the same rights as the Class A common stock, and therefore both are treated as the same class of stock for purposes of the earnings per share calculation. Basic net loss per share attributable to common stockholders is calculated by dividing the net loss attributable to common stockholders by the weighted-average shares outstanding during the period. For purposes of the diluted net income (loss) per share attributable to common stockholders calculation, stock options, restricted stock units (“RSUs”) and warrants are considered to be common stock equivalents. All common stock equivalents have been excluded from the calculation of diluted net loss per share attributable to common stockholders, as their effect would be anti-dilutive for all periods presented. Therefore, basic and diluted net loss per share were the same for both periods presented.

Fair Value of Financial Instruments

Fair value is defined as the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. To increase the comparability of fair value measures, the following hierarchy prioritizes the inputs to valuation methodologies used to measure fair value:

Level 1 - Valuations based on quoted prices for identical assets and liabilities in active markets.

Level 2 - Valuations based on observable inputs other than quoted prices included in Level 1, such as quoted prices for similar assets and liabilities in active markets, quoted prices for identical or similar assets and liabilities in markets that are not active, or other inputs that are observable or can be corroborated by observable market data.

Level 3 - Valuations based on unobservable inputs reflecting the Company's own assumptions, consistent with reasonably available assumptions made by other market participants. These valuations require significant judgment.

The estimated fair value of financial instruments disclosed in the financial statements has been determined by using available market information and appropriate valuation methodologies. The carrying value of all current assets and current liabilities approximates fair value because of their short-term nature.

Cash and Restricted Cash

The Company maintains its cash balances at banks and financial institutions. The balances are insured up to the legal limit. The Company maintains cash balances that may, at times, exceed this insured limit.

Under the provisions of the Company's former revolving credit facility, the MidCap Credit Facility (as such term is defined, and further described in Note 9), the Company had a lockbox arrangement with the banking institution whereby daily lockbox receipts were contractually utilized to pay down outstanding balances on the MidCap Credit Facility debt. Lockbox receipts that had not yet been applied to the MidCap Credit Facility were classified as restricted cash in the accompanying consolidated balance sheets. The following table provides a reconciliation of cash and restricted cash included in the consolidated balance sheets to the amounts included in the statements of cash flows (in thousands).

	December 31,	
	2022	2021
Cash	$ 16,989	$ 30,393
Restricted cash	—	35
Total cash and restricted cash shown in statements of cash flows	$ 16,989	$ 30,428

Accounts Receivable and Allowances

Accounts receivable in the accompanying balance sheets are presented net of allowances for doubtful accounts and other credits. The Company grants credit to customers in the normal course of business, but generally does not require collateral or any other security to support its receivables.

The Company evaluates the collectability of accounts receivable based on a combination of factors. In circumstances where a specific customer is unable to meet its financial obligations to the Company, a provision to the allowance for doubtful accounts is recorded to reduce the net recognized receivable to the amount that is reasonably expected to be collected. For all other customers, a provision to the allowance for doubtful accounts is recorded based on factors including the length of time the receivables are past due, the current business environment and the Company's historical experience. Provisions to the allowance for doubtful accounts are recorded to general and administrative expenses. Account balances are charged off against the allowance when it is probable that the receivable will not be recovered. The Company's allowance for doubtful accounts was approximately $0.1 million as of December 31, 2022 and 2021.

Inventories

Inventories, consisting of purchased materials, direct labor and manufacturing overhead, are stated at the lower of cost or net realizable value, with cost determined generally using the average cost method. Inventory write-downs for unprocessed and certain processed donor tissue are recorded based on the estimated amount of inventory that will not pass the quality control process based on historical data. At each balance sheet date, the Company also evaluates inventories for excess quantities, obsolescence or shelf life expiration. This evaluation includes analysis of the Company's current and future strategic plans, historical sales levels by product, projections of future demand, the risk of technological or competitive obsolescence for products, general market conditions and a review of the shelf life expiration dates for products. To the extent that management determines there is excess or obsolete inventory or quantities with a shelf life that is too near its expiration for the Company to reasonably expect that it can sell those products prior to their expiration, the Company adjusts the carrying value to estimated net realizable value.

Property and Equipment

Property and equipment are stated at cost less accumulated depreciation. Depreciation is computed on the straight-line method over the following estimated useful lives of the assets:

Processing and research equipment	5 to 10 years
Office equipment and furniture	3 to 5 years
Computer hardware and software	3 years

Leasehold improvements are amortized on the straight-line method over the shorter of the lease term or the estimated useful life of the asset.

Repairs and maintenance costs are expensed as incurred.

Leases

In February 2016, the FASB issued ASU No 2016-02 “Leases” to increase the transparency and comparability about leases among entities. Additional ASUs have been issued subsequent to ASU 2016-02 to provide supplementary clarification and implementation guidance for leases related to, among other things, the application of certain practical expedients, the rate implicit in the lease, lessee reassessment of lease classification, lessor reassessment of lease term and purchase options, variable payments that depend on an index or rate and certain transition adjustments. ASU 2016-02 and these additional ASUs are now codified as Accounting Standards Codification Standard 842 - “Leases” (“ASC 842”). ASC 842 supersedes the lease accounting guidance in Accounting Standards Codification 840 “Leases” (“ASC 840”) and requires lessees to recognize a lease liability and a corresponding lease asset for virtually all lease contracts. It also requires additional disclosures about leasing arrangements. The Company elected to utilize the “package” of expedients, as defined in ASC 842, which retain the lease classification and initial direct costs for any leases that existed prior to adoption of the standard. Accordingly, previously reported financial information has not been restated to reflect the application of the new standard to the comparative periods presented. Aziyo adopted the standard in the fourth quarter of 2022 for the full 2022 year resulting in the recognition of a Right-of-use (“ROU”) asset and operating lease liability on the Company’s consolidated balance sheet of approximately $2.4 million as of January 1, 2022. As the ROU asset and the lease payable obligation were essentially the same upon adoption of ASC 842, there was no cumulative effect impact on the Company’s accumulated deficit.

The Company determines if an arrangement contains a lease at inception. ROU assets represent the Company’s right to use an underlying asset for the lease term and lease liabilities represent the Company’s obligation to make lease payments arising from that lease. For leases with a term greater than 12 months, ROU assets and liabilities are recognized at the lease commencement date based on the estimated present value of lease payments over the lease term. The lease term includes the option to extend the lease when it is reasonably certain the Company will exercise that option. When available, the Company uses the rate implicit in the lease to discount lease payments to present value. In the case the implicit rate is not available, the Company uses its incremental borrowing rate based on information available at the lease commencement date, including publicly available data for instruments with similar characteristics, to determine the present value of lease payments. The Company combines lease and non-lease elements for office leases.

Long-Lived Assets

Purchased intangible assets with finite lives are carried at acquired fair value, less accumulated amortization. Amortization is computed over the estimated useful lives of the respective assets.

The Company periodically evaluates the period of depreciation or amortization for long-lived assets to determine whether current circumstances warrant revised estimates of useful lives. The Company reviews its property and equipment and intangible assets for impairment whenever events or changes in circumstances indicate the carrying value of an asset may not be recoverable. Impairment exists when the carrying value of the company’s asset exceeds the related estimated undiscounted future cash flows expected to be derived from the asset. If impairment exists, the carrying value of that asset is adjusted to its fair value. A discounted cash flow analysis is used to estimate an asset’s fair value, using assumptions

that market participants would apply. The results of impairment tests are subject to management's estimates and assumptions of projected cash flows and operating results. Changes in assumptions or market conditions could result in a change in estimated future cash flows and could result in a lower fair value and therefore an impairment, which could impact reported results. There were no impairment losses for the years ended December 31, 2022 and 2021.

Revenue Recognition

The Company's revenue is generated from contracts with customers in accordance with ASC 606. The core principle of ASC 606 is that the Company recognizes revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the Company expects to be entitled in exchange for those goods or services. The ASC 606 revenue recognition model consists of the following five steps: (1) identify the contracts with a customer, (2) identify the performance obligations in the contract, (3) determine the transaction price, (4) allocate the transaction price to the performance obligations in the contract and (5) recognize revenue when (or as) the entity satisfies a performance obligation.

As noted above, the Company enters into contracts to primarily sell and distribute products to healthcare providers or commercial partners, or are produced and sold under contract manufacturing arrangements with corporate customers which are billed under ship and bill contract terms. Revenue is recognized when the Company has met its performance obligations pursuant to its contracts with its customers in an amount that the Company expects to be entitled to in exchange for the transfer of control of the products to the Company's customers. For all product sales, the Company has no further performance obligations and revenue is recognized at the point control transfers which occurs either when: i) the product is shipped via common carrier; or ii) the product is delivered to the customer or distributor, in accordance with the terms of the agreement.

A portion of the Company's product revenue is generated from consigned inventory maintained at hospitals and from inventory physically held by direct sales representatives. For these types of products sales, the Company retains control until the product has been used or implanted, at which time revenue is recognized.

The Company elected to account for shipping and handling activities as a fulfillment cost rather than a separate performance obligation. Amounts billed to customers for shipping and handling are included as part of the transaction price and recognized as revenue when control of the underlying products is transferred to the customer. The related shipping and freight charges incurred by the Company are included in sales and marketing costs. Shipping and handling costs were approximately $0.3 million for both the years ended December 31, 2022 and 2021.

Contracts with customers state the final terms of the sale, including the description, quantity, and price of each implant distributed. The payment terms and conditions in the Company's contracts vary; however, as a common business practice, payment terms are typically due in full within 30 to 60 days of delivery. The Company, at times, extends volume discounts to customers.

The Company permits returns of its products in accordance with the terms of contractual agreements with customers. Allowances for returns are provided based upon analysis of the Company's historical patterns of returns matched against the revenues from which they originated. The Company records estimated returns as a reduction of revenue in the same period revenue is recognized.

Deferred Rent

Prior to the adoption of ASU 2016-02 (as noted above) in the year ended December 31, 2022, the Company recognized rent expense by the straight-line method over the lease term. Funds received from the lessor used to reimburse the Company for the cost of leasehold improvements are recorded as a deferred credit resulting from a lease incentive and are amortized over the lease term as a reduction of rent expense.

Stock-Based Compensation Plans

The Company accounts for its stock-based compensation plans in accordance with FASB Accounting Standards Codification ("ASC") 718, *Accounting for Stock Compensation*. FASB ASC 718 requires the measurement and recognition of compensation expense for all stock-based awards made to employees and directors, including employee stock options and restricted stock. Stock-based compensation cost is measured at the grant date, based on the calculated fair value of the award, and is recognized as an expense on a straight-line basis over the requisite service period of the entire award.

Research and Development Costs

Research and development costs, which include mainly salaries, outside services and supplies, are expensed as incurred.

Concentration of Credit Risk

Financial instruments that potentially subject the Company to significant concentrations of credit risk consist primarily of cash. At December 31, 2022 and 2021, the Company maintained $17.8 million and $30.9 million, respectively, in bank deposit accounts that are in excess of the $0.25 million insurance provided by the Federal Deposit Insurance Corporation in one federally insured financial institution. The Company has not experienced any losses in such accounts.

Comprehensive Income (Loss)

Comprehensive income (loss) comprises net income (loss) and other changes in equity that are excluded from net income (loss). For the years ended December 31, 2022 and 2021, the Company's net loss equaled its comprehensive loss and accordingly, no additional disclosure is presented.

Income Taxes

The Company uses the asset and liability method of accounting for income taxes. Deferred income taxes are recorded to reflect the tax consequences on future years for differences between the tax basis of assets and liabilities and their financial reporting amounts at each year-end based on enacted tax laws and statutory tax rates applicable to the periods in which the differences are expected to affect taxable income. Valuation allowances are established when necessary to reduce deferred tax assets to amounts that are more likely than not to be realized.

The Company is subject to income taxes in the federal and state jurisdictions. Tax regulations within each jurisdiction are subject to the interpretation of the related tax laws and regulations and require significant judgment to apply. In accordance with the authoritative guidance on accounting for uncertainty in income taxes, the Company recognizes tax liabilities for uncertain tax positions when it is more likely than not that a tax position will not be sustained upon examination and settlement with various taxing authorities. Liabilities for uncertain tax positions are measured based upon the largest amount of benefit that is more likely than not (greater than 50%) of being realized upon settlement. The Company's policy is to recognize interest and/or penalties related to income tax matters in income tax expense.

Segment Reporting

Operating segments are components of an entity that engage in business activities with discrete financial information available that is regularly reviewed by the chief operating decision maker ("CODM") in order to assess performance and allocate resources. The Company's CODM is its President and Chief Executive Officer. As discussed further in Note 19, the Company has determined in its fourth quarter of 2022 that its operating and reportable segments are consistent with its major product groupings – device protection, women's health, orthobiologics and cardiovascular. Segment results for the year ended December 31, 2021 have been restated to conform to the new segment presentation. See Note 19 for further discussion.

Note 3. Recently Issued Accounting Standards

In June 2016, the FASB issued ASU 2016-13, Financial Instruments – Credit Losses (Topic 326): Disclosure Framework – Measurement of Credit Losses on Financial Instruments, which requires financial assets measured at amortized cost, including trade receivables, be presented net of the amount expected to be collected. The measurement of all expected credit losses will be based on relevant information about the credit quality of customers, past events, including historical experience, and reasonable and supportable forecasts that affect the collectability of the reported amount. In October 2019, the FASB voted to approve a proposal to defer the effective date of ASC 2016-13 for certain entities, including emerging growth companies that take advantage of the extended transition period, to fiscal years beginning after December 15, 2022. The Company is currently evaluating the impact of adopting this new guidance on its consolidated financial statements and timing of adoption.

Note 4. Stock-Based Compensation

In 2015, the Company established the Aziyo Biologics, Inc. 2015 Stock Option/Stock Issuance Plan, as amended (the "2015 Plan") which provided for the granting of incentive and non-qualified stock options to employees, directors and consultants of the Company. On October 7, 2020, in connection with the Company's IPO, the Company adopted the Aziyo Biologics, Inc. 2020 Incentive Award Plan (the "2020 Plan"), which authorizes the grant of incentive and non-qualified stock options, restricted stock, restricted stock units and stock appreciation rights to employees, directors and consultants. Shares of Class A common stock totaling 1,636,000 were initially reserved for issuance pursuant to the 2020 Plan. In addition, the shares reserved for issuance under the 2020 Plan will also include shares reserved but not issued under the 2015 Plan as well as an annual increase as set forth in the 2020 Plan. As of December 31, 2022, the Company had 656,689 shares of Class A common stock available for issuance under the 2020 Plan.

On June 21, 2022, C. Randal Mills, Ph.D., a member of the Board of Directors (the "Board") of the Company, was appointed as the Company's Interim President and Chief Executive Officer, succeeding Ronald Lloyd, who stepped down as the Company's President and Chief Executive Officer and as a member of the Board. In connection with his appointment as the Interim President and Chief Executive Officer, Dr. Mills and the Company entered into an employment agreement for an initial term of 90 days (such period, the "Interim Period"). On August 9, 2022, Dr. Mills was appointed to the role of President and Chief Executive Officer of the Company, thereby ending the Interim Period, and his employment agreement was extended pursuant to the terms thereof.

In accordance with the terms of his employment agreement, Dr. Mills (1) received a stock option award to purchase 456,278 shares of Class A common stock of the Company (the "Option Grant") on June 21, 2022; three-fifths of such Option Grant is subject to time-based vesting (the "Time-Based Options") and two-fifths of such Option Grant is subject to performance-based vesting (the "Performance Based Options") and (2) is eligible to receive 224,734 restricted stock units (the "RSU Grant"); three-fifths of such RSU Grant is subject to time-based vesting (the "Time-Based RSUs") and two-fifths of such RSU Grant is subject to performance-based vesting (the "Performance-Based RSUs"). One-third of the Time-Based Options vested on August 9, 2022 (end of the Interim Period), and two-thirds of the Time-Based Options vest over a four-year vesting schedule with 25% vesting on the first anniversary of June 21, 2022 and the remaining portion vesting in twelve equal quarterly installments. One-third of the Time-Based RSUs vest on the grant date, and two-thirds of the Time-Based RSUs vest over a four-year vesting schedule in equal annual installments. The Performance-Based Options and Performance-Based RSUs each vest in equal installments upon the achievement of certain share price thresholds for twenty consecutive days of trading at each respective threshold. Pursuant to the terms of the employment agreement, all of these awards were deemed granted on June 21, 2022, for purposes of and in accordance with ASC 718, *Accounting for Stock Based Compensation*; however, the RSUs had not been legally granted as of December 31, 2022. It is anticipated that such RSUs will be legally granted prior to June 30, 2023, and the vested shares underlying the award will be deemed outstanding as of such time.

In connection with his resignation as President and Chief Executive Officer, Mr. Lloyd and the Company entered into a separation agreement, pursuant to which Mr. Lloyd remained a full-time, non-officer employee of the Company through September 30, 2022 to assist with the transition of his duties to his successor. On September 30, 2022, Mr. Lloyd received: (i) cash severance in an amount equal to his base salary for a period of 12 months and 100% of his annual target bonus and (ii) the COBRA benefits, during the 12-month period following September 30, 2022. The Company recognized

Mr. Lloyd's severance costs totaling approximately $1.0 million over the period from June 21, 2022 through September 30, 2022, and as of December 31, 2022, all such expenses remaining to be paid were included in Accrued Expenses in the accompanying consolidated balance sheets.

Stock Options

The Company's policy is to grant stock options at an exercise price equal to 100% of the market value of a share of Class A common stock at closing on the date of the grant. The Company's stock options have contractual terms of seven to ten years, and vest over a four-year period from the date of grant.

A summary of stock option activity under the Company's 2015 Plan and 2020 Plan for the years ended December 31, 2022 and 2021 is as follows:

	Number of Shares	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (years)	Aggregate Intrinsic Value (in thousands)
Outstanding, December 31, 2021	1,386,811	$ 13.28	7.8	$ 179
Granted	1,246,904	$ 5.91		
Exercised	(13,887)	$ 5.57		
Forfeited	(755,089)	$ 10.83		
Outstanding, December 31, 2022	1,864,739	$ 9.41	7.5	$ 8
Vested and exercisable, December 31, 2022	723,793	$ 11.25	5.0	$ -

As of December 31, 2022, there was approximately $4.3 million of total unrecognized compensation expense related to unvested stock options. These costs are expected to be recognized over a weighted- average period of 2.5 years. The weighted average grant date fair value of options granted during the years ended December 31, 2022 and 2021 were $3.30 and $7.26, respectively. The total intrinsic value of options exercised was not material for both the years ended December 31, 2022 and 2021.

The Company uses the Black-Scholes model to value its stock option grants and expenses the related compensation cost using the straight-line method over the vesting period. The fair value of stock options is determined on the grant date using assumptions for the estimated fair value of the underlying common stock, expected term, expected volatility, dividend yield, and the risk-free interest rate. Before the completion of the Company's IPO, the Board of Directors determined the fair value of common stock considering the state of the business, input from management, third party valuations and other considerations. The Company uses the simplified method for estimating the expected term used to determine the fair value of options. The expected volatility of the Class A common stock is primarily based on the historical volatility of comparable companies in the industry whose share prices are publicly available. The Company uses a zero-dividend yield assumption as the Company has not paid dividends since inception nor does it anticipate paying dividends in the future. The risk-free interest rate approximates recent U.S. Treasury note auction results with a similar life to that of the option. The period expense is then determined based on the valuation of the options and is recognized on a straight-line basis over the requisite service period for the entire award.

The following weighted-average assumptions were used to determine the fair value of options during the years ended December 31, 2022 and 2021:

	Year Ended December 31,	
	2022	2021
Expected term (years)	6.2	5.9
Risk-free interest rate	2.3 %	1.0 %
Volatility factor	63.8 %	63.6 %
Dividend yield	—	—

For the Performance-Based Options granted as described above, the Company accounted for the awards as market condition awards and used an option pricing model, the Monte Carlo model, to determine the fair value of the respective equity instruments and an expense recognition term of approximately three years.

Restricted Stock Units

Restricted stock units ("RSUs") represent rights to receive common shares at a future date. There is no exercise price and no monetary payment is required for receipt of restricted stock units or the shares issued in settlement of the award.

A summary of the RSU activity under the Company's 2020 Plan for the year ended December 31, 2022 is as follows:

	Number of Shares Underlying RSUs	Weighted-Average Grant Date Fair Value
Unvested, December 31, 2021	235,985	$ 15.98
Granted	586,083	$ 4.08
Vested	(238,617)	$ 6.64
Forfeited	(211,144)	$ 11.40
Unvested, December 31, 2022	372,307	$ 5.90

The total fair value of the RSUs granted during the year ended December 31, 2022 and 2021 of $2.4 million and $1.3 million, respectively was based on the fair market value of the Company's Class A common stock on the date of grant. The fair value at the time of the grant is amortized to expense on a straight-line basis over the vesting period of three to four years.

During the year ended December 31, 2022, the Company granted 289,282 Performance-Based RSUs, with 209,054 still outstanding at December 31, 2022. All such RSUs, including those granted to Dr. Mills and described above, vest only if or when the Company's Class A common stock closing price is at or exceeds a defined share price for a defined period of time. As such, all of these awards have been accounted for as market condition awards. Given the nature of these market condition arrangements, an option pricing model, the Monte Carlo model, was used to determine the fair value of these RSUs as well as the expense recognition term of two to three years using the graded vesting method.

As of December 31, 2022, $1.5 million of unrecognized compensation costs related to RSUs is expected to be recognized over a weighted average period of two years.

Employee Stock Purchase Plan

The Company makes shares of its Class A common stock available for purchase under the Aziyo Biologics, Inc. 2020 Employee Stock Purchase Plan (the "ESPP"). The ESPP provides for separate six-month offering periods that begin in March and September of each year. Under the ESPP, employees may purchase a limited number of shares of Aziyo Class A common stock at 85% of the fair market value on either the first day of the offering period or the purchase date, whichever is lower. The ESPP is considered compensatory for purposes of stock-based compensation expense. The number of shares reserved under the ESPP will automatically increase on the first day of each fiscal year through January 1, 2030, in an amount equal to the lesser of (i) 1% of the total shares of Class A common stock outstanding on the final day of the immediately preceding calendar year; or (ii) a lesser number of shares determined by the Company's board of directors. As of December 31, 2022, the total shares of Class A common stock authorized for issuance under the ESPP was 380,997, of which 279,345 remained available for future issuance. During the year ended December 31, 2022, 74,408 shares of Class A common stock were issued under the ESPP.

Stock-Based Compensation Expense

Stock-based compensation expense recognized during the years ended December 31, 2022 and 2021 comprised of the following (in thousands):

	Year Ended December 31,	
	2022	2021
Sales and marketing	$ 1,047	$ 654
General and administrative	1,935	2,186
Research and development	483	531
Cost of goods sold	182	164
Total stock-based compensation expense	$ 3,647	$ 3,535

Note 5. Inventory

Inventory as of December 31, 2022 and 2021 was comprised of the following (in thousands):

	December 31, 2022	December 31, 2021
Raw materials	$ 1,716	$ 1,880
Work in process	623	834
Finished goods	7,713	6,840
Total	$ 10,052	$ 9,554

Note 6. Property and Equipment

Property and equipment as of December 31, 2022 and 2021 were comprised of the following (in thousands):

	December 31,	
	2022	2021
Processing and research equipment	$ 4,348	$ 3,853
Leasehold improvements	613	606
Office equipment and furniture	188	187
Computer hardware and software	998	994
	6,147	5,640
Less: accumulated depreciation and amortization	(4,744)	(4,440)
Property and equipment, net	$ 1,403	$ 1,200

Depreciation and amortization expense on property and equipment totaled approximately $0.3 million and $0.3 million for the years ended December 31, 2022 and 2021, respectively, of which approximately $0.2 million and $0.1 million, respectively, are included within cost of goods sold in the accompanying consolidated statements of operations.

Note 7. Leases

The Company leases two production facilities, one administrative and research facility and one administrative facility under non-cancelable operating lease arrangements that expire through November 2025. All leases contain renewal options and escalation clauses based upon increases in the lessors' operating expenses and other charges.

The following is a summary of the Company's ROU assets and operating lease liabilities as of December 31, 2022 (in thousands):

	Classification on the Balance Sheet	December 31, 2022
Assets		
Operating leases assets	Operating lease right-of-use assets and other	$ 1,576
Liabilities		
Operating leases current liabilities	Current operating lease liabilities and other	682
Operating leases non-current liabilities	Long-term operating lease liabilities	956
Total lease liabilities		$ 1,638
Weighted average remaining lease term		2.5
Weighted average discount rate		7.2%

For the year ended December 31, 2022, the Company recognized operating lease cost of approximately $1.0 million and expenses related to non-lease elements such as building maintenance and utilities of $0.5 million. Cash paid for amounts included in the measurement of operating lease liabilities are included in operating cash flows and were approximately $1.0 million for the year ended December 31, 2022.

For the year ended December 31, 2021, the Company recorded rent expense on a straight-line basis over the life of the lease and the difference between the average rent expense and cash payments for rent was recorded as deferred rent and included in accrued liabilities on the balance sheet as of December 31, 2021. Rent expense for the year ended December 31, 2021 was approximately $1.2 million and is included as a component of either cost of goods sold or general and administrative expenses.

The table below reconciles the Company's future cash obligations to the operating lease liabilities recorded on the balance sheet as of December 31, 2022 (in thousands):

Years ending December 31,	
2023	$ 774
2024	554
2025	470
Total minimum lease payments	1,798
Less: amount of lease payments representing interest	(160)
Present value of future minimum lease payments	1,638
Less: current operating lease liabilities	(682)
Long-term operating lease liabilities	$ 956

Note 8. Intangible Assets

On May 31, 2017, the Company completed an asset purchase agreement with CorMatrix Cardiovascular, Inc. ("CorMatrix") and acquired all CorMatrix commercial assets and related intellectual property. A substantial portion of the assets acquired consisted of intangible assets related to the acquired products and customer relationships. Management determined that the estimated acquisition-date fair values of the intangible assets related to acquired products and customer relationships were $29.3 million and $4.7 million, respectively.

The components of identified intangible assets as of December 31, 2022 and 2021 are as follows (in thousands):

	December 31, 2022			December 31, 2021		
	Cost	Accumulated Amortization	Net	Cost	Accumulated Amortization	Net
Acquired products	$ 29,317	$ (16,334)	$ 12,983	$ 29,317	$ (13,409)	$ 15,908
Customer relationships	4,723	(2,637)	2,086	4,723	(2,165)	2,558
Total	$ 34,040	$ (18,971)	$ 15,069	$ 34,040	$ (15,574)	$ 18,466

Acquired products and customer relationships are both amortized over a ten-year period. Amortization expense totaled approximately $3.4 million for each of the years ended December 31, 2022 and 2021, which is included in cost of goods sold in the accompanying consolidated statements of operations. Annual amortization expense is expected to be approximately $3.4 million during the years ended December 31, 2023 through 2026 and approximately $1.5 million during the year ended December 31, 2027.

Note 9. Long-Term Debt

On May 31, 2017, Aziyo entered into a $12 million term loan facility (the “MidCap Loan Facility”) and an $8.0 million asset-backed revolving line of credit (the “MidCap Credit Facility”), under which the Company’s borrowing capacity was limited by certain qualifying assets, with a financial institution (the “May 2017 Financing”). The MidCap Loan Facility was amended in December 2017, February 2018 and July 2019 (all amendments being considered modifications) such that an additional $1.5 million, $3.0 million, and $3.5 million, respectively were received by the Company bringing the total aggregate principal amount outstanding under the MidCap Loan Facility to $20 million. The borrowings under the MidCap Loan Facility and the MidCap Credit Facility were fully repaid with a portion of the proceeds from the SWK Loan Facility (as defined below) as more fully described below.

On August 10, 2022 (the “Closing Date”), the Company entered into a senior secured term loan facility with SWK Funding LLC, as agent, and other lenders party thereto (the “SWK Loan Facility”) for an aggregate principal amount of $25 million. An initial draw of $21 million drawn was made on the Closing Date with the additional $4 million drawn on December 14, 2022 upon satisfaction of the amended terms enabling such receipt. The SWK Loan Facility also allows for the establishment of a separate, new asset-based revolving loan facility of up to $8 million, which had not been entered into as of December 31, 2022. The SWK Loan Facility matures on August 10, 2027 and accrues interest, payable quarterly in arrears. Principal amortization of the SWK Loan Facility starts on November 15, 2024, which amortization may be extended to November 17, 2025 if certain conditions have been satisfied. Principal payments during the amortization period will be limited based on revenue-based caps. As of December 31, 2022, quarterly principal payments are scheduled to begin on November 15, 2024, in an amount equal to 5% of the Initial Term Loan with the balance paid at maturity. The SWK Loan Facility also includes both revenue and liquidity covenants, restrictions as to payment of dividends, and is secured by all assets of the Company, subject to certain customary exceptions. As of December 31, 2022, Aziyo was in compliance with its financial covenants under the agreement governing the SWK Loan Facility (the “SWK Loan Facility Agreement”).

All of the SWK Loan Facility borrowings take the form of Secured Overnight Financing Rate (“SOFR”) loans and bear interest at a rate per annum equal to the sum of an applicable margin of (i) 7.75% and the “Term SOFR Rate” (based upon an interest period of 3 months), or (ii) if the Company has elected the PIK Interest option (as defined below), 4.75% and the “Term SOFR Rate.” The Company may elect a portion of the interest due, to be paid in-kind at a rate per annum of 4.5% (“PIK Interest”), and such election may be made (x) until November 15, 2024 if the conditions to draw the Additional Term Loan have not been met, or (y) if such conditions to draw the Additional Term Loan have been satisfied, until November 17, 2025. The “Term SOFR Rate” is subject to a floor of 2.75%. The agreement governing the SWK Loan Facility also includes an exit fee equal to 6.5% of the aggregate principal amount funded prior to termination and prepayment penalties equal to: (i) if such prepayment occurs prior to the first anniversary of the Closing Date, 2% of the aggregate principal amount funded prior to the termination plus remaining unpaid interest payments scheduled to be paid during the first year of the loan or (ii) if such prepayment occurs after the first anniversary of the Closing Date but prior to the second anniversary of the Closing Date, 2% of the aggregate principal amount funded prior to the termination. The

weighted average interest rate on the SWK Loan Facility was 12.6% for the period from August 10, 2022 through December 31, 2022.

On August 10, 2022, the Company issued to SWK Funding LLC a warrant (the "Warrant") to purchase, in the aggregate, up to 187,969 shares of Class A common stock of the Company, $0.001 par value per share at an exercise price of $6.65 per share. The Warrant is immediately exercisable for up to 187,969 shares of Class A common stock from time to time on or after the Closing Date. The exercise price and number of shares of Class A common stock issuable upon exercise of the Warrant are subject to adjustment in the event of stock dividends, stock splits and certain other events affecting the Class A common stock. Unless earlier exercised or terminated in accordance with its terms, the Warrant will expire on the seventh anniversary of the Closing Date. Upon issuance, the Company valued the Warrant at approximately $0.6 million using the Black-Scholes model. The recognition of the Warrant as well as deferred financing costs of approximately $0.5 million incurred in securing the SWK Loan Facility served to reduce the recorded value of the associated debt. The debt discount and deferred financing costs will be recognized as interest expense through the maturity of the loan.

The Company used $16 million of the proceeds of the SWK Loan Facility to repay all outstanding obligations on the MidCap Loan Facility and MidCap Credit Facility. Such payment included (i) $12.8 million to repay all outstanding principal and accrued interest on the MidCap Loan Facility, (ii) $1.7 million to pay the prepayment and exit fees on the MidCap Loan Facility and (iii) $1.5 million to repay the outstanding balance, accrued interest and exit fees on the MidCap Credit Facility. The prepayment fees, payment of unaccrued exit fees and the write-off of unamortized deferred financing costs resulted in a loss to the Company of approximately $1.2 million which has been recorded as other income, net in the accompanying consolidated statements of operations for the year ended December 31, 2022.

The SWK Loan Facility Agreement requires certain mandatory prepayments, subject to certain exceptions, with: (1) 100% of any net casualty proceeds in excess of $250,000 and (2) for non-ordinary course asset sales, an amount equal to the difference between (x) the proportion of divested gross profit (as defined in the SWK Loan Facility Agreement) to the Company's total gross profit (as defined in the SWK Loan Facility Agreement) multiplied by the outstanding loans under the SWK Loan Facility and (y) the difference between $1,000,000 and the aggregate sale proceeds of any assets previously sold during the fiscal year. No such mandatory prepayments were required during the year ended December 31, 2022.

Borrowings under the MidCap Loan Facility, as amended, bore interest at a rate per annum equal to the sum of (x) the greater of (i) 2.25% and (ii) the applicable London Interbank Offered Rate for U.S. dollar deposits divided by 1.00 minus the maximum effective reserve percentage for Eurocurrency funding ("LIBOR") plus (y) 7.25%. The weighted average interest rate on MidCap Loan Facility was 9.5% from January 1, 2022 through August 10, 2022 (the "Repayment Date") and for the year ended December 31, 2021.

Borrowings under the MidCap Credit Facility bore interest at a rate per annum equal to the sum of (x) the greater of (i) 2.25% and (ii) LIBOR plus (y) 4.95%. The weighted average interest rate on MidCap Credit Facility was 7.2% from January 1, 2022 through the Repayment Date and for the year ended December 31, 2021.

During 2017, the Company restructured certain of its liabilities with a tissue supplier and entered into an unsecured promissory note totaling $2.1 million. The note bears interest at 5% and includes quarterly interest-only payments in 2017 and quarterly interest and principal payments from March 31, 2018 through August 31, 2021. The Company used $1.4 million of the proceeds from the SWK Loan Facility to repay the remaining balance on the promissory note; however the accrued interest on the promissory note was forgiven by the lender. Such forgiveness resulted in a gain to the Company of approximately $0.4 million which has been recorded as other income, net in the accompanying consolidated statements of operations for the year ended December 31, 2022.

In May 2020, Aziyo entered into a promissory note with Silicon Valley Bank that provided for the receipt by the Company of loan proceeds totaling approximately $3.0 million (the "PPP Loan") pursuant to the Paycheck Protection Program under the Coronavirus Aid, Relief and Economic Security Act (the "CARES Act"). In September 2021, Aziyo was notified by the U.S. Small Business Administration that the entire balance of the Company's PPP Loan and all related accrued interest was forgiven. Such forgiveness resulted in a gain to the Company of approximately $3.0 million which

has been recorded as other income, net in the accompanying consolidated statements of operations for the year ended December 31, 2021.

As of December 31, 2022, the contractual maturities of the long-term debt are as follows (in thousands):

Years ending December 31,	Term Loan
2023	$ —
2024	1,263
2025	5,051
2026	5,051
2027	13,890
Total	25,255
Debt Discount	(562)
Deferred Financing Costs	(433)
Total, net	24,260
Current Portion	—
Long-term Debt	$ 24,260

The fair value of all debt instruments, which is based on inputs considered to be Level 2 under the fair value hierarchy, approximates the respective carrying values as of December 31, 2022 and 2021.

Note 10. Revenue Interest Obligation

As part of the CorMatrix asset acquisition described in Note 8, the Company assumed a restructured, long-term obligation (the "Revenue Interest Obligation") to Ligand Pharmaceuticals ("Ligand") with an estimated present value on the acquisition date of $27.7 million. Subject to annual minimum payments of $2.75 million per year, the terms of the Revenue Interest Obligation require Aziyo to pay Ligand, 5% of future sales of the products Aziyo acquired from CorMatrix, including CanGaroo, ProxiCor, Tyke and VasCure, as well as products substantially similar to those products, such as the version of CanGaroo that Aziyo is currently developing that is designed to include antibiotics.

Furthermore, a $5.0 million payment will be due to Ligand if cumulative sales of these products exceed $100 million and a second $5.0 million will be due if cumulative sales exceed $300 million during the ten-year term of the agreement which expires on May 31, 2027.

The Company recorded the present value of the estimated total future payments under the Revenue Interest Obligation as a long-term obligation, with the short-term portion as of December 31, 2022 comprised of (i) the 2023 minimum payments, (ii) the first $5.0 million sales milestone payment noted above and (iii) the unpaid portion of the 2022 minimum payments. The short-term portion as of December 31, 2021 was comprised of the 2022 minimum payments. Interest expense related to the Revenue Interest Obligation of approximately $2.7 million was recorded for both the years ended December 31, 2022 and 2021. See Note 11 for discussion of the value of this obligation.

Note 11. Fair Value Measurements

The following table sets forth by level, within the fair value hierarchy, the liabilities that are measured at fair value on a recurring basis (in thousands):

	Fair Value Measurements at December 31, 2021 Using:			
	Level 1	Level 2	Level 3	Total
Liabilities:				
Revenue Interest Obligation*	—	—	19,290	19,290
Total	$ —	$ —	$ 19,290	$ 19,290

	Fair Value Measurements at December 31, 2022 Using:			
	Level 1	Level 2	Level 3	Total
Liabilities:				
Revenue Interest Obligation*	—	—	14,906	14,906
Total	$ —	$ —	$ 14,906	$ 14,906

*Net Present Value; see discussion of value below

The Company has estimated the value of the Revenue Interest Obligation, including contingent milestone payments and estimated sales-based payments, based on assumptions related to future sales of the acquired products. At each reporting period, the value of the Revenue Interest Obligation is re-measured based on current estimates of future payments, with changes to be recorded in the consolidated statements of operations using the catch-up method. In connection with our estimation at December 31, 2022, it was determined that the estimated future payments, discounted at the original discount rate, had decreased since the prior estimates. Such decrease was primarily the result of anticipated changes to our strategic partnerships relative to sales of both our CanGaroo and cardiovascular product lines that will impact the timing and extent of such sales and, thereby, will reduce expected future payments to Ligand. The change to estimated future payments yielded a reduction to the total Revenue Interest Obligation of approximately $5.0 million for the year ended December 31, 2022 with such amount recognized as a gain in Other income, net in our consolidated statement of operations. There was no change to estimated future payments during the year ended December 31, 2021 and thus, no re-measurement gain or loss was recognized..

The following table provides a rollforward of the aggregate fair value of the Revenue Interest Obligation categorized with Level 3 inputs for the years ended December 31, 2022 and 2021 (in thousands):

Balance as of January 1, 2021	$ 19,383
Payments on Revenue Interest Obligation	(2,747)
Interest accrued to Revenue Interest Obligation	2,654
Balance as of December 31, 2021	$ 19,290
Payments on Revenue Interest Obligation	(2,075)
Interest accrued to Revenue Interest Obligation	2,653
Gain on revaluation of revenue interest obligation	(4,962)
Balance as of December 31, 2022	$ 14,906

Note 12. Income Taxes

The Company is subject to income taxes in the United States. Income taxes are accounted for under the asset and liability method. Deferred income tax assets and liabilities are calculated based on the difference between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases using the enacted income tax rates expected to be in effect during the years in which the temporary differences are expected to reverse.

The reconciliation of the U.S. federal statutory rate to the consolidated effective tax rate is as follows:

	Years Ended December 31,	
	2022	2021
Tax benefit at U.S. statutory rate	21.0 %	21.0 %
State income tax benefit, net of federal benefit	1.9 %	1.6 %
Nondeductible expenses	(0.3)%	1.6 %
State law changes	0.5 %	0.4 %
Other	0.1 %	0.3 %
Change in valuation allowance	(23.3)%	(25.1)%
Income tax expense	(0.1)%	(0.2)%

Deferred income taxes reflect the net tax effects of temporary differences between the carrying amount of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes as well as net operating loss

carryforwards. As of December 31, 2022 and 2021, significant components of the Company's net deferred income taxes are as follows (in thousands):

	December 31, 2022	December 31, 2021
Deferred tax assets:		
Tax goodwill	$ 2,947	$ 3,267
Net operating loss carryforwards	19,743	14,794
Inventory	491	647
Acquired intangibles	1,452	1,174
Revenue interest obligation	774	1,347
Interest expense	2,533	1,866
Research and development costs	1,749	-
Operating lease liability	364	-
FiberCel litigation costs	669	-
Other	2,045	1,314
Total assets	32,767	24,409
Deferred tax liabilities:		
Operating lease right-to-use assets	(350)	-
Prepaid expenses	(562)	(200)
Total liabilities	(912)	(200)
Total net deferred tax asset	31,855	24,209
Valuation allowance	(31,855)	(24,209)
Net deferred tax asset, net of valuation allowance	$ —	$ —

The Company did not recognize any deferred benefit for income taxes for the years ended December 31, 2022 and 2021, as the increases to the respective net deferred tax assets of $7.6 million and $6.2 million, respectively, were offset by corresponding increases to the Company's deferred tax asset valuation allowance due to uncertainty of realizing the deferred tax assets.

The Company evaluates the need for deferred tax asset valuation allowances based on a more likely than not standard. The ability to realize deferred tax assets depends on the ability to generate sufficient taxable income within the carryback or carryforward periods provided for in the tax law for each applicable tax jurisdiction. Valuation allowances are established when necessary to reduce deferred tax assets to amounts that are more likely than not to be realized. Based on the uncertainty of future taxable income generation, as of December 31, 2022 and 2021, the Company has provided valuation allowances against all deferred tax assets.

The Company regularly assesses the realizability of its deferred tax assets. Changes in historical earnings performance and future earnings projections, among other factors, may cause the Company to adjust its valuation allowance, which would impact the Company's income tax expense in the period the Company determines that these factors have changed.

The income tax expense for the years ended December 31, 2022 and 2021 relates to current amounts due on certain state tax obligations.

As of December 31, 2022, the Company had net operating loss carryforwards for federal income tax purposes of approximately $86.9 million, comprised of $17.7 million that will expire beginning in 2036 and $69.3 million that have no expiration date. The Company also had state net operating loss carryforwards of approximately $26.4 million that will expire beginning in 2030. Utilization of the net operating loss carryforwards may be subject to an annual limitation under Section 382 of the Code, and corresponding provisions of state law, due to ownership changes that have occurred previously or that could occur in the future. These ownership changes may limit the amount of carryforwards that can be utilized annually to offset future taxable income. The Company has not conducted a study to assess whether a change of control has occurred or whether there have been multiple changes of control since inception due to the significant

complexity and cost associated with such a study. If the Company has experienced a change of control, as defined by Section 382, at any time since inception, utilization of the net operating loss carryforwards would be subject to an annual limitation under Section 382. Any limitation may result in expiration of a portion of the net operating loss carryforwards before utilization.

As of December 31, 2022, the Company had no unrecognized tax benefits.

Note 13. Stockholders' Equity

Public Offering of Common Stock

On December 1, 2022, the Company issued and sold 2,350,000 shares of its Class A common stock at a price to the public of $4.75 per share in a registered underwritten public offering, resulting in net proceeds to the Company of approximately $10.2 million, after deducting underwriting discounts and offering expense.

Private Placement of Common Stock

On December 8, 2021, the Company closed on a private investment in public equity (PIPE) financing, thereby receiving net proceeds of approximately $13.8 million, after deducting offering costs. The PIPE investors purchased an aggregate of 2,122,637 shares of the Company's Class A common stock and an aggregate of 1,179,244 shares of the Company's Class B common stock (which are convertible on a one-for-one basis into shares of Class A common stock), in each case, at a price of $4.24 per share.

Note 14. Retirement Plan

The Company has a defined contribution savings plan under section 401(k) of the Internal Revenue Code. The plan covers substantially all employees. The Company matches employee contributions made to the plan according to a specified formula. The Company's matching contributions totaled approximately $0.3 million and $0.4 million for the years ended December 31, 2022 and 2021, respectively.

Note 15. Net Loss Per Share

(in thousands, except share and per share data)	Year Ended December 31, 2022	2021
Numerator:		
Net loss	$ (32,897)	$ (24,832)
Denominator:		
Weighted average number of common shares - basic and diluted	13,832,887	10,444,767
Net loss per share - basic and diluted	$ (2.38)	$ (2.38)

The Company's potential dilutive securities have been excluded from the computation of diluted net loss per share as the effect would be anti-dilutive. Therefore, the weighted average number of common shares outstanding used to calculate both basic and diluted net loss per share attributable to common stockholders is the same. The Company excluded the following potential common shares, presented based on amounts outstanding at period end, from the computation of diluted net loss per share attributable to common stockholders:

	December 31, 2022	2021
Options to purchase common stock	1,864,739	1,386,811
Restricted stock units	372,307	235,985
Class A common stock warrants	187,969	—
Total	2,425,015	1,622,796

Note 16. Distribution Agreements

ViBone Exclusivity Agreement

In August 2018, the Company entered into an agreement with Surgalign Holdings, Inc. (formerly RTI Surgical, Inc.) ("Surgalign Holdings") for the exclusive distribution in the United States of the Company's ViBone® cellular bone product. Such agreement includes requirements that Surgalign Holdings purchase certain annual minimum quantities for years 2019 through 2021 and also included an upfront payment of $2.0 million for the exclusivity. Such upfront payment was recorded as deferred revenue and was amortized into revenue through the 2021 minimum purchase period. During each of the year ended December 31, 2021, Aziyo recognized approximately $0.6 million as revenue.

Significant Customers

The Company sells certain of its products under large contract manufacturing or distribution arrangements. The following table presents percentage of total revenues derived from the Company's largest customers:

	Year Ended December 31,	
	2022	2021
Percent of revenues derived from:		
Customer A	11%	10%
Customer B	5%	4%
Customer C	-	11%

	December 31, 2022	December 31, 2021
Percent of accounts receivable derived from:		
Customer A	12%	12%
Customer B	10%	4%
Customer C	-	-

In December 2021, the Company terminated our distribution agreement with Medtronic (Company C in the tables above) as a result of the Company's voluntary recall of the Company's FiberCel product.

Note 17. Commitment and Contingencies

Cook Biotech License and Supply Agreements

Aziyo has entered into a license agreement with Cook Biotech ("Cook") for an exclusive, worldwide license to the porcine tissue for use in the Company's Cardiac Patch and CanGaroo products, subject to certain co-exclusive rights retained by Cook. The term of such license is through the date of the last to expire of the licensed Cook patents, which is anticipated to be July 2031. Along with this license agreement, Aziyo entered into a supply agreement whereby Cook would be the exclusive supplier to Aziyo of the licensed porcine tissue. Under certain limited circumstances, Aziyo has the right to manufacture the licensed product and pay Cook a royalty of 3% of sales of the Aziyo-manufactured tissue. The supply agreement expires on the same date as the related license agreement. No royalties were paid to Cook during the years ended December 31, 2022 and 2021. Aziyo has also entered into an amendment to the Cook license agreement (the "Cook Amendment") in order to add fields of exclusive use. Specifically, the Cook Amendment provides for a worldwide exclusive license to the porcine tissue for use with neuromodulation devices in addition to cardiovascular devices. The Cook Amendment includes license fee payments of $0.1 million per year in each of the years 2021 through 2026. Such license payments would accelerate if a change in control, as defined, occurs within Aziyo. The Company, in its sole discretion, can terminate the license agreement at any time.

Legal Proceedings

From time to time, the Company may be involved in claims and proceedings arising in the course of the Company's business. The outcome of any such claims or proceedings, regardless of the merits, is inherently uncertain. The Company records accruals for contingencies when it is probable that a liability has been incurred and the amount can be reasonably estimated. These accruals are adjusted periodically as assessments change or additional information becomes available.

FiberCel Litigation

In June 2021, the Company announced a voluntary recall of a single lot of FiberCel fiber viable bone matrix. Since September 2021, 58 lawsuits (60 plaintiffs) in Indiana, Delaware, Florida, Maryland, Colorado, Michigan, Ohio, Kentucky, Oregon, North Carolina, Louisiana and Illinois have been filed against Aziyo Biologics Inc., certain Medtronic entities, and others alleging that the plaintiffs were exposed to and/or contracted tuberculosis and/or suffered substantial symptoms and complications following the implantation of FiberCel during spinal fusion operations. Such lawsuits were filed in Indiana state court (collectively, the "Indiana State Complaints"); the Superior Court of the State of Delaware (collectively, the "Delaware State Complaints"); the Circuit Court of Maryland (collectively, the "Maryland State Complaints"); the Court of Common Pleas of Ohio ("Ohio State Complaint"); the Northern District of Ohio ("Ohio Federal Complaint"); the U.S. District Court for the Western District of North Carolina ("North Carolina Federal Complaint"); the U.S. District Court for the Northern District of Florida ("Florida Federal Complaint"); U.S. District Court for the Eastern District of Michigan and the Eastern District of Michigan (collectively "Michigan Federal Complaints."); the U.S. District Court for the District of Colorado ("Colorado Federal Complaint"); the U.S. District Court for the District of Oregon ("Oregon Federal Complaint"); the Fayette, Kentucky Circuit Court and the U.S. District Court for the Eastern District of Kentucky (collectively, "Kentucky Complaints."); the U.S. District Court for the Western District of Louisiana ("Louisiana Federal Complaint") and the Circuit Court of Cook County, Illinois ("Illinois State Complaint").

Plaintiffs in the Indiana State Complaints allege a cause of action under Indiana's Product Liability Act, citing manufacturing defects, defective design and failure to properly warn and instruct, and several of the complaints allege loss of consortium. Plaintiffs in these actions assert that the defendants are strictly liable or have breached the duty of care owed to plaintiffs by failing to exercise reasonable care in designing, manufacturing, marketing and labeling FiberCel and are seeking various types of damages, including economic damages, non-economic damages and loss of consortium. Plaintiffs in one of the Indiana State Complaints allege causes of action for product liability, negligence, breach of express and implied warranties, and punitive damages. Each of the plaintiffs in the Delaware State Complaints alleges negligence, breach of implied warranty, breach of express warranty, and medical monitoring and punitive damages, and two also allege loss of consortium. Plaintiffs in the Delaware State Complaints are seeking economic, consequential, and punitive damages. The Maryland State Complaints assert claims of negligence, breach of implied warranty, breach of express warranty, medical monitoring, and loss of consortium. The Florida Federal Complaint contains three strict liability claims for defective design, defective manufacture, and failure to warn. A claim for punitive damages is also pled. The Ohio State Complaint alleges causes of action for product liability and negligence and seeks compensatory damages. The Colorado Federal Complaint asserts causes of action for strict product liability, misrepresentation, negligence, breach of express warranty, and breach of implied warranty of merchantability. The Michigan Federal Complaints assert causes of action for negligence, gross negligence breach of implied warranty, breach of express warranty, intentional infliction of emotional distress, and liability under the res ipsa loquitur doctrine. The Michigan Federal Complaints seek compensatory damages and punitive damages. The North Carolina Federal Complaint alleges causes of action for negligence, defective design, breach of implied warranty, breach of express warranty, and loss of consortium, and seeks both compensatory and punitive damages. The Oregon Federal Complaint asserts strict liability claims for defective design, defective manufacture, and failure to warn, and seeks compensatory damages. The Ohio Federal Complaint asserts strict liability claims for defective manufacturing, inadequate warning, nonconformance with representations, and also alleges loss of consortium and seeks compensatory damages. The Kentucky Complaints assert strict liability claims based on manufacturing defect, design defect, failure to warn, negligence, breach of implied warranty, breach of express warranty, and seek recovery for medical monitoring, loss of consortium, compensatory damages, and punitive damages. The Louisiana Federal Complaint asserts claims of violation of the Louisiana products liability act, negligence and gross negligence, breach of implied warranty, breach of express warranty and seek recovery for medical monitoring.

In addition to the above, there are 47 claims related to the FiberCel recall that have not yet resulted in a lawsuit. The Company refers to all of the aforementioned litigation, or claim notices, collectively as the "FiberCel Litigation."

Since August 2022, the Company has engaged in a process to negotiate and attempt to resolve many of the cases in the FiberCel Litigation. In total, Aziyo's liability in 26 of the cases was settled for a total of approximately $7.3 million. Settlement agreements have been executed in 20 of those cases and settlements of the remaining six cases are pending finalization of the related settlement agreements. Of these settled matters, 11 cases were both settled and paid as of December 31, 2022 for a total cash outlay of $3.6 million. For the remaining 81 cases for which settlements have not been reached, the Company estimated a probable loss related to each case and has recorded a liability at an estimated amount of $13.7 million bringing the total estimated liability at December 31, 2022 to $17.4 million, which is recorded as Contingent Liability for FiberCel Litigation in the accompanying consolidated balance sheets. Although the Company believes there is a possibility that a loss in excess of the amount recognized exists, the Company is unable to estimate the possible loss or range of loss in excess of the amount recognized at this time. In order to reasonably estimate the liability for the unsettled FiberCel Litigation cases, the Company, along with outside legal counsel, has assessed a variety of factors, including (i) the extent of the injuries incurred, (ii) recent experience on the settled claims, (iii) settlement offers made to the other parties to the litigation and (iv) any other factors that may have a material effect on the FiberCel Litigation. While the Company believes its estimated liability to be reasonable, the actual loss amounts are highly variable and turn on a case-by-case analysis of the relevant facts. As more information is learned about asserted claims and potential future trends, adjustments may be made to this Contingent Liability for FiberCel Litigation as appropriate.

Defense costs are recognized in the accompanying consolidated statements of operations as incurred.

The Company has purchased insurance coverage that, subject to common contract exclusions, provided coverage for the FiberCel Litigation product liability losses as well as legal defense costs. Additionally, the Company has various potential indemnity and/or contribution rights against third party sources with respect to certain product liability losses. When settlements are reached and/or amounts are recorded in the related Contingent Liability for FiberCel Litigation, the Company calculates amounts due to be reimbursed pursuant to the terms of the coverage and related agreements, and pursuant to other indemnity or contribution claims, in respect of product liability losses and related defense costs. The amounts probable of reimbursement or recovery from this calculation are recorded as receivables. The determination that the recorded receivables are probable of collection is based on the terms of agreements reached in respect of indemnity and contribution claims as well as the advice of the Company's outside legal counsel. These receivables at December 31, 2022 totaled $13.8 million and are recorded as Receivables of FiberCel Litigation Costs in the accompanying consolidated balance sheets.

The indemnity and contribution receivables amount at December 31, 2022 represents amounts that are not believed to be subject to any current dispute. At December 31, 2022, the Company continues to pursue up to $3.8 million or more in additional amounts in respect of such indemnity and contribution claims and as such, has not been reflected as part of this receivable. The Company will vigorously pursue its position with respect to this amount.

As of both December 31, 2022 and December 31, 2021, the Company was not a party to, or aware of, any legal matters or claims with material financial exposure, except for the FiberCel Litigation.

Note 18. Related Party Transactions

As part of the contribution of assets transacted from Tissue Banks International, now KeraLink International ("KeraLink"), to Aziyo upon formation of the Company, a provision existed which guaranteed a certain level of working capital, as defined, on the opening balance sheet of Aziyo. Such guarantee was largely finalized in 2016; however, an additional $0.4 million was received by the Company in connection with a settlement reached in 2018. Furthermore, as part of the 2018 settlement, it was agreed that when KeraLink sells its Aziyo common shares for net proceeds greater than $550,000, KeraLink is obligated to pay Aziyo $550,000 within three days of such cash being received. In May 2021, KeraLink sold Aziyo common shares for proceeds in excess of $550,000, and as such, remitted $550,000 to Aziyo in full satisfaction of the 2018 settlement. Amounts received in connection with this settlement were recorded as other income, net in the accompanying consolidated statements of operations for the year ended December 31, 2021.

Note 19. Segment Information

The Company operates in four segments. These segments are based on financial information that is utilized by the Company's CODM to assess performance and allocate resources. The Company determined its operating and reportable segments to be consistent with its major product groupings – Device Protection, Women's Health, Orthobiologics and Cardiovascular.

For the years ended December 31, 2022 and 2021, the Company's net sales disaggregated by segment were as follows (in thousands):

	Year Ended December 31,	
	2022	2021
Net sales:		
Device protection	$ 9,093	$ 7,902
Women's health	7,474	5,046
Orthobiologics	25,338	26,934
Cardiovascular	7,282	7,508
Total Net Sales	$ 49,187	$ 47,390

For the years ended December 31, 2022 and 2021, the Company's gross profit disaggregated by segment were as follows (in thousands):

	Year Ended December 31,	
	2022	2021
Gross profit:		
Device protection	$ 6,114	$ 5,761
Women's health	3,137	914
Orthobiologics	7,583	9,742
Cardiovascular	5,785	6,001
Gross profit, excluding intangible asset amortization	22,619	22,418
Intangible asset amortization expense	3,397	3,396
Gross profit	$ 19,222	$ 19,022

The following table is a reconciliation of segment gross profit to the consolidated loss before provision for income taxes for the years ended December 31, 2022 and 2021 (in thousands):

	Year Ended December 31,	
	2022	2021
Gross profit	$ 19,222	$ 19,022
Adjustments:		
Sales and marketing	(20,195)	(18,825)
General and administrative	(16,627)	(13,687)
Research and development	(8,940)	(9,266)
FiberCel litigation costs	(5,200)	(276)
Loss from operations	(31,740)	(23,032)
Interest expense	5,282	5,324
Other income, net	(4,159)	(3,579)
Loss before provision for income taxes	$ (32,863)	$ (24,777)

During the years ended December 31, 2022 and 2021, the Company did not have any international product sales to specific countries where such country-specific sales represented material product sales, and the Company did not own any long-lived assets outside the United States.

AZIYO BIOLOGICS, INC.
2020 INCENTIVE AWARD PLAN

ARTICLE 1.

PURPOSE

The purpose of the Aziyo Biologics, Inc. 2020 Incentive Award Plan (as it may be amended or restated from time to time, the "Plan") is to promote the success and enhance the value of Aziyo Biologics, Inc. (the "Company") by linking the individual interests of Directors, Employees, and Consultants to those of Company stockholders and by providing such individuals with an incentive for outstanding performance to generate superior returns to Company stockholders. The Plan is further intended to provide flexibility to the Company in its ability to motivate, attract, and retain the services of Directors, Employees, and Consultants upon whose judgment, interest, and special effort the successful conduct of the Company's operation is largely dependent.

ARTICLE 2.

DEFINITIONS AND CONSTRUCTION

Wherever the following terms are used in the Plan they shall have the meanings specified below, unless the context clearly indicates otherwise. The singular pronoun shall include the plural where the context so indicates.

2.1 "Administrator" shall mean the Board or a Committee to the extent that the Board's powers or authority under the Plan have been delegated to such Committee.

2.2 "Affiliate" shall mean (a) any Subsidiary; and (b) any domestic eligible entity that is disregarded, under Treasury Regulation Section 301.7701-3, as an entity separate from either (i) the Company or (ii) any Subsidiary.

2.3 "Applicable Accounting Standards" shall mean Generally Accepted Accounting Principles in the United States, International Financial Reporting Standards or such other accounting principles or standards as may apply to the Company's financial statements under United States federal securities laws from time to time.

2.4 "Applicable Law" shall mean any applicable law, including, without limitation: (a) provisions of the Code, the Securities Act, the Exchange Act and any rules or regulations thereunder; (b) corporate, securities, tax or other laws, statutes, rules, requirements or regulations, whether federal, state, local or foreign; and (c) rules of any securities exchange or automated quotation system on which the Shares are listed, quoted or traded.

2.5 "Automatic Exercise Date" shall mean, with respect to an Option or a Stock Appreciation Right, the last business day of the applicable Option Term or Stock Appreciation Right Term that was initially established by the Administrator for such Option or Stock Appreciation Right (*e.g.*, the last business day prior to the tenth anniversary of the date of grant of

such Option or Stock Appreciation Right if the Option or Stock Appreciation Right initially had a ten-year Option Term or Stock Appreciation Right Term, as applicable).

2.6 "Award" shall mean an Option, a Stock Appreciation Right, a Restricted Stock award, a Restricted Stock Unit award, an Other Stock or Cash Based Award or a Dividend Equivalent award, which may be awarded or granted under the Plan.

2.7 "Award Agreement" shall mean any written notice, agreement, terms and conditions, contract or other instrument or document evidencing an Award, including through electronic medium, which shall contain such terms and conditions with respect to an Award as the Administrator shall determine consistent with the Plan.

2.8 "Board" shall mean the Board of Directors of the Company.

2.9 "Change in Control" shall mean and includes each of the following:

(a) A transaction or series of transactions (other than an offering of Common Stock to the general public through a registration statement filed with the Securities and Exchange Commission) whereby any "person" or related "group" of "persons" (as such terms are used in Sections 13(d) and 14(d)(2) of the Exchange Act) directly or indirectly acquires beneficial ownership (within the meaning of Rules 13d-3 and 13d-5 under the Exchange Act) of securities of the Company possessing more than 50 % of the total combined voting power of the Company's securities outstanding immediately after such acquisition; provided, however, that the following acquisitions shall not constitute a Change in Control: (i) any acquisition by the Company or any of its Subsidiaries; (ii) any acquisition by an employee benefit plan maintained by the Company or any of its Subsidiaries, (iii) any acquisition which complies with Sections 2.9(c)(i), 2.9(c)(ii) or 2.9(c)(iii); or (iv) in respect of an Award held by a particular Holder, any acquisition by the Holder or any group of persons including the Holder (or any entity controlled by the Holder or any group of persons including the Holder); or

(b) The Incumbent Directors cease for any reason to constitute a majority of the Board;

(c) The consummation by the Company (whether directly involving the Company or indirectly involving the Company through one or more intermediaries) of (x) a merger, consolidation, reorganization, or business combination, (y) a sale or other disposition of all or substantially all of the Company's assets in any single transaction or series of related transactions or (z) the acquisition of assets or stock of another entity, in each case other than a transaction:

(i) which results in the Company's voting securities outstanding immediately before the transaction continuing to represent (either by remaining outstanding or by being converted into voting securities of the Company or the person that, as a result of the transaction, controls, directly or indirectly, the Company or owns, directly or indirectly, all or substantially all of the Company's assets or otherwise succeeds to the business of the Company (the Company or such person, the "Successor Entity")) directly or indirectly, at least a majority of the combined voting power of the Successor Entity's outstanding voting securities immediately after the transaction, and

(ii) after which no person or group beneficially owns voting securities representing 50% or more of the combined voting power of the Successor Entity; provided, however, that no person or group shall be treated for purposes of this Section 2.9(c)(ii) as beneficially owning 50% or more of the combined voting power of the Successor Entity solely as a result of the voting power held in the Company prior to the consummation of the transaction; and

(iii) after which at least a majority of the members of the board of directors (or the analogous governing body) of the Successor Entity were Board members at the time of the Board's approval of the execution of the initial agreement providing for such transaction; or

(d) The date which is 10 business days prior to the completion of a liquidation or dissolution of the Company.

Notwithstanding the foregoing, if a Change in Control constitutes a payment event with respect to any Award (or any portion of an Award) that provides for the deferral of compensation that is subject to Section 409A, to the extent required to avoid the imposition of additional taxes under Section 409A, the transaction or event described in subsection (a), (b), (c) or (d) with respect to such Award (or portion thereof) shall only constitute a Change in Control for purposes of the payment timing of such Award if such transaction also constitutes a "change in control event," as defined in Treasury Regulation Section 1.409A-3(i)(5).

The Administrator shall have full and final authority, which shall be exercised in its sole discretion, to determine conclusively whether a Change in Control has occurred pursuant to the above definition, the date of the occurrence of such Change in Control and any incidental matters relating thereto; provided that any exercise of authority in conjunction with a determination of whether a Change in Control is a "change in control event" as defined in Treasury Regulation Section 1.409A-3(i)(5) shall be consistent with such regulation.

2.10 "Code" shall mean the Internal Revenue Code of 1986, as amended from time to time, together with the regulations and official guidance promulgated thereunder, whether issued prior or subsequent to the grant of any Award.

2.11 "Committee" shall mean the Compensation Committee of the Board, or another committee or subcommittee of the Board which may be comprised of one or more Directors and/or executive officers of the Company as appointed by the Board, to the extent permitted in accordance with Applicable Law.

2.12 "Common Stock" shall mean the Class A common stock of the Company.

2.13 "Company" shall have the meaning set forth in Article 1.

2.14 "Consultant" shall mean any consultant or adviser engaged to provide services to the Company or any parent of the Company or Affiliate who qualifies as a consultant or advisor under the applicable rules of the Securities and Exchange Commission for registration of shares on a Form S-8 Registration Statement.

2.15 "Director" shall mean a member of the Board, as constituted from time to time.

2.16 "Director Limit" shall have the meaning set forth in Section 4.6.

2.17 "Dividend Equivalent" shall mean a right to receive the equivalent value (in cash or Shares) of dividends paid on Shares, awarded under Section 9.2.

2.18 "DRO" shall mean a "domestic relations order" as defined by the Code or Title I of the Employee Retirement Income Security Act of 1974, as amended from time to time, or the rules thereunder.

2.19 "Effective Date" shall mean the day prior to the Public Trading Date.

2.20 "Eligible Individual" shall mean any person who is an Employee, a Consultant or a Non-Employee Director, as determined by the Administrator.

2.21 "Employee" shall mean any officer or other employee (as determined in accordance with Section 3401(c) of the Code and the Treasury Regulations thereunder) of the Company or of any parent of the Company or Affiliate.

2.22 "Equity Restructuring" shall mean a nonreciprocal transaction between the Company and its stockholders, such as a stock dividend, stock split, spin-off, rights offering or recapitalization through a large, nonrecurring cash dividend, that affects the number or kind of Shares (or other securities of the Company) or the share price of Common Stock (or other securities) and causes a change in the per-share value of the Common Stock underlying outstanding Awards.

2.23 "Exchange Act" shall mean the Securities Exchange Act of 1934, as amended from time to time.

2.24 "Exchange Program" shall mean a program under which (i) outstanding Awards are surrendered or cancelled in exchange for Awards of the same type (which may have higher or lower exercise prices and different terms), Awards of a different type, and/or cash, (ii) Holders would have the opportunity to transfer any outstanding Awards to a financial institution or other person or entity selected by the Administrator, and/or (iii) the exercise price of an outstanding Award is reduced or increased. The Administrator will determine the terms and conditions of any Exchange Program in its sole discretion.

2.25 "Fair Market Value" shall mean, as of any given date, the value of a Share determined as follows:

(a) If the Common Stock is (i) listed on any established securities exchange (such as the New York Stock Exchange, the Nasdaq Capital Market, the Nasdaq Global Market and the Nasdaq Global Select Market), (ii) listed on any national market system or (iii) quoted or traded on any automated quotation system, its Fair Market Value shall be the closing sales price for a Share as quoted on such exchange or system for such date or, if there is no closing sales price for a Share on the date in question, the closing sales price for a Share on the last preceding date

for which such quotation exists, as reported in *The Wall Street Journal* or such other source as the Administrator deems reliable;

(b) If the Common Stock is not listed on an established securities exchange, national market system or automated quotation system, but the Common Stock is regularly quoted by a recognized securities dealer, its Fair Market Value shall be the mean of the high bid and low asked prices for such date or, if there are no high bid and low asked prices for a Share on such date, the high bid and low asked prices for a Share on the last preceding date for which such information exists, as reported in *The Wall Street Journal* or such other source as the Administrator deems reliable; or

(c) If the Common Stock is neither listed on an established securities exchange, national market system or automated quotation system nor regularly quoted by a recognized securities dealer, its Fair Market Value shall be established by the Administrator in its discretion.

Notwithstanding the foregoing, with respect to any Award granted on the pricing date of the Company's initial public offering, the Fair Market Value shall mean the initial public offering price of a Share as set forth in the Company's final prospectus relating to its initial public offering filed with the Securities and Exchange Commission.

2.26 "Greater Than 10% Stockholder" shall mean an individual then owning (within the meaning of Section 424(d) of the Code) more than 10% of the total combined voting power of all classes of stock of the Company or any subsidiary corporation (as defined in Section 424(f) of the Code) or parent corporation thereof (as defined in Section 424(e) of the Code).

2.27 "Holder" shall mean a person who has been granted an Award.

2.28 "Incentive Stock Option" shall mean an Option that is intended to qualify as an incentive stock option and conforms to the applicable provisions of Section 422 of the Code.

2.29 "Incumbent Directors" shall mean for any period of 12 consecutive months, individuals who, at the beginning of such period, constitute the Board together with any new Director(s) (other than a Director designated by a person who shall have entered into an agreement with the Company to effect a transaction described in Section 2.9(a) or 2.9(c)) whose election or nomination for election to the Board was approved by a vote of at least a majority (either by a specific vote or by approval of the proxy statement of the Company in which such person is named as a nominee for Director without objection to such nomination) of the Directors then still in office who either were Directors at the beginning of the 12-month period or whose election or nomination for election was previously so approved. No individual initially elected or nominated as a director of the Company as a result of an actual or threatened election contest with respect to Directors or as a result of any other actual or threatened solicitation of proxies by or on behalf of any person other than the Board shall be an Incumbent Director.

2.30 "Non-Employee Director" shall mean a Director of the Company who is not an Employee.

2.31 "Non-Employee Director Equity Compensation Policy" shall have the meaning set forth in Section 4.6.

2.32 "Non-Qualified Stock Option" shall mean an Option that is not an Incentive Stock Option or which is designated as an Incentive Stock Option but does not meet the applicable requirements of Section 422 of the Code.

2.33 "Option" shall mean a right to purchase Shares at a specified exercise price, granted under Article 5. An Option shall be either a Non-Qualified Stock Option or an Incentive Stock Option; provided, however, that Options granted to Non-Employee Directors and Consultants shall only be Non-Qualified Stock Options.

2.34 "Option Term" shall have the meaning set forth in Section 5.4.

2.35 "Organizational Documents" shall mean, collectively, the Company's certificate of incorporation, bylaws or other similar organizational documents relating to the creation and governance of the Company.

2.36 "Other Stock or Cash Based Award" shall mean a cash payment, cash bonus award, stock payment, stock bonus award, performance award or incentive award that is paid in cash, Shares or a combination of both, awarded under Section 9.1, which may include, without limitation, deferred stock, deferred stock units, performance awards, retainers, committee fees, and meeting-based fees.

2.37 "Permitted Transferee" shall mean, with respect to a Holder, any "family member" of the Holder, as defined in the General Instructions to Form S-8 Registration Statement under the Securities Act (or any successor form thereto), or any other transferee specifically approved by the Administrator after taking into account Applicable Law.

2.38 "Performance Criteria" shall mean the criteria (and adjustments) that the Administrator selects for an Award for purposes of establishing the Performance Goal or Performance Goals for a Performance Period.

2.39 "Performance Goals" shall mean, for a Performance Period, one or more goals established in writing by the Administrator for the Performance Period based upon one or more Performance Criteria. Depending on the Performance Criteria used to establish such Performance Goals, the Performance Goals may be expressed in terms of overall Company performance or the performance of an Affiliate, division, business unit, or an individual. The achievement of each Performance Goal shall be determined with reference to Applicable Accounting Standards or other methodology as determined appropriate by the Administrator.

2.40 "Performance Period" shall mean one or more periods of time, which may be of varying and overlapping durations, as the Administrator may select, over which the attainment of one or more Performance Goals will be measured for the purpose of determining a Holder's right to, vesting of, and/or the payment in respect of, an Award.

2.41 "Plan" shall have the meaning set forth in Article 1.

2.42 "Prior Plan" shall mean the Aziyo Biologics, Inc. 2015 Stock Option/Stock Issuance Plan, as amended.

2.43 "Program" shall mean any program adopted by the Administrator pursuant to the Plan containing the terms and conditions intended to govern a specified type of Award granted under the Plan and pursuant to which such type of Award may be granted under the Plan.

2.44 "Public Trading Date" shall mean the first date upon which Common Stock is listed (or approved for listing) upon notice of issuance on any securities exchange or designated (or approved for designation) upon notice of issuance as a national market security on an interdealer quotation system.

2.45 "Restricted Stock" shall mean Common Stock awarded under Article 7 that is subject to certain restrictions and may be subject to risk of forfeiture or repurchase.

2.46 "Restricted Stock Units" shall mean the right to receive Shares awarded under Article 8.

2.47 "SAR Term" shall have the meaning set forth in Section 5.4.

2.48 "Section 409A" shall mean Section 409A of the Code and the Department of Treasury regulations and other interpretive guidance issued thereunder, including, without limitation, any such regulations or other guidance that may be issued after the Effective Date.

2.49 "Securities Act" shall mean the Securities Act of 1933, as amended.

2.50 "Shares" shall mean shares of Common Stock.

2.51 "Stock Appreciation Right" shall mean an Award entitling the Holder (or other person entitled to exercise pursuant to the Plan) to exercise all or a specified portion thereof (to the extent then exercisable pursuant to its terms) and to receive from the Company an amount determined by multiplying (i) the difference obtained by subtracting (x) the exercise price per share of such Award from (y) the Fair Market Value on the date of exercise of such Award by (ii) the number of Shares with respect to which such Award shall have been exercised, subject to any limitations the Administrator may impose.

2.52 "Subsidiary" shall mean any entity (other than the Company), whether domestic or foreign, in an unbroken chain of entities beginning with the Company if each of the entities other than the last entity in the unbroken chain beneficially owns, at the time of the determination, securities or interests representing at least fifty percent (50%) of the total combined voting power of all classes of securities or interests in one of the other entities in such chain.

2.53 "Substitute Award" shall mean an Award granted under the Plan in connection with a corporate transaction, such as a merger, combination, consolidation or acquisition of property or stock, in any case, upon the assumption of, or in substitution for, outstanding equity awards previously granted by a company or other entity; provided, however, that in no event shall the term "Substitute Award" be construed to refer to an award made in connection with the cancellation and repricing of an Option or Stock Appreciation Right.

2.54 "Termination of Service" shall mean the date the Holder ceases to be an Eligible Individual. The Administrator, in its sole discretion, shall determine the effect of all matters and

questions relating to any Termination of Service, including, without limitation, whether a Termination of Service has occurred, whether a Termination of Service resulted from a discharge for cause and all questions of whether particular leaves of absence constitute a Termination of Service; provided, however, that, with respect to Incentive Stock Options, unless the Administrator otherwise provides in the terms of any Program, Award Agreement or otherwise, or as otherwise required by Applicable Law, a leave of absence, change in status from an employee to an independent contractor or other change in the employee-employer relationship shall constitute a Termination of Service only if, and to the extent that, such leave of absence, change in status or other change interrupts employment for the purposes of Section 422(a)(2) of the Code and the then-applicable regulations and revenue rulings under said Section. For purposes of the Plan, a Holder's employee-employer relationship or consultancy relations shall be deemed to be terminated in the event that the Affiliate employing or contracting with such Holder ceases to remain an Affiliate following any merger, sale of stock or other corporate transaction or event (including, without limitation, a spin-off).

ARTICLE 3.

SHARES SUBJECT TO THE PLAN

3.1 Number of Shares.

(a) Subject to Sections 3.1(b) and 12.2, Awards may be made under the Plan covering an aggregate number of Shares equal to the sum of: (i) 1,636,000 and (ii) any Shares which as of the Effective Date are available under issuance under the Prior Plan, or are subject to awards under the Prior Plan which are forfeited or lapse unexercised and which following the Effective Date are not issued under the Prior Plan; and (iii) an annual increase on the first day of each calendar year beginning on January 1, 2021 and ending on and including January 1, 2030, equal to the lesser of (A) 4% of the Shares outstanding (on an as-converted basis) on the last day of the immediately preceding fiscal year and (B) such smaller number of Shares as determined by the Board; provided, however, no more than 1,636,000 Shares may be issued upon the exercise of Incentive Stock Options. Any Shares distributed pursuant to an Award may consist, in whole or in part, of authorized and unissued Common Stock, treasury Common Stock or Common Stock purchased on the open market.

(a) If (i) any Shares are forfeited or expire, are surrendered pursuant to an Exchange Program, are converted to shares of another person in connection with a recapitalization, reorganization, merger, consolidation, split-up, spin-off, combination, exchange of shares or other similar event, or such Award is settled for cash (in whole or in part) (including Shares repurchased by the Company under Section 7.5 at the same price paid by the Holder) or (ii) after the Effective Date, any Shares subject to an award under the Prior Plan are forfeited or expire, are converted to shares of another person in connection with a recapitalization, reorganization, merger, consolidation, split-up, spin-off, combination, exchange of shares or other similar event, are surrendered pursuant to the Exchange Program or such award under the Prior Plan is settled for cash (in whole or in part) (including Shares repurchased by the Company), the Shares subject to such Award or award under the Prior Plan shall, to the extent of such forfeiture, surrender, expiration or cash settlement, again be available for future grants of Awards under the Plan. Notwithstanding anything to the contrary contained herein, the following Shares shall not be added

to the Shares authorized for grant under Section 3.1(a) and shall not be available for future grants of Awards: (i) Shares tendered by a Holder or withheld by the Company in payment of the exercise price of an Option; (ii) Shares tendered by the Holder or withheld by the Company to satisfy any tax withholding obligation with respect to an Award; (iii) Shares subject to a Stock Appreciation Right or other stock-settled Award (including Awards that may be settled in cash or stock) that are not issued in connection with the settlement or exercise, as applicable, of the Stock Appreciation Right or other stock-settled Award; and (iv) Shares purchased on the open market by the Company with the cash proceeds received from the exercise of Options. Any Shares repurchased by the Company under Section 7.5 at the same price paid by the Holder so that such Shares are returned to the Company shall again be available for Awards. The payment of Dividend Equivalents in cash in conjunction with any outstanding Awards shall not be counted against the Shares available for issuance under the Plan. Notwithstanding the provisions of this Section 3.1(b), no Shares may again be optioned, granted or awarded if such action would cause an Incentive Stock Option to fail to qualify as an incentive stock option under Section 422 of the Code.

(b) Substitute Awards may be granted on such terms as the Administrator deems appropriate, notwithstanding limitations on Awards in the Plan. Substitute Awards shall not reduce the Shares authorized for grant under the Plan, except as may be required by reason of Section 422 of the Code, and Shares subject to such Substitute Awards shall not be added to the Shares available for Awards under the Plan as provided in Section 3.1(b) above. Additionally, in the event that a company acquired by the Company or any Affiliate or with which the Company or any Affiliate combines has shares available under a pre-existing plan approved by its stockholders and not adopted in contemplation of such acquisition or combination, the shares available for grant pursuant to the terms of such pre-existing plan (as adjusted, to the extent appropriate, using the exchange ratio or other adjustment or valuation ratio or formula used in such acquisition or combination to determine the consideration payable to the holders of common stock of the entities party to such acquisition or combination) may be used for Awards under the Plan and shall not reduce the Shares authorized for grant under the Plan (and Shares subject to such Awards shall not be added to the Shares available for Awards under the Plan as provided in Section 3.1(b) above); provided that Awards using such available Shares shall not be made after the date awards or grants could have been made under the terms of the pre-existing plan, absent the acquisition or combination, and shall only be made to individuals who were not employed by or providing services to the Company or its Affiliates immediately prior to such acquisition or combination.

ARTICLE 4.

GRANTING OF AWARDS

4.1 Participation. The Administrator may, from time to time, select from among all Eligible Individuals those to whom an Award shall be granted and shall determine the nature and amount of each Award, which shall not be inconsistent with the requirements of the Plan. Except for any Non-Employee Director's right to Awards that may be required pursuant to the Non-Employee Director Equity Compensation Policy as described in Section 4.6, no Eligible Individual or other person shall have any right to be granted an Award pursuant to the Plan and neither the Company nor the Administrator is obligated to treat Eligible Individuals, Holders or any other persons uniformly. Participation by each Holder in the Plan shall be voluntary and nothing in the

Plan or any Program shall be construed as mandating that any Eligible Individual or other person shall participate in the Plan.

4.2 Award Agreement. Each Award shall be evidenced by an Award Agreement that sets forth the terms, conditions and limitations for such Award as determined by the Administrator in its sole discretion (consistent with the requirements of the Plan and any applicable Program). Award Agreements evidencing Incentive Stock Options shall contain such terms and conditions as may be necessary to meet the applicable provisions of Section 422 of the Code. The Administrator, in its sole discretion, may grant Awards to Eligible Individuals that are based on one or more Performance Criteria or achievement of one or more Performance Goals or any such other criteria or goals as the Administrator shall establish.

4.3 Limitations Applicable to Section 16 Persons. Notwithstanding any other provision of the Plan, the Plan, and any Award granted or awarded to any individual who is then subject to Section 16 of the Exchange Act, shall be subject to any additional limitations set forth in any applicable exemptive rule under Section 16 of the Exchange Act (including Rule 16b-3 of the Exchange Act and any amendments thereto) that are requirements for the application of such exemptive rule. To the extent permitted by Applicable Law, the Plan and Awards granted or awarded hereunder shall be deemed amended to the extent necessary to conform to such applicable exemptive rule.

4.4 At-Will Service. Nothing in the Plan or in any Program or Award Agreement hereunder shall confer upon any Holder any right to continue in the employ of, or as a Director or Consultant for, the Company or any Affiliate, or shall interfere with or restrict in any way the rights of the Company and any Affiliate, which rights are hereby expressly reserved, to discharge any Holder at any time for any reason whatsoever, with or without cause, and with or without notice, or to terminate or change all other terms and conditions of employment or engagement, except to the extent expressly provided otherwise in a written agreement between the Holder and the Company or any Affiliate.

4.5 Foreign Holders. Notwithstanding any provision of the Plan or applicable Program to the contrary, in order to comply with the laws in countries other than the United States in which the Company and its Affiliates operate or have Employees, Non-Employee Directors or Consultants, or in order to comply with the requirements of any foreign securities exchange or other Applicable Law, the Administrator, in its sole discretion, shall have the power and authority to: (a) determine which Affiliates shall be covered by the Plan; (b) determine which Eligible Individuals outside the United States are eligible to participate in the Plan; (c) modify the terms and conditions of any Award granted to Eligible Individuals outside the United States to comply with Applicable Law (including, without limitation, applicable foreign laws or listing requirements of any foreign securities exchange); (d) establish subplans and modify exercise procedures and other terms and procedures, to the extent such actions may be necessary or advisable; provided, however, that no such subplans and/or modifications shall increase the share limitation contained in Section 3.1 or the Director Limit; and (e) take any action, before or after an Award is made, that it deems advisable to obtain approval or comply with any necessary local governmental regulatory exemptions or approvals or listing requirements of any foreign securities exchange.

4.6 Non-Employee Director Awards.

(a) Non-Employee Director Equity Compensation Policy. The Administrator, in its sole discretion, may provide that Awards granted to Non-Employee Directors shall be granted pursuant to a written nondiscretionary formula established by the Administrator (the "Non-Employee Director Equity Compensation Policy"), subject to the limitations of the Plan. The Non-Employee Director Equity Compensation Policy shall set forth the type of Award(s) to be granted to Non-Employee Directors, the number of Shares to be subject to Non-Employee Director Awards, the conditions on which such Awards shall be granted, become exercisable and/or payable and expire, and such other terms and conditions as the Administrator shall determine in its sole discretion. The Non-Employee Director Equity Compensation Policy may be modified by the Administrator from time to time in its sole discretion and pursuant to the exercise of its business judgment, taking into account such factors, circumstances and considerations as it shall deem relevant from time to time.

(b) Director Limit. Notwithstanding any provision to the contrary in the Plan or in the Non-Employee Director Equity Compensation Policy, the sum of the grant date fair value of equity-based Awards and the amount of any cash-based Awards or other fees granted to a Non-Employee Director during any calendar year shall not exceed $750,000 (the "Director Limit"), increased to $1,000,000 in the fiscal year of his or her initial service as a Non-Employee Director (the applicable amount, the "Director Limit"). The Administrator may make exceptions to this limit for individual Non-Employee Directors in extraordinary circumstances, as the Administrator may determine in its discretion, provided that the Non-Employee Director receiving such additional compensation may not participate in the decision to award such compensation or in other contemporaneous compensation decisions involving Non-Employee Directors.

ARTICLE 5.

GRANTING OF OPTIONS AND STOCK APPRECIATION RIGHTS

5.1 Granting of Options and Stock Appreciation Rights to Eligible Individuals. The Administrator is authorized to grant Options and Stock Appreciation Rights to Eligible Individuals from time to time, in its sole discretion, on such terms and conditions as it may determine, which shall not be inconsistent with the Plan, including any limitations in the Plan that apply to Incentive Stock Options.

5.2 Qualification of Incentive Stock Options. The Administrator may grant Options intended to qualify as Incentive Stock Options only to employees of the Company, any of the Company's present or future "parent corporations" or "subsidiary corporations" as defined in Sections 424(e) or (f) of the Code, respectively, and any other entities the employees of which are eligible to receive Incentive Stock Options under the Code. No person who qualifies as a Greater Than 10% Stockholder may be granted an Incentive Stock Option unless such Incentive Stock Option conforms to the applicable provisions of Section 422 of the Code. To the extent that the aggregate fair market value of stock with respect to which "incentive stock options" (within the meaning of Section 422 of the Code, but without regard to Section 422(d) of the Code) are exercisable for the first time by a Holder during any calendar year under the Plan, and all other plans of the Company and any parent corporation or subsidiary corporation thereof (as defined in Section 424(e) and 424(f) of the Code, respectively), exceeds $100,000, the Options shall be treated as Non-Qualified Stock Options to the extent required by Section 422 of the Code. The

rule set forth in the immediately preceding sentence shall be applied by taking Options and other "incentive stock options" into account in the order in which they were granted and the fair market value of stock shall be determined as of the time the respective options were granted. Any interpretations and rules under the Plan with respect to Incentive Stock Options shall be consistent with the provisions of Section 422 of the Code. Neither the Company nor the Administrator shall have any liability to a Holder, or any other person, (a) if an Option (or any part thereof) which is intended to qualify as an Incentive Stock Option fails to qualify as an Incentive Stock Option or (b) for any action or omission by the Company or the Administrator that causes an Option not to qualify as an Incentive Stock Option, including, without limitation, the conversion of an Incentive Stock Option to a Non-Qualified Stock Option or the grant of an Option intended as an Incentive Stock Option that fails to satisfy the requirements under the Code applicable to an Incentive Stock Option.

5.3 Option and Stock Appreciation Right Exercise Price. The exercise price per Share subject to each Option and Stock Appreciation Right shall be set by the Administrator, but shall not be less than 100% of the Fair Market Value of a Share on the date the Option or Stock Appreciation Right, as applicable, is granted (or, as to Incentive Stock Options, on the date the Option is modified, extended or renewed for purposes of Section 424(h) of the Code). In addition, in the case of Incentive Stock Options granted to a Greater Than 10% Stockholder, such price shall not be less than 110% of the Fair Market Value of a Share on the date the Option is granted (or the date the Option is modified, extended or renewed for purposes of Section 424(h) of the Code). Notwithstanding the foregoing, in the case of an Option or Stock Appreciation Right that is a Substitute Award, the exercise price per share of the Shares subject to such Option or Stock Appreciation Right, as applicable, may be less than the Fair Market Value per share on the date of grant; provided that the exercise price of any Substitute Award shall be determined in accordance with the applicable requirements of Section 424 and 409A of the Code.

5.4 Option and SAR Term. The term of each Option (the "Option Term") and the term of each Stock Appreciation Right (the "SAR Term") shall be set by the Administrator in its sole discretion; provided, however, that the Option Term or SAR Term, as applicable, shall not be more than (a) ten (10) years from the date the Option or Stock Appreciation Right, as applicable, is granted to an Eligible Individual (other than a Greater Than 10% Stockholder), or (b) five (5) years from the date an Incentive Stock Option is granted to a Greater Than 10% Stockholder. Except as limited by the requirements of Section 409A or Section 422 of the Code and regulations and rulings thereunder or the first sentence of this Section 5.4 and without limiting the Company's rights under Section 10.6, the Administrator may extend the Option Term of any outstanding Option or the SAR Term of any outstanding Stock Appreciation Right, and may extend the time period during which vested Options or Stock Appreciation Rights may be exercised, in connection with any Termination of Service of the Holder or otherwise, and may amend, subject to Section 10.6 and 12.1, any other term or condition of such Option or Stock Appreciation Right relating to such Termination of Service of the Holder or otherwise.

5.5 Option and SAR Vesting. The period during which the right to exercise, in whole or in part, an Option or Stock Appreciation Right vests in the Holder shall be set by the Administrator and set forth in the applicable Award Agreement. Notwithstanding the foregoing and unless determined otherwise by the Company, in the event that on the last business day of the term of an Option or Stock Appreciation Right (other than an Incentive Stock Option) (a) the

exercise of the Option or Stock Appreciation Right is prohibited by Applicable Law, as determined by the Company, or (b) Shares may not be purchased or sold by the applicable Participant due to any Company insider trading policy (including blackout periods) or a "lock-up" agreement undertaken in connection with an issuance of securities by the Company, the term of the Option or Stock Appreciation Right shall be extended until the date that is thirty (30) days after the end of the legal prohibition, black-out period or lock-up agreement, as determined by the Company; provided, however, in no event shall the extension last beyond the ten year term of the applicable Option or Stock Appreciation Right. Unless otherwise determined by the Administrator in the Award Agreement, the applicable Program or by action of the Administrator following the grant of the Option or Stock Appreciation Right, (i) no portion of an Option or Stock Appreciation Right which is unexercisable at a Holder's Termination of Service shall thereafter become exercisable and (ii) the portion of an Option or Stock Appreciation Right that is unexercisable at a Holder's Termination of Service shall automatically expire thirty (30) days following such Termination of Service.

ARTICLE 6.

EXERCISE OF OPTIONS AND STOCK APPRECIATION RIGHTS

6.1 Exercise and Payment. An exercisable Option or Stock Appreciation Right may be exercised in whole or in part. However, unless the Administrator otherwise determines, an Option or Stock Appreciation Right shall not be exercisable with respect to fractional Shares and the Administrator may require that, by the terms of the Option or Stock Appreciation Right, a partial exercise must be with respect to a minimum number of Shares. Payment of the amounts payable with respect to Stock Appreciation Rights pursuant to this Article 6 shall be in cash, Shares (based on its Fair Market Value as of the date the Stock Appreciation Right is exercised), or a combination of both, as determined by the Administrator.

6.2 Manner of Exercise. All or a portion of an exercisable Option or Stock Appreciation Right shall be deemed exercised upon delivery of all of the following to the Secretary of the Company, the stock plan administrator of the Company or such other person or entity designated by the Administrator, or his, her or its office, as applicable:

(a) A written notice of exercise in a form the Administrator approves (which may be electronic) complying with the applicable rules established by the Administrator. The notice shall be signed or otherwise acknowledge electronically by the Holder or other person then entitled to exercise the Option or Stock Appreciation Right or such portion thereof;

(b) Such representations and documents as the Administrator, in its sole discretion, deems necessary or advisable to effect compliance with Applicable Law.

(c) In the event that the Option shall be exercised pursuant to Section 10.3 by any person or persons other than the Holder, appropriate proof of the right of such person or persons to exercise the Option or Stock Appreciation Right, as determined in the sole discretion of the Administrator; and

(d) Full payment of the exercise price and applicable withholding taxes for the Shares with respect to which the Option or Stock Appreciation Right, or portion thereof, is exercised, in a manner permitted by the Administrator in accordance with Sections 10.1 and 10.2.

6.3 Expiration of Option Term or SAR Term: Automatic Exercise of In-The-Money Options and Stock Appreciation Rights. Unless otherwise provided by the Administrator in an Award Agreement or otherwise or as otherwise directed by an Option or Stock Appreciation Rights Holder in writing to the Company, each vested and exercisable Option and Stock Appreciation Right outstanding on the Automatic Exercise Date with an exercise price per Share that is less than the Fair Market Value per Share as of such date shall automatically and without further action by the Option or Stock Appreciation Rights Holder or the Company be exercised on the Automatic Exercise Date. In the sole discretion of the Administrator, payment of the exercise price of any such Option shall be made pursuant to Section 10.1(b) or 10.1(c) and the Company or any Subsidiary shall be entitled to deduct or withhold an amount sufficient to satisfy all taxes associated with such exercise in accordance with Section 10.2. Unless otherwise determined by the Administrator, this Section 6.3 shall not apply to an Option or Stock Appreciation Right if the Holder of such Option or Stock Appreciation Right incurs a Termination of Service on or before the Automatic Exercise Date. For the avoidance of doubt, no Option or Stock Appreciation Right with an exercise price per Share that is equal to or greater than the Fair Market Value per Share on the Automatic Exercise Date shall be exercised pursuant to this Section 6.3.

6.4 Notification Regarding Disposition. The Holder shall give the Company prompt written or electronic notice of any disposition or other transfers (other than in connection with a Change in Control) of Shares acquired by exercise of an Incentive Stock Option which occurs within (a) two years from the date of granting (including the date the Option is modified, extended or renewed for purposes of Section 424(h) of the Code) such Option to such Holder, or (b) one year after the date of transfer of such Shares to such Holder. Such notice shall specify the date of such disposition or other transfer and the amount realized, in cash, other property, assumption of indebtedness or other consideration, by the Holder in such disposition or other transfer.

ARTICLE 7.

AWARD OF RESTRICTED STOCK

7.1 Award of Restricted Stock. The Administrator is authorized to grant Restricted Stock, or the right to purchase Restricted Stock, to Eligible Individuals, and shall determine the terms and conditions, including the restrictions applicable to each award of Restricted Stock, which terms and conditions shall not be inconsistent with the Plan or any applicable Program, and may impose such conditions on the issuance of such Restricted Stock as it deems appropriate. The Administrator shall establish the purchase price, if any, and form of payment for Restricted Stock; provided, however, that if a purchase price is charged, such purchase price shall be no less than the par value, if any, of the Shares to be purchased, unless otherwise permitted by Applicable Law. In all cases, legal consideration shall be required for each issuance of Restricted Stock to the extent required by Applicable Law.

7.2 Vesting of Restricted Stock. At the time of grant, the Administrator shall specify the date or dates on which the Restricted Stock shall become fully vested and nonforfeitable, and

may specify such conditions to vesting as it deems appropriate, including, without limitation, vesting based upon the Holder's duration of service to the Company or any Affiliate or one or more Performance Goals, in each case on a specified date or dates or over any period or periods, as determined by the Administrator. An Award of Restricted Stock shall only be eligible to vest while the Holder is an Employee, a Consultant or a Director, as applicable; provided, however, that the Administrator, in its sole discretion, may provide (in an Award Agreement or otherwise) that a Restricted Stock award may become vested subsequent to a Termination of Service in the event of the occurrence of certain events, including a Change in Control, the Holder's death, retirement or disability or any other specified Termination of Service, subject to Section 11.7.

7.3 Rights as Stockholders. Subject to Section 7.5, upon issuance of Restricted Stock, the Holder shall have, unless otherwise provided by the Administrator, all of the rights of a stockholder with respect to said Shares, subject to the restrictions in the Plan, any applicable Program and/or the applicable Award Agreement, including the right to receive all dividends and other distributions paid or made with respect to the Shares to the extent such dividends and other distributions have a record date that is on or after the date on which the Holder to whom such Restricted Stock are granted becomes the record holder of such Restricted Stock; provided, however, that, in the sole discretion of the Administrator, any extraordinary dividends or distributions with respect to the Shares may be subject to the restrictions set forth in Section 7.4.

7.4 Restrictions. All shares of Restricted Stock (including any shares received by Holders thereof with respect to shares of Restricted Stock as a result of stock dividends, stock splits or any other form of recapitalization) and, unless the Administrator provides otherwise, any property (other than cash) transferred to Holders in connection with an extraordinary dividend or distribution shall be subject to such restrictions and vesting requirements as the Administrator shall provide in the applicable Program or Award Agreement.

7.5 Repurchase or Forfeiture of Restricted Stock. Except as otherwise determined by the Administrator, if no price was paid by the Holder for the Restricted Stock, upon a Termination of Service during the applicable restriction period, the Holder's rights in unvested Restricted Stock then subject to restrictions shall lapse, and such Restricted Stock shall be surrendered to the Company and cancelled without consideration on the date of such Termination of Service. If a price was paid by the Holder for the Restricted Stock, upon a Termination of Service during the applicable restriction period, the Company shall have the right to repurchase from the Holder the unvested Restricted Stock then subject to restrictions at a cash price per share equal to the price paid by the Holder for such Restricted Stock or such other amount as may be specified in the applicable Program or Award Agreement.

7.6 Section 83(b) Election. If a Holder makes an election under Section 83(b) of the Code to be taxed with respect to the Restricted Stock as of the date of transfer of the Restricted Stock rather than as of the date or dates upon which the Holder would otherwise be taxable under Section 83(a) of the Code, the Holder shall be required to deliver a copy of such election to the Company promptly after filing such election with the Internal Revenue Service along with proof of the timely filing thereof with the Internal Revenue Service.

ARTICLE 8.

AWARD OF RESTRICTED STOCK UNITS

8.1 Grant of Restricted Stock Units. The Administrator is authorized to grant Awards of Restricted Stock Units to any Eligible Individual selected by the Administrator in such amounts and subject to such terms and conditions as determined by the Administrator. A Holder will have no rights of a stockholder with respect to Shares subject to any Restricted Stock Unit unless and until the Shares are delivered in settlement of the Restricted Stock Unit.

8.2 Vesting of Restricted Stock Units. At the time of grant, the Administrator shall specify the date or dates on which the Restricted Stock Units shall become fully vested and nonforfeitable, and may specify such conditions to vesting as it deems appropriate, including, without limitation, vesting based upon the Holder's duration of service to the Company or any Affiliate, one or more Performance Goals or other specific criteria, in each case on a specified date or dates or over any period or periods, as determined by the Administrator. An Award of Restricted Stock Units shall only be eligible to vest while the Holder is an Employee, a Consultant or a Director, as applicable; provided, however, that the Administrator, in its sole discretion, may provide (in an Award Agreement or otherwise) that a Restricted Stock Unit award may become vested subsequent to a Termination of Service in the event of the occurrence of certain events, including a Change in Control, the Holder's death, retirement or disability or any other specified Termination of Service, subject to Section 11.7.

8.3 Maturity and Payment. At the time of grant, the Administrator shall specify the maturity date applicable to each grant of Restricted Stock Units, which shall be no earlier than the vesting date or dates of the Award and may be determined at the election of the Holder (if permitted by the applicable Award Agreement); provided that, except as otherwise determined by the Administrator, and subject to compliance with Section 409A, in no event shall the maturity date relating to each Restricted Stock Unit occur following the later of (a) the 15th day of the third month following the end of the calendar year in which the applicable portion of the Restricted Stock Unit vests; and (b) the 15th day of the third month following the end of the Company's fiscal year in which the applicable portion of the Restricted Stock Unit vests. On the maturity date, the Company shall, in accordance with the applicable Award Agreement and subject to Section 10.4(f), transfer to the Holder one unrestricted, fully transferable Share for each Restricted Stock Unit scheduled to be paid out on such date and not previously forfeited, or in the sole discretion of the Administrator, an amount in cash equal to the Fair Market Value of such Shares on the maturity date or a combination of cash and Common Stock as determined by the Administrator.

ARTICLE 9.

AWARD OF OTHER STOCK OR CASH BASED AWARDS AND DIVIDEND EQUIVALENTS

9.1 Other Stock or Cash Based Awards. The Administrator is authorized to grant Other Stock or Cash Based Awards, including awards entitling a Holder to receive Shares or cash to be delivered immediately or in the future, to any Eligible Individual. Subject to the provisions of the Plan and any applicable Program, the Administrator shall determine the terms and conditions of

each Other Stock or Cash Based Award, including the term of the Award, any exercise or purchase price, Performance Criteria and Performance Goals, transfer restrictions, vesting conditions and other terms and conditions applicable thereto, which shall be set forth in the applicable Award Agreement. Other Stock or Cash Based Awards may be paid in cash, Shares, or a combination of cash and Shares, as determined by the Administrator, and may be available as a form of payment in the settlement of other Awards granted under the Plan, as stand-alone payments, as a part of a bonus, deferred bonus, deferred compensation or other arrangement, and/or as payment in lieu of compensation to which an Eligible Individual is otherwise entitled.

9.2 Dividend Equivalents. Dividend Equivalents may be granted by the Administrator, either alone or in tandem with another Award, based on dividends declared on the Common Stock, to be credited as of dividend payment dates during the period between the date the Dividend Equivalents are granted to a Holder and the date such Dividend Equivalents terminate or expire, as determined by the Administrator. Such Dividend Equivalents shall be converted to cash or additional Shares by such formula and at such time and subject to such restrictions and limitations as may be determined by the Administrator. Notwithstanding the foregoing, no Dividend Equivalents shall be payable with respect to Options or Stock Appreciation Rights.

ARTICLE 10.

ADDITIONAL TERMS OF AWARDS

10.1 Payment. The Administrator shall determine the method or methods by which payments by any Holder with respect to any Awards granted under the Plan shall be made, including, without limitation: (a) cash, wire transfer of immediately available funds or check, (b) Shares (including, in the case of payment of the exercise price of an Award, Shares issuable pursuant to the exercise of the Award) or Shares held for such minimum period of time as may be established by the Administrator, in each case, having a Fair Market Value on the date of delivery equal to the aggregate payments required, (c) delivery of a written or electronic notice that the Holder has placed a market sell order with a broker acceptable to the Company with respect to Shares then issuable upon exercise or vesting of an Award, and that the broker has been directed to pay a sufficient portion of the net proceeds of the sale to the Company in satisfaction of the aggregate payments required; provided that payment of such proceeds is then made to the Company upon settlement of such sale, (d) other form of legal consideration acceptable to the Administrator in its sole discretion, or (e) any combination of the above permitted forms of payment. Notwithstanding any other provision of the Plan to the contrary, no Holder who is a Director or an "executive officer" of the Company within the meaning of Section 13(k) of the Exchange Act shall be permitted to make payment with respect to any Awards granted under the Plan, or continue any extension of credit with respect to such payment, with a loan from the Company or a loan arranged by the Company in violation of Section 13(k) of the Exchange Act.

10.2 Tax Withholding. The Company or any Affiliate shall have the authority and the right to deduct or withhold, or require a Holder to remit to the Company, an amount sufficient to satisfy federal, state, local and foreign taxes (including the Holder's FICA, employment tax or other social security contribution obligation) required by law to be withheld with respect to any taxable event concerning a Holder arising as a result of the Plan or any Award. The Administrator may, in its sole discretion and in satisfaction of the foregoing requirement, or in satisfaction of

such additional withholding obligations as a Holder may have elected, allow a Holder to satisfy such obligations by any payment means described in Section 10.1 hereof, including without limitation, by allowing such Holder to elect to have the Company or any Affiliate withhold Shares otherwise issuable under an Award (or allow the surrender of Shares). The number of Shares that may be so withheld or surrendered shall be limited to the number of Shares that have a Fair Market Value on the date of withholding or repurchase no greater than the aggregate amount of such liabilities based on the maximum statutory withholding rates in such Holder's applicable jurisdictions for federal, state, local and foreign income tax and payroll tax purposes that are applicable to such taxable income. The Administrator shall determine the fair market value of the Shares, consistent with applicable provisions of the Code, for tax withholding obligations due in connection with a broker-assisted cashless Option or Stock Appreciation Right exercise involving the sale of Shares to pay the Option or Stock Appreciation Right exercise price or any tax withholding obligation.

10.3 Transferability of Awards.

(a) Except as otherwise provided in Sections 10.3(b) and 10.3(c):

(i) No Award under the Plan may be sold, pledged, assigned or transferred in any manner other than (A) by will or the laws of descent and distribution or (B) subject to the consent of the Administrator, pursuant to a DRO, unless and until such Award has been exercised or the Shares underlying such Award have been issued, and all restrictions applicable to such Shares have lapsed;

(ii) No Award or interest or right therein shall be liable for or otherwise subject to the debts, contracts or engagements of the Holder or the Holder's successors in interest or shall be subject to disposition by transfer, alienation, anticipation, pledge, hypothecation, encumbrance, assignment or any other means whether such disposition be voluntary or involuntary or by operation of law by judgment, levy, attachment, garnishment or any other legal or equitable proceedings (including bankruptcy) unless and until such Award has been exercised, or the Shares underlying such Award have been issued, and all restrictions applicable to such Shares have lapsed, and any attempted disposition of an Award prior to satisfaction of these conditions shall be null and void and of no effect, except to the extent that such disposition is permitted by Section 10.3(a)(i); and

(iii) During the lifetime of the Holder, only the Holder may exercise any exercisable portion of an Award granted to such Holder under the Plan, unless it has been disposed of pursuant to a DRO. After the death of the Holder, any exercisable portion of an Award may, prior to the time when such portion becomes unexercisable under the Plan or the applicable Program or Award Agreement, be exercised by the Holder's personal representative or by any person empowered to do so under the deceased Holder's will or under the then-applicable laws of descent and distribution.

(b) Notwithstanding Section 10.3(a), the Administrator, in its sole discretion, may determine to permit a Holder or a Permitted Transferee of such Holder to transfer an Award other than an Incentive Stock Option (unless such Incentive Stock Option is intended to become a Nonqualified Stock Option) to any one or more Permitted Transferees of such Holder, subject to

the following terms and conditions: (i) an Award transferred to a Permitted Transferee shall not be assignable or transferable by the Permitted Transferee other than (A) to another Permitted Transferee of the applicable Holder or (B) by will or the laws of descent and distribution or, subject to the consent of the Administrator, pursuant to a DRO; (ii) an Award transferred to a Permitted Transferee shall continue to be subject to all the terms and conditions of the Award as applicable to the original Holder (other than the ability to further transfer the Award to any person other than another Permitted Transferee of the applicable Holder); (iii) the Holder (or transferring Permitted Transferee) and the receiving Permitted Transferee shall execute any and all documents requested by the Administrator, including, without limitation documents to (A) confirm the status of the transferee as a Permitted Transferee, (B) satisfy any requirements for an exemption for the transfer under Applicable Law and (C) evidence the transfer; and (iv) the transfer of an Award to a Permitted Transferee shall be without consideration. In addition, and further notwithstanding Section 10.3(a), hereof, the Administrator, in its sole discretion, may determine to permit a Holder to transfer Incentive Stock Options to a trust that constitutes a Permitted Transferee if, under Section 671 of the Code and other Applicable Law, the Holder is considered the sole beneficial owner of the Incentive Stock Option while it is held in the trust.

(c) Notwithstanding Section 10.3(a), a Holder may, in the manner determined by the Administrator, designate a beneficiary to exercise the rights of the Holder and to receive any distribution with respect to any Award upon the Holder's death. A beneficiary, legal guardian, legal representative, or other person claiming any rights pursuant to the Plan is subject to all terms and conditions of the Plan and any Program or Award Agreement applicable to the Holder and any additional restrictions deemed necessary or appropriate by the Administrator. If the Holder is married or a domestic partner in a domestic partnership qualified under Applicable Law and resides in a community property state, a designation of a person other than the Holder's spouse or domestic partner, as applicable, as the Holder's beneficiary with respect to more than 50% of the Holder's interest in the Award shall not be effective without the prior written or electronic consent of the Holder's spouse or domestic partner. If no beneficiary has been designated or survives the Holder, payment shall be made to the person entitled thereto pursuant to the Holder's will or the laws of descent and distribution. Subject to the foregoing, a beneficiary designation may be changed or revoked by a Holder at any time; provided that the change or revocation is delivered in writing to the Administrator prior to the Holder's death.

10.4 Conditions to Issuance of Shares.

(a) The Administrator shall determine the methods by which Shares shall be delivered or deemed to be delivered to Holders. Notwithstanding anything herein to the contrary, the Company shall not be required to issue or deliver any certificates or make any book entries evidencing Shares pursuant to the exercise of any Award, unless and until the Administrator has determined that the issuance of such Shares is in compliance with Applicable Law and the Shares are covered by an effective registration statement or applicable exemption from registration. In addition to the terms and conditions provided herein, the Administrator may require that a Holder make such reasonable covenants, agreements and representations as the Administrator, in its sole discretion, deems advisable in order to comply with Applicable Law.

(b) All share certificates delivered pursuant to the Plan and all Shares issued pursuant to book entry procedures are subject to any stop-transfer orders and other restrictions as

the Administrator deems necessary or advisable to comply with Applicable Law. The Administrator may place legends on any share certificate or book entry to reference restrictions applicable to the Shares (including, without limitation, restrictions applicable to Restricted Stock).

(c) The Administrator shall have the right to require any Holder to comply with any timing or other restrictions with respect to the settlement, distribution or exercise of any Award, including a window-period limitation, as may be imposed in the sole discretion of the Administrator.

(d) Unless the Administrator otherwise determines, no fractional Shares shall be issued and the Administrator, in its sole discretion, shall determine whether cash shall be given in lieu of fractional Shares or whether such fractional Shares shall be eliminated by rounding down.

(e) The Company, in its sole discretion, may (i) retain physical possession of any stock certificate evidencing Shares until any restrictions thereon shall have lapsed and/or (ii) require that the stock certificates evidencing such Shares be held in custody by a designated escrow agent (which may but need not be the Company) until the restrictions thereon shall have lapsed, and that the Holder deliver a stock power, endorsed in blank, relating to such Shares.

(f) Notwithstanding any other provision of the Plan, unless otherwise determined by the Administrator or required by Applicable Law, the Company shall not deliver to any Holder certificates evidencing Shares issued in connection with any Award and instead such Shares shall be recorded in the books of the Company (or, as applicable, its transfer agent or stock plan administrator).

10.5 Forfeiture and Claw-Back Provisions. All Awards (including any proceeds, gains or other economic benefit actually or constructively received by a Holder upon any receipt or exercise of any Award or upon the receipt or resale of any Shares underlying the Award and any payments of a portion of an incentive-based bonus pool allocated to a Holder) shall be subject to the provisions of any claw-back policy implemented by the Company, including, without limitation, any claw-back policy adopted to comply with the requirements of Applicable Law, including, without limitation, the Dodd-Frank Wall Street Reform and Consumer Protection Act and any rules or regulations promulgated thereunder, whether or not such claw-back policy was in place at the time of grant of an Award, to the extent set forth in such claw-back policy and/or in the applicable Award Agreement.

10.6 Amendment of Awards. Subject to Applicable Law, the Administrator may amend, modify or terminate any outstanding Award, including but not limited to, substituting therefor another Award of the same or a different type, changing the date of exercise or settlement, and converting an Incentive Stock Option to a Non-Qualified Stock Option. The Holder's consent to such action shall be required unless (a) the Administrator determines that the action, taking into account any related action, would not materially and adversely affect the Holder, or (b) the change is otherwise permitted under the Plan (including, without limitation, under Section 12.2 or 12.10).

10.7 Lock-Up Period. The Company may, in connection with registering the offering of any Company securities under the Securities Act, prohibit Holders from, directly or indirectly, selling or otherwise transferring any Shares or other Company securities during a period of up to

one hundred eighty days following the effective date of a Company registration statement filed under the Securities Act, or such longer period as determined by the underwriter. In order to enforce the foregoing, the Company shall have the right to place restrictive legends on the certificates of any securities of the Company held by the Holder and to impose stop transfer instructions with the Company's transfer agent with respect to any securities of the Company held by the Holder until the end of such period.

10.8 Data Privacy. As a condition of receipt of any Award, each Holder explicitly and unambiguously consents to the collection, use and transfer, in electronic or other form, of personal data as described in this Section 10.8 by and among, as applicable, the Company and its Affiliates for the exclusive purpose of implementing, administering and managing the Holder's participation in the Plan. The Company and its Affiliates may hold certain personal information about a Holder, including but not limited to, the Holder's name, home address and telephone number, date of birth, social security or insurance number or other identification number, salary, nationality, job title(s), any shares of stock held in the Company or any of its Affiliates, details of all Awards, in each case, for the purpose of implementing, managing and administering the Plan and Awards (the "Data"). The Company and its Affiliates may transfer the Data amongst themselves as necessary for the purpose of implementation, administration and management of a Holder's participation in the Plan, and the Company and its Affiliates may each further transfer the Data to any third parties assisting the Company and its Affiliates in the implementation, administration and management of the Plan. These recipients may be located in the Holder's country, or elsewhere, and the Holder's country may have different data privacy laws and protections than the recipients' country. Through acceptance of an Award, each Holder authorizes such recipients to receive, possess, use, retain and transfer the Data, in electronic or other form, for the purposes of implementing, administering and managing the Holder's participation in the Plan, including any requisite transfer of such Data as may be required to a broker or other third party with whom the Company or any of its Affiliates or the Holder may elect to deposit any Shares. The Data related to a Holder will be held only as long as is necessary to implement, administer, and manage the Holder's participation in the Plan. A Holder may, at any time, view the Data held by the Company with respect to such Holder, request additional information about the storage and processing of the Data with respect to such Holder, recommend any necessary corrections to the Data with respect to the Holder or refuse or withdraw the consents herein in writing, in any case without cost, by contacting his or her local human resources representative. The Company may cancel the Holder's ability to participate in the Plan and, in the Administrator's discretion, the Holder may forfeit any outstanding Awards if the Holder refuses or withdraws his or her consents as described herein. For more information on the consequences of refusal to consent or withdrawal of consent, Holders may contact their local human resources representative.

ARTICLE 11.

ADMINISTRATION

11.1 Administrator. The Committee shall administer the Plan (except as otherwise permitted herein). To the extent required to comply with the provisions of Rule 16b-3, it is intended that each member of the Committee will be, at the time the Committee takes any action with respect to an Award that is subject to Rule 16b-3, a "non-employee director" within the meaning of Rule 16b-3. Additionally, to the extent required by Applicable Law, each of the

individuals constituting the Committee shall be an "independent director" under the rules of any securities exchange or automated quotation system on which the Shares are listed, quoted or traded. Notwithstanding the foregoing, any action taken by the Committee shall be valid and effective, whether or not members of the Committee at the time of such action are later determined not to have satisfied the requirements for membership set forth in this Section 11.1 or the Organizational Documents. Except as may otherwise be provided in the Organizational Documents or as otherwise required by Applicable Law, (a) appointment of Committee members shall be effective upon acceptance of appointment, (b) Committee members may resign at any time by delivering written or electronic notice to the Board and (c) vacancies in the Committee may only be filled by the Board. Notwithstanding the foregoing, (i) the full Board, acting by a majority of its members in office, shall conduct the general administration of the Plan with respect to Awards granted to Non-Employee Directors and, with respect to such Awards, the term "Administrator" as used in the Plan shall be deemed to refer to the Board and (ii) the Board or Committee may delegate its authority hereunder to the extent permitted by Section 11.6.

11.2 Duties and Powers of Administrator. It shall be the duty of the Administrator to conduct the general administration of the Plan in accordance with its provisions. The Administrator shall have the power to interpret the Plan, all Programs and Award Agreements, and to adopt such rules for the administration, interpretation and application of the Plan and any Program as are not inconsistent with the Plan, to interpret, amend or revoke any such rules and to amend the Plan or any Program or Award Agreement; provided that the rights or obligations of the Holder of the Award that is the subject of any such Program or Award Agreement are not materially and adversely affected by such amendment, unless the consent of the Holder is obtained or such amendment is otherwise permitted under Section 10.6 or Section 12.10. In its sole discretion, the Board may at any time and from time to time exercise any and all rights and duties of the Committee in its capacity as the Administrator under the Plan except with respect to matters which under Rule 16b-3 under the Exchange Act or any successor rule, or any regulations or rules issued thereunder, or the rules of any securities exchange or automated quotation system on which the Shares are listed, quoted or traded are required to be determined in the sole discretion of the Committee.

11.3 Action by the Administrator. Unless otherwise established by the Board, set forth in any Organizational Documents or as required by Applicable Law, a majority of the Administrator shall constitute a quorum and the acts of a majority of the members present at any meeting at which a quorum is present, and acts approved in writing by all members of the Administrator in lieu of a meeting, shall be deemed the acts of the Administrator. Each member of the Administrator is entitled to, in good faith, rely or act upon any report or other information furnished to that member by any officer or other employee of the Company or any Affiliate, the Company's independent certified public accountants, or any executive compensation consultant or other professional retained by the Company to assist in the administration of the Plan. Neither the Administrator nor any member or delegate thereof shall have any liability to any person (including any Holder) for any action taken or omitted to be taken or any determination made in good faith with respect to the Plan or any Award.

11.4 Authority of Administrator. Subject to the Organizational Documents, any specific designation in the Plan and Applicable Law, the Administrator has the exclusive power, authority and sole discretion to:

(a) Designate Eligible Individuals to receive Awards;

(b) Determine the type or types of Awards to be granted to each Eligible Individual (including, without limitation, any Awards granted in tandem with another Award granted pursuant to the Plan);

(c) Determine the number of Awards to be granted and the number of Shares to which an Award will relate;

(d) Determine the terms and conditions of any Award granted pursuant to the Plan, including, but not limited to, the exercise price, grant price, purchase price, any Performance Criteria and/or Performance Goals, any restrictions or limitations on the Award, any schedule for vesting, lapse of forfeiture restrictions or restrictions on the exercisability of an Award, and accelerations or waivers thereof, and any provisions related to non-competition and claw-back and recapture of gain on an Award, based in each case on such considerations as the Administrator in its sole discretion determines;

(e) Institute and determine the terms and conditions of an Exchange Program;

(f) Determine whether, to what extent, and under what circumstances an Award may be settled in, or the exercise price of an Award may be paid in cash, Shares, other Awards, or other property, or an Award may be canceled, forfeited, or surrendered;

(g) Prescribe the form of each Award Agreement, which need not be identical for each Holder;

(h) Decide all other matters that must be determined in connection with an Award;

(i) Establish, adopt, or revise any Programs, rules and regulations as it may deem necessary or advisable to administer the Plan;

(j) Interpret the terms of, and any matter arising pursuant to, the Plan, any Program or any Award Agreement; and

(k) Make all other decisions and determinations that may be required pursuant to the Plan or as the Administrator deems necessary or advisable to administer the Plan.

11.5 Decisions Binding. The Administrator's interpretation of the Plan, any Awards granted pursuant to the Plan, any Program or any Award Agreement and all decisions and determinations by the Administrator with respect to the Plan are final, binding and conclusive on all persons.

11.6 Delegation of Authority. The Board or Committee may from time to time delegate to a committee of one or more Directors or one or more officers of the Company the authority to grant or amend Awards or to take other administrative actions pursuant to this Article 11; provided, however, that in no event shall an officer of the Company be delegated the authority to grant Awards to, or amend Awards held by, the following individuals: (a) individuals who are subject

to Section 16 of the Exchange Act, or (b) officers of the Company (or Directors) to whom authority to grant or amend Awards has been delegated hereunder; provided, further, that any delegation of administrative authority shall only be permitted to the extent it is permissible under any Organizational Documents and Applicable Law. Any delegation hereunder shall be subject to the restrictions and limits that the Board or Committee specifies at the time of such delegation or that are otherwise included in the applicable Organizational Documents, and the Board or Committee, as applicable, may at any time rescind the authority so delegated or appoint a new delegatee. At all times, the delegatee appointed under this Section 11.6 shall serve in such capacity at the pleasure of the Board or the Committee, as applicable, and the Board or the Committee may abolish any committee at any time and re-vest in itself any previously delegated authority.

11.7 Acceleration. Subject to the Organizational Documents, any specific designation in the Plan and Applicable Law, the Administrator has the exclusive power, authority and sole discretion to accelerate, wholly or partially, the vesting or lapse of restrictions (and, if applicable, the Company shall cease to have a right of repurchase) of any Award or portion thereof at any time after the grant of an Award, subject to whatever terms and conditions it selects under Section 12.2.

ARTICLE 12.

MISCELLANEOUS PROVISIONS

12.1 Amendment, Suspension or Termination of the Plan.

(a) Except as otherwise provided in Section 12.1(b), the Plan may be wholly or partially amended or otherwise modified, suspended or terminated at any time or from time to time by the Board; provided that, except as provided in Section 10.6 and Section 12.10, no amendment, suspension or termination of the Plan shall, without the consent of the Holder, materially and adversely affect any rights or obligations under any Award theretofore granted or awarded, unless the Award itself otherwise expressly so provides.

(b) Notwithstanding Section 12.1(a), the Board may not, except as provided in Section 12.2, increase the limit imposed in Section 3.1 on the maximum number of Shares which may be issued under the Plan without approval of the Company's stockholders given within twelve (12) months before or after such action.

(c) No Awards may be granted or awarded during any period of suspension or after termination of the Plan, and notwithstanding anything herein to the contrary, in no event may any Incentive Stock Option be granted under the Plan after the tenth (10^{th}) anniversary of the earlier of (i) the date on which the Plan was adopted by the Board and (ii) the date the Plan was approved by the Company's stockholders. The annual increase to the aggregate number of Shares that may be issued or transferred pursuant to Awards under the Plan (set forth in Section 3.1(a) hereof) shall terminate on the tenth (10^{th}) anniversary of the earlier of (i) the date on which the Plan was adopted by the Board and (ii) the date the Plan was approved by the Company's stockholders and, from and after such tenth (10^{th}) anniversary, no additional share increases shall occur pursuant to Section 3.1(a) hereof.

12.2 Changes in Common Stock or Assets of the Company, Acquisition or Liquidation of the Company and Other Corporate Events.

(a) In the event of any stock dividend, stock split, combination or exchange of shares, merger, consolidation or other distribution (other than normal cash dividends) of Company assets to stockholders, or any other change affecting the shares of the Company's stock or the share price of the Company's stock other than an Equity Restructuring, the Administrator may make equitable adjustments to reflect such change with respect to: (i) the aggregate number and kind of Shares that may be issued under the Plan (including, but not limited to, adjustments of the limitations in Section 3.1 on the maximum number and kind of Shares which may be issued under the Plan); (ii) the number and kind of Shares (or other securities or property) subject to outstanding Awards; (iii) the terms and conditions of any outstanding Awards (including, without limitation, any applicable Performance Criteria and Performance Goals with respect thereto); (iv) the grant or exercise price per share for any outstanding Awards under the Plan and (v) the number and kind of Shares (or other securities or property) for which automatic grants are subsequently to be made to new and continuing Non-Employee Directors pursuant to any Non-Employee Director Compensation Policy adopted in accordance with Section 4.6.

(b) In the event of any transaction or event described in Section 12.2(a) or any unusual or nonrecurring transactions or events affecting the Company, any Affiliate of the Company, or the financial statements of the Company or any Affiliate, or of changes in Applicable Law or Applicable Accounting Standards, the Administrator, in its sole discretion, and on such terms and conditions as it deems appropriate, either by the terms of the Award or by action taken prior to the occurrence of such transaction or event, is hereby authorized to take any one or more of the following actions whenever the Administrator determines that such action is appropriate in order to prevent dilution or enlargement of the benefits or potential benefits intended to be made available under the Plan or with respect to any Award under the Plan, to facilitate such transactions or events or to give effect to such changes in Applicable Law or Applicable Accounting Standards:

(i) To provide for the termination of any such Award in exchange for an amount of cash and/or other property with a value equal to the amount that would have been attained upon the exercise of such Award or realization of the Holder's rights (and, for the avoidance of doubt, if as of the date of the occurrence of the transaction or event described in this Section 12.2 the Administrator determines in good faith that no amount would have been attained upon the exercise of such Award or realization of the Holder's rights, then such Award may be terminated by the Company without payment);

(ii) To provide that such Award be assumed by the successor or survivor corporation, or a parent or subsidiary thereof, or shall be substituted for by similar options, rights or awards covering the stock of the successor or survivor corporation, or a parent or subsidiary thereof, with appropriate adjustments as to the number and kind of shares and applicable exercise or purchase price, in all cases, as determined by the Administrator;

(iii) To make adjustments in the number and type of Shares of the Company's stock (or other securities or property) subject to outstanding Awards, and/or in the terms and conditions of (including the grant or exercise price), and the criteria included in, outstanding Awards and Awards which may be granted in the future;

(iv) To provide that such Award shall be exercisable or payable or fully vested with respect to all Shares covered thereby, notwithstanding anything to the contrary in the Plan or the applicable Program or Award Agreement;

(v) To replace such Award with other rights or property selected by the Administrator; and/or

(vi) To provide that the Award cannot vest, be exercised or become payable after such event.

(c) In connection with the occurrence of any Equity Restructuring, and notwithstanding anything to the contrary in Sections 12.2(a) and 12.2(b):

(i) The number and type of securities subject to each outstanding Award and the exercise price or grant price thereof, if applicable, shall be equitably adjusted (and the adjustments provided under this Section 12.2(c)(i) shall be nondiscretionary and shall be final and binding on the affected Holder and the Company); and/or

(ii) The Administrator shall make such equitable adjustments, if any, as the Administrator, in its sole discretion, may deem appropriate to reflect such Equity Restructuring with respect to the aggregate number and kind of Shares that may be issued under the Plan (including, but not limited to, adjustments of the limitation in Section 3.1 on the maximum number and kind of Shares which may be issued under the Plan).

(d) Notwithstanding any other provision of the Plan, in the event of a Change in Control, unless the Administrator elects to (i) terminate an Award in exchange for cash, rights or property, or (ii) cause an Award to become fully exercisable and no longer subject to any forfeiture restrictions prior to the consummation of a Change in Control, pursuant to Section 12.2, (A) such Award (other than any portion subject to performance-based vesting) shall continue in effect or be assumed or an equivalent Award (which may include, without limitation, an Award settled in cash) substituted by the successor corporation or a parent or subsidiary of the successor corporation and (B) the portion of such Award subject to performance-based vesting shall be subject to the terms and conditions of the applicable Award Agreement and, in the absence of applicable terms and conditions, the Administrator's discretion.

(e) In the event that the successor corporation in a Change in Control refuses to assume or substitute for an Award (other than any portion subject to performance-based vesting), the Administrator may cause (i) any or all of such Award (or portion thereof) to terminate in exchange for cash, rights or other property pursuant to Section 12.2(b)(i) or (ii) any or all of such Award (or portion thereof) to become fully exercisable immediately prior to the consummation of such transaction and all forfeiture restrictions on any or all of such Award to lapse. If any such Award is exercisable in lieu of assumption or substitution in the event of a Change in Control, the Administrator shall notify the Holder that such Award shall be fully exercisable for a period of fifteen (15) days from the date of such notice, contingent upon the occurrence of the Change in Control, and such Award shall terminate upon the expiration of such period.

(f) For the purposes of this Section 12.2, an Award shall be considered assumed if, following the Change in Control, the Award confers the right to purchase or receive, for each

Share subject to the Award immediately prior to the Change in Control, the consideration (whether stock, cash, or other securities or property) received in the Change in Control by holders of Common Stock for each Share held on the effective date of the transaction (and if holders were offered a choice of consideration, the type of consideration chosen by the holders of a majority of the outstanding Shares); provided, however, that if such consideration received in the Change in Control was not solely common stock of the successor corporation or its parent, the Administrator may, with the consent of the successor corporation, provide for the consideration to be received upon the exercise of the Award, for each Share subject to an Award, to be solely common stock of the successor corporation or its parent equal in fair market value to the per-share consideration received by holders of Common Stock in the Change in Control.

(g) The Administrator, in its sole discretion, may include such further provisions and limitations in any Award, agreement or certificate, as it may deem equitable and in the best interests of the Company that are not inconsistent with the provisions of the Plan.

(h) Unless otherwise determined by the Administrator, no adjustment or action described in this Section 12.2 or in any other provision of the Plan shall be authorized to the extent it would (i) cause the Plan to violate Section 422(b)(1) of the Code, (ii) result in short-swing profits liability under Section 16 of the Exchange Act or violate the exemptive conditions of Rule 16b-3 of the Exchange Act, or (iii) cause an Award to fail to be exempt from or comply with Section 409A.

(i) The existence of the Plan, any Program, any Award Agreement and/or the Awards granted hereunder shall not affect or restrict in any way the right or power of the Company or the stockholders of the Company to make or authorize any adjustment, recapitalization, reorganization or other change in the Company's capital structure or its business, any merger or consolidation of the Company, any issue of stock or of options, warrants or rights to purchase stock or of bonds, debentures, preferred or prior preference stocks whose rights are superior to or affect the Common Stock or the rights thereof or which are convertible into or exchangeable for Common Stock, or the dissolution or liquidation of the Company, or any sale or transfer of all or any part of its assets or business, or any other corporate act or proceeding, whether of a similar character or otherwise.

(j) If the event of any pending stock dividend, stock split, combination or exchange of shares, merger, consolidation or other distribution (other than normal cash dividends) of Company assets to stockholders, or any other change affecting the Shares or the share price of the Common Stock including any Equity Restructuring, for reasons of administrative convenience, the Administrator, in its sole discretion, may refuse to permit the exercise of any Award during a period of up to thirty (30) days prior to the consummation of any such transaction.

12.3 Approval of Plan by Stockholders. The Plan shall be submitted for the approval of the Company's stockholders within twelve (12) months after the date of the Board's initial adoption of the Plan.

12.4 No Stockholders Rights. Except as otherwise provided herein or in an applicable Program or Award Agreement, a Holder shall have none of the rights of a stockholder with respect to Shares covered by any Award until the Holder becomes the record owner of such Shares.

12.5 Paperless Administration. In the event that the Company establishes, for itself or using the services of a third party, an automated system for the documentation, granting or exercise of Awards, such as a system using an internet website or interactive voice response, then the paperless documentation, granting or exercise of Awards by a Holder may be permitted through the use of such an automated system.

12.6 Effect of Plan upon Other Compensation Plans. The adoption of the Plan shall not affect any other compensation or incentive plans in effect for the Company or any Affiliate. Nothing in the Plan shall be construed to limit the right of the Company or any Affiliate: (a) to establish any other forms of incentives or compensation for Employees, Directors or Consultants of the Company or any Affiliate, or (b) to grant or assume options or other rights or awards otherwise than under the Plan in connection with any proper corporate purpose including without limitation, the grant or assumption of options in connection with the acquisition by purchase, lease, merger, consolidation or otherwise, of the business, stock or assets of any corporation, partnership, limited liability company, firm or association.

12.7 Compliance with Laws. The Plan, the granting and vesting of Awards under the Plan and the issuance and delivery of Shares and the payment of money under the Plan or under Awards granted or awarded hereunder are subject to compliance with all Applicable Law (including but not limited to state, federal and foreign securities law and margin requirements), and to such approvals by any listing, regulatory or governmental authority as may, in the opinion of counsel for the Company, be necessary or advisable in connection therewith. Any securities delivered under the Plan shall be subject to such restrictions, and the person acquiring such securities shall, if requested by the Company, provide such assurances and representations to the Company as the Company may deem necessary or desirable to assure compliance with all Applicable Law. The Administrator, in its sole discretion, may take whatever actions it deems necessary or appropriate to effect compliance with Applicable Law, including, without limitation, placing legends on share certificates and issuing stop-transfer notices to agents and registrars. Notwithstanding anything to the contrary herein, the Administrator may not take any actions hereunder, and no Awards shall be granted, that would violate Applicable Law. To the extent permitted by Applicable Law, the Plan and Awards granted or awarded hereunder shall be deemed amended to the extent necessary to conform to Applicable Law.

12.8 Titles and Headings, References to Sections of the Code or Exchange Act. The titles and headings of the Sections in the Plan are for convenience of reference only and, in the event of any conflict, the text of the Plan, rather than such titles or headings, shall control. References to sections of the Code or the Exchange Act shall include any amendment or successor thereto.

12.9 Governing Law. The Plan and any Programs and Award Agreements hereunder shall be administered, interpreted and enforced under the internal laws of the State of Delaware without regard to conflicts of laws thereof or of any other jurisdiction.

12.10 Section 409A. To the extent that the Administrator determines that any Award granted under the Plan is subject to Section 409A, the Plan, the Program pursuant to which such Award is granted and the Award Agreement evidencing such Award shall incorporate the terms and conditions required by Section 409A. In that regard, to the extent any Award under the Plan or any other compensatory plan or arrangement of the Company or any of its Affiliates is subject

to Section 409A, and such Award or other amount is payable on account of a Holder's Termination of Service (or any similarly defined term), then (a) such Award or amount shall only be paid to the extent such Termination of Service qualifies as a "separation from service" as defined in Section 409A, and (b) if such Award or amount is payable to a "specified employee" as defined in Section 409A then to the extent required in order to avoid a prohibited distribution under Section 409A, such Award or other compensatory payment shall not be payable prior to the earlier of (i) the expiration of the six-month period measured from the date of the Holder's Termination of Service, or (ii) the date of the Holder's death. To the extent applicable, the Plan, the Program and any Award Agreements shall be interpreted in accordance with Section 409A. Notwithstanding any provision of the Plan to the contrary, in the event that following the Effective Date the Administrator determines that any Award may be subject to Section 409A, the Administrator may (but is not obligated to), without a Holder's consent, adopt such amendments to the Plan and the applicable Program and Award Agreement or adopt other policies and procedures (including amendments, policies and procedures with retroactive effect), or take any other actions, that the Administrator determines are necessary or appropriate to (A) exempt the Award from Section 409A and/or preserve the intended tax treatment of the benefits provided with respect to the Award, or (B) comply with the requirements of Section 409A and thereby avoid the application of any penalty taxes under Section 409A. The Company makes no representations or warranties as to the tax treatment of any Award under Section 409A or otherwise. The Company shall have no obligation under this Section 12.10 or otherwise to take any action (whether or not described herein) to avoid the imposition of taxes, penalties or interest under Section 409A with respect to any Award and shall have no liability to any Holder or any other person if any Award, compensation or other benefits under the Plan are determined to constitute non-compliant, "nonqualified deferred compensation" subject to the imposition of taxes, penalties and/or interest under Section 409A.

12.11 Unfunded Status of Awards. The Plan is intended to be an "unfunded" plan for incentive compensation. With respect to any payments not yet made to a Holder pursuant to an Award, nothing contained in the Plan or any Program or Award Agreement shall give the Holder any rights that are greater than those of a general creditor of the Company or any Affiliate.

12.12 Indemnification. To the extent permitted under Applicable Law and the Organizational Documents, each member of the Administrator (and each delegate thereof pursuant to Section 11.6) shall be indemnified and held harmless by the Company from any loss, cost, liability, or expense that may be imposed upon or reasonably incurred by such member in connection with or resulting from any claim, action, suit, or proceeding to which he or she may be a party or in which he or she may be involved by reason of any action or failure to act pursuant to the Plan or any Award Agreement and against and from any and all amounts paid by him or her, with the Board's approval, in satisfaction of judgment in such action, suit, or proceeding against him or her; provided he or she gives the Company an opportunity, at its own expense, to handle and defend the same before he or she undertakes to handle and defend it on his or her own behalf and, once the Company gives notice of its intent to assume such defense, the Company shall have sole control over such defense with counsel of the Company's choosing. The foregoing right of indemnification shall not be available to the extent that a court of competent jurisdiction in a final judgment or other final adjudication, in either case not subject to further appeal, determines that the acts or omissions of the person seeking indemnity giving rise to the indemnification claim resulted from such person's bad faith, fraud or willful criminal act or omission. The foregoing right

of indemnification shall not be exclusive of any other rights of indemnification to which such persons may be entitled pursuant to the Organizational Documents, as a matter of law, or otherwise, or any power that the Company may have to indemnify them or hold them harmless.

12.13 Relationship to Other Benefits. No payment pursuant to the Plan shall be taken into account in determining any benefits under any pension, retirement, savings, profit sharing, group insurance, welfare or other benefit plan of the Company or any Affiliate except to the extent otherwise expressly provided in writing in such other plan or an agreement thereunder.

12.14 Expenses. The expenses of administering the Plan shall be borne by the Company and its Affiliates.

* * * * *

I hereby certify that the foregoing Plan was duly adopted by the Board of Directors of Aziyo Biologics, Inc. on September 27, 2020.

* * * * *

I hereby certify that the foregoing Plan was approved by the stockholders of Aziyo Biologics, Inc. on September 29, 2020.

Executed on this 29th day of September, 2020.

/s/ Jeffrey Hamet
Corporate Secretary

AZIYO BIOLOGICS, INC.
2020 INCENTIVE AWARD PLAN

STOCK OPTION GRANT NOTICE AND
STOCK OPTION AGREEMENT

Aziyo Biologics, Inc., a Delaware corporation (the "Company"), pursuant to its 2020 Incentive Award Plan, as amended from time to time (the "Plan"), hereby grants to the holder listed below ("Participant") an option to purchase the number of Shares set forth below (the "Option"). The Option is subject to the terms and conditions set forth in this Stock Option Grant Notice (the "Grant Notice"), the Plan and the Stock Option Agreement attached hereto as Exhibit A including any Appendix thereto (the "Agreement"), each of which is incorporated into this Grant Notice by reference. Unless otherwise defined herein, the terms defined in the Plan shall have the same defined meanings in this Grant Notice and the Agreement.

Participant:	
Grant Date:	
Exercise Price Per Share:	
Total Exercise Price:	
Total Number of Shares Subject to Option:	
Expiration Date:	The earlier of (i) ten years as of the Grant Date or (ii) the termination, expiration or cancellation of the Option in accordance with the terms of the Plan.
Type of Option:	☐ Incentive Stock Option ☐ Non-Qualified Stock Option
Vesting Schedule:	

By Participant's signature below, Participant agrees to be bound by the terms and conditions of the Plan, the Agreement and the Grant Notice. Participant has reviewed the Plan, the Agreement and the Grant Notice in their entirety, has had an opportunity to obtain the advice of counsel prior to executing the Grant Notice and fully understands all provisions of the Plan, the Agreement and the Grant Notice. Participant hereby agrees to accept as binding, conclusive and final all decisions or interpretations of the Administrator upon any questions arising under the Plan, the Agreement and the Grant Notice.

AZIYO BIOLOGICS, INC.	**PARTICIPANT**
By: _____	By: _____
Print Name:	Print Name:
Title:	

EXHIBIT A
TO STOCK OPTION GRANT NOTICE

STOCK OPTION AGREEMENT

Pursuant to the Grant Notice to which this Agreement is attached, the Company has granted to Participant an Option under the Plan to purchase the number of Shares set forth in the Grant Notice.

ARTICLE I.
GENERAL

1.1 Defined Terms. Capitalized terms not specifically defined herein shall have the meanings specified in the Plan or the Grant Notice. For purposes of this Agreement,

(a) "Cause" shall have the meaning ascribed to such term in any relevant employment agreement between Participant and a Company Group Member; *provided* that, in the absence of such agreement containing such definition, "Cause" shall mean (i) Participant performing his or her duties, in the good faith opinion of the Board, in a grossly negligent or reckless manner or with willful malfeasance, (ii) Participant exhibiting habitual drunkenness or engaging in substance abuse, (iii) Participant committing any material violation of any state of any state or federal law relating to the workplace environment (including, without limitation, laws relating to sexual harassment or age, sex or other prohibited discrimination) or any material violation of any Company Group policy, (iv) Participant willfully failing or refusing to perform in the usual manner at the usual time those duties which he or she regularly and routinely performs in connection with the business of the Company Group or such other duties reasonably related to the capacity in which he or she is employed hereunder which may be assigned to him or her by the Board, (v) Participant performing any material action when specifically and reasonably instructed not to do so by the Chairman or the Board, (vi) Participant materially breaching Participant's material breach of this Agreement or any other confidentiality, non-compete or non-solicitation covenant with a Company Group Member, (vii) Participant committing any fraud or using or appropriating for his or her personal use or benefit any funds, properties or opportunities of the Company Group not authorized by the Board to be so used or appropriated; or (viii) Participant being convicted of any felony or any other crime related to his or her employment or involving moral turpitude. The Company Group Member shall not be entitled to terminate Participant for Cause pursuant to clause (iii), (iv), (v) or (vi) unless the Company provides written notice stating in reasonable detail the basis for termination and a fifteen (15) day opportunity to cure to Participant (unless (1) the Company reasonably determines that providing such opportunity to cure to Participant is reasonably likely to have a material adverse effect on its business, financial condition, results of operation, prospects or assets, (2) the facts and circumstances underlying such termination are not able to be cured or (3) the Company has previously provided Participant an opportunity to cure the applicable issues; in the case of (1), (2) or (3), the Company may terminate Participant without providing an opportunity to cure).

(b) "Cessation Date" shall mean the date of Participant's Termination of Service (regardless of the reason for such termination).

(c) "Company Group" shall mean the Company and its Affiliates.

(d) "Company Group Member" shall mean each member of the Company Group.

(e) "Disability" shall have the meaning ascribed to such term in any relevant employment agreement between Participant and a Company Group Member; *provided* that, in the absence of such agreement containing such definition, "Disability" shall mean permanent disability or incapacity as

determined in accordance with the Company's disability insurance policy, if such a policy is then in effect, or if no such policy is then in effect, such permanent disability or incapacity shall be determined by the Board in its good faith judgment based upon inability to perform the essential functions of his or her position, with reasonable accommodation by the Company, for a period in excess of 180 days during any period of 365 calendar days.

1.2 Incorporation of Terms of Plan. Except where this Agreement explicitly states that this Agreement prevails over the Plan, the Option is subject to the terms and conditions set forth in this Agreement and the Plan, each of which is incorporated herein by reference. In the event of any inconsistency between the Plan and this Agreement, the terms of the Plan shall control.

ARTICLE II.
GRANT OF OPTION

2.1 Grant of Option. In consideration of Participant's past and/or continued employment with or service to any Company Group Member, and for other good and valuable consideration that the Administrator has determined exceeds the aggregate par value of the Shares subject to the Award, effective as of the grant date set forth in the Grant Notice (the "Grant Date"), the Company hereby grants to Participant the Option to purchase any part or all of an aggregate number of Shares set forth in the Grant Notice upon the terms and conditions set forth in the Grant Notice, the Plan and this Agreement, subject to adjustment as provided in Article 12 of the Plan.

2.2 Exercise Price. The exercise price per Share of the Shares subject to the Option (the "Exercise Price") shall be as set forth in the Grant Notice.

2.3 Consideration to the Company. In consideration of the grant of the Option by the Company, Participant agrees to render faithful and efficient services to any Company Group Member. Nothing in the Plan, the Grant Notice or this Agreement shall confer upon Participant any right to continue in the employ or service of any Company Group Member or shall interfere with or restrict in any way the rights of the Company Group, which rights are hereby expressly reserved, to discharge or terminate the services of Participant at any time for any reason whatsoever, with or without Cause, except to the extent expressly provided otherwise in a written agreement between any Company Group Member and Participant.

ARTICLE III.
PERIOD OF EXERCISABILITY

3.1 Commencement of Exercisability.

(a) Subject to Participant's continued employment with or service to a Company Group Member through the applicable vesting date and subject to anything in the Grant Notice, the Plan or this Agreement to the contrary, the Option shall become vested and exercisable in such amounts and at such times as are set forth in the Grant Notice.

(b) Unless otherwise determined by the Administrator or as set forth in a written agreement between Participant and the Company, any portion of the Option that has not become vested and exercisable on or prior to the Cessation Date (including, without limitation, pursuant to any employment or similar agreement by and between Participant and the Company) shall be forfeited on the Cessation Date and shall not thereafter become vested or exercisable.

3.2 Duration of Exercisability. The installments provided for in the vesting schedule set forth in the Grant Notice are cumulative. Each such installment that becomes vested and exercisable pursuant to

the vesting schedule set forth in the Grant Notice shall remain vested and exercisable until it becomes unexercisable under Section 3.3 hereof. Once the Option becomes unexercisable, it shall be forfeited immediately.

3.3 Expiration of Option. The Option may not be exercised to any extent by anyone after the first to occur of the following events:

(a) The expiration date set forth in the Grant Notice;

(b) Except as the Administrator may otherwise approve, the expiration of six (6) months from the Cessation Date by reason of Participant's Termination of Service due to death or, Disability; and

(c) Except as the Administrator may otherwise approve, immediately upon the Cessation Date by reason of Participant's Termination of Service by the Company Group for Cause.

(d) Except as the Administrator may otherwise approve, the expiration of ninety (90) days from the date of Participant's Termination of Service for any other reason.

ARTICLE IV.
EXERCISE OF OPTION

4.1 Person Eligible to Exercise. During the lifetime of Participant, only Participant may exercise the Option or any portion thereof. After the death of Participant, any exercisable portion of the Option may, prior to the time when the Option becomes unexercisable under Section 3.3 hereof, be exercised by Participant's personal representative or by any person empowered to do so under the deceased Participant's will or under the then Applicable Laws of descent and distribution.

4.2 Partial Exercise. Subject to Section 5.5, any exercisable portion of the Option or the entire Option, if then wholly exercisable, may be exercised in whole or in part at any time prior to the time when the Option or portion thereof becomes unexercisable under Section 3.3 hereof.

4.3 Additional Requirements. In order for the Company to issue Shares upon the exercise of the Option, Participant hereby agrees to sign any and all documents required by any applicable law and/or reasonably required by the Administrator. Participant further agrees that in the event that the Company and its counsel deem it necessary or advisable, in their sole discretion, the issuance of Shares may be conditioned upon certain representations, warranties, and acknowledgements by Participant.

4.4 Compliance with Law. The Company shall not be obligated to issue any Shares upon the exercise of the Option if such issuance, in the opinion of the Company, might constitute a violation by the Company of any provision of law.

ARTICLE V.
OTHER PROVISIONS

5.1 Tax Withholding. Notwithstanding any other provision of this Agreement:

(a) The Company Group shall have the authority to deduct or withhold, or require Participant to remit to the applicable Company Group Member, an amount sufficient to satisfy any applicable federal, state, local and foreign taxes (including the employee portion of any FICA obligation) required by Applicable Law to be withheld with respect to any taxable event arising pursuant to this

Agreement. The Company Group may withhold or Participant may make such payment in one or more of the forms specified below:

(i) by a bank wire transfer, an ACH (automated clearing house) mechanism, or any other means of electronic funds transfer made payable to the Company Group Member with respect to which the withholding obligation arises;

(ii) by the deduction of such amount from other compensation payable to Participant;

(iii) with respect to any withholding taxes arising in connection with the exercise of the Option, with the consent of the Administrator, by requesting that the Company withhold a net number of Shares issuable upon the exercise of the Option having a then current Fair Market Value not exceeding the amount necessary to satisfy the withholding obligation of the Company Group based on the maximum statutory withholding rates in Participant's applicable jurisdictions for federal, state, local and foreign income tax and payroll tax purposes that are applicable to such taxable income;

(iv) with respect to any withholding taxes arising in connection with the exercise of the Option, with the consent of the Administrator, by tendering to the Company vested Shares held for such period of time as may be required by the Administrator in order to avoid adverse accounting consequences and having a then current Fair Market Value not exceeding the amount necessary to satisfy the withholding obligation of the Company Group based on the maximum statutory withholding rates in Participant's applicable jurisdictions for federal, state, local and foreign income tax and payroll tax purposes that are applicable to such taxable income;

(v) with respect to any withholding taxes arising in connection with the exercise of the Option, through the delivery of a notice that Participant has placed a market sell order with a broker acceptable to the Company with respect to Shares then issuable to Participant pursuant to the Option, and that the broker has been directed to pay a sufficient portion of the net proceeds of the sale to the Company Group Member with respect to which the withholding obligation arises in satisfaction of such withholding taxes; *provided* that payment of such proceeds is then made to the applicable Company Group Member at such time as may be required by the Administrator, but in any event not later than the settlement of such sale; or

(vi) in any combination of the foregoing.

(b) With respect to any withholding taxes arising in connection with the Option, in the event Participant fails to provide timely payment of all sums required pursuant to Section 5.1(a), the Company shall have the right and option, but not the obligation, to treat such failure as an election by Participant to satisfy all or any portion of Participant's required payment obligation pursuant to Section 5.1(a)(ii) or Section 5.1(a)(iii) above, or any combination of the foregoing as the Company may determine to be appropriate. The Company shall not be obligated to deliver any certificate representing Shares issuable with respect to the exercise of the Option to, or to cause any such Shares to be held in book-entry form by, Participant or his or her legal representative unless and until Participant or his or her legal representative shall have paid or otherwise satisfied in full the amount of all federal, state, local and foreign taxes applicable with respect to the taxable income of Participant resulting from the exercise of the Option or any other taxable event related to the Option.

(c) In the event any tax withholding obligation arising in connection with the Option will be satisfied under Section 5.1(a)(iii), then the Company may elect to instruct any brokerage firm determined acceptable to the Company for such purpose to sell on Participant's behalf a whole number of

Shares from those Shares then issuable upon the exercise of the Option as the Company determines to be appropriate to generate cash proceeds sufficient to satisfy the tax withholding obligation and to remit the proceeds of such sale to the Company Group Member with respect to which the withholding obligation arises. Participant's acceptance of this Option constitutes Participant's instruction and authorization to the Company and such brokerage firm to complete the transactions described in this Section 5.1(c), including the transactions described in the previous sentence, as applicable. The Company may refuse to issue any Shares to Participant until the foregoing tax withholding obligations are satisfied, *provided* that no payment shall be delayed under this Section 5.1(c) if such delay will result in a violation of Section 409A.

(d) In the event of any broker-assisted sale of Shares in connection with the payment of withholding taxes as provided in Section 5.1(a)(v) or Section 5.1(c) or the payment of the Exercise Price as provided in Section 4.4(c): (a) any Shares to be sold through a broker-assisted sale will be sold on the day the tax withholding obligation or exercise of the Option, as applicable, occurs or arises, or as soon thereafter as practicable; (b) such Shares may be sold as part of a block trade with other participants in the Plan in which all participants receive an average price; (c) Participant will be responsible for all broker's fees and other costs of sale, and Participant agrees to indemnify and hold the Company harmless from any losses, costs, damages, or expenses relating to any such sale; (d) to the extent the proceeds of such sale exceed the applicable tax withholding obligation or Exercise Price, the Company agrees to pay such excess in cash to Participant as soon as reasonably practicable; (e) Participant acknowledges that the Company or its designee is under no obligation to arrange for such sale at any particular price, and that the proceeds of any such sale may not be sufficient to satisfy the applicable tax withholding obligation or Exercise Price; and (f) in the event the proceeds of such sale are insufficient to satisfy the applicable tax withholding obligation, Participant agrees to pay immediately upon demand to the Company Group Member with respect to which the withholding obligation arises an amount in cash sufficient to satisfy any remaining portion of the applicable Company Group Member's withholding obligation.

(e) Any tax consequences arising from the grant or exercise of the Option, from the payment for Shares covered thereby or from any other event or act (of the Company and/or its Affiliates, or Participant), hereunder, shall be borne solely by Participant. Participant is ultimately liable and responsible for, and, to the extent permitted by Applicable Law, agrees to indemnify and keep indemnified the Company Group from, all taxes owed in connection with the Option, regardless of any action any Company Group Member takes with respect to any tax withholding obligations that arise in connection with the Option. No Company Group Member makes any representation or undertaking regarding the treatment of any tax withholding in connection with the awarding, vesting or exercise of the Option or the subsequent sale of Shares. The Company Group does not commit and is under no obligation to structure the Option to reduce or eliminate Participant's tax liability.

(f) The receipt of the Option and the acquisition of the Shares to be issued upon the exercise of the Option may result in tax consequences. PARTICIPANT IS ADVISED TO CONSULT A TAX ADVISOR WITH RESPECT TO THE TAX CONSEQUENCES OF RECEIVING OR EXERCISING THIS OPTION OR DISPOSING OF THE SHARES.

5.2 Obligations to the Company. Participant agrees to comply with the restrictive covenants set forth on Annex A, and Participant acknowledges and agrees that the grant of the Option shall be in material part in consideration of Participant's affirmation of Participant's agreement to comply with the covenants set forth therein.

5.3 Rights as Stockholder. Neither Participant nor any person claiming under or through Participant will have any of the rights or privileges of a stockholder of the Company in respect of any Shares purchasable upon the exercise of any part of the Option unless and until certificates representing such Shares (which may be in book-entry form) will have been issued and recorded on the records of the Company or

its transfer agents or registrars and delivered to Participant (including through electronic delivery to a brokerage account). No adjustment will be made for a dividend or other right for which the record date is prior to the date of such issuance, recordation and delivery, except as provided in Section 12.2 of the Plan. Except as otherwise provided herein, after such issuance, recordation and delivery, Participant will have all the rights of a stockholder of the Company with respect to such Shares, including, without limitation, the right to receipt of dividends and distributions on such Shares.

5.4 Administration. The Administrator shall have the power to interpret the Plan, the Grant Notice and this Agreement and to adopt such rules for the administration, interpretation and application of the Plan, the Grant Notice and this Agreement as are consistent therewith and to interpret, amend or revoke any such rules. All actions taken and all interpretations and determinations made by the Administrator will be final and binding upon Participant, the Company and all other interested persons. To the extent allowable pursuant to Applicable Law, no member of the Committee or the Board will be personally liable for any action, determination or interpretation made with respect to the Plan, the Grant Notice or this Agreement.

5.5 Whole Shares. The Option may only be exercised for whole Shares and in no case may a fraction of a Share be purchased..

5.6 Option Not Transferable. Subject to Section 4.1 hereof, the Option may not be sold, pledged, assigned or transferred in any manner other than by will or the laws of descent and distribution, unless and until the Shares underlying the Option have been issued, and all restrictions applicable to such Shares have lapsed. Neither the Option nor any interest or right therein or part thereof shall be liable for the debts, contracts or engagements of Participant or his or her successors in interest or shall be subject to disposition by transfer, alienation, anticipation, pledge, encumbrance, assignment or any other means whether such disposition be voluntary or involuntary or by operation of law by judgment, levy, attachment, garnishment or any other legal or equitable proceedings (including bankruptcy), and any attempted disposition thereof shall be null and void and of no effect, except to the extent that such disposition is permitted by the preceding sentence. Notwithstanding the foregoing, with the consent of the Administrator, if the Option is a Non-Qualified Stock Option, it may be transferred to Permitted Transferees pursuant to any conditions and procedures the Administrator may require.

5.7 Adjustments. Participant acknowledges that the Option is subject to adjustment, modification and termination in certain events as provided in this Agreement and the Plan, including Section 12.2 of the Plan.

5.8 Notices. Any notice to be given under the terms of this Agreement to the Company shall be addressed to the Company in care of the Secretary of the Company at the Company's principal office, and any notice to be given to Participant shall be addressed to Participant at Participant's last address or email address reflected on the Company's records. By a notice given pursuant to this Section 5.8, either party may hereafter designate a different address for notices to be given to that party. Any notice shall be deemed duly given when sent via email or when sent by certified mail (return receipt requested) and deposited (with postage prepaid) in a post office or branch post office regularly maintained by the United States Postal Service.

5.9 Titles. Titles are provided herein for convenience only and are not to serve as a basis for interpretation or construction of this Agreement.

5.10 Governing Law. The laws of the State of Delaware shall govern the interpretation, validity, administration, enforcement and performance of the terms of this Agreement regardless of the law that might be applied under principles of conflicts of laws.

5.11 Conformity to Securities Laws. Participant acknowledges that the Plan, the Grant Notice and this Agreement are intended to conform to the extent necessary with all Applicable Laws, including, without limitation, the provisions of the Securities Act and the Exchange Act, and any and all regulations and rules promulgated thereunder by the Securities and Exchange Commission and state securities laws and regulations. Notwithstanding anything herein to the contrary, the Plan shall be administered, and the Option is granted and may be exercised, only in such a manner as to conform to Applicable Law. To the extent permitted by Applicable Law, the Plan, the Grant Notice and this Agreement shall be deemed amended to the extent necessary to conform to Applicable Law.

5.12 Amendment, Suspension and Termination. To the extent permitted by the Plan, this Agreement may be wholly or partially amended or otherwise modified, suspended or terminated at any time or from time to time by the Administrator or the Board, *provided* that, except as may otherwise be provided by the Plan, no amendment, modification, suspension or termination of this Agreement shall adversely affect the Option in any material way without the prior written consent of Participant.

5.13 Successors and Assigns. The Company may assign any of its rights under this Agreement to single or multiple assignees, and this Agreement shall inure to the benefit of the successors and assigns of the Company. Subject to the restrictions on transfer set forth in Section 5.6 and the Plan, this Agreement shall be binding upon and inure to the benefit of the heirs, legatees, legal representatives, successors and assigns of the parties hereto.

5.14 Limitations Applicable to Section 16 Persons. Notwithstanding any other provision of the Plan or this Agreement, if Participant is subject to Section 16 of the Exchange Act, the Plan, the Option, the Grant Notice and this Agreement shall be subject to any additional limitations set forth in any applicable exemptive rule under Section 16 of the Exchange Act (including any amendment to Rule 16b-3 of the Exchange Act) that are requirements for the application of such exemptive rule. To the extent permitted by Applicable Law, this Agreement shall be deemed amended to the extent necessary to conform to such applicable exemptive rule.

5.15 No Other Rights. Participant hereby acknowledges that participation in the Plan is voluntary. The value of the Option is an extraordinary item of compensation outside the scope of Participant's normal compensation rights, if any. As such, the Option is not part of normal or expected compensation for purposes of calculating any payments due to severance, resignation, redundancy, end of service, bonuses, long-service awards, pensions or retirement benefits or similar payments. The Plan is discretionary in nature and may be amended, cancelled, or terminated by the Company, in its sole discretion, at any time. The grant of the Option under the Plan is a one-time benefit and does not create any contractual or other right to receive any other grant of the Option or other Awards under the Plan in the future. Future grants, if any, will be at the sole discretion of the Company, including, but not limited to, the timing of the grant, the form of the Award, number of Shares subject to an Award, vesting, and exercise or settlement provisions, as relevant.

5.16 Not a Contract of Employment. Nothing in this Agreement or in the Plan shall confer upon Participant any right to continue to serve as an Employee or other service provider of any Company Group Member or shall interfere with or restrict in any way the rights of the Company Group, which rights are hereby expressly reserved, to discharge or terminate the services of Participant at any time for any reason whatsoever, with or without Cause, except to the extent expressly provided otherwise in a written agreement between a Company Group Member and Participant.

5.17 Entire Agreement. The Plan, the Grant Notice and this Agreement (including any exhibit hereto) constitute the entire agreement of the parties and supersede in their entirety all prior undertakings and agreements of the Company and Participant with respect to the subject matter hereof.

5.18 No Obligation to Exercise the Option. The grant and acceptance of the Option imposes no obligation on Participant to exercise.

5.19 Section 409A. This Award is not intended to constitute "nonqualified deferred compensation" within the meaning of Section 409A. However, notwithstanding any other provision of the Plan, the Grant Notice or this Agreement, if at any time the Administrator determines that this Award (or any portion thereof) may be subject to Section 409A, the Administrator shall have the right in its sole discretion (without any obligation to do so or to indemnify Participant or any other person for failure to do so) to adopt such amendments to the Plan, the Grant Notice or this Agreement, or adopt other policies and procedures (including amendments, policies and procedures with retroactive effect), or take any other actions, as the Administrator determines are necessary or appropriate for this Award either to be exempt from the application of Section 409A or to comply with the requirements of Section 409A.

5.20 Agreement Severable. In the event that any provision of the Grant Notice or this Agreement is held invalid or unenforceable, such provision will be severable from, and such invalidity or unenforceability will not be construed to have any effect on, the remaining provisions of the Grant Notice or this Agreement.

5.21 Limitation on Participant's Rights. Participation in the Plan confers no rights or interests other than as herein provided. This Agreement creates only a contractual obligation on the part of the Company as to amounts payable and shall not be construed as creating a trust. Neither the Plan nor any underlying program, in and of itself, has any assets. Participant shall have only the right to receive Shares as a general unsecured creditor with respect to the Option, as and when exercised pursuant to the terms hereof.

5.22 Counterparts. The Grant Notice may be executed in one or more counterparts, including by way of any electronic signature, subject to Applicable Law, each of which shall be deemed an original and all of which together shall constitute one instrument.

5.23 Incentive Stock Options. Participant acknowledges that to the extent the aggregate Fair Market Value of Shares (determined as of the time the option with respect to the Shares is granted) with respect to which Incentive Stock Options, including this Option (if applicable), are exercisable for the first time by Participant during any calendar year exceeds $100,000 or if for any other reason such Incentive Stock Options do not qualify or cease to qualify for treatment as "incentive stock options" under Section 422 of the Code, such Incentive Stock Options shall be treated as Non-Qualified Stock Options. Participant further acknowledges that the rule set forth in the preceding sentence shall be applied by taking the Option and other stock options into account in the order in which they were granted, as determined under Section 422(d) of the Code and the Treasury Regulations thereunder. Participant also acknowledges that an Incentive Stock Option exercised more than three (3) months after Participant's Termination of Service, other than by reason of death or disability, will be taxed as a Non-Qualified Stock Option.

5.24 Notification of Disposition. If this Option is designated as an Incentive Stock Option, Participant shall give prompt written notice to the Company of any disposition or other transfer of any Shares acquired under this Agreement if such disposition or transfer is made (a) within two (2) years from the Grant Date or (b) within one (1) year after the transfer of such Shares to Participant. Such notice shall specify the date of such disposition or other transfer and the amount realized, in cash, other property, assumption of indebtedness or other consideration, by Participant in such disposition or other transfer.

Annex A

See attached.

AZIYO BIOLOGICS, INC.
2020 INCENTIVE AWARD PLAN

RESTRICTED STOCK UNIT AWARD GRANT NOTICE AND RESTRICTED STOCK UNIT AGREEMENT

Aziyo Biologics, Inc., a Delaware corporation (the "Company"), pursuant to its 2020 Incentive Award Plan, as amended from time to time (the "Plan"), in connection with its initial public offering, hereby grants to the holder listed below ("Participant") the number of Restricted Stock Units set forth below (the "RSUs"). The RSUs are subject to the terms and conditions set forth in this Restricted Stock Unit Grant Notice (the "Grant Notice"), the Restricted Stock Unit Agreement attached hereto as Exhibit A (the "Agreement") and the Plan, each of which is incorporated herein by reference. Unless otherwise defined herein, the terms defined in the Plan shall have the same defined meanings in the Grant Notice and the Agreement.

Participant:	_____
Grant Date:	_____
Number of RSUs:	[_____]
Type of Shares Issuable:	Class A Common Stock
Vesting Date:	The RSUs will vest on the third anniversary of the Grant Date, subject to the Participant's continued employment with or service to a Company Group Member through such date.

Withholding Tax Election: By accepting this Award electronically through the Plan service provider's online grant acceptance policy, the Participant understands and agrees that as a condition of the grant of the RSUs hereunder, the Participant is required to, and hereby affirmatively elects to (the "Sell to Cover Election"), (1) sell that number of Shares determined in accordance with Section 2.5 of the Agreement as may be necessary to satisfy all applicable withholding obligations with respect to any taxable event arising in connection with the RSUs and similarly sell such number of Shares as may be necessary to satisfy all applicable withholding obligations with respect to any other awards of restricted stock units granted to the Participant under the Plan or any other equity incentive plans of the Company or its predecessor, and (2) to allow the Agent (as defined in the Agreement) to remit the cash proceeds of such sale(s) to the Company. Furthermore, the Participant directs the Company to make a cash payment equal to the required tax withholding from the cash proceeds of such sale(s) directly to the appropriate taxing authorities. **The Participant has carefully reviewed Section 2.5 of the Agreement and the Participant hereby represents and warrants that on the date hereof he or she is not aware of any material, nonpublic information with respect to the Company or any securities of the Company, is not subject to any legal, regulatory or contractual restriction that would prevent the Agent from conducting sales, does not have, and will not attempt to exercise, authority, influence or control over any sales of Shares effected by the Agent pursuant to the Agreement, and is entering into the Agreement and this election to "sell to cover" in good faith and not as part of a plan or scheme to evade the prohibitions of Rule 10b5-1 (regarding trading of the Company's securities on the basis of material nonpublic information) under the Securities Exchange Act of 1934, as amended (the "Exchange Act"). It is the Participant's intent that this election to "sell to cover" comply with the requirements of Rule 10b5-1(c)(1)(i)(B) under the Exchange Act and be interpreted to comply with the requirements of Rule 10b5-1(c) under the Exchange Act.**

By Participant's signature below, Participant agrees to be bound by the terms and conditions of the Plan, the Agreement and the Grant Notice. Participant has reviewed the Plan, the Agreement and the Grant Notice in their entirety, has had an opportunity to obtain the advice of counsel prior to executing the Grant Notice and fully understands all provisions of the Plan, the Agreement and the Grant Notice. Participant hereby agrees to accept as binding, conclusive and final all decisions or interpretations of the Administrator upon any questions arising under the Plan, the Agreement and the Grant Notice.

AZIYO BIOLOGICS, INC.	**PARTICIPANT**
By: _____	By: _____
Print Name:	Print Name:
Title:	

EXHIBIT A
TO RESTRICTED STOCK UNIT AWARD GRANT NOTICE

RESTRICTED STOCK UNIT AWARD AGREEMENT

Pursuant to the Grant Notice to which this Agreement is attached, the Company has granted to Participant the number of RSUs set forth in the Grant Notice.

ARTICLE I.

GENERAL

Section 1.1 Defined Terms. Capitalized terms not specifically defined herein shall have the meanings specified in the Plan or the Grant Notice. For purposes of this Agreement,

(a) "Change in Control" shall mean a Change in Control (as defined under the Plan) that constitutes a "change in control event" as defined in Treasury Regulation Section 1.409A-3(i)(5).

(b) "Company Group" shall mean the Company and its Affiliates.

(c) "Company Group Member" shall mean each member of the Company Group.

(d) "Disability" shall mean any disability or incapacity that (i) renders Participant unable to substantially perform his duties hereunder for ninety (90) days during any 12-month period or (ii) would reasonably be expected to render Executive unable to substantially perform his or her duties for ninety (90) days during any 12-month period, in each case as determined by the Board in its good faith judgment.

Section 1.2 Incorporation of Terms of Plan. The RSUs and the shares of Common Stock issued to Participant hereunder ("Shares") are subject to the terms and conditions set forth in this Agreement and the Plan, which is incorporated herein by reference. In the event of any inconsistency between the Plan and this Agreement, the terms of the Plan shall control.

ARTICLE II.

AWARD OF RESTRICTED STOCK UNITS

Section 2.1 Award of RSUs

(a) In consideration of Participant's past and/or continued employment with or service to a Company Group Member and for other good and valuable consideration, effective as of the grant date set forth in the Grant Notice (the "Grant Date"), the Company has granted to Participant the number of RSUs set forth in the Grant Notice, upon the terms and conditions set forth in the Grant Notice, the Plan and this Agreement, subject to adjustment as provided in Section 12.2 of the Plan. Each RSU represents the right to receive one Share at the times and subject to the conditions set forth herein. However, unless and until the RSUs have vested, Participant will have no right to the payment of any Shares subject thereto. Prior to the actual delivery of any Shares, the RSUs will represent an unsecured obligation of the Company, payable only from the general assets of the Company.

Section 2.2 Vesting of RSUs.

(a) Subject to Participant's continued employment with or service to a Company Group Member on the Vesting Date, and subject to the terms of this Agreement, including, without limitation, Section 2.2(d), the RSUs shall vest on the Vesting Date as set forth in the Grant Notice.

(b) In the event Participant incurs a Termination of Service prior to the Vesting Date, except as may be otherwise provided herein or by the Administrator or as set forth in a written agreement between Participant and the Company, Participant shall immediately forfeit any and all RSUs granted under this Agreement , and Participant's rights in any such RSUs shall lapse and expire.

(c) Notwithstanding the Grant Notice or the provisions of Section 2.2(a) and Section 2.2(b), in the event of Participant's death or in the event Participant incurs a Disability prior to the Vesting Date, the RSUs shall become vested with respect to all Shares covered thereby on the date of such Termination of Service.

(d) Notwithstanding the Grant Notice or the provisions of Section 2.2(a) and Section 2.2(b), in the event of the occurrence of a Change in Control prior to the Vesting Date, the RSUs shall become vested with respect to all Shares covered thereby on the date of the consummation of such Change in Control, subject to Participant's continued employment with or service to a Company Group Member through such Change in Control.

Section 2.3

(a) Distribution or Payment of RSUs. Participant's RSUs shall be distributed in Shares (either in book-entry form or otherwise) on or within two business days following the Vesting Date. Notwithstanding the foregoing, the Company may delay a distribution or payment in settlement of RSUs if it reasonably determines that such payment or distribution will violate federal securities laws or any other Applicable Law, *provided* that such distribution or payment shall be made at the earliest date at which the Company reasonably determines that the making of such distribution or payment will not cause such violation, as required by Treasury Regulation Section 1.409A-2(b)(7)(ii), and *provided further* that no payment or distribution shall be delayed under this Section 2.3(a) if such delay will result in a violation of Section 409A.

(b) All distributions shall be made by the Company in the form of whole Shares, and any fractional share shall be distributed in cash in an amount equal to the value of such fractional share determined based on the Fair Market Value as of the date immediately preceding the date of such distribution.

Section 2.4 Conditions to Issuance of Certificates. The Company shall not be required to issue or deliver any certificate or certificates for any Shares or to cause any Shares to be held in book-entry form prior to the fulfillment of all of the following conditions: (a) the admission of the Shares to listing on all stock exchanges on which such Shares are then listed, (b) the completion of any registration or other qualification of the Shares under any state or federal law or under rulings or regulations of the Securities and Exchange Commission or other governmental regulatory body, which the Administrator shall, in its absolute discretion, deem necessary or advisable, (c) the obtaining of any approval or other clearance from any state or federal governmental agency that the Administrator shall, in its absolute discretion, determine to be necessary or advisable, (d) the receipt by the Company of full payment for such Shares, which may be in one or more of the forms of consideration permitted under Section 2.5, and (e) the receipt of full payment of any applicable withholding tax in accordance with Section 2.5 by the Company Group Member with respect to which the applicable withholding obligation arises.

Section 2.5 Tax Withholding. Notwithstanding any other provision of this Agreement:

(a) As set forth in Section 10.2 of the Plan, the Company shall have the authority and the right to deduct or withhold, or to require the Participant to remit to the Company, an amount sufficient to satisfy all applicable federal, state and local taxes required by law to be withheld with respect to any taxable event arising in connection with the Restricted Stock Units. In satisfaction of such tax withholding obligations and in accordance with the Sell to Cover Election included in the Grant Notice, the Participant has irrevocably elected to sell the portion of the Shares to be delivered under the Restricted Stock Units necessary so as to satisfy the tax withholding obligations and shall execute any letter of instruction or agreement required by the Company's transfer agent (together with any other party the Company determines necessary to execute the Sell to Cover Election, the "Agent") to cause the Agent to irrevocably commit to forward the proceeds necessary to satisfy the tax withholding obligations directly to the Company and/or its Affiliates. Notwithstanding any other provision of this Agreement, the Company shall not be obligated to deliver any new certificate representing Shares to the Participant or the Participant's legal representative or enter such Shares in book entry form unless and until the Participant or the Participant's legal representative shall have paid or otherwise satisfied in full the amount of all federal, state and local taxes applicable to the taxable income of the Participant resulting from the grant or vesting of the Restricted Stock Units or the issuance of Shares. In accordance with Participant's Sell to Cover Election pursuant to the Grant Notice, the Participant hereby acknowledges and agrees:

(i) The Participant hereby appoints the Agent as the Participant's agent and authorizes the Agent to (1) sell on the open market at the then prevailing market price(s), on the Participant's behalf, as soon as practicable on or after the Shares are issued upon the vesting of the Restricted Stock Units, that number (rounded up to the next whole number) of the Shares so issued necessary to generate proceeds to cover (x) any tax withholding obligations incurred with respect to such vesting or issuance and (y) all applicable fees and commissions due to, or required to be collected by, the Agent with respect thereto and (2) apply any remaining funds to the Participant's federal tax withholding.

(ii) The Participant hereby authorizes the Company and the Agent to cooperate and communicate with one another to determine the number of Shares that must be sold pursuant to subsection (i) above.

(iii) The Participant understands that the Agent may effect sales as provided in subsection (i) above in one or more sales and that the average price for executions resulting from bunched orders will be assigned to the Participant's account. In addition, the Participant acknowledges that it may not be possible to sell Shares as provided by subsection (i) above due to (1) a legal or contractual restriction applicable to the Participant or the Agent, (2) a market disruption, or (3) rules governing order execution priority on the national exchange where the Shares may be traded. The Participant further agrees and acknowledges that in the event the sale of Shares would result in material adverse harm to the Company, as determined by the Company in its sole discretion, the Company may instruct the Agent not to sell Shares as provided by subsection (i) above. In the event of the Agent's inability to sell Shares, the Participant will continue to be responsible for the timely payment to the Company and/or its Affiliates of all federal, state, local and foreign taxes that are required by applicable laws and regulations to be withheld, including but not limited to those amounts specified in subsection (i) above.

(iv) The Participant acknowledges that regardless of any other term or condition of this Section 2.5(a), the Agent will not be liable to the Participant for (1) special, indirect, punitive, exemplary, or consequential damages, or incidental losses or damages of any kind, or (2) any failure to perform or for any delay in performance that results from a cause or

circumstance that is beyond its reasonable control.

(v) The Participant hereby agrees to execute and deliver to the Agent any other agreements or documents as the Agent reasonably deems necessary or appropriate to carry out the purposes and intent of this Section 2.5(a). The Agent is a third-party beneficiary of this Section 2.5(a).

(vi) This Section 2.5(a) shall terminate not later than the date on which all tax withholding obligations arising in connection with the vesting of the Award have been satisfied.

(b) The Company shall not be obligated to deliver any certificate representing Shares issuable with respect to the RSUs to, or to cause any such Shares to be held in book-entry form by, Participant or his or her legal representative unless and until Participant or his or her legal representative shall have paid or otherwise satisfied in full the amount of all federal, state, local and foreign taxes applicable with respect to the taxable income of Participant resulting from the vesting or settlement of the RSUs or any other taxable event related to the RSUs.

(c) Participant is ultimately liable and responsible for all taxes owed in connection with the RSUs, regardless of any action the Company or any other Company Group Member takes with respect to any tax withholding obligations that arise in connection with the RSUs. No Company Group Member makes any representation or undertaking regarding the treatment of any tax withholding in connection with the awarding, vesting or payment of the RSUs or the subsequent sale of Shares. The Participating Companies do not commit and are under no obligation to structure the RSUs to reduce or eliminate Participant's tax liability.

Section 2.6 Rights as Stockholder. Neither Participant nor any Person claiming under or through Participant will have any of the rights or privileges of a stockholder of the Company in respect of any Shares deliverable hereunder unless and until certificates representing such Shares (which may be in book-entry form) will have been issued and recorded on the records of the Company or its transfer agents or registrars and delivered to Participant (including through electronic delivery to a brokerage account). Except as otherwise provided herein, after such issuance, recordation and delivery, Participant will have all the rights of a stockholder of the Company with respect to such Shares, including, without limitation, the right to receipt of dividends and distributions on such Shares.

Section 2.7 Restrictive Covenants. Participant agrees to comply with the restrictive covenants set forth in Sections 7 through 10 in the employment agreement between Participant and a Company Group Member (the "Restrictive Covenants"), which are hereby incorporated by reference, and Participant acknowledges and agrees that the grant of the RSUs shall be in material part in consideration of Participant's reaffirmation of Participant's agreement to comply with the covenants set forth therein. In the event the Participant materially breaches the Restrictive Covenants or any other written covenants between such Participant and any Company Group Member, the Participant shall immediately forfeit any and all RSUs granted under this Agreement (whether or not vested), and Participant's rights in any such RSUs shall lapse and expire.

ARTICLE III.

OTHER PROVISIONS

Section 3.1 Administration. The Administrator shall have the power to interpret the Plan, the Grant Notice and this Agreement and to adopt such rules for the administration, interpretation and application of the Plan, the Grant Notice and this Agreement as are consistent therewith and to interpret,

amend or revoke any such rules. All actions taken and all interpretations and determinations made by the Administrator will be final and binding upon Participant, the Company and all other interested Persons. To the extent allowable pursuant to Applicable Law, no member of the Committee or the Board will be personally liable for any action, determination or interpretation made with respect to the Plan, the Grant Notice or this Agreement.

Section 3.2 RSUs Not Transferable. The RSUs may not be sold, pledged, assigned or transferred in any manner other than by will or the laws of descent and distribution, unless and until the Shares underlying the RSUs have been issued, and all restrictions applicable to such Shares have lapsed. No RSUs or any interest or right therein or part thereof shall be liable for the debts, contracts or engagements of Participant or his or her successors in interest or shall be subject to disposition by transfer, alienation, anticipation, pledge, encumbrance, assignment or any other means whether such disposition be voluntary or involuntary or by operation of law by judgment, levy, attachment, garnishment or any other legal or equitable proceedings (including bankruptcy), and any attempted disposition thereof shall be null and void and of no effect, except to the extent that such disposition is permitted by the preceding sentence. Notwithstanding the foregoing, with the consent of the Administrator, the RSUs may be transferred to Permitted Transferees, pursuant to any such conditions and procedures the Administrator may require.

Section 3.3 Adjustments. The Administrator may accelerate the vesting of all or a portion of the RSUs in such circumstances as it, in its sole discretion, may determine. Participant acknowledges that the RSUs and the Shares subject to the RSUs are subject to adjustment, modification and termination in certain events as provided in this Agreement and the Plan, including Section 12.2 of the Plan.

Section 3.4 Notices. Any notice to be given under the terms of this Agreement to the Company shall be addressed to the Company in care of the Secretary of the Company at the Company's principal office, and any notice to be given to Participant shall be addressed to Participant at Participant's last address reflected on the Company's records. By a notice given pursuant to this Section 3.4, either party may hereafter designate a different address for notices to be given to that party. Any notice shall be deemed duly given when sent via email or when sent by certified mail (return receipt requested) and deposited (with postage prepaid) in a post office or branch post office regularly maintained by the United States Postal Service or similar foreign entity.

Section 3.5 Titles. Titles are provided herein for convenience only and are not to serve as a basis for interpretation or construction of this Agreement.

Section 3.6 Governing Law. The laws of the State of Delaware shall govern the interpretation, validity, administration, enforcement and performance of the terms of this Agreement regardless of the law that might be applied under principles of conflicts of laws.

Section 3.7 Conformity to Securities Laws. Participant acknowledges that the Plan, the Grant Notice and this Agreement, are intended to conform to the extent necessary with all Applicable Laws, including, without limitation, the provisions of the Securities Act and the Exchange Act, and any and all regulations and rules promulgated thereunder by the Securities and Exchange Commission, and state securities laws and regulations. Notwithstanding anything herein to the contrary, the Plan shall be administered, and the RSUs are granted, only in such a manner as to conform to Applicable Law. To the extent permitted by Applicable Law, the Plan, the Grant Notice and this Agreement, shall be deemed amended to the extent necessary to conform to Applicable Law.

Section 3.8 Amendment, Suspension and Termination. To the extent permitted by the Plan, this Agreement may be wholly or partially amended or otherwise modified, suspended or terminated at

any time or from time to time by the Administrator or the Board, *provided* that, except as may otherwise be provided by the Plan, no amendment, modification, suspension or termination of this Agreement shall adversely affect the RSUs in any material way without the prior written consent of Participant.

Section 3.9 Successors and Assigns. The Company may assign any of its rights under this Agreement to single or multiple assignees, and this Agreement shall inure to the benefit of the successors and assigns of the Company. Subject to the restrictions on transfer set forth in Section 3.2 and the Plan, this Agreement shall be binding upon and inure to the benefit of the heirs, legatees, legal representatives, successors and assigns of the parties hereto.

Section 3.10 Limitations Applicable to Section 16 Persons. Notwithstanding any other provision of the Plan or this Agreement, if Participant is subject to Section 16 of the Exchange Act, the Plan, the RSUs, the Grant Notice and this Agreement shall be subject to any additional limitations set forth in any applicable exemptive rule under Section 16 of the Exchange Act (including any amendment to Rule 16b-3 of the Exchange Act) that are requirements for the application of such exemptive rule. To the extent permitted by Applicable Law, this Agreement shall be deemed amended to the extent necessary to conform to such applicable exemptive rule.

Section 3.11 Not a Contract of Employment. Nothing in this Agreement or in the Plan shall confer upon Participant any right to continue to serve as an employee or other service provider of any Company Group Member or shall interfere with or restrict in any way the rights of any Company Group Member, which rights are hereby expressly reserved, to discharge or terminate the services of Participant at any time for any reason whatsoever, with or without cause, except to the extent (i) expressly provided otherwise in a written agreement between a Company Group Member and Participant or (ii) where such provisions are not consistent with applicable foreign or local laws, in which case such applicable foreign or local laws shall control.

Section 3.12 Entire Agreement. The Plan, the Grant Notice and this Agreement (including any exhibit hereto) constitute the entire agreement of the parties and supersede in their entirety all prior undertakings and agreements of the Company and Participant with respect to the subject matter hereof.

Section 3.13 Section 409A. The intent of the parties is that the payments and benefits under this Agreement comply with or be exempt from Section 409A of the Internal Revenue Code of 1986, as amended, and the regulations and guidance promulgated thereunder (collectively, "Section 409A") and, accordingly, to the maximum extent permitted, this Agreement shall be interpreted to be in compliance therewith.

Section 3.14 Agreement Severable. In the event that any provision of the Grant Notice or this Agreement is held invalid or unenforceable, such provision will be severable from, and such invalidity or unenforceability will not be construed to have any effect on, the remaining provisions of the Grant Notice or this Agreement.

Section 3.15 Limitation on Participant's Rights. Participation in the Plan confers no rights or interests other than as herein provided. This Agreement creates only a contractual obligation on the part of the Company as to amounts payable and shall not be construed as creating a trust. Neither the Plan nor any underlying program, in and of itself, has any assets. Participant shall have only the rights of a general unsecured creditor of the Company with respect to amounts credited and benefits payable, if any, with respect to the RSUs.

Section 3.16 Counterparts. The Grant Notice may be executed in one or more counterparts, including by way of any electronic signature, subject to Applicable Law, each of which shall be deemed an original and all of which together shall constitute one instrument.

* * * * *

Aziyo Biologics, Inc.
12510 Prosperity Drive, Suite 370
Silver Spring, MD 20904

March 22, 2023

Mr. Thomas Englese

Re: Termination of Employment

Dear Tom:

This letter agreement (this "Letter Agreement") sets forth the understanding by and between you and Aziyo Biologics, Inc. (collectively with its affiliates, and any successor(s) thereto, the "Company"), regarding the termination of your employment with the Company. Capitalized terms used but not otherwise defined herein shall have the meanings assigned to such terms in that certain Amended and Restated Employment Agreement by and between the Company and you, dated as of December 23, 2022, (the "Employment Agreement").

1. Termination of Employment; Transition Services. Your employment with the Company will terminate on March 24, 2023 (the "Separation Date"), and, effective as of the Separation Date, you shall resign as Chief Commercial Officer of the Company and from all offices and positions you may hold at the Company and its affiliates. This Letter Agreement constitutes notice of termination pursuant to the terms of the Employment Agreement. Notwithstanding the foregoing, you and the Company acknowledge and agree that, during the period beginning on the Separation Date and ending on October 8, 2023 (the "Transition Period"), you shall assist the Company with the orderly transition of your duties to your successor and provide certain advisory services to the Company, including assisting with the completion of the strategic partnerships that are in process as of the Separation Date, advising on strategic decisions impacting the sales organization, including territory alignment and compensation plans, and providing other mentoring services as requested (collectively, the "Transition Services").

2. Severance Benefits. The termination of your employment on the Separation Date will be treated as a termination by the Company without Cause pursuant to the terms of the Employment Agreement. In consideration for and subject to your continued compliance with the Restrictive Covenants (as defined below) in accordance with Section 3 below, your execution and non-revocation of the Release (as defined below) in accordance with Section 4 below and Exhibit A hereto, and your compliance with the terms of this Letter Agreement (including, without limitation, your good faith cooperation with the Company in accordance with Section 6 below), you shall be entitled to receive the following severance payments and benefits (collectively, the "Severance Benefits"), in addition to the Accrued Obligations, following the Separation Date:

a. Cash severance pursuant to Section 4(a)(i) of the Employment Agreement, calculated based on your current base salary of $396,000, payable (less applicable withholdings) in installments in accordance with the Company's current payroll practices during the 12-month period following the Separation Date (provided that any installment that is delayed pursuant to Section 4 shall be paid in a lump-sum

on the first payroll date following the date the Release becomes irrevocable in accordance with its terms);

b. The COBRA benefits set forth in Section 4(a)(ii) of the Employment Agreement, in accordance with the terms of such Section 4(a)(ii), during the 12-month period following the Separation Date;

c. Notwithstanding anything to the contrary in the Employment Agreement, you will remain eligible to receive an Annual Bonus for the Company's 2022 fiscal year following the Separation Date, which Annual Bonus, if any, shall be determined in accordance with Section 2(b)(ii) of the Employment Agreement and shall be payable in cash (less applicable withholdings) on the date as of which annual bonuses for such fiscal year are paid to other executives of the Company (or, if later, the first payroll date following the date the Release becomes irrevocable in accordance with its terms); and

d. Notwithstanding anything to the contrary in the Aziyo Biologics, Inc. 2020 Incentive Award Plan (the "2020 Equity Plan") and the Aziyo Biologics, Inc. 2015 Stock Option/Stock Issuance Plan (the "2015 Equity Plan" and, collectively with the 2020 Equity Plan, the "Equity Plans") and any award agreements thereunder, subject to your continued performance of the Transition Services, as determined by the Board in good faith, as of each applicable vesting date (i) all of the outstanding equity awards that you received under the Equity Plans as of the Separation Date shall remain outstanding following the Separation Date and shall continue to vest on their original vesting dates during the Transition Period, (ii) all of the restricted stock units (the "RSUs") awarded to you pursuant to the 2020 Equity Plan that remain outstanding and unvested as of the last day of the Transition Period shall accelerate and vest in full on the last day of the Transition Period, and shall be settled in shares of the Company's common stock following such date in accordance with the requirements set forth in the applicable award agreement, and (iii) except as provided in Sections 2(d)(i) and (ii) above, any equity awards that are outstanding as of the end of Transition Period shall be automatically forfeited upon the expiration of the Transition Period.

For the avoidance of doubt, other than the Accrued Obligations and the Severance Benefits, you will have no further rights to any payments or benefits in connection with the termination of your employment or the performance of the Transition Services following the Separation Date.

3. Restrictive Covenants. You acknowledge and agree that Sections 7, 8, 9 and 10 of the Employment Agreement (collectively, the "Restrictive Covenants") remain in full force and effect in accordance with their terms following the Separation Date and that no Severance Benefits will be payable following the date that you first violate any of the Restrictive Covenants.

4. Release. The Severance Benefits are contingent upon and subject to your execution and non-revocation of the General Release attached hereto as Exhibit A (the "Release") following the Separation Date in accordance with its terms (and you acknowledge and agree that you will not execute the Release, and the Company will not accept the Release from you, prior to the Separation

Date). No Severance Benefits will be paid or provided prior to the date the Release becomes irrevocable in accordance with its terms and, to the extent you do not execute the Release, or you subsequently revoke the Release during the applicable revocation period, you acknowledge and agree that you are not entitled to any Severance Benefits (provided that, for the avoidance of doubt, such failure to execute the Release or revocation of the Release does not affect the remainder of this Letter Agreement, which shall continue in full force and effect).

5. Return of Property. You agree to promptly deliver to the Company, within ten (10) days following the Separation Date (i) all correspondence, drawings, manuals, letters, notes, notebooks, reports, programs, plans, proposals, financial documents, or any other documents that are or contain proprietary information or trade secrets of or relating to the Company, including all physical and digital copies thereof, and (ii) all other Company property (including, without limitation, any personal computer or wireless device and related accessories, passwords, keys, credit cards and other similar items) which is in your possession, custody or control. The Company will provide you with pre-paid shipping labels for the return of such property.

6. Cooperation. You acknowledge and agree that, in addition to the Transition Services, following the Separation Date, you shall cooperate with and assist the Company, upon the Company's reasonable request, with respect to any ongoing or future internal investigation or administrative, regulatory or judicial proceeding involving matters within the scope of your duties and responsibilities to the Company during your employment with the Company (including, without limitation, being available to the Company upon reasonable notice for interviews and factual investigations and appearing at the Company's reasonable request to give testimony without requiring service of a subpoena or other legal process); provided, however, that any such request by the Company shall not unreasonably interfere with your personal schedule or ability to engage in gainful employment.

7. Section 409A. It is intended that the Severance Benefits, to the greatest extent possible, comply with or satisfy an exemption from the application of Section 409A and shall be interpreted to be consistent therewith. In this regard, Sections 4(c) and 13(f) of the Employment Agreement are hereby incorporated by reference and made a part of this Letter Agreement.

8. Entire Agreement. This Letter Agreement sets forth the entire agreement between you and the Company with respect to the subject matter set forth herein and supersedes and replaces any and all prior oral or written agreements or understandings between you and the Company with respect to the subject matter hereof (including, without limitation, the Employment Agreement); provided, that, for the avoidance of doubt, the provisions of the Employment Agreement which by their terms survive termination of employment will remain in full force and effect in accordance with their terms (as may be amended by this Letter Agreement). This Letter Agreement may be amended only by a subsequent writing signed by both parties. You represent that you have signed this Letter Agreement knowingly and voluntarily.

[signature page follows]

Please indicate your acceptance of the terms and provisions of this Letter Agreement by signing both copies of this Letter Agreement and returning one copy to me. The other copy is for your files. By signing below, you acknowledge and agree that you have carefully read this Letter Agreement and Exhibit A hereto in their entirety; fully understand and agree to their terms and provisions; have received good, valuable and sufficient consideration for your agreement to execute and comply with this Letter Agreement; will comply with the Restrictive Covenants; and intend and agree that this Letter Agreement is final and legally binding on you and the Company. All payments described in this Letter Agreement will be subject to the withholding of any amounts required by federal, state or local law. This Letter Agreement will be governed and construed under the internal laws of the State of Maryland and may be executed in several counterparts.

Very truly yours,

/s/ C. Randal Mills
C. Randal Mills
President & CEO

Agreed, Acknowledged and Accepted as of the first date set forth above:

/s/ Thomas Englese
Thomas Englese

EXHIBIT A

GENERAL RELEASE

For valuable consideration, the receipt and adequacy of which are hereby acknowledged, the undersigned does hereby release and forever discharge the "Releasees" hereunder, consisting of Aziyo Biologics, Inc., (the "Company") and its partners, subsidiaries, associates, affiliates, successors, heirs, assigns, agents, directors, officers, employees, representatives, lawyers, insurers, and all persons acting by, through, under or in concert with them, or any of them, of and from any and all manner of action or actions, cause or causes of action, in law or in equity, suits, debts, liens, contracts, agreements, promises, liability, claims, demands, damages, losses, costs, attorneys' fees or expenses, of any nature whatsoever, known or unknown, fixed or contingent (hereinafter called "Claims"), which the undersigned now has or may hereafter have against the Releasees, or any of them, by reason of any matter, cause, or thing whatsoever from the beginning of time to the date hereof. The Claims released herein include, without limiting the generality of the foregoing, any Claims in any way arising out of, based upon, or related to the employment or termination of employment of the undersigned by the Releasees, or any of them; any alleged breach of any express or implied contract of employment; any alleged torts or other alleged legal restrictions on Releasees' right to terminate the employment of the undersigned; and any alleged violation of any federal, state or local statute or ordinance including, without limitation, Title VII of the Civil Rights Act of 1964, the Age Discrimination In Employment Act, the Americans With Disabilities Act, the Maryland Fair Employment Practices Act, the Health Care Worker Whistleblower Protection Act, the Maryland False Claims Act, the Maryland Parental Leave Act, the Maryland Healthy Working Families Act, the New Jersey Law Against Discrimination, the New Jersey Conscientious Employee Protection Act, the New Jersey Family Leave Act, the New Jersey Security and Financial Empowerment Act, the New Jersey Family Leave Insurance provisions of the New Jersey Temporary Disability Benefits Law, the New Jersey Earned Sick Leave Law, the New Jersey Wage Payment Law, the New Jersey Wage and Hour Law and the New Jersey Works' Compensation Laws. Notwithstanding the foregoing, this general release (the "Release") shall not operate to release any rights or claims of the undersigned (i) to payments or benefits under that certain Letter Agreement dated as of March 22, 2023 by and between the undersigned and the Company, to which this Release is attached as an exhibit, (ii) to payments or benefits under any equity award agreement between the undersigned and the Company, (iii) to reimbursement of expenses pursuant to Section 2(b)(iv) of the Amended and Restated Employment Agreement dated as of December 23, 2022 by and between the undersigned and the Company, (iv) to accrued or vested benefits the undersigned may have, if any, as of the date hereof under any applicable plan, policy, practice, program, contract or agreement with the Company, (v) to any Claims, including claims for indemnification and/or advancement of expenses arising under any indemnification agreement between the undersigned and the Company or under the bylaws, certificate of incorporation or other similar governing document of the Company, (vi) to any Claims which cannot be waived by an employee under applicable law or (vii) with respect to the undersigned's right to communicate directly with, cooperate with, or provide information to, any federal, state or local government regulator.

IN ACCORDANCE WITH THE OLDER WORKERS BENEFIT PROTECTION ACT OF 1990, THE UNDERSIGNED IS HEREBY ADVISED AS FOLLOWS:

(A) THE EXECUTIVE HAS THE RIGHT TO CONSULT WITH AN ATTORNEY BEFORE SIGNING THIS RELEASE;

(B) THE EXECUTIVE HAS FORTY-FIVE (45) DAYS TO CONSIDER THIS RELEASE BEFORE SIGNING IT; AND

(C) THE EXECUTIVE HAS SEVEN (7) DAYS AFTER SIGNING THIS RELEASE TO REVOKE THIS RELEASE, AND THIS RELEASE WILL BECOME EFFECTIVE UPON THE EXPIRATION OF THAT REVOCATION PERIOD.

The undersigned represents and warrants that there has been no assignment or other transfer of any interest in any Claim which the Executive may have against Releasees, or any of them, and the undersigned agrees to indemnify and hold Releasees, and each of them, harmless from any liability, Claims, demands, damages, costs, expenses and attorneys' fees incurred by Releasees, or any of them, as the result of any such assignment or transfer or any rights or Claims under any such assignment or transfer. It is the intention of the parties that this indemnity does not require payment as a condition precedent to recovery by the Releasees against the undersigned under this indemnity.

Notwithstanding anything herein, the undersigned acknowledges and agrees that, pursuant to 18 USC Section 1833(b), the undersigned will not be held criminally or civilly liable under any federal or state trade secret law for the disclosure of a trade secret that is made: (i) in confidence to a federal, state, or local government official, either directly or indirectly, or to an attorney, and solely for the purpose of reporting or investigating a suspected violation of law; or (ii) in a complaint or other document filed in a lawsuit or other proceeding, if such filing is made under seal.

The undersigned agrees that if the Executive hereafter commences any suit arising out of, based upon, or relating to any of the Claims released hereunder or in any manner asserts against Releasees, or any of them, any of the Claims released hereunder, then the undersigned agrees to pay to Releasees, and each of them, in addition to any other damages caused to Releasees thereby, all attorneys' fees incurred by Releasees in defending or otherwise responding to said suit or Claim.

The undersigned further understands and agrees that neither the payment of any sum of money nor the execution of this Release shall constitute or be construed as an admission of any liability whatsoever by the Releasees, or any of them, who have consistently taken the position that they have no liability whatsoever to the undersigned.

The undersigned further understands and agrees that the Executive has forty-five (45) days to consider this Release before accepting and dating this Release, and that the Executive's failure to so accept within this time period will result in the Company's offer to enter into this Release. The Executive also acknowledges that he has received Annex A attached to this Agreement, which sets forth the following information regarding the Executive's decisional business unit: (i) the job titles of the employees in the Executive's decisional business unit, (ii) the age of such employees and (iii) whether such employees have or have not been selected for the group termination and offered a severance payment in connection therewith. The Executive may revoke this Release within seven (7) days after the Executive signs it.

IN WITNESS WHEREOF, the undersigned has executed this Release this _22nd_ day of March, 2023.

/s/ Thomas Englese
Thomas Englese

Annex A

The Older Workers' Benefit Protection Act requires that when a group of employees is asked to sign a release of claims in connection with a group termination program, those individuals 40 years of age and older must be provided with certain information, including the individuals covered by the program; any eligibility factors the Company used to determine who is selected and not selected for termination; the applicable time limits for the program; and the job titles and ages of all individuals selected and not selected for termination. The Company encourages the Executive to discuss this information with his attorney before signing the attached Agreement, which contains a full release and covenant not to sue.This information is set forth below.

Decisional Unit. The decisional unit to which this program applies is Commerical- AM.

Eligibility Factors. In determining who should be retained and who should be selected for layoff, the Company generally considered the following factors: elimination of a business type; adjustment of department focus; realignment of reporting structure; technical knowledge; work quality; production; criticality of skills; versatility/ transferability of skills; judgment; work performance, initiative. Depending upon the specific position, some of the above referenced factors were more important than others and in some instances, not all factors were applicable or considered.

Time Limits: Employees forty (40) and older will have forty-five (45) days to sign and return to the Company the Letter Agreement, which contains the Release. If the Letter Agreement is not returned by the close of business on that date, the Employee will no longer be eligible for the Severance Benefits.

The following is a list by job title and age of all individuals in the Decisional Unit who were selected for the Company's group termination program.

Title	**Age**
Sr. Sales Coordinator	42
Director, Marketing	56
Marketing Manager	37
Area Sales Director	71
Technical Sales Representative	35
Chief Commercial Officer	50
Vice President, Sales	50
Technical Sales Representative	27
Territory Business Manager	50
Territory Business Manager	29
Area Sales Director	50
Territory Business Manager	58
Technical Sales Representative	30

The following is a list by job title and age of all individuals in the Decisional Unit who were not selected for the Company's group termination program:

Title	**Age**
Territory Business Manager	41
Territory Business Manager	35
Territory Business Manager	33
Territory Business Manager	50
Territory Business Manager	48
Area Sales Director	56
Territory Business Manager	42
Territory Business Manager	48
Territory Business Manager	44
Area Sales Director & Director of Education	52
Director, National Accounts	60
Territory Business Manager	73
Director, National Accounts	62
Territory Business Manager	37
Territory Business Manager	56
Territory Business Manager	63
Territory Business Manager	34

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the incorporation by reference in the Registration Statements on Form S-3 (No. 333-267197, 333-262295) and Form S-8 (No. 333-249391) of Aziyo Biologics, Inc. of our report dated March 23, 2023 relating to the financial statements, which appears in this Form 10-K.

/s/ PricewaterhouseCoopers LLP
Baltimore, Maryland
March 23, 2022

Exhibit 31.1

CERTIFICATION PURSUANT TO

RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, C. Randal Mills, certify that:

1. I have reviewed this Annual Report on Form 10-K of Aziyo Biologics, Inc.;

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

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

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

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

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

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

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

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

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

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

Date: March 23, 2023

By: /s/ C. Randal Mills
C. Randal Mills
President and Chief Executive Officer
(principal executive officer)

Exhibit 31.2

CERTIFICATION PURSUANT TO

RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Matthew Ferguson, certify that:

1. I have reviewed this Annual Report on Form 10-K of Aziyo Biologics, Inc.;

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

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

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

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

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

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

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

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

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

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

Date: March 23, 2023

By: /s/ Matthew Ferguson
Matthew Ferguson
Chief Financial Officer
(principal financial officer)

Exhibit 32.1

CERTIFICATION PURSUANT TO

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

In connection with the Annual Report of Aziyo Biologics, Inc. (the "Company") on Form 10-K for the fiscal year ended December 31, 2022 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

1. the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

2. the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: March 23, 2023

By: /s/ C. Randal Mills
C. Randal Mills
President and Chief Executive Officer
(principal executive officer)

The foregoing certification is being furnished solely to accompany the Report pursuant to 18 U.S.C. § 1350, and is not being filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and is not to be incorporated by reference into any filing of the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

Exhibit 32.2

CERTIFICATION PURSUANT TO

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

In connection with the Annual Report of Aziyo Biologics, Inc. (the "Company") on Form 10-K for the fiscal year ended December 31, 2022 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

1. the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

2. the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: March 23, 2023

By: /s/ Matthew Ferguson
Matthew Ferguson
Chief Financial Officer
(principal financial officer)

The foregoing certification is being furnished solely to accompany the Report pursuant to 18 U.S.C. § 1350, and is not being filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and is not to be incorporated by reference into any filing of the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing.