AZIYO®
BIOLOGICS

Annual Report
Fiscal Year 2021

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, 2021
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 Global 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, 2021, the last business day of the registrant's most recently completed second fiscal quarter, was approximately $28,649,130 based on the closing price of $9.61 of the registrant's Class A common stock as reported on the Nasdaq Global 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 4, 2022, there were 9,245,146 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 2022 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, 2021, 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 statements regarding our results of operations, financial position, projected growth in total net sales, 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 forgiveness of all or a portion of our loan pursuant to the CARES Act 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, in some cases, you can identify forward-looking statements by terms such as "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, although not all forward-looking statements contain these words. No forward-looking statement is a guarantee of future results, performance, or achievements, and one should avoid placing undue reliance on such statements.

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 assumptions, and actual results may differ materially from those expressed or implied in the forward-looking statements 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. These risks and uncertainties include, but are not limited to:

- our ability to enhance our products, expand our product indications and develop, acquire and commercialize additional product offerings;
- our dependence on our commercial partners and independent sales agents to generate a substantial portion of our net sales;
- our ability to maintain our relationships with our existing contract manufacturing customers and enter into agreements with new contract manufacturing customers, or if existing contract manufacturing customers reduce purchases of our products;
- our ability to successfully expand, manage and maintain our direct sales force;
- our ability to achieve or sustain profitability;
- the adverse impacts of the novel strain of coronavirus disease, COVID-19, or any other future pandemic, epidemic or outbreak of an infectious disease in the United States or worldwide;
- adverse changes in general domestic and global economic conditions and instability and disruption of credit markets, including as a result of the current COVID-19 pandemic or any other outbreak of an infectious disease;

- physician awareness of the distinctive characteristics, benefits, safety, clinical efficacy and cost-effectiveness of our products;

- the continued and future acceptance of our products by the medical community;

- our ability to obtain regulatory approval or other marketing authorizations by the U.S. Food and Drug Administration (the "FDA") and comparable foreign authorities for our products and product candidates;

- our ability to defend against the various lawsuits related to our recall of a single lot of FiberCel and avoid a material adverse financial consequence; and

- our ability to obtain, maintain and adequately protect our intellectual property rights.

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 IA "Risk Factors." These and other factors could cause our future performance to differ materially from our assumptions and estimates.

RISK FACTOR 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:

- our long-term growth depends on our ability to enhance our products, expand our product indications and develop, acquire and commercialize additional product offerings;
- 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 and 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 plan to expand our direct sales force coinciding with new product launches, and if we are unable to successfully expand, manage and maintain our direct sales force, we may not be able to generate greater market share and revenue growth;
- we have incurred operating losses since our inception, expect to continue to incur significant expenses and operating losses in the future, and may not be able to achieve or sustain profitability;
- 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 business has been, and may continue to be, adversely affected by the outbreak of the novel strain of coronavirus disease, COVID-19, and may be adversely affected by any future pandemic, epidemic or outbreak of an infectious disease in the United States or worldwide;
- adverse changes in general domestic and global economic conditions and instability and disruption of credit markets, including as a result of the current COVID-19 pandemic or any other outbreak of an infectious disease, could adversely affect our business, financial condition, results of operations and liquidity;
- 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 raw materials 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;

- 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; 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, concentrating on patients receiving implantable medical devices. From our proprietary tissue processing platforms, we have developed a portfolio of advanced regenerative medical products that are designed to be very similar to natural biological material. Our proprietary products, which we refer to as our Core Products, are designed to address the implantable electronic device/cardiovascular, orthopedic/spinal repair and soft tissue reconstruction markets, which represented a combined $3 billion market opportunity in the United States in 2020. To expand our commercial reach, we have commercial relationships with major medical device companies, such as Boston Scientific and Biotronik, to promote and sell some of our Core Products. We believe our focus on our unique regenerative medicine platforms and our Core Products 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 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 other complications that can be triggered by a device implant.

Our Core 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 scar-tissue formation, capsular contraction, erosion, migration, non-union of implants and implant rejection. We believe that we have developed the only biological envelope, which is covered by a number of patents, that forms a natural, systemically vascularized pocket for holding implanted electronic devices. We have a proprietary processing technology for manufacturing bone regenerative products for use in orthopedic/spinal repair that preserves a cell's ability to regenerate bone and decelerates cell apoptosis, or programmed cell death. We have a patented cell removal technology that produces undamaged extracellular matrices for use in soft tissue reconstruction. In pre-clinical and clinical studies, our products have supported and, in some cases,

accelerated tissue healing, and thereby improved patient outcomes. Our Core and Non-Core product portfolio is highlighted in the table below.

Market		Product Brands	Description	Go-To-Market Strategy
CORE PRODUCTS	**Implantable Electronic Devices and Cardiovascular**	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
		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
	Orthopedic and Spinal Repair	FiberCel ViBone OsteGro V	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
	Soft Tissue Reconstruction	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	Direct and independent sales agents
NON-CORE PRODUCTS	**Contract Manufacturing**	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

Our growth strategy is focused on increasing penetration in our target markets. We believe we can expand our commercial penetration in these markets and thereby grow our business by increasing our direct sales force and developing and launching more clinically relevant products from our pipeline and, when possible and appropriate, from acquisitions.

Our go-to-market strategy includes a hybrid of a direct sales force, commercial partners and independent sales agents. As of December 31, 2021, we had 31 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 target markets.

We have a well-established and scalable manufacturing platform, consisting of two facilities that are supported by our corporate headquarters. 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 our implantable electronic device/cardiovascular products. Our Richmond, California location is our human tissue products facility. We believe we have sufficient operating capacity at both our Roswell and Richmond facilities to support future growth.

Net sales from our Core Products grew from $36.2 million for the year ended December 31, 2020 to $37.6 million for the year ended December 31, 2021, representing an annual growth rate of 4%. Our total net sales increased from $42.7 million for the year ended December 31, 2020 to $47.4 million for the year ended December 31, 2021, representing annual growth of 11%. Our gross margins declined from 48% in the year ended December 31, 2020 to 40% in the year ended December 31, 2021. Our gross margins, excluding intangible asset amortization, decreased from 56% in the year ended December 31, 2020 to 47% in the year ended December 31, 2021. We incurred a net loss of $21.8 million for the year ended December 31, 2020 and $24.8 million for the year ended December 31, 2021.

Gross margin, excluding intangible asset amortization, is a non-GAAP financial measure. See "Non-GAAP Financial Measures" under Part II, Item 7. "Management's Discussion and Analysis of Financial Condition and Results of Operations" for a discussion regarding our use of gross margin, excluding intangible asset amortization, including its limitations and a reconciliation to the most directly comparable GAAP financial measure.

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 Core 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:

Well-positioned in Large, Attractive and Growing Markets. We believe that the implantable electronic devices/cardiovascular, the orthopedic/spinal repair and the soft tissue reconstruction markets, which represented a combined $3 billion market opportunity in the United States in 2020, will continue to experience accelerated growth, given advancements in implantable medical device technologies to treat more medical conditions and shifting global demographics that include an aging population; a greater incidence of comorbidities, such as diabetes, obesity and cardiovascular and peripheral vascular diseases; and increasing numbers of mastectomies and lumpectomies. 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 reduced inflammation, scar-tissue formation and foreign body response.

Regenerative Medicine Technology Focus. Our scientific expertise and know-how in regenerative medicine technology has allowed us to develop our proprietary platforms to create differentiated biomaterials, including our Core Products: CanGaroo, ProxiCor, Tyke, VasCure, Fiber VBM, ViBone, OsteGro V and SimpliDerm. These types of products, which are designed to more closely resemble natural products than similar traditionally processed products, 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 Core 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 implantable electronic devices/cardiovascular, orthopedic/spinal repair and soft tissue reconstructive procedures, 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 using the full complement of our products.

Large and Growing Body of Clinical Data and FDA Cleared Products. We have significant regulatory experience in obtaining FDA clearance for regenerative medicine products requiring 510(k) clearance and in navigating the comprehensive regulatory framework that applies to human cells, tissues and cellular and tissue-based products, or HCT/Ps. We have and continue to develop a body of pre-clinical, clinical and patient outcomes data, including third-party publications that reviewed the technical and clinical attributes of our products. We believe that our extensive in vivo and clinical data give us a competitive advantage.

Relationships with Care Providers. Our medical and commercial teams have established extensive customer relationships in the healthcare industry. We have developed excellent relationships with physicians, nurses and hospital administrators. We believe we are well-positioned to leverage these relationships to increase our penetration in our target markets.

Commercial Relationships with Major Medical Device Companies. We have commercial agreements with major medical device companies, including Boston Scientific, Biotronik, Surgalign Holdings and others, which we collectively refer to as our commercial partners, to promote or commercialize some of our products. Our 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. 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 three commercial Core Products in the past three years. In addition to our current core commercial products, we have a pipeline of products being developed for the implantable electronic devices/cardiovascular

market, the orthopedic/spinal repair market and the soft tissue reconstruction market that we expect to launch in the future. 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.

Expanding the Reach of Our Direct Sales Force. As of December 31, 2021, we had 31 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. Our sales team provides the critical knowledge of the advantages that our biological products provide for patients over those of our competitors. We plan to grow our sales organization in order to launch new products, expand our network of hospital and physician customers, drive deeper penetration in current accounts and provide additional technical assistance to our commercial partners. We believe there is a significant opportunity to grow our business through this continued expansion of our commercial footprint.

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 Core Products/Solutions

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

Implantable Electronic Devices/Cardiovascular Market

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, 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

Implantable electronic devices are now the standard of care for patients suffering from cardiac arrhythmias and heart failure. Such devices 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% mean 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, 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, is not associated with the 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 CanGaroo that combines the envelope with antibiotics and is designed to reduce the risk of infection following surgical implantation of an electronic device. As a first step, we recently completed a feasibility study that demonstrated the targeted release of antibiotics for CanGaroo. Based on feedback from the FDA, we believe that this product candidate will require clearance of a 510(k) submission to be marketed in the United States. In 2021, we completed both the product design and manufacturing validation for the CanGaroo with antibiotics. We anticipate submitting the required 510(k) by the end of the first quarter of 2022.

Commercial Approach

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 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.

Additional 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 extra cellular 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.

Orthopedic/Spinal Repair 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 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 grafting material to cause two vertebrae to grow together into one. 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 such comorbidities as diabetes and obesity.

The addition of a bone material to sites of fixation for repair 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 morbidity 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 results in less cells, prevents 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.

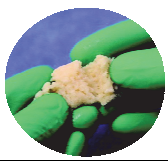
Our Solution

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 (three-dimensional scaffold appropriate for bone formation). These products, which have handling properties that support their placement by the surgeon and their integration with the patient's bone, are intended for use in patients mainly receiving orthopedic and spinal implants to enhance the bone repair process and include Fiber VBM, ViBone and OsteGro V, all of which are viable, cellular bone matrices.

Fiber VBM is a fiber-based bone repair product made from human tissue and engineered to be like natural tissue. It 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. Fiber VBM provides handling properties that are critical for use as a bone void filler in various orthopedic and spinal procedures. Fiber VBM contains cancellous bone particles with preserved living cells and demineralized cortical bone fibers to facilitate bone repair and healing.

ViBone is a particle-based bone repair product designed to perform and handle in a manner similar to an autograft and is marketed for use as allograft bone. ViBone contains cancellous and demineralized cortical bone particles.

OsteGro V, our newest product, leverages our proprietary process designed to protect and preserve native bone cells. OsteGro V is marketed for use for the repair, replacement or reconstruction of bone defects and contains cancellous bone particles as well as demineralized cortical bone particles and fibers designed to enhance product handling.

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 products that offer features that we believe are either an improvement to currently available technologies or offer new features or enhancements, such as improved delivery or handling properties. These products are currently in development, and we expect these products to 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 an agreement with Surgalign Holdings for the sale of ViBone and ViBone Moldable and have agreements in place with many other commercial partners for the sale of Fiber VBM and OsteGro V, or such private label offering of each. 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.

Soft Tissue Reconstruction 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, which is one of the most common applications of biologic matrices.

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. Active infections are also typically a contraindication to using a synthetic graft.

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 that which occurs naturally.

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

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 2019, there were more than 100,000 post-mastectomy breast reconstructions, of which approximately 68% 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, following a mastectomy, 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 2019, plastic surgeons used HADMs in approximately 66,000 women (approximately 109,000 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 12, 2021, 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.

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 is a key enabler for these prepectoral procedures, the sizes of ADMs required for these procedures 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. Our goal is to develop SimpliDerm for these prepectoral procedures in larger size pieces with possibly reduced production costs. Given the market potential and if required by the FDA, 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.

Our Non-Core Products: Contract Manufacturing

We fulfill tissue processing contracts through our contract manufacturing services at our Richmond, California facility in order to utilize as much as possible of the starting 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. 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 and have multiple customers for most of our products. For the year ended December 31, 2021, our net sales from contract manufacturing was approximately $9.8 million, representing approximately 21% of our total net sales.

Clinical Data

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

Implantable Electronic Device

Pre-clinical Studies

In a pre-clinical rabbit model, the CanGaroo Envelope was more successful in providing a barrier surrounding a cardiovascular implantable electronic device ("CIED") compared to a pacemaker canister alone. Substantial tissue ingrowth was observed in the CanGaroo Envelopes, which were observed to promote stabilization of the device when compared to implantation with only standard fixation methods, such as sutures through the CIED header or no fixation at all.

Clinical Studies

To evaluate our CanGaroo Envelope, we have conducted three post-market studies involving 1,577 patients. We are also conducting a retrospective study of approximately 100 patients and an additional 500-patient retrospective registry study.

SECURE Study

The SECURE Study was a prospective, single arm, observational, post-market study assessing patients who underwent the implantation of a CIED in a CanGaroo Envelope. The endpoints of the study were to determine: (a) the proportion of patients with CanGaroo-related adverse events and (b) the incidence of major infections observed in the pocket. A total of 1,026 patients were enrolled at 39 centers. The mean number of risk factors for CIED complications was 2.2 and the most common risk factors included congestive heart failure, obesity, device replacement/revision, diabetes and use of an oral systemic anticoagulant. There were 16 patients categorized as having had possible (n=14, 1.4%) and probable (n=2, 0.2%) CanGaroo-related events. Fourteen (1.4%) were in the former and two (0.2%) were in the latter category. The specific treatment-related adverse events included the following: one fever (0.1%); five hematomas (0.5%); one implantable cardiac device pocket erosion (0.1%); one pain (0.1%); four major pocket infections (0.4%); one superficial cellulitis (0.1%); and three superficial CIED infections (0.3%). In the total study population, twelve (1.2%) patients developed a major pocket infection. Even though migration was not an endpoint in the study, no such events were reported.

A total of 231 patients received CanGaroo Envelopes hydrated in an antibiotic solution containing gentamicin. The hydration solution was not recorded for nine patients enrolled in the study. The remaining 786 patients received a CanGaroo Envelope hydrated in saline alone or with another antibiotic. A post-hoc, subgroup analysis of the SECURE Study data prepared for the 2020 Heart Rhythm Society scientific sessions showed that after a mean follow-up time of 267 ± 180 days, the pocket infection rate was 0% in subjects with envelopes hydrated in a solution containing gentamicin (n = 73) and 0.6% in the subset of patients who received envelopes hydrated only with saline (n = 160).

We believe these results provide evidence supporting the safety of the CanGaroo Envelope when used for the implantation of CIEDs in humans.

CARE Study

The CARE Study was a retrospective, consecutive case series, 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 over a three-month follow-up period of time. All envelopes were hydrated using sterile saline prior to implantation. The most common risk factors among enrolled patients included systemic anticoagulants, obesity, diabetes, congestive heart failure and renal insufficiency.

After a mean follow-up time of 98 ± 64 days, five patients (5.2%) developed a hematoma requiring intervention, and one patient (1.1%) developed a pocket infection. None of these events were deemed to be related to the CanGaroo Envelope.

The low rates of CanGaroo Envelope complications observed in the CARE Study support the safety of the product when used in a human CIED implantation.

CARE Plus Study

The CARE Plus Study was a single-center, post-market, retrospective cohort study of the outcomes in patients who received a CanGaroo Envelope, Medtronic's synthetic TYRX envelope or no envelope during their CIED implantation. Planned assessments will evaluate adverse patient outcomes and any adverse events that occurred following implantation.

An interim analysis was published as an abstract in Circulation and presented at the American Heart Association (AHA) 2021 Conference which compared the patient risk profiles and outcomes of 248 patients from the CARE Plus study who received either no envelope (n=57), a CanGaroo (biologic) Envelope (n=89) hydrated in antibiotics, or a TYRX (non-biologic) Envelope (n=102) during their CIED implantation procedure as of a cutoff date of December 31, 2020. As of the cutoff date, patients who received antibacterial envelopes (biologic or non-biologic) were younger ($p=0.017$), received higher power devices more often (37.2% vs. 15.8%, $p=0.004$), were undergoing more reoperative procedures (47.1% vs. 0.0%, $p<0.001$), and had more infection risk factors (81.2% vs. 49.1%, $p<0.001$) than patients who received no envelope with their CIED procedure. Biologic envelopes tended to be used at a greater frequency in higher infection risk patients (84.3% vs. 78.4%) and more reoperative procedures (62.2% vs. 37.8%) than non-biologic envelopes. Total CIED implant site infection rates were low (0.4%, in accordance with the WRAP-IT study reported rate of 0.7%) with no difference between the higher infection risk envelope group and lower infection risk no envelope group (envelope 0.5% vs. no envelope 0%, $p=0.584$). There was also no discernable difference in infection rates between biologic and non-biologic antibacterial envelopes. No significant difference between the envelope and no envelope groups were seen in hematomas ($p=0.176$), or the incidence of other adverse events such as lead dislodgement/revision, pocket revision, device migration or erosion, Twiddler's Syndrome, erythema/fever, or site drainage ($p=0.722$).

HEAL Study

The HEAL Study is an ongoing retrospective cohort study of approximately 100 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, including those used with a CanGaroo Envelope. We enrolled our first patient in this study in February 2021. Patients evaluated in the study will be from one of three cohorts based on whether a CanGaroo Envelope, Medtronic's synthetic 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 by using photographs.

CanGaroo Registry Study

The CanGaroo Registry Study is a prospective, multi-center registry of up to 500 participants. The objective is to explore the participant clinical profiles, procedural details, and post-implant outcomes of participants who receive the CanGaroo Envelope or no envelope at time of initial (*de novo*) implantation. We enrolled our first patient in this study in June 2021 and have enrolled approximately 250 patients as of February 25, 2022. Patients aged 65 years or younger at time of enrollment have the option to participate in an extended follow-up period for up to five years.

Orthopedic/Spinal Repair

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, ViBone exhibited 58% less apoptosis and had a 2.1-fold greater cell proliferation capability as compared to allografts processed by traditional methods. The cells from ViBone produced increased levels of the bone forming protein markers osteocalcin (20%), osteopontin (50%) and collagen type 1 (40%), when incubated in osteogenic cell culture media, compared to traditionally processed allografts, suggesting greater osteogenic potential. ViBone was tested for osteoinductive properties and was observed to have 9.1-fold higher levels of bone morphogenic protein 2 and 3.8-fold higher levels of bone morphogenic protein 7 than traditionally processed allografts. Additional growth factor testing for ViBone demonstrated higher amounts of transforming growth factor beta 1 (10.8-fold); insulin-like growth factor 1 (9.5-fold); and basic fibroblast growth factor (4.1-fold). 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 ViBone was 6.1-fold greater than traditionally processed allografts. Also, there was a 1.9-fold increase in chemotaxis, or stem cell migration, toward ViBone as compared to traditionally processed allografts, supporting ViBone's enhanced osteoinductive properties. In order to evaluate the osteoinductivity in vivo, ViBone was implanted in athymic rats. At 28 days, new bone formation was observed.

Clinical Studies

A prospective, multi-center, post-market clinical study was conducted to evaluate outcomes in patients undergoing cervical or lumbar interbody fusion surgery using ViBone. One hundred eighteen patients were enrolled in the cervical and lumbar groups and followed for 12 months post-procedure.

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. Histological slides of SimpliDerm and native dermal matrix were prepared for microscopic examination, using hematoxylin and eosin ("H&E"), Verhoff-Van Gieson ("VVG"), and collagen type IV 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

Currently, we are collecting clinical data in an Investigational Review Board ("IRB") approved, retrospective, multi-center study evaluating patients who have undergone breast reconstruction post-mastectomy with SimpliDerm and patients receiving other HADMs. These data will inform us as to the design of future clinical feasibility and pivotal studies to support potential regulatory applications for a breast reconstruction indication for SimpliDerm.

An interim analysis of 59 patients (108 breasts) was published which reported initial 30-day follow up data on patients who received either SimpliDerm or AlloDerm RTU acellular dermal matrices (ADMs) during their immediate 2-stage breast reconstruction following mastectomy as of October 31, 2020. Reconstructions were primarily prepectoral (95.4%), used tissue expanders (100%), and followed a skin sparing approach to mastectomy (64%). Procedural technique and postprocedural follow up did not differ between groups. There were no significant differences between ADM groups in patient demographics, medical history, operative procedure, or clinical outcomes. The collective adverse event rate (22%) aligned with previous ADM literature, did not differ between the groups in this dataset, and none of the AEs in this dataset were considered serious. The interim results from this study suggested comparable initial clinical outcomes with SimpliDerm and AlloDerm RTU after immediate 2-stage breast reconstruction.

A subsequent analysis was performed of patients from four sites as of July 2021 who underwent immediate, 2-stage reconstruction with either SimpliDerm (n=38) or AlloDerm RTU (n=69) after mastectomy and were followed out to exchange to permanent implant(s), tissue expander(s) explant, or death. Immediate breast reconstruction with tissue expanders and ADM was performed on 107 patients (181 breasts). Overall mean patient age was 51.4 ± 12.4 years, and mean Body Mass Index was 28.0 ± 5.8 kg/m2. Significantly more patients in the SimpliDerm group were of Hispanic or Latino ethnicity (34.2% vs. 7.2%; P<.001). Reconstructions were predominantly prepectoral (82.3%). A total of 35 adverse events (AEs) occurred in 27 (25.2%) patients, with no difference in AE type, classification, or rates between ADM groups. No AEs were considered related to either ADM. The observed AE profiles and rates are similar to those published for other ADMs in immediate breast reconstruction. These results demonstrate comparable clinical outcomes with SimpliDerm and AlloDerm RTU through a median of 133.5 days (~four months) following immediate 2-stage breast reconstruction.

Competition

We operate in highly competitive markets that are subject to rapid technological change. Success in these markets depends primarily 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 Core 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 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 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 an agreement with Surgalign Holdings for the sale of ViBone and ViBone Moldable and have agreements in place with many other commercial partners for the sale of Fiber VBM and OsteGro V, or such private label offering of each. 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 soft tissue reconstruction product, is sold using independent sales agents. As of December 31, 2021, we had 31 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, Kuwait, Mexico and Saudi Arabia sell our products. Sales generated in the United States represented greater than 95% of our net sales in 2021.

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 with regenerative medicine graduate programs. 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 orthopedic/spinal repair 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 donated human tissue and porcine 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, 2021, we owned

approximately 15 U.S. patents, six U.S. patent applications, three foreign patents (in Australia, Europe, and Hong Kong), and four foreign patent applications (in Thailand and India, as well as applications with the World Intellectual Property Organization); and we in-licensed four U.S. patents, five foreign patents (in Australia, Canada, Japan, and Europe), and two U.S. and two foreign patent applications (in China, as well as an application with the European Patent Office). Our owned patent portfolio includes 14 U.S. patents and three 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 adjustment or 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 IA. “Risk Factors - Risks Related to Intellectual Property.”

As of December 31, 2021, 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 IA. “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 2021, 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 responsible 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.

Over the last several years, the FDA has proposed reforms to its 510(k) clearance process, and such proposals could include increased requirements for clinical data and a longer review period, or could make it more difficult for manufacturers to utilize the 510(k) clearance process for their products. For example, in November 2018, FDA officials announced steps that the FDA intended to take to modernize the premarket notification pathway under Section 510(k) of the FDCA. Among other things, the FDA announced that it planned to develop proposals to drive manufacturers utilizing the 510(k) pathway toward the use of newer predicates. These proposals included plans to potentially sunset certain older devices that were used as predicates under the 510(k) clearance pathway, and to potentially publish a list of devices that have been cleared on the basis of demonstrated substantial equivalence to predicate devices that are more than 10 years old. These proposals have not yet been finalized or adopted, and the FDA may work with Congress to implement such proposals through legislation.

More recently, in September 2019, the FDA issued revised 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 continues to develop and maintain a list of device types appropriate for the "safety and performance based" pathway and to develop product-specific guidance documents that identify the performance criteria and recommended testing methods for each such device type.

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, though we may decide to seek a PMA for our SimpliDerm product for use in breast reconstruction indications.

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/or 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

Prior to April 2017, the European Union ("EU") required that all medical devices placed on the market in the EU must meet the relevant requirements laid out in Directive 93/42/EEC ("the Medical Devices Directive") and/or Directive 90/385/EEC ("the Active Implantable Medical Devices Directive") (collectively the "Directives"). In April 2017, the European Parliament passed the Medical Devices Regulation (Regulation 2017/745), which repealed and replaced the aforementioned EU Directives. The Medical Devices Regulation, among other things, is intended to establish a uniform, transparent, predictable and sustainable regulatory framework across the EU for medical devices and ensure a high level of safety and health while supporting innovation. The Medical Devices Regulation entered into application on May 26, 2021.

Medical devices that were CE marked under the Directives prior to May 26, 2021 may continue to be placed on the EU market until their certifications expire or on May 26, 2024, whichever occurs first. 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. However, as of May 26, 2021, some of the Medical Devices Regulation requirements apply in place of the corresponding requirements of the Medical Devices Directive, including 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 require that our devices be certified under the new regime set forth in the 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 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 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 manufacturers' 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 Medical Devices Regulation was adopted with the aim of ensuring better protection of public health and patient safety. The 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 Medical Devices Regulation is directly applicable in EU member states without the need for member states to implement into national law. This aims at increasing harmonization across the EU.

The Medical Devices Regulation became effective on May 26, 2021. The new Regulation among other things:

- strengthens the rules on placing devices on the market (e.g. reclassification of certain devices and wider scope than the Medical Devices Directive) and reinforces surveillance once they are available;
- establishes explicit provisions on manufacturers' responsibilities for the follow-up of the quality, performance and safety of devices placed on the market;
- establishes explicit provisions on importers' and distributors' obligations and responsibilities;
- imposes an obligation to identify a responsible person who is ultimately responsible for all aspects of compliance with the requirements of the new regulation;
- improves the traceability of medical devices throughout the supply chain to the end-user or patient through the introduction of a unique identification number, to increase the ability of manufacturers and regulatory authorities to trace specific devices through the supply chain and to facilitate the prompt and efficient recall of medical devices that have been found to present a safety risk;
- sets up a central database (Eudamed) to provide patients, healthcare professionals and the public with comprehensive information on products available in the EU; and
- strengthens rules for the assessment of certain high-risk devices, such as implants, which may have to undergo a clinical evaluation consultation procedure by experts before they are placed on the market.

The 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 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 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 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 Medical Devices Directive continue to apply. A serious incident is defined as any malfunction or deterioration in the characteristics or performance of a device made available on the market, including use-error due to ergonomic features, as well as any inadequacy in the information supplied by the manufacturer and any undesirable side-effect, which, directly or indirectly, might have led or might lead to the death of a patient or user or of other persons or to a temporary or permanent serious deterioration of a patient's, user's or other person's state of health or a serious public health threat. Manufacturers are required to take FSCAs 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. 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 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.

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

Following a national referendum and enactment of legislation by the government of the United Kingdom (the "UK"), the UK formally withdrew from the European Union on January 31, 2020, commonly referred to as "Brexit," and, following the expiry of the Brexit transitional period on December 31, 2020, the UK now operates under a distinct regulatory regime and certain European Union laws now only apply to the UK in respect of Northern Ireland (as laid out in the Protocol on Ireland and Northern Ireland). The Medicines and Healthcare products Regulatory Agency ("MHRA"), is now the UK's standalone regulator. Although the UK and European Union 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 European Union in this regard.

European Union 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, new

legislation such as Medical Devices Regulation (Regulation 2017/745) will not be 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 European Union and the UK. CE marks issued by EU-based Notified Bodies will continue to be recognized by the UK until June 30, 2023, but from July 1, 2023, new devices placed on the Great Britain market will need to conform with the new UK Conformity Assessment (UKCA) marking requirements. Since January 1, 2021, medical devices placed on the market in the UK must be registered with the MHRA, following a grace period ranging from four to 12 months. 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 Protocol on Ireland and Northern Ireland, products placed on the market in Northern Ireland will continue to be subject to the European Union regulatory regime. A public consultation by the UK Medicines and Healthcare products Regulatory Agency ("MHRA") was opened until end of November 2021 on the post-Brexit regulatory framework for medical devices and diagnostics. The consultation proposes amendments to the UK Medical Devices Regulations 2002 (which are based on EU legislation, primarily the 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. The regime is expected to come into force in July 2023, coinciding with the end of the acceptance period for EU CE marks in Great Britain, subject to appropriate transitional arrangements. The consultation indicated that the MHRA will publish guidance in relation to the changes to the regulatory framework and may rely more heavily on guidance to add flexibility to the regime.

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

Compliance with complex foreign and United States laws and regulations that apply to our international operations increases our cost of doing business in international jurisdictions and could expose us or our employees to fines and penalties in the United States and abroad. These numerous and sometimes conflicting laws and regulations include the United States Foreign Corrupt Practices Act of 1977 (the "FCPA"). The FCPA prohibits United States companies, companies whose securities are listed for trading in the United States and other entities, and their officers, directors, employees, shareholders acting on their behalf and agents from offering, promising, authorizing or making payments to foreign officials for the purpose of influencing official decisions or obtaining or retaining business abroad or other benefits or otherwise obtaining favorable treatment. The FCPA also requires companies to maintain records that fairly and accurately reflect transactions and maintain a system of internal accounting controls sufficient to assure management's control, authority and responsibility over our assets. In many countries, hospitals are government-owned and healthcare professionals employed by such hospitals, with whom we regularly interact, may meet the definition of a foreign official for purposes of the FCPA. Additionally, recently enacted U.S. legislation increases the monetary reward available to whistleblowers who report violations of federal securities laws, including the FCPA, which may result in increased scrutiny and allegations of violations of these laws and regulations. We maintain and update our policies and procedures and internal controls designed to provide reasonable assurance that we, our employees, partners and other intermediaries comply with the anti-corruption laws to which we are subject. However, there can be no assurance that such policies or procedures or internal controls will work effectively at all times or protect us against liability under these or other laws for actions taken by our employees, partners or other intermediaries with respect to our business. Violations of these laws and regulations could result in fines, criminal sanctions against us, our officers, or our employees, prohibitions on the conduct of our business, financial condition, results of operations, cash flows and damage to our reputation. In addition, investigations of any potential, actual or alleged violations of such laws or policies related to us, including any such investigation by U.S. or non-U.S. authorities, could harm our business.

Laws and Regulations Governing Data Privacy and Security

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 state data breach notification laws, state health information privacy laws, and federal and state consumer protection laws and regulations (e.g., Section 5 of the FTC Act), 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. We may also be subject to U.S. federal rules, regulations and guidance concerning data security for medical devices, including guidance from the FDA. State laws may be more stringent, broader in scope or offer greater individual rights with respect to protected health information ("PHI") than HIPAA, and state laws may differ from each other, which may complicate compliance efforts. Entities that are found to be in violation of HIPAA, as the result of a breach of unsecured PHI, a complaint about privacy practices, or an audit by HHS, may be subject to significant civil, criminal, and administrative fines and penalties and/or additional reporting and oversight obligations if required to enter into a resolution agreement and corrective action plan with HHS to settle allegations of HIPAA non-compliance.

California recently enacted the California Consumer Privacy Act (the "CCPA"), which creates new individual privacy rights for California consumers, as defined in the law, and places increased privacy and security obligations on entities handling certain personal information of consumers or households. The CCPA requires covered companies to provide new disclosures to consumers about such companies' data collection, use and sharing practices, provide such consumers new ways to opt-out of certain sales or transfers of personal information, and provide consumers with additional causes of action. The CCPA went into effect on January 1, 2020, and as of July 1, 2020, the California Attorney General may bring enforcement actions for violations. Although there are limited exemptions for certain health-related information, including certain clinical study data, as currently written, the CCPA may impact our business activities and exemplifies the vulnerability of our business to the evolving regulatory environment related to health-related and other personal information. Additionally, a new California ballot initiative, the California Privacy Rights Act, was voted into law by

California residents in November 2020. It imposes additional data protection obligations on companies doing business in California, including additional consumer rights processes and opt outs for certain uses of sensitive data. It also creates a new California data protection agency specifically tasked to enforce the law, which will likely result in increased regulatory scrutiny of California businesses in the areas of data protection and security. Similar laws have been proposed in other states and at the federal level, and if passed, such laws may have potentially conflicting requirements that would make compliance challenging.

EU member states, Switzerland, and other countries have also adopted data protection laws and regulations, which impose significant compliance obligations. For instance, the collection and use of personal health data in the EEA is governed by the provisions of the General Data Protection Regulation (the "GDPR"). The GDPR became effective on May 25, 2018, repealing its predecessor directive and increasing responsibility and liability of medical device companies in relation to the processing of personal data of individuals within the EEA. The GDPR imposes strict obligations and restrictions on the ability to collect, analyze, and transfer personal data, including health data from clinical studies and adverse event reporting. In particular, these obligations and restrictions concern the consent of the individuals to whom the personal data relates, the information provided to the individuals, the transfer of personal data out of the EEA, security breach notifications, security and confidentiality of the personal data, and the imposition of substantial potential fines for breaches of the data protection obligations. Data protection authorities from the different EU and EEA member states may interpret the GDPR and national laws differently and impose additional requirements, which add to the complexity of processing personal data in the EU and the EEA Guidance on implementation and compliance practices are often updated or otherwise. The United Kingdom has mirrored the GDPR in domestic law with the amended Data Protection Act 2018 (the "UK GDPR"). On June 28, 2021, the European Commission adopted an adequacy decision for the UK that will enable data transfers from European Union member states to the UK for a four-year period, subject to subsequent extensions. Compliance with these and any other applicable privacy and data security laws and regulations is a rigorous and time-intensive process, and we may be required to put in place additional mechanisms ensuring compliance with the new data protection rules. If we fail to comply with any such laws or regulations, we may face significant fines and penalties that could adversely affect our business, financial condition and results of operations.

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 of 2% per fiscal year and reduced payments to several types of Medicare providers. The Coronavirus Aid, Relief and Economic Stability Act (the "CARES Act"), which was signed into law on March 27, 2020, and subsequent legislative amendments suspended the reductions from May 1, 2020, through March 31, 2022, and extended the sequester through 2030. 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, 2021, we had 176 employees, 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, 2021, 43% of our workforce and 31% of our leadership (at the director level and above) were female. In addition, as of December 31, 2021, 53% 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.

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.

COVID-19

We continue to closely monitor the impact of the pandemic related to COVID-19 and its variants on our 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 our products has decreased significantly, 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 and the access of our sales representatives to the associated healthcare facilities has been curtailed 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 our products have been postponed or cancelled, which has negatively impacted sales of our products. These measures and challenges will likely continue for the duration of the pandemic, which is uncertain, and will likely continue to reduce our net sales and negatively impact our business, financial condition and results of operations.

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 and its variants. Such orders or restrictions resulted in reduced operations at our manufacturing facilities, travel restrictions and cancellation of events, and have restricted the ability of our sales representatives and those of our commercial partners and independent sales agents to attend procedures in which our products are used, among other effects, thereby significantly and negatively impacting our operations.

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, emergence of new variants, and the effectiveness of actions to contain the disease or treat its impact, among others. As new information regarding COVID-19 and its variants continues to emerge, it is difficult to predict the degree to which this disease will ultimately 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 issuing the recall, we have been working 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 have 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. Of these 113 patients, CDC has identified at least 75 patients who have exhibited clinical or diagnostic findings consistent with tuberculosis infection.

The CDC has advised us that the CDC, working with state health agencies, has contacted all patients treated with the recalled lot of FiberCel to help ensure they are directed to appropriate medical treatment and has informed us that all patients were started on standard four-drug treatment for tuberculosis. We have learned from the CDC that eight patients who received the product from the recalled lot have died; however, the cause of death for each patient is still being investigated through the review of medical records.

Samples of the recalled product have now undergone 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 have undergone PCR analysis and cell culture testing and have all tested negative for Mycobacterium tuberculosis. Based on these findings, we have no reason to believe that other units of FiberCel have been affected.

As part of our continuing cooperation with the FDA and CDC and our efforts to conduct a prompt and fulsome investigation into this matter, we have reviewed the processes for screening donors and producing FiberCel and have not identified 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 have 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 have developed and begun utilizing 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 16 to the consolidated financial statements included elsewhere in this Annual Report.

Corporate History

We were incorporated in Delaware in August 2015 as a subsidiary of TBI, now KeraLink. In November 2015, all of the assets and substantially all of the liabilities of the musculoskeletal division of TBI were contributed to us and 75% of the ownership interests in us were transferred to HighCape Partners QP, L.P. ("HighCape Partners QP"), certain of its affiliates, and Deerfield Private Design Fund III, L.P. ("Deerfield").

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 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 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 occurs, 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. See "Forward-Looking Statements." 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.

Risks Related to Our Business

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.

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*."

Our success depends on our ability to maintain the value and reputation of the Aziyo name.

We believe that the "Aziyo" name is important to attracting and retaining customers, and enhancing our name depends largely on our ability to provide high-quality and safe products. Our name could be harmed if we fail to achieve these objectives or if our public image were to be tarnished by events yielding negative perceptions and publicity. For example, in June 2021, we issued a voluntary recall pertaining to a single donor lot of our FiberCel Fiber Viable Bone Matrix ("FiberCel"), 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 products from this specific lot, following our learning of post-surgical infections in patients treated with FiberCel, including some patients who tested positive for tuberculosis, including eight cases that resulted in fatalities (the "FiberCel Recall"). Following the public announcement of our voluntary recall, there has been various media coverage surrounding the recall and patients impacted, as well as lawsuits filed against us, which are described in Part I, Item 3, "Legal Proceedings" and Note 16 to the consolidated financial statements included elsewhere in this Annual Report. 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.

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. 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 result in flat or declining sales in that territory, 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 feel is underperforming.

In order to increase our sales, particularly with respect to our Core Products, 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 and our business, financial condition and results of operations could be materially and adversely affected.

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 Surgalign Spine Technologies, one of our commercial partners, accounted for 10% of our net sales during the year ended December 31, 2021 and represented 12% of our accounts receivable as of December 31, 2021. Sales to Medtronic accounted for 11% of our net sales during the twelve months ended December 31, 2021 and represented none of our accounts receivable as of December 31, 2021. As more fully described elsewhere in this Annual Report, we issued a voluntary recall in June 2021 pertaining to a single donor lot of our FiberCel product after learning of post-surgical infections in several patients treated with the product, including some of whom tested positive for tuberculosis, and eight of whom suffered a fatal outcome. FiberCel was distributed by Medtronic and, in June 2021, Medtronic notified us that sales of FiberCel as well as all such other Non-Core products supplied to Medtronic would be suspended until further notice. In October 2021, we were informed by Medtronic that they would no longer be distributing cellular bone products such as FiberCel and, in December 2021, the two companies mutually terminated the associated FiberCel distribution agreement.

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 and 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 sales of our Non-Core Products, which is composed primarily of purchases from our contract manufacturing customers. Sales of our Non-Core Products represented approximately 20.7% and 15.1% of our total net sales for the years ended December 31, 2021 and 2020, 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.

We plan to expand our direct sales force coinciding with new product launches, and if we are unable to successfully expand, manage and maintain our direct sales force, we may not be able to generate greater market share and revenue growth.

Prior to the CorMatrix Acquisition, we had a very small direct sales force and sold our Core Products primarily through independent sales agents or to other companies for resale or incorporation into their products. Though our orthopedic/spinal repair products are now primarily sold through our commercial partners, we currently utilize our direct sales force to sell CanGaroo and our cardiovascular products. As of December 31, 2021, our direct sales organization consisted of 31 sales representatives, who are focused on increasing market access and market penetration by selling our products, managing our commercial partners, and providing technical assistance. Our operating results are directly

dependent upon the efforts of these employees. If our direct sales force fails to adequately promote, market and sell our products and effectively manage and assist our commercial partners, our net sales may be adversely affected.

In addition, in order to launch new products, expand our network of hospital and physician customers, drive deeper penetration in our current accounts and provide additional technical assistance to our commercial partners, we plan to expand the size and geographic scope of our direct sales force. This growth may require us to split or adjust existing sales territories, which may adversely affect our ability to retain customers in those territories. Additionally, our future success will depend largely on our ability to continue to hire, train, retain and motivate skilled sales and marketing personnel with significant industry experience and technical knowledge of regenerative medicine and related products. Because the competition for their services is high, we cannot assure you we will be able to hire and retain additional personnel on favorable or commercially reasonable terms, if at all. Failure to hire or retain qualified sales personnel would prevent us from expanding our business and generating additional revenue. In addition, it typically takes a substantial period of time before newly hired sales personnel are effective. Though we currently utilize commercial partners and independent sales agents to sell certain of our products, there is no guarantee that we will be able to establish relationships with additional parties, or that our existing commercial partners and independent sales agents will purchase or otherwise commercialize any products we may seek to introduce in the future. If we are unable to expand our sales and marketing capabilities, we may not be able to effectively commercialize our new and current products, which could have a material adverse effect on our business, financial condition and results of operations.

We are working to grow our direct sales force, which may result in higher fixed costs and may slow our ability to reduce costs in the face of a sudden decline in demand for our products.

A key component of our growth involves continuing to expand the size and geographic scope of our direct sales force. Our direct sales force may subject us to higher fixed costs than those of other companies that market competing products primarily through third parties due to the costs that we will bear associated with employee benefits, training and managing sales personnel. As a result, we could be at a competitive disadvantage relative to competitors who rely more heavily on third parties to market and sell their products. Additionally, these fixed costs may slow our ability to reduce costs in the face of a sudden decline in demand for our products, which could have a material adverse effect on our business, financial condition and results of operations.

We have incurred operating losses since our inception, expect to continue to incur significant expenses and operating losses in the future, and may not be able to achieve or sustain profitability.

We have incurred net losses since our inception in 2015. For the year ended December 31, 2021, we had net losses of $24.8 million and as of December 31, 2021, we had an accumulated deficit of $105.1 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 our IPO and private placement 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 grow our sales organization, 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. Until such time as we are able to generate sufficient sales from our products, we expect to finance our operations through equity offerings, debt financings or other capital sources, which may include collaborations or license agreements with other companies or

other strategic transactions such as an asset sale. We may not be able to raise additional funds or enter into such other agreements or arrangements when needed on favorable terms or at all. If we fail to raise capital or enter into such agreements in the short-term, we will be unable to fund our operations and capital expenditure requirements at that time which may result in there being substantial doubt about our ability to continue as a going concern.

If we do not achieve or sustain profitability, it will be more difficult for us to finance our business and accomplish our strategic objectives, either of which would have a material adverse effect on our business, financial condition and results of operations and cause the market price of our Class A common stock to decline. In addition, failure of our products to significantly penetrate existing or new markets would negatively affect our business, financial condition and results of operations.

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

If a pandemic, epidemic or outbreak of an infectious disease occurs in the United States or worldwide, our business may be adversely affected. In December 2019, a novel strain of coronavirus, SARS-CoV-2, was identified in Wuhan, China. Since then, SARS-CoV-2, and the resulting disease, COVID-19, has spread to most countries and all 50 states within the United States. The COVID-19 pandemic has negatively impacted our business, financial condition and results of operations by significantly decreasing and delaying the number of procedures performed using our products, and we expect the pandemic to continue to negatively impact our business, financial condition and results of operations. Similar to the general trend in elective and other surgical procedures, the number of procedures performed using our products has decreased significantly as healthcare organizations in the United States have prioritized the treatment of patients with COVID-19 or have otherwise altered their operations to prepare for and respond to the pandemic. For example, in the United States, governmental authorities 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 the novel coronavirus, and to focus limited resources and personnel capacity on the treatment of COVID-19 patients. Beginning in March 2020, a significant number of procedures using our products have been postponed or cancelled, which has negatively impacted sales of our products. Decreases in procedures have been most prevalent in regions experiencing significant outbreaks, while healthcare organizations in other regions have continued to undertake procedures using our products at reduced levels as compared to before the pandemic. The COVID-19 pandemic could also adversely impact the initiation, continuation and completion of our clinical studies by, for example, 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 could result in increased costs, delays in advancing our product development, delays in testing the effectiveness of our technology or termination of the clinical studies altogether. These measures and challenges will likely continue for the duration of the pandemic, which is uncertain, and may continue to reduce our net sales and negatively impact our business, financial condition and results of operations while the pandemic continues. Further, even after the pandemic ultimately subsides, we anticipate there will be a substantial backlog of patients seeking procedures and appointments for a variety of medical conditions and, as a result, patients seeking procedures performed using our products will have to navigate limited provider capacity. We believe this limited capacity of providers, hospitals and other healthcare facilities could have a significant adverse effect on our business, financial condition and results of operations during and following the COVID-19 pandemic.

Numerous state and local jurisdictions, including those where our facilities are located, have imposed, and others in the future may impose, "shelter-in-place" orders, quarantines, executive orders and similar government orders and restrictions for their residents to control the spread of COVID-19. Such orders or restrictions have resulted in reduced operations at our manufacturing facilities, travel restrictions and cancellation of events and have restricted the ability of our sales representatives and those of our commercial partners and independent sales agents to attend procedures in which our products are used, among other effects, thereby significantly and negatively impacting our operations. Other disruptions or potential disruptions include restrictions on the ability of our sales representatives and other personnel, and those of our commercial partners and independent sales agents, to travel and access customers for training and case support; inability of our suppliers to manufacture and deliver to us on a timely basis or at all; delays in our ability to obtain medical records for tissue donors, which we need in order to release our products; disruptions in our production schedule and ability to manufacture and assemble products; inventory shortages or obsolescence; delays in actions of regulatory bodies; delays

in clinical studies; diversion of or limitations on employee resources that would otherwise be focused on the operations of our business, including because of sickness of employees or their families or the desire of employees to avoid contact with groups of people; delays in growing or reductions in our direct sales force, including through delays in hiring, lay-offs, furloughs or other losses of sales representatives; restrictions in our ability to ship our products to customers; business adjustments or disruptions of certain third parties, including suppliers, medical institutions and clinical investigators with whom we conduct business; negative impact on our customers' credit profiles, which may adversely impact our future collection experience; and additional government requirements or other incremental mitigation efforts that may further impact our or our suppliers' capacity to manufacture our products. 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 others developments. As new information regarding COVID-19 continues to emerge, it is difficult to predict what impact this disease will ultimately have on our business.

Adverse changes in general domestic and global economic conditions and instability and disruption of credit markets, including as a result of the current COVID-19 pandemic or any other outbreak of an infectious disease, 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. While the potential economic impact brought by, and the duration of, any pandemic, epidemic or outbreak of an infectious disease, including COVID-19, may be difficult to assess or predict, the current COVID-19 pandemic has resulted in, and may continue to result in, significant disruption of global financial markets. 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 health 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, the current COVID-19 pandemic and any other disruption in the capital and credit markets could impede our access to capital, which could be further adversely affected if we are unable to maintain our current credit ratings. 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. Similarly, if our suppliers face challenges in obtaining credit or other financial difficulties, they may be unable to provide the materials required to manufacture our products. 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.

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 Bone Repair 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 16 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 will 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 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 perform most of our research and development activity and manufacture our 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 components, 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 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 orthopedic/spinal repair and soft tissue reconstruction markets, as well as our contract manufacturing products, 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. 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 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 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 components or raw materials through higher prices to our customers. If the cost of key components 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 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 has 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 45 separate lawsuits alleging that the plaintiffs contracted tuberculosis and/or suffered substantial symptoms and complications following the implantation of FiberCel during spinal fusion operations.

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. For example, we and certain Medtronic entities have been named in complaints alleging that plaintiffs contracted tuberculosis following the implantation of FiberCel during spinal fusion operations and seeking unspecified compensatory and punitive damages and medical monitoring. See Part I, Item 3, "Legal Proceedings" and Note 16 to the consolidated financial statements included elsewhere in this Annual Report.

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. It is also possible that 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. Our excess insurance carrier has recently asserted that claims related to the FiberCel litigation are not covered under our policy. 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 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. 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 16 to the consolidated financial statements included elsewhere in this Annual Report. We have incurred and will continue to incur costs to defend these lawsuits and are not currently able to estimate damage amounts, if any, that we may be required to pay in connection with 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. Given the inherent difficulty of predicting the outcome of litigation and costs involved to defend against the claims, we are currently unable to reasonably estimate the possible loss or range of loss with respect to these lawsuits. Any unfavorable outcome that results in the payment of substantial damages could 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; and
- general economic conditions as well as 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, 2021, we had $23.3 million of indebtedness outstanding, consisting of $17.1 million outstanding under our Term 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 $0.1 million of unamortized deferred financing costs), $4.8 million outstanding under our Revolving Credit 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") (with $2.1 million of additional borrowings available thereunder), and a $1.4 million promissory note payable to one of our suppliers. 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 Term Loan Facility and Revolving Credit Facility contain, 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 agreements governing our Term Loan Facility and Revolving Credit Facility also contain a financial covenant, which is tested on a monthly basis, and requires us to achieve a specified minimum net product revenue (as defined therein) for the preceding 12-month period. While we were in compliance with all covenants under these agreements as of December 31, 2021, we have had past breaches requiring waivers and there can be no guarantee that we will not breach these covenants in the future. To this end, the mutual termination of our Supply Agreement for FiberCel with Medtronic referred to in Note 15 to the consolidated financial statements included elsewhere in this Annual Report would have triggered an event of default; however, such event of default was waived by our lenders. Furthermore, the Supply Agreement's termination may negatively affect future revenues and as such, our ability to comply with the revenue covenants in the future is uncertain.

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 be able to incur significant additional indebtedness in the future. Although the agreements governing our Term Loan Facility and Revolving Credit Facility contain 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 Term Loan Facility and Revolving Credit Facility to terminate the agreement, following a cure period. Such events include, without limitation, legal proceedings which could be implicated based on the facts involving the FiberCel Recall and the related litigation. If the lender were to terminate either the Term Loan Facility or the Revolving Credit 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 licensing 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 licensing arrangements with third parties, it may be necessary to relinquish some rights to our technologies or our products, or grant licenses on terms that are not favorable to us.

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, 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 cyberattacks by hackers or viruses or breaches due to employee error, malfeasance or other disruptions. We rely extensively on IT systems, networks and services, including internet sites, data hosting and processing facilities and tools, physical security systems and other hardware, software and technical applications and platforms, some of which are managed, hosted, provided and/or used by third parties or their vendors, to assist in conducting our business. A significant breakdown, invasion, corruption, destruction or interruption of critical information technology systems or infrastructure, by our workforce, others with authorized access to our systems or unauthorized persons could negatively impact operations. The ever-increasing use and evolution of technology, including cloud-based computing, creates opportunities for the unintentional dissemination or intentional destruction of confidential information stored in our or our third-party providers' systems, portable media or storage devices. We could also experience a business interruption, theft of confidential information or reputational damage from industrial espionage attacks, malware or other cyber-attacks, which may compromise our system infrastructure or lead to data leakage, either internally or at our third-party providers.

Unauthorized disclosure of sensitive or confidential patient or employee data, including personally identifiable information, whether through breach of computer systems, systems failure, employee negligence, fraud or misappropriation, or otherwise, or unauthorized access to or through our information systems and networks, whether by our employees or third parties, 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. Although we have general liability and cybersecurity insurance coverage, our insurance 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.

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. Phishing, social engineering and other 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. 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. Any such breakdowns or breaches, 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.

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. 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 added a new General Counsel. This change, 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 primarily through 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 and trade sanctions against embargoed countries, which are administered by the Office of Foreign Assets Control within the Department of the Treasury ("OFAC") as well as the laws and regulations administered by the Department of Commerce. These regulations limit our ability to market, sell, distribute or otherwise transfer our products or technology to prohibited countries 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 currently are and, as we increase our international presence and global sales, will increasingly be, exposed to trade and economic sanctions and other restrictions imposed by the United States, the EU and other governments and organizations. The U.S. Departments of Justice, Commerce, State and Treasury and other federal agencies and authorities have a broad range of civil and criminal penalties they may seek to impose against corporations and individuals for violations of economic sanctions laws, export control laws, the FCPA, and other federal statutes and regulations, including those established by OFAC. In addition, the U.K. Bribery Act of 2010 (the "Bribery Act") prohibits both domestic and international bribery, as well as bribery across both private and public sectors. An organization that "fails to prevent bribery" by anyone associated with the organization can be charged under the Bribery Act unless the organization can establish the defense of having implemented "adequate procedures" to prevent bribery. Under these laws and regulations, as well as other anti-corruption laws, anti-money laundering laws, export control laws, customs laws, sanctions laws and other laws governing our operations, various government agencies may require export licenses, may seek to impose modifications to business practices, including cessation of business activities in sanctioned countries or with sanctioned persons or entities and modifications to compliance programs, which may increase compliance costs, and may subject us to fines, penalties and other sanctions. A violation of these laws or regulations would negatively affect our business, financial condition and results of operations.

As our international operations increase, we expect to implement policies and procedures designed to ensure compliance by us and our directors, officers, employees, representatives, consultants and agents with the FCPA, OFAC restrictions, the Bribery Act and other export control, anti-corruption, anti-money-laundering and anti-terrorism laws and regulations. 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, OFAC restrictions, the Bribery Act or other export control, anti-corruption, 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 which 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 $65.5 million and state NOLs of approximately $18.2 million as of December 31, 2021. 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 following the adoption of the December 2017 tax reform legislation known as H.R. 1, commonly referred to as the Tax Cuts and Jobs Act (the "TCJA") in the United States.

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 TCJA 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 determined 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.

We may face additional issues associated with the voluntary recall of the single donor lot of FiberCel if we are unable to show that we initiated a timely recall and recalled all deficient lots.

In June 2021, we issued a voluntary recall pertaining to a single donor lot of 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 who tested positive for tuberculosis. We investigated the source of the infections in coordination with our distributor of the product, the FDA and the CDC. The FDA has since inspected our Richmond, California production facility and this did not result in any Form-483 observations. We have 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. Of these 113 patients, CDC has identified at least 75 patients who have exhibited clinical or diagnostic findings consistent with tuberculosis infection. The CDC has advised us that the CDC, working with state health agencies, has contacted all patients treated with the recalled lot of FiberCel to help ensure they are directed to appropriate medical treatment and has informed us that all patients were started on standard four-drug treatment for tuberculosis. If it is determined that there are other lots that are similarly affected or we experience the same or similar circumstances in the future, this could adversely affect our ability to generate revenue and have an adverse effect on our financial condition and results of operations. Moreover, we may face additional issues associated with our voluntary recall if we are unable to show that we initiated a timely recall.

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/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.

To the extent we sell medical devices in EU member states, our products must comply with the general safety and performance requirements of the Medical Devices Regulation (Regulation (EU) No 2017/745). Compliance with these requirements is a prerequisite to be able to affix the European Conformity, or 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 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, or 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.

The EU-UK Trade and Cooperation Agreement, or TCA, came into effect on January 1, 2021. The TCA does not specifically refer to medical devices. However, as a result of Brexit, the EU Medical Devices Regulation will not be implemented in the UK, and previous legislation that mirrored the EU Medical Devices Regulation in the UK law has been revoked. The regulatory regime for medical devices in Great Britain (England, Scotland and Wales) will continue to be based on the requirements derived from current EU legislation, and the UK may choose to retain regulatory flexibility or align with the EU Medical Devices Regulation going forward. CE markings will continue to be recognized in the UK, and certificates issued by EU-recognized notified bodies will be valid in the UK, until June 30, 2023. For medical devices placed on the market in Great Britain after this period, the UKCA, marking will be mandatory. In contrast, UKCA marking and certificates issued by UK notified bodies will not be recognized on the EU market. The TCA 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 bodies 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 body 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 or the Competent Authorities of the European Union member states, 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 European Union 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 European Union member states, and foreign regulatory bodies 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 EEA, we must comply with the EU medical device vigilance system. Under this system, serious incidents and Field Safety Corrective Actions, or FSCAs must be reported to the relevant authorities of the EEA countries. 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 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, or 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.

Depending on the corrective action we take to redress a product's deficiencies or defects, the FDA 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, 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 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 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 Medical Devices Regulation.

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, 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. Over the last several years, the FDA has proposed reforms to its 510(k) clearance process, and such proposals could include increased requirements for clinical data and a longer review period, or could make it more difficult for manufacturers to utilize the 510(k) clearance process for their products. For example, in November 2018, FDA officials announced steps that the FDA intended to take to modernize the premarket notification pathway under Section 510(k) of the FDCA. Among other things, the FDA announced that it planned to develop proposals to drive manufacturers utilizing the 510(k) pathway toward the use of newer predicates. These proposals included plans to potentially sunset certain older devices that were used as predicates under the 510(k) clearance pathway, and to potentially publish a list of devices that have been cleared on the basis of demonstrated substantial equivalence to predicate devices that are more than 10 years old. These proposals have not yet been finalized or adopted, and the FDA may work with Congress to implement such proposals through legislation. Accordingly, it is unclear the extent to which any proposals, if adopted, could impose additional regulatory requirements on us that could delay our ability to obtain new 510(k) clearances, increase the costs of compliance or restrict our ability to maintain our current clearances, or otherwise create competition that may negatively affect our business.

More recently, 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.

In addition, FDA regulations and guidance are often revised or reinterpreted by the FDA in ways that may significantly affect our business and our products. Any new statutes, regulations or revisions or reinterpretations of existing regulations may impose additional costs or lengthen review times of any future products or make it more difficult to obtain clearance or approval for, manufacture, market or distribute our products. We cannot determine what effect changes in regulations, statutes, legal interpretation or policies, when and if promulgated, enacted or adopted may have on our business in the future. Such changes could, among other things, require: additional testing prior to obtaining clearance or approval; changes to manufacturing methods; recall, replacement or discontinuance of our products; or additional record keeping.

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 breast reconstruction procedures. As a result, we may be required to conduct clinical studies and/or seek approval of a PMA or BLA 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, or 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 European Union 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 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 ability to hire and retain key personnel and accept the payment of user fees and other events that may otherwise affect the FDA's ability to perform routine functions. Average review times at the FDA 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 and other agencies 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 by necessary government agencies, 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 July 2020, the FDA resumed certain on-site inspections of domestic manufacturing facilities subject to a risk-based prioritization system. The FDA utilized this risk-based assessment system to assist in determining when and where it was safest to conduct prioritized domestic inspections. Additionally, on April 15, 2021, the FDA issued a guidance document in which the FDA described its plans to conduct voluntary remote interactive evaluations of certain drug manufacturing facilities and clinical research sites, among other facilities. According to the guidance, the FDA may request such remote interactive evaluations where the FDA determines that remote evaluation would be appropriate based on mission needs and travel limitations. In May 2021, the FDA outlined a detailed plan to move toward a more consistent state of inspectional operations, and in July 2021, the FDA resumed standard inspectional operations of domestic facilities and was continuing to maintain this level of operation as of September 2021. More recently, 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. Regulatory authorities outside the United States may adopt 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, the EMA or other regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities, it could significantly impact the ability of the FDA, the EMA or other regulatory authorities 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 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.

We expect additional state and federal 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.

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, including state data breach notification laws, state health information privacy laws, and federal and state consumer protection laws and regulations (e.g., Section 5 of the FTC Act), that 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. We may also be subject to U.S. federal rules, regulations and guidance concerning data security for medical devices, including guidance from the FDA. In addition, 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. 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, or the 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 is expected to increase 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, recently passed in California. The CPRA significantly amends the CCPA and will impose 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 will also create a new California data protection agency authorized to issue substantive regulations and could result in increased privacy and information security enforcement. The majority of the provisions will go into effect on January 1, 2023, and additional compliance investment and potential business process changes may be required. Similar laws have passed in Virginia 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.

Foreign data protection laws, including the EU General Data Protection Regulation (the "GDPR"), which became effective in May 2018, may also apply to health-related and other personal information obtained outside of the United States. The GDPR imposes stringent data protection requirements for the processing of personal data in the EEA, including, for example, higher standards for obtaining consent from individuals to process their personal data, more robust disclosures to individuals and a strengthened individual data rights regime, shortened timelines for data breach notifications, limitations on retention and secondary use of information (including for research purposes), increased

requirements pertaining to health data and pseudonymised (i.e., key-coded) data and additional obligations when we contract third party processors in connection with the processing of the personal data. 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 (the "CJEU") invalidated the EU-U.S. Privacy Shield Framework, or the Privacy Shield, under which personal data could be transferred from the EEA to U.S. entities who had self-certified under the Privacy Shield scheme. While the CJEU upheld the adequacy of the standard contractual clauses (a standard form of contract approved by the European Commission as an adequate personal data transfer mechanism, and potential alternative to the Privacy Shield), it made clear that reliance on them alone may not necessarily be sufficient in all circumstances. Use of the standard contractual clauses must now be assessed on a case-by-case basis taking into account the legal regime applicable in the destination country, in particular applicable surveillance laws and rights of individuals and additional measures and/or contractual provisions may need to be put in place, however, the nature of these additional measures is currently uncertain. The CJEU went on to state that if a competent supervisory authority believes that the standard contractual clauses cannot be complied with in the destination country and the required level of protection cannot be secured by other means, such supervisory authority is under an obligation to suspend or prohibit that transfer. The European Commission issued revised standard contractual clauses on June 4, 2021 to account for the decision of the CJEU and recommendations made by the European Data Protection Board. The revised standard contractual clauses must be used for relevant new data transfers from September 27, 2021; existing standard contractual clauses arrangements must be migrated to the revised clauses by December 27, 2022. There is some uncertainty around whether the revised clauses can be used for all types of data transfers, particularly whether they can be relied on for data transfers to non-EEA entities subject to the GDPR. The revised standard contractual clauses apply only to the transfer of personal data outside of the EEA and not the United Kingdom; the UK's Information Commissioner's Office launched a public consultation on its draft revised data transfers mechanisms in August 2021. As supervisory authorities issue further guidance on personal data export mechanisms, including circumstances where the standard contractual clauses 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. European data protection law provides that EU and EEA member states may make their own further laws and regulations limiting the processing of health-related data, which could limit our ability to use and share personal data or could cause our costs to increase, and harm our business and financial condition. 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.

From January 1, 2021, we are 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. The European Commission has adopted an adequacy decision in favor of the UK, enabling data transfers from EU member states to the UK without additional safeguards. However, the UK adequacy decision will automatically expire in June 2025 unless the European Commission re-assesses and renews/ extends that decision and remains under review by the Commission during this period. In September 2021, the UK government launched a consultation on its proposals for wide-ranging reform of UK data protection laws following Brexit. There is a risk that any material changes which are made to the UK data protection regime could result in the European Commission reviewing the UK adequacy decision, and the UK losing its adequacy decision if the European Commission deems the UK to no longer provide adequate protection for personal data. The relationship between the UK and the European Union in relation to certain aspects of data protection law remains unclear, and it is unclear how UK data protection laws and regulations will develop in the medium to longer term, and how data transfers to and from the UK will be regulated in the long term. These changes will lead to additional costs and increase our overall risk exposure.

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.

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;
- developments related to the COVID-19 pandemic;
- 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;
- 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 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 and variants such as Delta. 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, 2021, our principal stockholders each holding more than 5% of our Class A common stock collectively control approximately 65.3% of our outstanding Class A common stock. As a result, these stockholders, if they act together, will be able to control the management and affairs of our company and 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 common stock in the public market, or the perception in the market that the holders of a large number of shares intend to sell their shares, could reduce the market price of our Class A common stock. As of December 31, 2021, we had outstanding 13,558,552 shares of Class A and Class B, collectively. This includes the 2,941,176 shares that we sold in our IPO and the 3,301,881 shares that we sold in our December 2021 private placement, which may be resold in the public market immediately without restriction. As a holder of our Class B common stock, Deerfield only has the right to convert each share of our Class B common stock into one share of Class A common stock at its election to the extent that as a result of such conversion, it would not beneficially own in excess of 4.9% of any class of our securities registered under the Exchange Act. As a result, Deerfield may not be deemed an "affiliate" for purposes of Rule 144 and, as a result, any securities it purchases may be freely tradable. Approximately 7.1 million of the remaining shares are restricted as a result of securities laws or lock-up agreements (which may be waived, with or without

notice, by Piper Sandler & Co. and Cowen and Company, LLC) but will become eligible to be sold at various times beginning 180 days after the date of the prospectus filed with the SEC on October 8, 2020 (the "Prospectus"), unless held by one of our affiliates, in which case the resale of those securities will be subject to volume limitations under Rule 144 of the Securities Act. Because Deerfield may not be deemed an "affiliate" for purposes of Rule 144, up to approximately 2.4 million shares of Class B common stock that Deerfield holds may become freely tradable and not subject to volume limitations following the 180-day lock-up period. Moreover, as of the date of this Annual Report, holders of an aggregate of up to approximately 7.1 million shares of our common stock have rights, subject to certain conditions and limitations, to require us to file registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or other stockholders, until such rights terminate pursuant to the terms of our Investor Rights Agreement. We also intend to register all shares of Class A common stock that we may issue under our equity compensation plans. Once we register these shares, they can be freely sold in the public market upon issuance, subject to volume limitations applicable to affiliates and the lock-up agreements.

The market price of our common stock may drop significantly when the restrictions on resale by our existing stockholders lapse or when we are required to register the sale of our stockholders' remaining shares of our common stock. A decline in the trading price of our 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 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, 2021, we had 190,754,854 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, 2021, we had a total of 1,386,811 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 $13.28 per share, 394,437 of which were vested as of such date, 235,855 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, 756,554 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 186,826 shares of our Class A common stock that will become 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. 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, 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 $1.07 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 incur increased costs as a result of operating as a public company, and our management will be 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 will incur significant legal, accounting and other expenses that we did not incur as a private company. 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 will need to devote a substantial amount of time to these compliance initiatives, which will divert their attention away from our core business operations and revenue-producing activities. Moreover, these rules and regulations will increase our legal and financial compliance costs and will make some activities more time-consuming and costly. For example, we expect that these rules and regulations may make it more difficult and more expensive for us to obtain director and officer liability insurance, which in turn could require 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.

We are a "controlled company" within the meaning of the Nasdaq Stock Market LLC ("Nasdaq") and, as a result, qualify for, and may rely on, exemptions from certain corporate governance requirements.

Affiliates of HighCape Partners control a majority of our outstanding Class A common stock. As a result, we qualify as a "controlled company" within the meaning of Nasdaq's corporate governance standards. A company of which more than 50% of the voting power for the election of directors is held by an individual, a group or another company is a "controlled company" within the meaning of Nasdaq's rules and may elect not to comply with certain corporate governance requirements of Nasdaq, including, among others:

- the requirement that a majority of our board of directors consist of independent directors;
- the requirement that we have a nominating and corporate governance committee that is comprised entirely of independent directors with a written charter addressing the committee's purpose and responsibilities;
- the requirement that we have a compensation committee that is comprised entirely of independent directors with a written charter addressing the committee's purpose and responsibilities;
- the requirement for an annual performance evaluation of the nominating and corporate governance and compensation committees.

For so long as we remain a controlled company, we may at any time and from time to time, utilize any or all of these exemptions. As a result, our board of directors and those committees may have more directors who do not meet Nasdaq's independence standards than they would if those standards were to apply. The independence standards are intended to ensure that directors who meet those standards are free of any conflicting interest that could influence their actions as directors. Accordingly, you may not have the same protections afforded to shareholders of companies that are subject to all of the corporate governance requirements of Nasdaq.

General Risk Factors

Uncertainty relating to the LIBOR calculation process and potential phasing out of LIBOR after 2021 may adversely affect the market value of our current or future debt obligations.

The London Inter-bank Offered Rate ("LIBOR") and certain other interest "benchmarks" may be subject to regulatory guidance and/or reform that could cause interest rates under our current or future debt agreements to perform

differently than in the past or cause other unanticipated consequences. The United Kingdom's Financial Conduct Authority, which regulates LIBOR, has announced that it intends to stop encouraging or requiring banks to submit LIBOR rates after 2021 or, in certain cases, 2023, and it is unclear if LIBOR will cease to exist or if new methods of calculating LIBOR will evolve. If LIBOR ceases to exist or if the methods of calculating LIBOR change from their current form, there may be adverse impacts on the financial markets generally and interest rates on borrowings under our Term Loan Facility and Revolving Credit Facility may be adversely affected.

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, and approximately 36,173 square feet of manufacturing, laboratory and office space in Richmond, California under a lease that expires in November 2025. 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 16 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 4, 2022, there were approximately 26 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 Term Loan Facility and our Revolving Credit Facility.

The issuances of securities described above were pursuant to Section 4(a)(2) or Rule 701 under the Securities Act, relative to transactions by an issuer not involving any public offering, to the extent an exemption from such registration was required.

Equity Compensation Plans

The information required by Item 5 of Form 10-K regarding equity compensation plans is incorporated herein by reference to Item 11. of Part III of this Annual Report on Form 10-K.

Recent Sales of Unregistered Securities

On December 8, 2021, we sold to several investors an aggregate of (i) 2,122,637 shares of our Class A common stock and (ii) 1,179,244 shares of our Class B common stock at a purchase price equal to $4.24 per share, for aggregate gross proceeds of approximately $14.0 million, before deducting offering expenses. This transaction was made in reliance on the exemption contained in Section 4(a)(2) of the Securities Act, as a transaction by an issuer not involving a public offering.

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 on Form 10-K (the "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. A discussion of the year ended December 31, 2020 compared to the year ended December 31, 2019 has been reported previously in our Annual Report on Form 10-K for the fiscal year ended December 31, 2020, filed with the SEC on March 15, 2021, in Part II, Item 7. "Management's Discussion and Analysis of Financial Condition and Results of Operations."

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, concentrating on patients receiving implantable medical devices. From our proprietary tissue processing platforms, we have developed a portfolio of advanced regenerative medical products that are designed to be very similar to natural biological material. Our proprietary products, which we refer to as our Core Products, are designed to address the implantable electronic device/cardiovascular, orthopedic/spinal repair and soft tissue reconstruction markets, which represented a combined $3 billion market opportunity in the United States in 2020. To expand our commercial reach, we have commercial relationships with major medical device companies, such as Boston Scientific and Biotronik, to promote and sell some of our Core Products. We

believe our focus on our unique regenerative medicine platforms and our Core Products will ultimately maximize our probability of continued clinical and commercial success and will create a long-term competitive advantage for us.

We estimate that more than two million patients were either implanted with medical devices, such as pacemakers, defibrillators, neuro-stimulators, spinal fusion and trauma fracture hardware or tissue expanders for breast reconstruction, in the United States in 2019. This number is driven by advances in medical device technologies 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 other complications that can be triggered by a device implant.

Our Core 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 scar-tissue formation, capsular contraction, erosion, migration, non-union of implants and implant rejection. We believe that we have developed the only biological envelope, which is covered by a number of patents, that forms a natural, systemically vascularized pocket for holding implanted electronic devices. We have a proprietary processing technology for manufacturing bone regenerative products for use in orthopedic/spinal repair that preserves a cell's ability to regenerate bone and decelerates cell apoptosis or programmed cell death. We have a patented cell removal technology that produces undamaged extracellular matrices for use in soft tissue reconstruction. In pre-clinical and clinical studies, our products have supported and, in some cases, accelerated tissue healing, and thereby improved patient outcomes.

Our Non-Core Products are those fulfilled through tissue processing contracts at our Richmond, California facility. These contracts serve to utilize as much as possible of the starting human biological material from which we produce our orthopedic/spinal repair and soft tissue reconstruction 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 selected customers.

We process all of our products at our two manufacturing facilities in Roswell, Georgia and Richmond, California, and stock inventory of raw materials, components and finished goods at those locations. We rely on a single or limited number of suppliers for certain raw materials and components. 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. We primarily ship our Core Products from our facilities directly to hospital customers.

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, more recently, our initial public offering consummated on October 13, 2020 (the "IPO") and a private placement of our common stock in December 2021. We have devoted the majority of our resources to acquisitions 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, 2021, we had 176 employees, of which 31 were direct sales representatives.

We have incurred significant operating losses since our inception. We incurred a net loss of $24.8 million and $21.8 million for the years ended December 31, 2021 and 2020, respectively. Our accumulated deficit as of December 31, 2021 was $105.1 million.

We expect to continue to incur significant expenses and operating losses for the foreseeable future as we seek to grow our sales organization and 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, 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. As a result, we anticipate that we will need additional funding to support our continuing operations and pursue our growth strategy. Until such time as we are able to generate sufficient sales from our products, we expect to finance our operations through equity offerings, debt financings or other capital sources, which may include collaborations or license agreements with other companies or other strategic transactions such as an asset sale. We may not be able to raise additional funds or enter into such other agreements or arrangements when needed on favorable terms or at all. If we fail to raise capital or enter into such agreements in the short-term, we will be unable to fund our operations and capital expenditure requirements at that time which may result in there being substantial doubt about our ability to continue as a going concern.

We believe that the net proceeds from our IPO, together with our existing cash, availability under our Revolving Credit Facility and cash generated from expected future commercial sales as well as the December 2021 PIPE financing (see below) will be sufficient to fund our operating expenses, debt service requirements and capital expenditure needs through at least twelve months from the issuance date of the consolidated financial statements included elsewhere in this Annual Report. We have based this estimate on assumptions that may prove to be wrong, and we could exhaust our available capital resources sooner than we expect.

Impact of COVID-19

We are closely monitoring the impact of the COVID-19 pandemic on our 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 our products has decreased significantly, 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 our products have been postponed or cancelled, which has negatively impacted sales of our products. These measures and challenges will likely continue for the duration of the pandemic, which is uncertain, and will likely continue to reduce our net sales 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, have 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. Such orders or restrictions have resulted in reduced operations at our manufacturing facilities, travel restrictions and cancellation of events, and have restricted the ability of our sales representatives and those of our commercial partners and independent sales agents to attend procedures in which our products are used, among other effects, thereby significantly and negatively impacting our operations.

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, it is difficult to predict the degree to which this disease will ultimately have on 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 issuing the recall, we have been working 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 have 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. Of these 113 patients, CDC has identified at least 75 patients who have exhibited clinical or diagnostic findings consistent with tuberculosis infection.

As part of our continuing cooperation with the FDA and CDC and our efforts to conduct a prompt and fulsome investigation into this matter, we have reviewed the processes for screening donors and producing FiberCel and have not identified 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.

To help ensure the safety of future production lots, we have 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 have developed and begun utilizing a methodology for testing processed viable cell bone matrix tissue products for Mycobacterium tuberculosis as a further enhancement of 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 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 Core Products and our Non-Core Products. With respect to our Core Products, CanGaroo and our cardiovascular products are sold to hospitals and other healthcare facilities primarily through our direct sales force, commercial partners or independent sales agents. Our orthopedic/spinal repair products are sold through commercial partners. Our soft tissue reconstruction product SimpliDerm is sold directly to hospitals and other healthcare facilities through independent sales agents. 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 our expenses to continue to increase for the foreseeable future as we grow our sales and marketing organization, expand our product development and clinical activities and increase our administrative infrastructure. 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 and customer service expenses. We expect sales and marketing expenses to grow commensurate with sales increases, and to an even larger degree in the near-term due to a continued focus on growing our direct sales force and increasing marketing activities to coincide with new product launches.

General and Administrative Expenses

General and administrative ("G&A") expenses consist 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 and public 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 orthopedic/spinal repair market and activities associated with the development of a CanGaroo Envelope with antibiotics. We also conduct clinical studies to validate the performance characteristics of our products and to capture patient data necessary to support our commercial efforts.

Results of Operations

Comparison of the Years Ended December 31, 2021 and 2020

	Year Ended December 31,					
	2021		2020		Change 2020 / 2021	
(in thousands, except percentages)	Amount	% of Net Sales	Amount	% of Net Sales	$	%
Net sales	$ 47,390	100.0 %	$ 42,682	100.0 %	$ 4,708	11.0 %
Cost of goods sold	28,368	59.9 %	22,121	51.8 %	6,247	28.2 %
Gross profit	19,022	40.1 %	20,561	48.2 %	(1,539)	(7.5)%
Sales and marketing	18,825	39.7 %	17,565	41.2 %	1,260	7.2 %
General and administrative	13,963	29.5 %	10,641	24.9 %	3,322	31.2 %
Research and development	9,266	19.6 %	5,954	13.9 %	3,312	55.6 %
Total operating expenses	42,054	88.7 %	34,160	80.0 %	7,894	23.1 %
Loss from operations	(23,032)	(48.6)%	(13,599)	(31.9)%	(9,433)	69.4 %
Interest expense	5,324	11.2 %	5,633	13.2 %	(309)	(5.5)%
Other (income) expense, net	(3,579)	(7.6)%	2,567	6.0 %	(6,146)	NM
Loss before provision of income taxes	(24,777)	(52.3)%	(21,799)	(51.1)%	(2,978)	13.7 %
Income tax expense	55	0.1 %	26	0.1 %	29	111.5 %
Net loss	**(24,832)**	**(52.4)%**	**(21,825)**	**(51.1)%**	**(3,007)**	**13.8 %**
Accretion of Convertible Preferred Stock	—	— %	3,510	8.2 %	(3,510)	NM
Net loss attributable to common stockholders	**$ (24,832)**	**(52.4)%**	**$ (25,335)**	**(59.4)%**	**$ 503**	**(2.0)%**

NM = not meaningful

Net Sales

Net sales increased $4.7 million, or 11.0%, to $47.4 million in the year ended December 31, 2021 compared to $42.7 million in the year ended December 31, 2020. The increase in net sales was due to growth in our Core Products and Non-Core Products of $1.4 million and $3.3 million, respectively.

Net sales information for our Core Products and Non-Core Products is summarized as follows:

	Year Ended December 31,					
	2021		2020		Change 2020 / 2021	
(in thousands, except percentages)	Amount	% of Net Sales	Amount	% of Net Sales	$	%
Products:						
Core Products	$ 37,603	79.3 %	$ 36,216	84.9 %	$ 1,387	3.8 %
Non-Core Products	9,787	20.7 %	6,466	15.1 %	3,321	51.4 %
Total Net Sales	**$ 47,390**	**100.0 %**	**$ 42,682**	**100.0 %**	**$ 4,708**	**11.0 %**

Net sales generated by our Core Products grew $1.4 million, or 3.8%, to $37.6 million in the year ended December 31, 2021 compared to $36.2 million in the year ended December 31, 2020. The Core Products net sales growth can be largely attributed to the volume growth of both our CanGaroo and SimpliDerm partially offset by a decline in our revenues from our bone repair products. A portion of the volume growth in CanGaroo and SimpliDerm was due to the impact of the of the COVID-19 pandemic, which negatively affected our sales principally during the second quarter of 2020, but a majority of the growth was due to increased demand in 2021 compared to 2020. The decline in net sales of our bone repair products can be attributed to the cessation of purchases by Medtronic of FiberCel following our recall of a single lot of FiberCel in June 2021. Sales of FiberCel to Medtronic were $4.9 million and $6.9 million in the years ended December 31, 2021 and 2020, respectively.

Net sales generated by our Non-Core Products increased $3.3 million, or 51.4%, to $9.8 million in the year ended December 31, 2021 from $6.5 million in the year ended December 31, 2020. The net sales increase was primarily due to revenues associated with new contracts signed in the latter half of 2020 and by one contract manufacturing customer building inventory for a new product launch, along with the decreased revenue impact of COVID-19 in the year ended December 31, 2021 compared to such impact in the year ended December 31, 2020.

Cost of Goods Sold

Cost of goods sold increased $6.2 million, or 28.2%, to $28.4 million in the year ended December 31, 2021 compared to $22.1 million in the year ended December 31, 2020, and included, in each period, $3.4 million of intangible asset amortization expenses. Gross margin was 40.1%, in the year ended December 31, 2021 compared to 48.2% in the year ended December 31, 2020. Gross margin, excluding intangible asset amortization, was 47.3%, in the year ended December 31, 2021 compared to 56.1% in the year ended December 31, 2020. The decrease in gross margin was primarily due to product mix as our Non-Core Product sales generally have lower margins than Core Products. Also contributing to the decreased gross margins in 2021 were lower yields in our orthopedic and spinal repair product lines related to heightened donor screening criteria ahead of the implementation of enhanced product testing, as well as write-downs of inventory in certain categories. Together the product yield and inventory writedowns negatively impacted gross margins in the year ended December 31, 2021 by approximately 4%. We do not expect these costs to continue at similar levels going forward.

Operating Expenses

Sales and Marketing

Sales and marketing expenses increased $1.2 million, or 7.2%, to $18.8 million in the year ended December 31, 2021 compared to $17.6 million in the year ended December 31, 2020. The increase was primarily the result of higher stock-based compensation after our IPO in October 2020 and increases in commissions paid to independent sales agents due to sales growth in our Core Products. As a percentage of sales, sales and marketing expenses declined to 39.7% in the year ended December 31, 2021 from 41.2% in the year ended December 31, 2020 primarily due to the growth in our "business to business" Non-Core Product revenues, as such revenues have limited associated selling costs.

General and Administrative

G&A expenses increased $3.4 million, or 31.2%, to $14.0 million in the year ended December 31, 2021 compared to $10.6 million in the year ended December 31, 2020. The increase was primarily due to costs of being a public company, most notably increases in directors and officers insurance, legal fees and stock-based compensation. As a percentage of net sales, G&A expenses rose to 29.5% in the year ended December 31, 2021 from 24.9% in the year ended December 31, 2020.

Research and Development

R&D expenses increased $3.3 million, or 55.6%, to $9.3 million in the year ended December 31, 2021 compared to $6.0 million in the year ended December 31, 2020. We continue to focus our R&D efforts on the development of our pipeline products with the growth in R&D expenses in the year ended December 31, 2021 largely attributable to the work performed on the development of our CanGaroo Envelope with antibiotics. In 2021, we completed both the product design and manufacturing validation for this next version of our CanGaroo Envelope.

Interest Expense

Interest expense was approximately $5.3 million and $5.6 million in the year ended December 31, 2021 and 2020, respectively. The decrease was due to lower draws on our Revolving Credit Agreement during the year ended December 31, 2021 and lower outstanding principal on our Term Loan Credit Agreement due to the commencement of principal payments in the third quarter of 2021. See "Credit Facilities" below for further discussion of these debt agreements and

Note 9 to the consolidated financial statements included elsewhere in this Annual Report for a description of our Revenue Interest Obligation and the interest expense related thereto.

Other (Income) Expense, net

Other (income) expense, net was approximately $3.6 million of income 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 8 and 17 to the consolidated financial statements included elsewhere in this Annual Report.

Other (income) expense, net was an expense of approximately $2.6 million in the year ended December 31, 2020 and was primarily attributable to the loss on early extinguishment of debt of $2.3 million. See Note 12 to the consolidated financial statements included elsewhere in this Annual Report for further discussion.

Accretion of Series A Preferred Stock

Accretion of Series A Preferred Stock was $3.5 million in the year ended December 31, 2020. The Accretion of Series A Preferred Stock relates to $3.5 million of deemed dividends related to the sale of the Convertible Preferred Stock in September 2020 below its fair value. See Note 12 to the consolidated financial statements included elsewhere in this Annual Report for additional information.

Non-GAAP Financial Measures

This Annual Report presents our gross margin, excluding intangible asset amortization, for the years ended December 31, 2021 and 2020. 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 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, 2021 and 2020 to the most directly comparable GAAP financial measure, which is our GAAP gross margin (in thousands).

	Year Ended December 31,	
	2021	2020
Net sales	$ 47,390	$ 42,682
Cost of goods sold	28,368	22,121
Gross profit	19,022	20,561
Intangible asset amortization expense	3,396	3,396
Gross profit, excluding intangible asset amortization	$ 22,418	$ 23,957
Gross margin	40.1 %	48.2 %
Gross margin, excluding intangible asset amortization	47.3 %	56.1 %

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, 2021, we had cash and restricted cash of approximately $30.4 million and availability under our Revolving Credit Facility of $2.1 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 more recently, proceeds from our IPO and a private placement of our common stock. Our historical cash outflows have primarily been associated with acquisition and integration, manufacturing costs, general and marketing, research and development, clinical activity, purchase of property and equipment used in the production activities of our Richmond, California facility 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, 2021, our accumulated deficit was $105.1 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, on December 8, 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.

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, 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. Additionally, as discussed below under "--- Credit Facilities," in August 2021, we commenced the principal repayment of our Term Debt with such repayments totaling approximately $556,000 per month through July 2024.

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, either refinance or restructure our Term Debt and Revolver or pursue asset sale transactions. However, such transactions may not be successful and we may not be able to raise additional equity or refinance our Term Debt and Revolver on acceptable terms, or at all. We believe that the net proceeds from our IPO, together with our existing cash, availability under our Revolving Credit Facility and cash generated from expected future commercial sales as well as the December 2021 PIPE financing will be sufficient to fund our operating expenses, debt service requirements and capital expenditure needs through at least twelve months from the issuance date of the consolidated financial statements included elsewhere in this Annual Report. We have based this estimate on assumptions that may prove to be wrong, and we could exhaust our available capital resources sooner than we expect.

Cash Flows for the Years Ended December 31, 2021 and 2020

	Year Ended December 31,	
	2021	2020
	(in thousands)	
Net cash (used in) provided by:		
Operating activities	$ (15,446)	$ (13,626)
Investing activities	(369)	(640)
Financing activities	6,711	51,208
Net decrease in cash	**$ (9,104)**	**$ 36,942**

Net Cash Used in Operating Activities

Net cash used in operating activities for the year ended December 31 2021 was $15.4 million compared to $13.6 million for the year ended December 31, 2020. The year-over-year change was primarily due to a higher net loss (after adjustment for non-cash charges and gains) offset by improved working capital performance, particularly as it relates to our management of inventory levels and collection of receivables.

Net Cash Used in Investing Activities

Net cash used in investing activities for the year ended December 31, 2021 was $0.4 million and approximately $0.6 million for the year ended December 31, 2020. 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, 2021 totaled $6.7 million compared to $51.2 million of cash provided by financing activities for the year ended December 31, 2020. The year-over-year net decrease of $44.5 million was primarily due to capital raises in the 2020 period of $51.9 million (including $43.0 million in net proceeds from the IPO) versus capital raises in the 2021 period of $14.0 million (including $13.8 million in net proceeds from our PIPE financing). Also contributing to this decrease were net repayments of $1.8 million on our Revolving Credit Facility in 2021 (versus net borrowings of $2.3 million in 2020) and principal payments of $2.8 million on our Term Loan Credit Agreement during the 2021 period.

Credit Facilities

General

On July 15, 2019, Aziyo and Aziyo Med, LLC, which we refer to collectively as the Borrowers, entered into an amended and restated term loan credit agreement (the "Term Loan Credit Agreement"), with Midcap Financial Trust, as agent and lender, and the other lenders party thereto, which provided for the conversion of our existing term loans into borrowing under the Term Loan Credit Agreement (consisting of a $8.5 million tranche (Term Loan Tranche 1), a $5.0 million tranche (Term Loan Tranche 2) and a $3.0 million tranche (Term Loan Tranche 3)), and established a new $3.5 million tranche (Term Loan Tranche 4) and a new $5.0 million tranche (Term Loan Tranche 5). Commitments in respect

of Term Loan Tranche 5 terminated without being borrowed on June 30, 2020. We refer to Term Loan Tranche 1, Term Loan Tranche 2, Term Loan Tranche 3 and Term Loan Tranche 4 collectively as the Term Loan Facility.

On July 15, 2019, the Borrowers also entered into an amended and restated revolving credit agreement (the "Revolving Credit Agreement"), with Midcap Funding IV Trust, as agent and lender, and the other lenders party thereto, which provided for an $8.0 million asset-based revolving credit facility (the "Revolving Credit Facility").

As of December 31, 2021, we had $17.1 million of indebtedness outstanding under our Term Loan Facility (net of $0.1 million of unamortized deferred financing costs) and $4.8 million outstanding under our Revolving Credit Facility (with $2.1 million of additional borrowings available thereunder).

Interest Rates and Fees

Borrowings under the Term Loan Facility accrue interest at a rate per year equal to the LIBOR Rate (as defined elsewhere in this Annual Report on Form 10-K) plus a margin of 7.25%. Borrowings under the Revolving Credit Facility bear interest at the per annum rate equal to the LIBOR Rate plus a margin of 4.95%. The LIBOR Rate is defined as the greater of 2.25% and the applicable London Interbank Offered Rate for U.S. dollar deposits divided by 1.00 minus the maximum effective reserve percentage for Eurocurrency funding.

Under the terms of the Revolving Credit Facility, we can borrow up to an amount (the "Borrowing Base"), equal to (1) 85.0% of the aggregate net amount at such time of the Eligible Accounts (as defined in the Revolving Credit Agreement), plus (2) 50% of the value of the Eligible Inventory (as defined in the Revolving Credit Agreement), valued at the lower of first-in-first-out cost or market cost, and after factoring in all rebates, discounts and other incentives or rewards associated with the purchase of the applicable Eligible Inventory (provided that the Borrowing Base will be automatically adjusted down, if necessary, such that the aggregate availability from Eligible Inventory shall never exceed the lesser of (x) an amount equal to 40.0% of the Borrowing Base and (y) $2,000,000).

In addition to paying interest on the principal amounts outstanding under the Revolving Credit Facility, we are required to pay an unused line fee to the lenders under the Revolving Credit Facility in respect of the unutilized commitments thereunder equal to 0.50% multiplied by the lesser of (1) the unutilized commitments and (2) $8,000,000 minus 40% of the Borrowing Base.

Mandatory Prepayments

The Term Loan Credit Agreement requires the Borrowers to prepay amounts outstanding under the Term Loan Facility, subject to certain exceptions, with: (1) 100% of any net casualty proceeds in excess of $250,000 with respect to assets upon which the agent maintains a lien and (2) 100% of the net cash proceeds of non-ordinary course asset sales or sales pertaining to collateral upon which the Borrowing Base is calculated. In addition, the Borrowers are required to prepay all outstanding obligations under the Term Loan Facility upon the termination of all commitments under the Revolving Credit Facility and the repayment of the outstanding borrowings thereunder. No such mandatory prepayments were required during the years ended December 31, 2021 and 2020.

The Revolving Credit Agreement requires the Borrowers to prepay amounts outstanding under the Revolving Credit Facility (or provide cash collateral up to the amount of any outstanding letter of credit obligations) to the extent outstanding borrowings under the Revolving Credit Facility exceed the lesser of (1) $8,000,000 and (2) the Borrowing Base.

Optional Prepayment

The Borrowers may prepay the Term Loan Facility in whole but not in part at any time with at least 10 business days' prior written notice, provided, however, that such prepayment shall be accompanied by a portion of the Exit Fee (as defined below) equal to the amount prepaid divided by the then-outstanding principal amount of borrowings outstanding under the Term Loan Facility, and a prepayment fee which, based on the amendment to the Term Loan Credit Agreement executed in January 2022, shall be equal to the amount prepaid multiplied by 3.0% until January 21, 2023 and 2.0%

thereafter. The "Exit Fee" is defined as an amount equal to 6.50% multiplied by the aggregate principal amount of all borrowings advanced to the Borrowers under the Term Loan Facility.

The Borrowers may prepay the Revolving Credit Facility in whole or in part at any time, provided, however, that any such partial prepayment shall be in an amount equal to $100,000 or a higher integral multiple of $25,000. Should the Revolving Credit Facility be terminated prior to its final maturity (see below), based on the amendment to the Revolving Credit Agreement executed in January 2022, the Borrowers must pay a fee equal to an amount determined by multiplying the amount of the Revolving Credit Facility so terminated by 3.0% until January 21, 2023 and 2.0% thereafter.

Amortization and Final Maturity

The Borrowers are required to make interest-only payments prior to the principal amortization start date. The Term Loan Facility provided that if certain conditions were satisfied prior to December 1, 2020 (including our completion of a qualified initial public offering and no continuing default or event of default), the principal amortization start date may, upon our request, be extended to August 1, 2021 (from the previous principal amortization start date of February 1, 2021). Based on the completion of our IPO, in January 2021, we exercised this interest-only period extension right and, as such, the principal payments in respect of borrowings under the Term Loan Facility commenced on August 1, 2021. Such principal payments shall be in an amount equal to the total principal amount of borrowings under the Term Loan Facility divided by 36, for a 36-month straight-line amortization of equal monthly principal payments. The remaining unpaid balance on the Term Loan Facility, together with all accrued and unpaid interest thereon and any remaining unpaid amount of the Exit Fee, is due and payable on July 15, 2024.

Outstanding borrowings under the Revolving Credit Facility do not amortize and are due and payable on July 15, 2024.

Security

All obligations under the Term Loan Facility and the Revolving Credit 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 each Borrower's assets, including all goods, equipment, inventory, contract rights or rights to payment of money, leases, license agreements, franchise agreements, general intangibles, commercial tort claims, documents, instruments (including any promissory notes), chattel paper (whether tangible or electronic), cash, deposit accounts, securities accounts, fixtures, letter of credit rights (whether or not the letter of credit is evidenced by a writing), securities, and all other investment property, supporting obligations, and financial assets, whether now owned or hereafter acquired, wherever located.

Covenants and Other Matters

The Term Loan Credit Agreement and the Revolving Credit Agreement each contain a number of covenants that, among other things and subject to certain exceptions, restrict the ability of the Borrowers to:

- 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, the Term Loan Credit Agreement and the Revolving Credit Agreement contain a financial covenant, which is tested on a monthly basis, and requires us to achieve a specified Minimum Net Product Revenue (as defined in the applicable credit agreement) for the preceding 12-month period. In January 2022, the Term Loan Credit Agreement and Revolving Credit Agreement were amended and all future Minimum Net Product Revenue covenant amounts were reset.

The Term Loan Credit Agreement and the Revolving Credit Agreement each 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.

The Term Loan Credit Agreement and the Revolving Credit Agreement also contain certain customary representations and warranties and affirmative covenants, and certain reporting obligations. In addition, the lenders will be permitted to accelerate all outstanding borrowings and other obligations, terminate outstanding commitments and exercise other specified remedies upon the occurrence of certain events of default (subject to certain grace periods and exceptions), which include, among other things, payment defaults, breaches of representations and warranties, covenant defaults, certain cross-defaults and cross-accelerations to other indebtedness, certain events of bankruptcy and insolvency, certain judgments and changes of control.

Supplier Promissory Note

During 2017, we restructured certain of our liabilities with a tissue supplier and entered into an unsecured promissory note. As of December 31, 2021, the balance of this promissory note totaled $1.4 million plus accrued interest. The note bears interest at 5% and is currently due in full; however, the notes are subordinated in payment to the Term Loan Facility and Revolving Credit Facility and in both 2021 and 2020, the Company's senior lender restricted payment of the amounts due.

PPP Loan

In May 2020, we entered into a promissory note with Silicon Valley Bank 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 in the accompanying Consolidated Statements of Operations for the year ended December 31, 2021.

2020 Bridge Notes

In April 2020, we entered into a bridge note purchase agreement pursuant to which we issued approximately $2.0 million in aggregate principal amount of convertible promissory notes (the "2020 Bridge Notes"), to HighCape Partners QP, HighCape Partners and Deerfield. The 2020 Bridge Notes had a maturity date of April 1, 2025 and accrued interest at

a rate of 5.0% per year. The aggregate principal amount of, and accrued interest on, the 2020 Bridge Notes automatically converted into an aggregate of 2,039,427 shares of our Series A convertible preferred stock upon the closing of our Series A convertible preferred stock financing in September 2020.

Funding Requirements

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

As of December 31, 2021, we had $23.3 million of indebtedness outstanding, consisting of $17.1 million outstanding under our Term Loan Facility (net of $0.1 million of unamortized deferred financing costs), $4.8 million outstanding under our Revolving Credit Facility (with $2.1 million of additional borrowings available thereunder), and a $1.4 million promissory note payable to one of our suppliers. In addition, as further described in Note 9 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.

Based on our current and planned business operations, we believe that the net proceeds from our IPO, together with our existing cash, availability under our Revolving Credit Facility and cash generated from expected future commercial sales as well as the December 2021 PIPE financing will be sufficient to fund our operating expenses, debt service requirements and capital expenditure needs through at least twelve months from the issuance date of the consolidated financial statement included elsewhere in this Annual Report. We have based this estimate on assumptions that may prove to be wrong, and we could exhaust our available capital resources sooner than we expect. 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 transactions. 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 (to the extent above the applicable insurance coverage), for example, in connection with claims involving the recall of FiberCel;
- 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 and preferred equity 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 Part I, Item 1A. "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."

Off-Balance Sheet Arrangements

As of December 31, 2021, 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, to Ligand, 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 $100.0 million and a second $5.0 million will be due if cumulative sales exceed $300.0 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. There was no change to estimated future payments during the years ended December 31, 2021 and 2020, 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.

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 100.0% 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 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. The period expense is then recognized on a straight-line basis over the requisite service period for the entire award.

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 Term Loan Facility and Revolving Credit Facility bear 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 during the years ended December 31, 2021 or 2020 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, 2021, 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. We believe this financial institution has sufficient assets and liquidity to conduct its operations in the ordinary course of business with little or no credit risk to us.

Our accounts receivable relate to sales to customers. To minimize credit risk, ongoing credit evaluations of all customers' financial condition are performed. One customer represented 10% or more of our accounts receivable as of December 31, 2021.

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.

Impact of Inflation

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, 2021 and 2020. 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.

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 until the earliest of: (i) the last day of the first fiscal year in which our annual gross revenues are $1.07 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.

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, 2021.

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, 2021, 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, 2021 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information.

None.

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections

Not applicable.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

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 2022 (the "2022 Annual Meeting of Stockholders"), which we intend to file with the SEC within 120 days of the year ended December 31, 2021.

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 2022 Annual Meeting of Stockholders, which we intend to file with the SEC within 120 days of the year ended December 31, 2021.

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, 2021.

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)	283,275	$ 6.41 (4)	—
2020 Plan (2)	1,339,521	$ 15.05 (4)	756,554
ESPP (3)	—	—	186,826
Equity Compensation Plans Not Approved by Stockholders	—	—	—
Total	1,622,796	$ 13.28	943,380

(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 initial public offering (the "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 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 2022 Annual Meeting of Stockholders, which we intend to file with the SEC within 120 days of the year ended December 31, 2021.

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 2022 Annual Meeting of Stockholders, which we intend to file with the SEC within 120 days of the year ended December 31, 2021.

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 2022 Annual Meeting of Stockholders, which we intend to file with the SEC within 120 days of the year ended December 31, 2021.

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
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

Exhibit Number	Description	Form	File No.	Exhibit	Filing Date	
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	
4.4	Description of Securities	10-K	001-39577	4.4	03/15/2021	
10.1	Amended and Restated Credit and Security Agreement (Term Loan), dated as of July 15, 2019, by and among the Registrant and Aziyo Med, LLC, as Borrowers, Midcap Financial Trust, as Agent and as a Lender, and the additional Lenders from time to time party thereto, as amended	S-1/A	333-248788	10.13	09/30/2020	
10.2	Amended and Restated Credit and Security Agreement (Revolving Loan), dated as of July 15, 2019, by and among the Registrant and Aziyo Med, LLC, as Borrowers, Midcap Funding IV Trust, as Agent and as a Lender, and the additional Lenders from time to time party thereto, as amended	S-1/A	333-248788	10.14	09/30/2020	
10.3	Second Amendment, dated January 21, 2022, to Amended and Restated Credit and Security Agreement (Revolving Loan), dated as of July 15, 2019, by and among the Registrant and Aziyo Med, LLC, as Borrowers, Midcap Funding IV Trust, as Agent and as a Lender, and the additional Lenders from time to time party thereto, as amended					*
10.4	Second Amendment, dated January 21, 2022, to Amended and Restated Credit and Security Agreement (Term Loan), dated as of July 15, 2019, by and among the Registrant and Aziyo Med, LLC, as Borrowers, Midcap Funding IV Trust, as Agent and as a Lender, and the additional Lenders from time to time party thereto, as amended					*
10.5	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	
10.6	Royalty Agreement, dated as of May 31, 2017, by and between Aziyo Med, LLC and Ligand Pharmaceuticals Incorporated	S-1	333-248788	10.15	09/14/2020	

Exhibit Number	Description	Form	File No.	Exhibit	Filing Date	
10.7	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	
10.8	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	
10.9†	Aziyo Biologics, Inc. 2015 Stock Option/Stock Issuance Plan (as amended)	S-1	333-248788	10.1	09/14/2020	
10.10†	Aziyo Biologics, Inc. 2020 Incentive Award Plan and form of award agreements thereunder	S-1/A	333-248788	10.2	09/30/2020	
10.11†	Aziyo Biologics, Inc. Non-Employee Director Compensation Program	S-1/A	333-248788	10.3	09/30/2020	
10.12†	Aziyo Biologics, Inc. 2020 Employee Stock Purchase Plan	S-1/A	333-248788	10.4	09/30/2020	
10.13†	Amended and Restated Employment Agreement, by and between the Registrant and Ronald Lloyd, dated as of September 30, 2020	S-1/A	333-248788	10.6	09/30/2020	
10.14†	Employment Agreement, by and between the Registrant and Thomas Englese, dated as of September 30, 2020	S-1/A	333-248788	10.8	09/30/2020	
10.15†	Employment Agreement, by and between the Registrant and Darryl Roberts, dated as of September 30, 2020	S-1/A	333-248788	10.10	09/30/2020	
10.16†	Employment Agreement, by and between the Registrant and Matthew Ferguson, dated as of September 30, 2020	S-1/A	333-248788	10.11	09/30/2020	
10.17†	Form of Indemnification Agreement for Directors and Officers	S-1/A	333-248788	10.12	09/30/2020	
21.1	Subsidiaries of Aziyo Biologics, Inc.					*
23.1	Consent of PricewaterhouseCoopers LLP					*
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.					*

Exhibit Number	Description	Form	File No.	Exhibit	Filing Date	
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					*
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.

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 8, 2022

By: /s/ RONALD LLOYD
Ronald Lloyd
President and Chief Executive Officer
(Principal Executive Officer)

Date: March 8, 2022

/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/Ronald Lloyd Ronald Lloyd	President, Chief Executive Officer and Director *(principal executive officer)*	March 8, 2022
/s/Matthew Ferguson Matthew Ferguson	Chief Financial Officer *(principal financial officer and principal accounting officer)*	March 8, 2022
/s/Kevin Rakin Kevin Rakin	Chairperson of the Board of Directors	March 8, 2022
/s/W. Matthew Zuga W. Matthew Zuga	Director	March 8, 2022
/s/Maybelle Jordan Maybelle Jordan	Director	March 8, 2022
/s/C. Randal Mills, Ph.D. C. Randal Mills, Ph.D.	Director	March 8, 2022
/s/Brigid A. Makes Brigid A. Makes	Director	March 8, 2022

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, 2021 and 2020, and the related consolidated statements of operations, of changes in convertible preferred stock and 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, 2021 and 2020, 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.

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.

Emphasis of Matter

As discussed in Note 2 to the consolidated financial statements, the Company has incurred losses and expects losses to continue for the foreseeable future, which may have an adverse impact on the Company's future liquidity. Management's evaluation of the events and conditions and management's plans to mitigate this matter are also described in Note 2.

/s/ PricewaterhouseCoopers LLP
Baltimore, Maryland
March 8, 2022

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, 2021	December 31, 2020
Assets		
Current assets:		
Cash	$ 30,393	$ 39,150
Restricted cash	35	382
Accounts receivable, net	5,996	7,166
Inventory	9,554	10,117
Prepaid expenses and other current assets	1,450	2,892
Total current assets	47,428	59,707
Property and equipment, net	1,200	1,162
Intangible assets, net	18,466	21,865
Other assets	76	76
Total assets	**$ 67,170**	**$ 82,810**
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 1,582	$ 2,054
Accrued expenses	6,375	6,323
Payables to tissue suppliers	2,467	2,295
Current portion of long-term debt	8,059	6,310
Current portion of revenue interest obligation	2,750	2,750
Revolving line of credit	4,763	6,514
Deferred revenue and other current liabilities	5	533
Total current liabilities	26,001	26,779
Long-term debt	10,410	17,811
Long-term revenue interest obligation	16,540	16,633
Other long-term liabilities	698	756
Total liabilities	53,649	61,979
Commitments and contingencies (Note 9)		
Stockholders' equity (deficit):		
Class A Common stock, $0.001 par value, 200,000,000 shares authorized as of December 31, 2021 and December 31, 2020, and 9,245,146 and 7,091,960 shares issued and outstanding, as of December 31, 2021 and December 31, 2020, respectively	9	7
Class B Common stock, $0.001 par value, 20,000,000 shares authorized, as of December 31, 2021 and December 31, 2020 and 4,313,406 and 3,134,162 issued and outstanding as of December 31, 2021 and December 31, 2020, respectively	4	3
Additional paid-in capital	118,599	101,080
Accumulated deficit	(105,091)	(80,259)
Total stockholders' equity	13,521	20,831
Total liabilities and stockholders' equity	**$ 67,170**	**$ 82,810**

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,	
	2021	**2020**
Net sales	$ 47,390	$ 42,682
Cost of goods sold	28,368	22,121
Gross profit	19,022	20,561
Sales and marketing	18,825	17,565
General and administrative	13,963	10,641
Research and development	9,266	5,954
Total operating expenses	42,054	34,160
Loss from operations	(23,032)	(13,599)
Interest expense	5,324	5,633
Other (income) expense, net	(3,579)	2,567
Loss before provision for income taxes	(24,777)	(21,799)
Income tax expense	55	26
Net loss	**(24,832)**	**(21,825)**
Accretion of Convertible Preferred Stock	—	3,510
Net loss attributable to common stockholders	**$ (24,832)**	**$ (25,335)**
Net loss per share - basic and diluted	**$ (2.38)**	**$ (8.88)**
Weighted average common shares outstanding - basic and diluted	10,444,767	2,852,541

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

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

	Convertible Preferred Stock		Common Stock		Class A Common Stock		Class B Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholder' Equity (Deficit)
	Number of Shares	Amount	Number of Shares	Amount	Number of Shares	Amount	Number of Shares	Amount			
Balance, December 31, 2019	**44,550,230**	**$ 44,449**	**648,277**	**1**	**—**	**—**	**—**	**—**	**1,826**	**(56,938)**	**(55,111)**
Issuance of Convertible Preferred Stock, net of issuance costs of $9	5,864,197	8,634	—	—	—	—	—	—	—	—	—
Proceeds from stock option exercises	—	—	402	—	—	—	—	—	2	—	2
Accretion of Convertible Preferred stock	—	3,510	—	—	—	—	—	—	(2,014)	(1,496)	(3,510)
Preferred stock warrant exercises	405,000	405	—	—	—	—	—	—	474	—	474
Net exercise of Common Stock warrants	—	—	5,204	—	—	—	—	—	—	—	—
Conversion of Preferred Stock to Class A and Class B Common Stock upon Initial Public Offering	(50,819,427)	(56,998)	—	—	4,232,195	4	2,398,868	2	56,992	—	56,998
Conversion of Common Stock to Class A and Class B Common Stock upon Initial Public Offering	—	—	(653,883)	(1)	653,883	1	—	—	—	—	—
Issuance of Class A and Class B Common Stock in Initial Public Offering, net of offering costs of $7,000	—	—	—	—	2,205,882	2	735,294	1	43,021	—	43,024
Stock-based compensation	—	—	—	—	—	—	—	—	779	—	779
Net loss	—	—	—	—	—	—	—	—	—	(21,825)	(21,825)
Balance, December 31, 2020	**—**	**$ —**	**—**	**—**	**7,091,960**	**7**	**3,134,162**	**3**	**101,080**	**(80,259)**	**20,831**
Proceeds from stock option exercises	—	—	—	—	3,305	—	—	—	26	—	26
Issuance 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**

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,	
	2021	**2020**
Net loss	$ (24,832)	$ (21,825)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	3,730	3,864
(Gain) loss on (forgiveness)/early extinguishment of debt	(3,029)	2,340
Gain on revaluation of revenue interest obligation and other	—	227
Amortization of deferred financing costs	121	121
Interest expense recorded as additional revenue interest obligation	2,654	2,682
Interest expense recorded as Convertible Preferred Stock	—	39
Stock-based compensation	3,535	779
Operating expense satisfied through Convertible Preferred Stock issuance	—	814
Changes in operating assets and liabilities:		
Accounts receivable	1,170	64
Inventory	563	(2,927)
Prepaid expenses and other	1,442	(1,455)
Accounts payable and accrued expenses	(420)	1,907
Obligations to tissue suppliers	172	(191)
Deferred revenue and other liabilities	(552)	(65)
Net cash used in operating activities	**(15,446)**	**(13,626)**
INVESTING ACTIVITIES:		
Expenditures for property, plant and equipment	(369)	(640)
Net cash used in investing activities	**(369)**	**(640)**
FINANCING ACTIVITIES:		
Proceeds from Initial Public Offering, net of offering costs	—	43,024
Proceeds from Private Placement, net of issuance costs	13,753	—
Proceeds from exercise of preferred stock warrants	—	405
Proceeds from issuance of Convertible Promissory Note	—	2,000
Net borrowings (repayments) under revolving line of credit	(1,751)	2,286
Proceeds from Convertible Preferred Stock issuance, net	—	3,441
Proceeds from stock option exercises	26	2
Proceeds from long-term debt	—	2,995
Repayments of long-term debt	(2,778)	(300)
Payments on revenue interest obligation	(2,747)	(2,645)
Proceeds from sales of common stock through Employee Stock Purchase Plan	208	—
Net cash provided by financing activities	**6,711**	**51,208**
Net (decrease) increase in cash and restricted cash	**(9,104)**	**36,942**
Cash and restricted cash, beginning of period	**39,532**	**2,590**
Cash and restricted cash, end of period	**$ 30,428**	**$ 39,532**
Supplemental Cash Flow and Non-Cash Financing Activities Disclosures:		
Cash paid for interest	$ 4,984	$ 5,113
Conversion of Convertible Promissory Note to Convertible Preferred Stock	$ —	$ 2,000
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 core products span the implantable electronic devices/cardiovascular-related market, the orthopedic/spinal repair market and the soft tissue reconstruction market ("Core Products"). 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 ("Non-Core Products") with corporate customers.

Reverse Stock Split and Initial Public Offering

On September 25, 2020, the Company's Board of Directors and stockholders approved an amendment to the Company's amended and restated certificate of incorporation to effect a 1-for-13.9549 reverse stock split of the Company's common stock, which was effected on September 29, 2020. The par value of the common stock was not adjusted as a result of the reverse stock split. Accordingly, all share and share-related information presented in these consolidated financial statements and the accompanying notes has been retroactively adjusted for all periods presented to give effect to the reverse stock split.

On October 13, 2020, in connection with the Company's initial public offering ("IPO"), Aziyo 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 of approximately $43.0 million, after deducting the underwriting discount of approximately $3.5 million and offering expenses of approximately $3.5 million.

Note 2. Summary of Significant Accounting Policies

Basis of Presentation

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. The Company believes that the net proceeds from its IPO, together with its existing cash, availability under its Revolving Line of Credit (the "Revolver") and cash generated from expected future commercial sales as well as the December 2021 private placement financing (see Note 12) will be sufficient to fund its operating expenses and capital expenditure requirements through at least one year after the issuance date of the consolidated financial statements for the year ended December 31, 2021

The Company expects its losses to continue for the foreseeable future and these losses, along with the monthly principal repayments of its Term Loan Facility, will continue to have an adverse effect on our financial position. 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. As such, in the short-term, the Company will seek to raise capital through the issuance of common stock,

either refinance or restructure its Term Loan Facility and Revolving Credit Facility (see Note 8) or pursue asset sale transactions in order to support its continuing operations and pursue its growth strategy. The Company may not be able to raise additional funds or enter into such other agreements or arrangements when needed on favorable terms or at all. If the Company fails to raise capital or enter into such agreements in the short-term, it will be unable to fund its operations and capital expenditure requirements at that time which may result in there being substantial doubt about its ability to continue as a going concern.

Reclassifications

Certain reclassifications have been made to prior year amounts to conform with current year financial statement presentation. The reclassifications relate to certain executive compensation costs and technical operations expenses at the Company's Richmond, California plant. As follows are the total amounts reclassified for the year ended December 31, 2020 along with the line items in the Consolidated Statement of Operations that were impacted (in thousands).

	Increase (Decrease) From Previously Reported Amounts
Sales and marketing	$ 720
General and administrative	(2,591)
Research and development	1,871

These reclassifications did not impact the Company's consolidated earnings or assets for the year ended December 31, 2020.

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 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 is closely monitoring the impact of the COVID-19 pandemic 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 decreased significantly, 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 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 will likely continue to reduce the Company's net sales and negatively impact its business, financial condition and results of operations while the pandemic continues.

Net Loss per Share Attributable to Common Stockholders

The Company calculates basic and diluted net loss per share attributable to common stockholders in conformity with the two-class method required for participating securities. The Convertible Preferred Stock was considered a participating security through the completion of the IPO (see Note 12). The two-class method requires income (loss) available to common stockholders for the period to be allocated between common and participating securities based upon their respective rights to share in the earnings as if all income (loss) for the period had been distributed. Under the two-

class method, the net loss attributable to common stockholders is not allocated to the Convertible Preferred Stock as the holders of the preferred stock do not have a contractual obligation to share in losses.

Our common stock has a dual class structure, consisting of Class A common stock and 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, Convertible Preferred Stock, stock options, and preferred and common stock 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 Revolving Credit Facility (see Note 8), the Company has a lockbox arrangement with the banking institution whereby daily lockbox receipts are contractually utilized to pay down outstanding balances on the Revolving Credit Facility debt. Lockbox receipts that have not yet been applied to the Revolving Credit Facility are 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,	
	2021	2020
Cash	$ 30,393	$ 39,150
Restricted cash	35	382
Total cash and restricted cash shown in statements of cash flows	$ 30,428	$ 39,532

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, 2021 and 2020.

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.

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, 2021 and 2020.

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, 2021 and 2020.

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

The Company recognizes 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, 2021 and 2020, the Company maintained $30.9 million and $40.0 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, 2021 and 2020, 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.

Note 3. Recently Issued Accounting Standards

In March 2020, the Financial Accounting Standards Board ("FASB") issued ASU 2020-04, Reference Rate Reform (Topic 848), Facilitation of the Effects of Reference Rate Reform on Financial Reporting. The ASU provides temporary relief from some of the existing rules governing contract modifications when the modification is related to the replacement of the London Interbank Offered Rate ("LIBOR") or other reference rates discontinued as a result of reference rate reform. The ASU specifically provides optional practical expedients for contract modification accounting related to contracts subject to ASC 310, Receivables, ASC 470, Debt, ASC 842, Leases, and ASC 815, Derivatives and Hedging. The ASU also establishes a general contract modification principle that entities can apply in other areas that may be affected by reference rate reform and certain elective hedge accounting expedients. For eligible contract modifications, the principle generally allows an entity to account for and present modifications as an event that does not require contract remeasurement at the modification date or reassessment of a previous accounting determination. That is, the modified contract is accounted for as a continuation of the existing contract. The standard was effective upon issuance on March 12, 2020, and the optional practical expedients can generally be applied to contract modifications made and hedging relationships entered into on or before December 31, 2022. Borrowings under the Company's term loan facility and

revolving line of credit bear interest based on LIBOR or an alternate rate. Provisions currently provide the Company with the ability to replace LIBOR with a different reference rate in the event that LIBOR ceases to exist.

In December 2019, the FASB issued ASU 2019-12, *Income Taxes (Topic 740), Simplifying the Accounting for Income Taxes,* which clarifies and simplifies certain aspects of the accounting for income taxes. The standard is effective for years beginning after December 15, 2020, and interim periods within annual periods beginning after December 15, 2020. The adoption of this standard on January 1, 2021 did not have a material impact on the Company's consolidated financial statements.

In November 2019, the FASB issued ASU 2019-10, "Financial Instruments - Credit Losses (Topic 326), Derivative and Hedging (Topic 815), and Leases (Topic 842), Effective Dates." The FASB deferred the effective dates of the new credit losses standard for all entities except filers with the Securities and Exchange Commission (the "SEC") that are not smaller reporting companies (SRCs) to fiscal years beginning after December 15, 2022, including interim periods within those fiscal years. The Board also aligned the effective dates of ASU 2017-04 on goodwill impairment with the new effective dates of the credit losses standard. The FASB deferred the effective dates of its new standards on hedging and leases for entities that are not public business entities (PBEs) (and for leases, for entities that are not non-for-profit (NFP) entities that have issues, or are conduit bond obligors for, certain securities; and are not employee benefit plans (EBPs) that file or furnish financial statements with or to the SEC) to fiscal years beginning after December 15, 2020, and interim periods in the following year. The FASB is also reconsidering its philosophy on establishing effective dates for major standards for private companies, NFPs, EBPs and smaller public companies. The board has developed a two-bucket approach that would give these entities more time to implement major new standards. The Company is evaluating this standard to determine if adoption will have a material impact on the Company's consolidated financial statements.

In August 2018, the FASB issued ASU 2018-13, "Fair Value Measurement (Topic 820), Disclosure Framework — Changes to the Disclosure Requirements for Fair Value Measurement." The standard eliminates, adds, and modifies certain disclosure requirements for fair value measurements. Entities will no longer be required to disclose the amount of and reasons for transfers between Level 1 and Level 2 of the fair value hierarchy, but public companies will be required to disclose the range and weighted average used to develop significant unobservable inputs for Level 3 fair value measurements. The standard is effective for annual reporting periods beginning after December 15, 2019. Adoption of this new standard in the first quarter of 2020 did not have a material impact on the Company's consolidated financial statements.

In June 2016, the FASB issued ASU 2016-13, *Financial Instruments – Credit Losses,* which changed the impairment model for most financial assets and certain other financial instruments. The standard requires the use of a forward-looking "expected loss" model for instruments measured at amortized cost that generally will result in the earlier recognition of allowances for losses. The standard is effective for years beginning after December 15, 2019, and interim periods within annual periods beginning after December 15, 2019. The adoption of this standard on January 1, 2020 did not have a material impact on the Company's consolidated financial results.

In February 2016, the FASB issued ASU 2016-02, Leases. The standard requires that lessees recognize a right-of-use asset and a lease liability for virtually all of their leases (other than leases that meet the definition of a short-term lease). The liability will be equal to the present value of lease payments. The asset will be based on the liability subject to certain adjustments. For income statement purposes, the FASB retained a dual model, requiring leases to be classified as either operating or finance. Operating leases will result in straight-line expense (similar to current operating leases) while finance leases will result in a front-loaded expense pattern (similar to current capital leases). In November 2019, the FASB issued 2019-10 which extended the adoption of ASU 2016-02 for the Company to be effective for periods ending after December 15, 2022. While early adoption is permitted, the Company intends to adopt in the fourth quarter of 2022 for the full 2022 year. The Company is evaluating this standard to determine if adoption will have a material impact on the Company's consolidated financial statements.

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, 2021, the Company had 756,554 shares of Class A common stock available for issuance under the 2020 Plan.

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, 2021 and 2020 is as follows:

	Number of Shares	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (years)	Aggregate Intrinsic Value (in thousands)
Outstanding, December 31, 2020	917,437	$ 13.68	8.1	$ 2,070
Granted	497,517	$ 12.63		
Exercised	(3,305)	$ 7.91		
Forfeited	(24,838)	$ 15.54		
Outstanding, December 31, 2021	1,386,811	$ 13.28	7.8	$ 179
Vested and exercisable, December 31, 2021	394,437	$ 10.47	5.3	$ 159

As of December 31, 2021, there was approximately $6.6 million of total unrecognized compensation expense related to unvested stock options. These costs are expected to be recognized over a weighted- average period of 2.8 years. The weighted average grant date fair value of options granted during the years ended December 31, 2021 and 2020 were $7.26 and $8.52, respectively. The total intrinsic value of options exercised was not material for both the years ended December 31, 2021 and 2020.

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, 2021 is as follows:

	Number of Shares Underlying RSUs	Weighted-Average Grant Date Fair Value
Unvested, December 31, 2020	147,883	$ 17.00
Granted	94,082	$ 14.25
Vested	—	$ —
Forfeited	(5,980)	$ 13.85
Unvested, December 31, 2021	235,985	$ 15.98

The total fair value of the RSUs granted during the twelve months ended December 31, 2021 and 2020 of $1.3 million and $2.5 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. As of December 31, 2021, $2.5 million of unrecognized compensation costs related to RSUs is expected to be recognized over a weighted average period of 2.3 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 our board of directors. As of December 31, 2021, the total shares of Class A common stock authorized for issuance under the ESPP was 214,069, of which 186,825 remained available for future issuance. During the year ended December 31, 2021, 27,244 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, 2021 and 2020 comprised of the following (in thousands):

	Year Ended December 31,	
	2021	2020
Sales and marketing	$ 654	$ 108
General and administrative	2,186	553
Research and development	531	93
Cost of goods sold	164	25
Total stock-based compensation expense	$ 3,535	$ 779

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, reduced by an estimated forfeiture rate, 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, 2021 and 2020:

	Year Ended December 31,	
	2021	2020
Expected term (years)	5.9	6.2
Risk-free interest rate	0.96 %	0.50 %
Volatility factor	64 %	55 %
Dividend yield	—	—

Note 5. Inventory

Inventory as of December 31, 2021 and 2020 was comprised of the following (in thousands):

	December 31, 2021	December 31, 2020
Raw materials	$ 1,880	$ 1,507
Work in process	834	708
Finished goods	6,840	7,902
Total	$ 9,554	$ 10,117

Note 6. Property and Equipment

Property and equipment as of December 31, 2021 and 2020 were comprised of the following (in thousands):

	December 31,	
	2021	2020
Processing and research equipment	$ 3,853	$ 3,585
Leasehold improvements	606	589
Office equipment and furniture	187	151
Computer hardware and software	994	1,197
	5,640	5,522
Less: accumulated depreciation and amortization	(4,440)	(4,360)
Property and equipment, net	$ 1,200	$ 1,162

Depreciation and amortization expense on property and equipment totaled approximately $0.3 million and $0.5 million for the years ended December 31, 2021 and 2020, respectively, of which approximately $0.1 million and $0.3 million, respectively, are included within cost of goods sold in the accompanying Consolidated Statements of Operations.

Note 7. 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, 2021 and 2020 are as follows (in thousands):

	December 31, 2021			December 31, 2020		
	Cost	Accumulated Amortization	Net	Cost	Accumulated Amortization	Net
Acquired products	$ 29,317	$ (13,409)	$ 15,908	$ 29,317	$ (10,483)	$ 18,834
Customer relationships	4,723	(2,165)	2,558	4,723	(1,692)	3,031
Total	$ 34,040	$ (15,574)	$ 18,466	$ 34,040	$ (12,175)	$ 21,865

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, 2021 and 2020, 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 each of the years ended December 31, 2022, 2023, 2024, 2025 and 2026.

Note 8. Long-Term Debt

On May 31, 2017, in connection with the Company's acquisition of CorMatrix described in Note 7, Aziyo entered into a $12 million term loan facility (the "Term Loan Facility") and an $8.0 million asset-backed revolving line of credit (the "Revolving Credit Facility"), under which the Company's borrowing capacity is limited by certain qualifying assets, with a financial institution (the "May 2017 Financing"). As of December 31, 2021 and 2020, the Company's borrowing capacity under its Revolving Credit Facility was $6.9 million and $8.0 million, respectively. The Term 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 Term Loan Facility to $20 million. Borrowings under the Term Loan Facility, as amended, bear 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 Term Loan Facility borrowings was 9.5% for both the years ended December 31, 2021 and 2020. The agreement governing the Term Loan Facility provides for interest only payments through January 2021 and interest and equal monthly principal payments from February 2021 through maturity in July 2024. However, the Term Loan Facility also provides that if certain conditions were satisfied prior to December 1, 2020 (including the completion of a qualified initial public offering and no continuing default or event of default), interest only payments may, upon our request, be extended to August 1, 2021. Accordingly, based on the Company's successful completion of its IPO, Aziyo exercised this interest-only period extension right and as such, interest and equal principal payments commenced on August 1, 2021 and will continue through maturity in July 2024.

The agreement that governs the Term Loan Facility, as amended, requires certain mandatory prepayments, subject to certain exceptions, with: (1) 100% of any net casualty proceeds in excess of $250,000 with respect to assets upon which the agent maintains a lien and (2) 100% of the net cash proceeds of non-ordinary course asset sales or sales pertaining to collateral upon which the borrowing base of the Revolving Credit Facility is calculated. In addition, the Company is required to prepay all outstanding obligations under the Term Loan Facility upon the termination of all commitments under the Revolving Credit Facility and the repayment of the outstanding borrowings thereunder. No such mandatory prepayments were required during the years ended December 31, 2021 and 2020.

The agreement governing the Term Loan Facility also includes an exit fee of 6.5% of the aggregate principal amount and prepayment penalties which, based on an amendment to the Term Loan Facility executed in January 2022, shall be equal to the amount prepaid multiplied by 3.0% until January 21, 2023 and 2.0% thereafter.

Borrowings under the Revolving Credit Facility bear 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 agreement governing the Revolving Credit Facility includes an unused line fee in an amount equal to 0.5% per annum of the unused borrowing capacity and based on an amendment to the Revolving Credit Facility executed in January 2022, prepayment penalties equal to $8.0 million multiplied by 3.0% until January 21, 2023 and 2.0% thereafter. The weighted average interest rate on Revolving Credit Facility borrowings was 7.2% for the years ended December 31, 2021 and 2020. Both debt instruments contain events of default, including,

most significantly, a failure to timely pay interest or principal, insolvency, or an action by the United States Food and Drug Administration or such other material adverse event impacting the operations of Aziyo. To this end, the mutual termination of our Supply Agreement for FiberCel with Medtronic referred to in Note 16 to the consolidated financial statements would have triggered an event of default; however, such event of default was waived by our lenders.

The debt instruments also include a financial covenant based on cumulative minimum net product revenue, as defined, restrictions as to payment of dividends, and are secured by all assets of the Company. As of December 31, 2021, Aziyo was in compliance with this financial covenant. In January 2022, the minimum net product revenue covenants were amended and all future amounts were reset.

In conjunction with the May 2017 Financing and the amendment thereto, the Company issued to the financial institution warrants to purchase 405,000 shares of Aziyo's Convertible Preferred Stock at $1.00 per share. The warrants were exercisable through the first to occur of (a) May 31, 2027 (in the case of warrants to purchase 360,000 shares of Convertible Preferred Stock) or December 14, 2027 (in the case of warrants to purchase 45,000 shares of Convertible Preferred Stock), and (b) the earlier of (i) a Sale Transaction (as defined in the Company's Certificate of Incorporation) or (ii) an initial public offering of the Company's common stock. All warrants were exercised in connection with the IPO noted in Note 1. The Company accounts for stock warrants in accordance with ASC Topic 815 Derivatives and Hedging - Contracts in Entity's Own Equity," as either derivative liabilities or as equity instruments depending on the specific terms of the warrant agreement. As described in Note 10, all of the Company's issued and outstanding Convertible Preferred Stock warrants are accounted for as a liability and are valued using the Black Scholes model. Upon issuance, the Company valued such warrants at $286,267. The recognition of these warrants served to reduce the recorded value of the associated Term Loan Facility borrowings. This resulting debt discount was recognized as interest expense through 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, 2020. The notes are subordinated in payment to the Term Loan Facility and Revolving Credit Facility and in both 2021 and 2020, the Company's senior lender restricted payment of the amounts due.

In April 2020, the Company issued convertible, subordinated promissory notes (the "2020 Bridge Notes") with a total principal of approximately $2.0 million. The 2020 Bridge Notes have an interest rate of 5%, are repayable upon demand by the holders any time after April 1, 2025 and shall automatically be converted into the Company's shares of capital stock upon the closing of an issuance of the Company's shares of capital stock to one or more investors that results in gross cash proceeds to the Company of at least Three Million Dollars ($3 million). The number of securities to be issued in connection with the conversion of these notes shall equal (i) the sum of the outstanding principal amount of, and all accrued but unpaid interest on, these notes divided by (ii) the cash purchase price per security paid by the investors in the financing. See Note 12 for discussion of the conversion of these notes into Convertible Preferred Stock in September 2020.

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"). 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 in the accompanying Consolidated Statements of Operations for the year ended December 31, 2021.

As of December 31, 2021, the contractual maturities of the long-term debt are as follows (in thousands):

Years ending December 31,	Term Loan	Note to Tissue Supplier	Total
2022	$ 6,667	$ 1,392	$ 8,059
2023	6,667	—	6,667
2024	3,889	—	3,889
Total	17,223	1,392	18,615
Deferred Financing Costs	(146)	—	(146)
Total, net	17,077	1,392	18,469
Current Portion	(6,667)	(1,392)	(8,059)
Long-term Debt	$ 10,410	$ —	$ 10,410

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, 2021 and 2020.

The Company had a warrant outstanding to purchase up to 7,656 shares of common stock, at an exercise price of $5.44 per share, which had been issued in connection with a prior financing arrangement. This warrant was fully exercised in connection with the IPO described in Note 1.

Note 9. Revenue Interest Obligation

As part of the CorMatrix asset acquisition described in Note 7, 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 annual minimum payments serving to establish the short-term portion. Interest expense related to the Revenue Interest Obligation of approximately $2.7 million was recorded for both the years ended December 31, 2021 and 2020. See Note 10 for discussion of the value of this obligation.

Note 10. 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, 2020 Using:			
	Level 1	Level 2	Level 3	Total
Liabilities:				
Revenue Interest Obligation*	$ —	$ —	$ 19,383	$ 19,383

	Fair Value Measurements at December 31, 2021 Using:			
	Level 1	Level 2	Level 3	Total
Liabilities:				
Revenue Interest Obligation*	$ —	$ —	$ 19,290	$ 19,290

*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. There was no change to estimated future payments during both the years ended December 31, 2021 and 2020 and thus, no re-measurement gain or loss was recognized.

The preferred stock warrant liability in the table below consisted of the fair value of warrants to purchase Convertible Preferred Stock (see Note 8) and was based on significant inputs not observable in the market, which represents a Level 3 measurement within the fair value hierarchy. The Company's valuation of the preferred stock warrants utilized the Black-Scholes option-pricing model, which incorporates assumptions and estimates to value the preferred stock warrants. The Company assessed these assumptions and estimates at each reporting period as updated information impacting the assumptions became available. An increase in the fair value of the preferred stock warrants during the year ended December 31, 2020 resulted in a loss to the Company of approximately $0.2 million and such charge was recognized as Other (income) expense in the Consolidated Statements of Operations. As described in Note 8, all preferred stock warrants were exercised in connection with the IPO and upon such exercise, the preferred stock warrant liability was reclassified to additional paid-in capital in the accompanying Consolidated Balance Sheets.

The following table provides a rollforward of the aggregate fair values of the preferred stock warrant liability and Revenue Interest Obligation categorized with Level 3 inputs for the years ended December 31, 2021 and 2020 (in thousands):

	Preferred Stock Warrant Liability	Revenue Interest Obligation
Balance as of January 1, 2020	$ 247	$ 19,346
Fair value adjustment to warrant liability	227	—
Payments on Revenue Interest Obligation	—	(2,645)
Interest accrued to Revenue Interest Obligation	—	2,682
Exercise of Preferred Stock Warrant	(474)	—
Balance as of December 31, 2020	$ —	$ 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

Note 11. 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,	
	2021	2020
Tax benefit at U.S. statutory rate	21.0%	21.0%
State income tax benefit, net of federal benefit	1.6%	1.1%
Nondeductible expenses	1.6%	(3.1)%
State law changes	0.4%	(3.0)%
Other	0.3%	(0.3)%
Change in valuation allowance	(25.1)%	(15.8)%
Income tax expense	(0.2)%	(0.1)%

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, 2021 and 2020, significant components of the Company's net deferred income taxes are as follows (in thousands):

	December 31,	
	2021	2020
Deferred tax assets:		
Tax goodwill	$ 3,267	$ 3,428
Net operating loss carryforwards	14,794	10,008
Inventory	647	949
Deferred revenue	-	131
Acquired intangibles	1,174	908
Revenue interest obligation	1,347	789
Interest expense	1,866	1,248
Other	1,314	1,094
Total assets	24,409	18,555
Deferred tax liabilities:		
Prepaid expenses	(200)	(556)
Total liabilities	(200)	(556)
Total net deferred tax asset	24,209	17,999
Valuation allowance	(24,209)	(17,999)
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, 2021 and 2020, as the increases to the respective net deferred tax assets of $6.2 million and $3.6 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, 2021 and 2020, 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, 2021 and 2020 relates to current amounts due on certain state tax obligations.

As of December 31, 2021, the Company had net operating loss carryforwards for federal income tax purposes of approximately $65.5 million, comprised of $17.7 million that will expire beginning in 2036 and $47.8 million that have no expiration date. The Company also had state net operating loss carryforwards of approximately $18.2 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, 2021, the Company had no unrecognized tax benefits.

Note 12. Stockholders' Equity

At inception, Aziyo was capitalized through the sale of 19.5 million shares of Series A Convertible Preferred Stock, par value $0.001 per share (the "Convertible Preferred Stock"). Since inception, the Company has issued an additional 30.9 million shares of Convertible Preferred Stock yielding proceeds of approximately $30.4 million, which were used for general corporate purposes and the CorMatrix Acquisition. During the year ended December 31, 2020, Convertible Preferred Stock offerings totaled approximately $5.4 million. The Convertible Preferred Stock issued during the year ended December 31, 2020 occurred primarily in September 2020 at which time the Company completed the sale of 3.0 million shares of Convertible Preferred Stock for net proceeds of approximately $3.0 million. At the same time, the 2020 Bridge Notes of $2.0 million (issued in April 2020), and related accrued interest, converted into approximately 2.0 million shares of Convertible Preferred Stock.

The fair value of the 3.0 million shares of Convertible Preferred Stock described above exceeded the purchase price of the Convertible Preferred Stock by $3.5 million. Such excess was accounted for as a deemed dividend to the Convertible Preferred Stock and was recorded as "Accretion of Convertible Preferred Stock" in the Consolidated Statements of Operations to arrive at "Net Loss Attributable to Common Shareholders" and is included in the numerator of basic Earnings Per Share. With respect to the Consolidated Statements of Changes in Convertible Preferred Stock and Stockholders' Deficit, these deemed dividends have been recorded such that Additional Paid-in Capital was first eliminated and any residual dividends served to reduce Accumulated Deficit. Additionally, the fair value of the 2.0 million shares of Convertible Preferred Stock issued upon conversion of Convertible Bridge Notes exceeded the face value of the Convertible Bridge Notes by $2.3 million. Such excess has been recorded as Loss on Early Extinguishment of Debt within Other (Income) Expense, net in the accompanying Consolidated Statements of Operations for the year ended December 31, 2020.

As consideration for the advisory services provided to Aziyo in connection with the CorMatrix Acquisition, an agreement was executed between Aziyo and HighCape Partners Management, L.P. whereby upon consummation by Aziyo of a sale transaction, as defined in the Company's Certificate of Incorporation, or an initial public offering of the Company's common stock, Aziyo would be required to pay HighCape a fee totaling $0.75 million. In September 2020, the Company's obligation in respect of this fee was extinguished in connection with the issuance of 375,000 shares of Convertible Preferred Stock. Such Convertible Preferred Stock and the associated expense was recorded at its fair value of approximately $0.8 million.

Dividends

The holders of Convertible Preferred Stock are entitled to receive noncumulative dividends as declared by the Board of Directors. The holders of Convertible Preferred Stock shall be entitled to receive dividends prior and in preference

to any payment of any dividend on common stock. No dividends were declared by the Board of Directors from inception through the conversion of such Convertible Preferred Stock to common stock as noted below.

Conversion

The Convertible Preferred Stock is convertible at the election of the holders into shares of the Company's common stock that would result in a conversion ratio of one share of common stock for every 13.9549 shares of Convertible Preferred Stock held. In addition to this voluntary conversion, each share of Convertible Preferred Stock will automatically be converted into shares of common stock upon (i) the written consent of the required holders (as defined) or (ii) the closing of the sale of shares of common stock to the public at a price of at least $5.00 per share (subject to appropriate adjustment in the event of any stock dividend, stock split, combination or other similar recapitalization with respect to the common stock), in an underwritten public offering pursuant to an effective registration statement under the Securities Act of 1933, as amended, resulting in at least $30 million of gross proceeds to the Company. In case of an underwritten public offering, immediately prior to closing, the holders of Convertible Preferred Stock are entitled to receive additional shares of (the "Liquidation Shares") of common stock as determined by dividing the Convertible Preferred Stock Preference Amount, as defined below, by the price per Common Shares in the underwritten public offering.

At the closing of the IPO, all outstanding shares of the Convertible Preferred Stock, including Convertible Preferred Stock resulting from the warrant exercises described in Note 8 and the Liquidation Shares, converted into 4,232,195 shares of Class A common stock and 2,398,868 shares of Class B common stock, and the related carrying value was reclassified to the respective common stock accounts and additional paid-in capital. Other than voting rights, the Class B common stock has the same rights as the Class A common stock. It was at the discretion of certain holders of the Convertible Preferred Stock that they receive non-voting Class B common stock. When such non-voting Class B common shares are sold by the current holders, they will automatically convert to Class A common stock. There were no shares of Convertible Preferred Stock outstanding as of the closing of the IPO on October 13, 2020.

The Convertible Preferred Stock does not have a mandatory redemption date. However, while it is not mandatorily redeemable, until conversion, the Convertible Preferred Stock was reclassified into mezzanine equity because it will become redeemable at the option of the stockholders upon the occurrence of certain deemed liquidation events that are considered not solely within the Company's control. That is, unless a majority of the holders of the then outstanding preferred stock, on an as-if-converted to common stock basis, elect otherwise, deemed liquidation events include a sale of all or substantially all of Aziyo's assets or a sale of at least fifty percent (50%) of the issued and outstanding voting securities, capital stock, or other comparable equity or ownership interest in Aziyo.

Upon issuance of the Convertible Preferred Stock, the Company assessed the embedded conversion and liquidation features of the securities. The Company determined that the preferred stock did not require the Company to separately account for the liquidation features.

At the IPO date, the Company authorized 10,000,000 shares of Preferred Stock with a par value per share of $0.001. If issued, this new Preferred Stock shall have the rights and preferences as determined by the Company's Board of Directors.

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 13. 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 $0.4 million and $0.2 million for the years ended December 31, 2021 and 2020, respectively.

Note 14. Net Loss Per Share Attributable to Common Stockholders

(in thousands, except share and per share data)	Year Ended December 31,	
	2021	2020
Numerator:		
Net loss attributable to common stockholders	$ (24,832)	$ (25,335)
Denominator:		
Weighted average number of common shares, basic and diluted	10,444,767	2,852,541
Net loss per common share attributable to common stockholders, basic and diluted	$ (2.38)	$ (8.88)

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,	
	2021	2020
Options to purchase common stock	1,386,811	917,437
Restricted stock units	235,985	147,883
Total	1,622,796	1,065,320

Note 15. 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 years ended December 31, 2021 and 2020, 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,	
	2021	2020
Percent of revenues derived from:		
Medtronic Sofamor Danek USA	11%	17%
Surgalign Holdings	10%	10%

	December 31,	
	2021	2020
Percent of accounts receivable derived from:		
Medtronic Sofamor Danek USA	—	34%
Surgalign Holdings	12%	13%

In June 2021, Medtronic notified the Company that sales of FiberCel Viable Bone Matrix ("FiberCel) as well as all such other Non-Core products supplied to Medtronic would be suspended until further notice. In October 2021, the Company was informed by Medtronic that they would no longer be distributing cellular bone products such as FiberCel and, in December 2021, the two companies mutually terminated the associated FiberCel distribution agreement.

Note 16. Commitment and Contingencies

Operating Leases

The Company leases two production facilities and one administrative and research 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 Company records 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 is recorded as deferred rent and is included in accrued liabilities on the balance sheet. Rent expense for the years ended December 31, 2021 and 2020 was approximately $1.2 million and $1.1 million, respectively, and is included as a component of either cost of goods sold or general and administrative expenses.

Future minimum lease commitments under non-cancelable operating leases as of December 31, 2021 are as follows (in thousands):

Years ending December 31,		
2022	$	1,175
2023		998
2024		781
2025		594
Total	$	3,548

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, 2021 and 2020. 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, 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. 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.

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.

Between June 21, 2021 and February 18, 2022, forty-five lawsuits in Indiana, Delaware, Florida, Maryland, Colorado, Michigan, Ohio, Kentucky, Oregon, and North Carolina have been filed against Aziyo Biologics Inc., certain Medtronic entities, and others alleging that the plaintiffs contracted tuberculosis and/or suffered substantial symptoms and complications following the implantation of FiberCel during spinal fusion operations. Twenty lawsuits were filed in Indiana state court, captioned, respectively: (1) John Dukes and Kimberly Smith v. Aziyo Biologics, Inc., et al., Case No. 49D02-2109-CT-032234 (case dismissed without prejudice on 09/16/2021 and re-filed on 09/24/2021); (2) Tamara and Richard Marksberry v. Aziyo Biologics, Inc., et al., Case No. 49D04-2106-CT-021649 (consolidated); (3) Ramon Cabello v. Aziyo Biologics, Inc., et al., Case No. 49D13-2106-CT-021650 (consolidated); (4) Luis Caban v. Aziyo Biologics, Inc., Case No. 49D13-2107-CT-022413 (consolidated); (5) Machell and Samuel Hargrave v. Aziyo Biologics, Inc., et al., Case No. 49D01-2106-CT-021275 (consolidated); (6) Georgia Flinn as Personal Representative of the Estate of Gregory Flinn v. Aziyo Biologics, Inc., et al., Case No. 49D12-2107-CT-024051 (consolidated); (7) Ruth and William Flynn v. v. Aziyo Biologics, Inc., et al., Case No. 49D12-2107-CT-024624 (consolidated); (8) Tracy Warner and Kristin Foate v. v. Aziyo Biologics, Inc., et al., Case No. 49D04-2107-CT-024631 (consolidated); (9) Donna Schilling v. v. Aziyo Biologics, Inc., et al., Case No. 49D04-2107-CT-024443 (consolidated); (10) Robby and Stephanie Anderson v. v. Aziyo Biologics, Inc., et al., Case No. 49D13-2107-CT-025221 (consolidated); (11) Max Shepard v. v. Aziyo Biologics, Inc., et al., Case No. 49D11-2108-CT-025984 (consolidated); (12) Leon Chew v. Aziyo Biologics, Inc., et al., Case No. 49D12-2108-CT-025967 (consolidated); (13) Candace Kozor, Kenneth Largin and Anthony Young v. Aziyo Biologics, Inc., et al., Case No. 49D04-2107-CT-024626 (consolidated); (14) James and Lauri Ann Jackson v. v. Aziyo Biologics, Inc., et al., Case No. 49D02-2108-CT-028321 (re-filed in state court and consolidated); (15) James and Kathy Shaw v. Aziyo Biologics, Inc., et al, Case No. 49D11-2108-CT-028669 (consolidated); (16) Larry Szynski v. Aziyo Biologics, Inc., et al., Case No. 49D05-2108-CT-029225 (consolidated); (17) Jerrold Jenkins v. Aziyo Biologics, Inc., et al., Case No. 49D03-2108-CT-029367 (consolidated; (18) Hon Vien v. Aziyo Biologics, Inc., et al., Case No. 49D01-2202-CT-004812; (19) Jayson Hartman v. Aziyo Biologics, et al., Case No. 49D12-2202-CT-004835; and (20) Randy Smith v. Aziyo Biologics, Inc., et al., Case No. 49D01-2202-CT-005184 (collectively, the "Indiana State Complaints"). Fifteen lawsuits were filed in the Superior Court of the State of Delaware, captioned respectively: (1) Richard Williams v. Aziyo, Biologics Inc., et al., C.A. No. N21C-06-166 EMD; (2) Jean and Shante Georges v. Aziyo, Biologics Inc., et al., C.A. No. N21C-06-256-DJB; (3) Marjorie Hitchens v. Aziyo, Biologics Inc., et al., C.A. No. N21C-06-214-DJB; (4) Larry and Joanne Fortner v. Aziyo, Biologics Inc., et al., C.A. No. N21C-06-215-DJB; (5) Nancy and John Smith v. Aziyo, Biologics Inc., et al., C.A. No. N21C-06-219-DJB; (6) Joan Trincia v. Aziyo, Biologics Inc., et al., C.A. No. N21C-06-220-DJB; (7) Bernadette Burgess v. Aziyo, Biologics Inc., et al., C.A. No. N21C-06-264-DJB; (8) Summer Fitzhugh v. Aziyo, Biologics Inc., et al., C.A. No. N21C-06-221-DJB; (9) Linda Shields v. Aziyo, Biologics Inc., et al., C.A. No. N21C-06-166-DJB; and (10) Sharon Riddick v. Aziyo, Biologics Inc., et al., C.A. No. N21C-07-005-EMD; (11) Carl Stevens v. Aziyo, Biologics Inc., et al., C.A. No. N21C-08-149-DJB; (12) Joel and Melissa Stanton v. Aziyo, Biologics Inc., et al., C.A. No. N21C-08-212-AML; (13) Bruce and Beverly Carroll v. Aziyo, Biologics Inc., et al., C.A. No. N21C-08-130-DJB; (14) Margaret Cook v. Aziyo, Biologics Inc., et al., C.A. No. N21C-08-131-DJB; (15) Robert Jr. and Kelly Aspinall v. Aziyo, Biologics Inc., et al., C.A.

No. N21C-09-065-DJB (collectively, the "Delaware State Complaints"). One lawsuit has been re-filed in the Circuit Court of Maryland (previously filed on 07/21/2021 and dismissed without prejudice on 08/12/2021 in the U.S. District Court of Maryland), captioned: Diana and James Hanson v. Aziyo Biologics, Inc., et al., Case No. C-02-CV-21-001094 ("Maryland State Complaint"). One lawsuit has been filed in the Court of Common Pleas of Ohio, captioned: Michelle and Charles Weethee v. Aziyo, Biologics Inc., et al., Case No. 2021 CV 03621 ("Ohio State Complaint"). One lawsuit has been filed in the Northern District of Ohio, captioned: Heath Raker and Neal Raker v. Aziyo Biologics, Inc., et al., Case No. 1:22-cv-54 ("Ohio Federal Complaint"). One lawsuit has been filed in the Circuit Court of Michigan, captioned: Ilona and Christian Hildebrandt v. Aziyo Biologics, Inc., Case No. 2021-003804-NP ("Michigan State Complaint"). One lawsuit has been filed in the Superior Court of North Carolina, captioned: Aurelia and Belvin Sherrill v. Aziyo Biologics, Inc., et al., Case No. 21cvs2797 ("North Carolina State Complaint"). One lawsuit has been filed in the U.S. District Court for the Northern District of Florida, captioned Deborah Rice v. Aziyo Biologics, Inc., et al., Case No. 5:21-cv-00135-MW-MJF ("Florida Federal Complaint"). One lawsuit has been filed in the U.S. District Court for the Eastern District of Michigan, captioned: Karrold Dudley v. Aziyo, Biologics Inc., et al., Case No. 2:21-cv-11813-GAD-EAS ("Michigan Federal Complaint"). One lawsuit has been filed in the U.S. District Court for the District of Colorado, captioned Christopher and Julie Buri v. Aziyo Biologics, Inc., et al., Case No. 1:21-cv-02789-SKC ("Colorado Federal Complaint"). One lawsuit has been filed in the U.S. District Court for the District of Oregon, captioned Christy Bryant v. Aziyo Biologics, Inc., et al., Case No. 1:21-cv-01759-AA ("Oregon Federal Complaint"). One lawsuit has been filed in Fayette, Kentucky Circuit Court, captioned Earl Wesley Robinson and Joyce Ann Robinson v. Aziyo Biologics, Inc., Case No. 21-CI-03842 ("Kentucky State Complaint"). Lastly, two lawsuits have been dismissed: (1) in the state court of Maryland, captioned Tracey and Stan Gearhart v. Aziyo Biologics, Inc., et al., Case No. C-02-CV-21-000997(dismissed without prejudice on 09/14/2021), and (2) in the U.S. District Court for the Northern District of Indiana, captioned: David Hahn v. Aziyo Biologics, Inc., et al., Case No. 2:21-cv-00265-PPS-JEM (dismissed without prejudice on 09/30/2021).

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 allege negligence, breach of implied warranty, breach of express warranty, 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 Complaint asserts claims of negligence, breach of implied warranty, breach of express warranty, medical monitoring, and loss of consortium. The Florida Federal Complaint also 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 Michigan State Complaint asserts causes of action for product defect and breach of implied warranty, product defect and breach of express warranty, negligence, gross negligence, and possible knowledge of defect, and seeks compensatory and exemplary 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 Complaint asserts causes of action for 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 Complaint seeks compensatory damages and punitive damages. The North Carolina State 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 State Complaint asserts strict liability claims based on manufacturing defect, design defect, and failure to warn. It also alleges negligence, breach of implied warranty, breach of express warranty, and seeks recovery for medical monitoring, loss of consortium, compensatory damages, and punitive damages. In addition to the above, there have been forty-two claims related to the FiberCel recall, which have not yet resulted in a lawsuit. We refer to all of the aforementioned litigation, or claim notices, collectively as the "FiberCel Litigation."

In order to reasonably estimate a loss or range of loss for the FiberCel Litigation, the Company must assess a variety of factors, including, (i) what claims, if any, will survive dispositive motion practice, (ii) the extent of the claims, particularly when damages are not specified or are indeterminate, (iii) how the discovery process will affect the litigation, (iv) the settlement posture of the other parties to the litigation and (v) any other factors that may have a material effect on the litigation. At present, it is not possible for Aziyo to estimate a range of probable loss in the FiberCel Litigation; however, while unknown, the probable loss could have a material effect on the Company's financial position and results of operations.

Should Aziyo be required to pay claims related to the FiberCel Litigation, the Company believes that certain settlements and judgments, as well as legal defense costs, may be covered in whole or in part under our insurance policies. In certain circumstances, insurance carriers reserve their rights to contest or deny coverage. We intend to contest vigorously any disputes with our insurance carriers and to enforce our rights under the terms of our insurance policies. Accordingly, we will record receivables with respect to amounts due under these policies only when the realization of the potential claim for recovery is considered probable. Amounts recovered under our insurance policies could be materially less than stated coverage limits and may not be adequate to cover damages, other relief and/or costs relating to claims. In addition, there is no guarantee that insurers will pay claims or that coverage will otherwise be available.

As of both December 31, 2021 and 2020, the Company was not a party to, or aware of, any material legal matters or claims except for the FiberCel Litigation.

Note 17. Related Party Transactions

Prior to the IPO, the Company had a management services agreement with an affiliate of HighCape Partners through which strategic, operational and management consulting services are provided to the Company. During the year ended 2020, the Company recorded expenses totaling $0.2 million for these services. The management services agreement terminated upon completion of the IPO and all amounts due thereunder were paid as of December 31, 2020.

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 in the accompanying Consolidated Statements of Operations for the year ended December 31, 2021.

Note 18. Segment Information

The Company operates as one segment, regenerative medicines. The segment is based on financial information that is utilized by the Company's Chief Operating Decision Maker ("CODM"), who is the Company's Chief Executive Officer, to assess performance and allocate resources.

For the years ended December 31, 2021 and 2020, the Company's net sales disaggregated by the major sources - Core Products and Non-Core Products (see Note 1) - were as follows (in thousands):

	Year Ended December 31,	
	2021	2020
Sales by product		
Core Products	$ 37,603	$ 36,216
Non-Core Products	9,787	6,466
Total Net Sales	$ 47,390	$ 42,682

During the years ended December 31, 2021 and 2020, 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.

EXECUTIVE OFFICERS

Ronald Lloyd
President and Chief Executive Officer

Peter Edwards
General Counsel

Thomas Englese
Chief Commercial Officer

Matthew Ferguson
Chief Financial Officer

Jerome Riebman, M.D.
Chief Medical Officer

Darryl Roberts, Ph.D.
Executive Vice President, Operations and Product Development

BOARD OF DIRECTORS

Kevin Rakin
Chair of the Board, Aziyo Biologics, Inc. and Co-Founder and General Partner, HighCape Partners

Maybelle Jordan
Chief Strategy Officer, Deerfield Device Design and Development Catalyst

Ronald Lloyd
President and Chief Executive Officer, Aziyo Biologics, Inc.

Brigid A. Makes
Part-time Chief Financial Officer, Nano Precision Medical, Inc. and Independent Consultant

C. Randal Mills, Ph.D.
Chief Executive Officer, Sanford Burnham Prebys Medical Discovery Institute

W. Matthew Zuga
Chief Financial Officer and Chief Business Officer, Acumen Pharmaceuticals, Inc. and Co-Founder and General Partner, HighCape Partners

CORPORATE AND STOCKHOLDER INFORMATION

Corporate Headquarters
Aziyo Biologics, Inc.
12510 Prosperity Drive, Suite 370
Silver Spring, Maryland 20904
www.aziyo.com

Transfer Agent
American Stock Transfer and Trust Company
6201 15th Avenue
Brooklyn, New York 11219
Phone: 1.800.937.5449
amstock.com

Investor Relations
investors@aziyo.com

Annual Meeting of Shareholders
Tuesday, June 7, 2022
1:00 p.m., Eastern Time via live webcast
www.virtualshareholdermeeting.com/AZYO2022

Common Stock Listing
Nasdaq: AZYO

Independent Registered Public Accounting Firm
PricewaterhouseCoopers LLP

Outside Counsel
Latham & Watkins LLP
New York, New York

Aziyo Biologics, Inc.
12510 Prosperity Drive, Suite 370
Silver Spring, MD 20904
Phone: 240-247-1147
Fax: 510-307-9896
www.aziyo.com